Governance of European Cooperation Processes in Health Technology Assessment

Networking, paving the way to convergence of practices?

MAGALI BOERS

**Governance of European Cooperation Processes
in Health Technology Assessment**
Networking, paving the way to convergence of practices?

Magali Boers

Governance of European Cooperation Processes in Health Technology Assessment
Networking, paving the way to convergence of practices?

Governance van Europese samenwerkingsprocessen in Health Technology Assessment
Netwerken, op weg naar convergentie van praktijken?

Thesis

to obtain the degree of Doctor from the
Erasmus University Rotterdam
by command of the
rector magnificus
Prof. dr. R.C.M.C. Engels
and in accordance with the decision of the Doctorate Board.
The public defence shall be held on
Thursday 12 November 2020 at 11.30 hrs

by

Magali Aurélie Nanda Elisabeth Boers
born in Tilburg

Erasmus University Rotterdam

DOCTORAL COMMITTEE:

Promotors:	Prof. dr. A. Boer
	Prof. dr. R. Harmsen
Other members:	Prof. dr. R.A. Bal
	Prof. dr. D.M.J. Delnoij
	Dr. J.K. Helderman

To Carlo,
Sarah, Lara and Noémie

"When an idea answers to the needs of an epoch,
it ceases to belong to those who invented it
and becomes more powerful than those who serve it.
If it naturally meets with resistance,
and is sometimes delayed by circumstances,
that by no means destroys its chances of success."
Jean Monnet, Memoirs

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

Tables

Figures

LIST OF ABBREVIATIONS

ATV	Added Therapeutic Value
BEPG	Broad Economic Policy Guidelines
CBA	Cost Benefit Analysis
CBHC Directive	Directive Cross-Border Health Care Directive, Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.
CEA	Cost Effectiveness Analysis
CHMP	Committee for Medicinal Products for Human Use, replaced the former CPMP
CJEU	Court of Justice of the European Union
CPMP	Committee for Proprietary Medicinal Products
DG	Directorate General of the European Commission
ECHTA/ECAHI	European Collaboration for Health Technology Assessment/ Assessment of Health Interventions, HTA cooperation project implemented from 1999-2001
EES	European Employment Strategy
EMA	European Medicines Agency
EMU	European Monetary Integration
EP	European Parliament
EPAR	European Public Assessment Report
EPSCO Council	Employment, Social Policy, Health and Consumer Affairs Council
EU HTA Network	Health Technology Assessment Network, established by the European Commission in 2013
EU	European Union
EUnetHTA	European Network for Health Technology Assessment, HTA cooperation network established in 2006
EUR-ASSESS	European HTA collaboration project implemented from 1994-1997
G10	G10 Medicines Group – High level group on innovation and provision of medicines in the EU
HEN	Health Evidence Network (WHO)
HLG	High Level Group on Health Services and Medical Care
HLPR	High Level Reflexion Process on Patient Mobility and Healthcare
HS	Horizon Scanning
HSS	Horizon Scanning System
HTA	Health Technology Assessment
HTA-Europe	European collaboration project in Health Technology Assessment implemented from 1997-1998

HTAi	Health Technology Assessment International
ICER	Incremental Cost-Effectiveness Ration
INAHTA	International Network of Agencies for Health Technology Assessment
ISTAHC	International Society of Technology Assessment in Health Care
JA	Joint Action
JCA	Joint Clinical Assessment
JSA	Joint Scientific Consultation
MCDA	Multi Criteria Decision Analysis
MS	EU Member States
MWP	Multiannual Work Plan
NCAPR	The Network of Competent Authorities on Pricing and Reimbursement
NMG	New Modes of Governance
NPAR	National Public Assessment Report
OECD	Organisation for Economic Cooperation and Development
OJEC	Official Journal of the European Communities
OJEU	Official Journal of the European Union
OMC	Open Method of Coordination
OTA	Office for Technology Assessment
POP-Database	Database of Present and Ongoing Projects
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trials
RE	Relative Effectiveness
REA	Relative Effectiveness Assessment
RWE	Real World Effectiveness
SEED	Shaping European Early Dialogues for health technologies
SI	Slovenian Presidency Initiative
STAMP	Commission Expert Group on Safe and Timely Access to Medicines for Patients
TEU	Treaty of the European Union
TFEU	Treaty of the Functioning of the European Union
TISP	Topic Identification Selection and Prioritisation
WG	Working Group in EUnetHTA
WHO	World Health Organisation

Introduction

"Europe will not be made all at once, or according to a single plan.
It will be built through concrete achievements which first create a de facto
solidarity."
Robert Schuman, Declaration of 9th May 1950

THE RESEARCH CONTEXT

When in January 2018, the European Commission published its proposal for an EU Regula-
tion on Health Technology Assessment (HTA) cooperation, most observers were caught by
surprise. The proposal comprised articles foreseeing harmonisation of certain aspects of
HTA, a policy domain falling under EU Member States competences. Soon the question
regarding the application of the subsidiarity principle was raised, as the role of the EU in this
area was not well understood. Although considered by some as a new policy field in which
convergence was being pursued, the process of HTA cooperation in Europe had nonetheless
been set in motion some twenty-five years earlier by so-called 'HTA doers'. From a purely HTA
arena initiative, seeking to develop the quality and quantity of HTA and its use in national
decision-making processes, it progressively evolved into an important European health policy
issue.

Health Technology Assessment (HTA) has emerged in the mid-1970s in the USA before it
spread a few years later to Europe where it has been developed in a variety of ways across
the EU Member States. HTA is often considered as an aid to national health policy processes
permitting to address health care resource constraints and ensure access to safe and efficient
health care (Raftery 2011). Assessments of health technologies regard a wide range of issues
comprising medical, social, economic and ethical aspects related to the availability and use of
a health technology. The aim is "to inform the formulation of safe, effective, health policies
that are patient focused and seek to achieve best value" (www.eunethta.eu).

Health technology refers to many aspects of the health care system ranging from pharma-
ceuticals, medical devices, diagnostic and treatment procedures, rehabilitation and preven-
tion methods as well as the management of systems where health care is provided (Banta
2003:122). The relationship between HTA and national decision-making processes varies
strongly among European countries. Differentiation can be found in terms of organisational
agency approaches, the scope of the assessments, methodologies used as well as assess-
ments' input in pricing and reimbursement processes and/or clinical guidelines. A partial
explanation for this is to be found in the variety of health care systems in Europe governed
by distinct policy and funding mechanisms (Garrido et al. 2008:83).

HTA cooperation in Europe has taken off in the early 1990s upon the initiative of actors
developing HTA in various EU Member States. At that time, few countries in Europe un-
dertook assessments of health technologies and HTA expertise was scarce. When national
health systems increasingly came under financial and budgetary constraints due to an aging
population and the introduction of new and often expensive health technologies, the need
to develop HTA in Europe became more widespread. Whilst systematic assessment of health

technologies gradually became a common feature across Europe, the approaches used in HTA and the input of HTA in regulatory processes were all but homogeneous.

At present, the European situation is characterised by a multiplicity of HTA bodies in Europe, each referring to different domestic health policy systems and decision-making processes based on divergent underlying values. In these circumstances, duplication of assessments can occur, potentially even producing different outcomes and impacts on regulatory procedures. Conversely, similar HTA conclusions and regulatory decisions can be based on independent assessments enshrined in distinct scientific traditions (e.g. Kanavos et al. 2010). To address these diversities, promote efficiency, enhance the input of HTA in national regulatory processes and increase capacity-building in European countries less familiar with HTA, cooperation initiatives between European HTA agencies have sought to reach some form of convergence of assessment practices.

These cooperation initiatives have risen from within the HTA community itself. As a very young scientific field searching its place in domestic health policy and decision-making processes, HTA agencies quickly recognised the need and common interest to work together. Building upon cooperation experience on the international level, HTA agencies in Europe aimed at fostering cooperation within the European Union framework by seeking support from the European institutions. These initiatives coincided with the ratification of the Maastricht Treaty which introduced public health as new policy domain of the EU. Hence, although resulting from an HTA arena initiative, HTA cooperation in Europe has quickly become associated to the development of EU health policy.

Since the start of HTA cooperation in Europe, three distinct periods can be identified. The first is situated from 1992-2001 and regards the initial cooperation initiatives with the implementation of projects establishing the basis of European HTA collaborative work. Three projects have been implemented during this time span: EUR-ASSESS (1994-1997), HTA-Europe (1997-1998) and ECHTA/ECAHI (1999-2001). The second phase runs from 2001-2005 and addresses developments in the field of European health policy which have been essential for the establishment of new HTA networks framing the cooperation in Europe. The third phase covers the period from 2006 to the present day and regards the attempts to develop and implement a sustainable EU framework for HTA cooperation through networks, such as, 'EUnetHTA' and the 'HTA Network', established by the European Commission (further referred to in this thesis as the 'EU HTA Network'). Finally, in 2018, an EU Regulation on HTA cooperation in Europe has been proposed by the European Commission and its adoption process is, to date, ongoing.

To organise the cooperation efforts, recourse to networking has, most often, been the chosen approach. Since the first cooperation initiatives, all subsequent European HTA networks have been able to count upon the support of the European Commission. Not restricting its involvement to support-lending policies, the Commission has in the course of the years become a key-actor in the cooperation processes. Congruence between HTA cooperation objectives and EU health policy, has led to agenda-alignment between both arenas. The latter permitted HTA to find its place on the EU policy agenda and to become in 2004 a 'political priority' on the EU institutional level.

In areas where the EU has only limited regulatory competences, such as health policy, soft governance could be a means to develop cooperation between European actors operating on multiple levels. Since the EU governance turn of the 2000s, the use of networks to implement policy processes has become a common feature in the Union. Although various governance modes have been applied in networks, use of soft governance in these structures has nevertheless been a privileged approach to produce new EU policy options and build support for these on behalf of domestic institutional representatives and stakeholders. In HTA cooperation too, the EU has resorted to networks to pursue its policy objectives through soft governance which comprised, besides HTA, wider EU public health policy issues.

This thesis will outline the events that have led to the present situation of HTA cooperation in Europe. It will underscore how HTA cooperation has been co-constructed by actors stemming from the HTA arena, high level Member States representatives and the European Commission. Convergence of practices and the establishment of a European framework for HTA cooperation have been common objectives pursued since the early cooperation initiatives. Considering the nature of HTA, falling under domestic decision-making processes, soft governance applied within networks has been the approach adopted to achieve that goal. However, as HTA aims to give input in domestic regulatory processes, it needs to respond to a (hard) regulatory policy requirements. The question thus arises to what extent cooperation and convergence of practices on a European level can be structured through soft governance, as the various national HTA regulations may hinder the establishment and implementation of new common European HTA agreements.

THE RESEARCH OBJECTIVES AND RESEARCH QUESTIONS

This thesis focuses on the governance of the HTA cooperation processes within the EU health policy framework. It seeks to understand how European HTA cooperation has been structured within the wider process of European integration and the development of an EU health policy. As the EU has very limited regulatory competences in this policy domain, the

role of soft governance is central to structure HTA collaboration and establish convergence of practices in this policy field. This research will seek to understand how soft governance has shaped HTA cooperation in the European Union through networking.The overarching research question of the thesis is formulated as follows:

- *Research Question: To what extent has soft governance, though networking, structured HTA cooperation within the framework of the European Union?*

To delimitate the scope of this Research Question (RQ), three Sub-Research Questions (SRQ) will be formulated which all relate to the overarching research question. These SRQ will permit to structure the research in a comprehensive manner by focusing on specific areas of the collaboration efforts: 1) the establishment of common methodologies and tools as pre-requisites for 'joint work'[1]; 2) uptake of joint work in national decision-making processes regarding pricing and reimbursement; 3) synergies between HTA and EU Market Authorisation regulation of pharmaceuticals. The first and second area are related to each other as besides the ability of developing common tools, methodologies and assessments, it is of interest to evaluate to what extent these are also used in national regulatory processes, as this represents an essential element of HTA. The first two areas are related to the overarching RQ by focusing on the goal of the cooperation efforts and the impact on the national regulatory environment. The third area connects the HTA cooperation to the European regulatory arena. It relates to the overarching RQ by looking on the impact of European HTA cooperation efforts on established European regulatory frameworks.

As aforementioned, the establishment of joint work in HTA, requires to proceed according to common methodologies, tools and practices. As HTA cooperation falls under exclusive national competences, convergence of practices can only be achieved through voluntary cooperation processes among HTA actors of the EU Member States. The first sub-research question will therefore examine the role of soft governance in the definition and implementation of strategic policy objectives leading to convergence of HTA tools, methodologies and practices in the EU. This question is being formulated as follows:

- *Sub-Research Question 1: Can convergence and harmonisation of HTA tools, methodologies and practices be achieved through soft governance in an EU setting?*

---

1 The term 'joint work' refers to the development of common methodologies, tools and joint health technology assessments. It includes literature reviews, structured information for rapid or full HTAs, Early Dialogues or scientific advice on Research & Development planning and study design (European Commission 2016: 4).

Second, HTA informs national decision-making processes regarding pricing and reimbursement. Again, these processes fall under the exclusive national competences of the Member States. As, such, even if an assessment of a health technology has been the result of a collaborative effort on a European level, Member States remain free to decide whether they want to use this 'joint HTA' or other forms of 'joint work' as input for the national regulatory processes. The latter is also referred to as 'uptake'. The second focus point of this research regards the question whether soft governance instruments have an impact on the use of common HTA tools, methodologies and practices in national decision-making processes. Hence, the second sub-research question in this thesis has been formulated as follows:

- *Sub-Research Question 2: Can national uptake of joint work in HTA be achieved through the use of soft governance in an EU setting?*

Third, in the EU there is also a strong relationship between market access assessment of pharmaceuticals and HTA processes of these same technologies. Indeed, before a pharmaceutical product may be commercialised on the EU Internal Market, it needs to receive a European Market Authorisation from the European Medicines Agency (EMA). To deliver such an authorisation, the EMA will assess a product on the basis of its safety and efficacy profile. Once a product has received EU authorisation, it will have to go through a European and/or national HTA process which partly will assess similar domains as done by the EMA. Attempt are being made to streamline the EMA processes with EU HTA processes. The third sub-research question will therefore examine whether synergies can be established through soft governance between HTA processes and European regulatory processes of pharmaceuticals. It has been formulated as follows:

- *Sub-Research Question 3: Can synergies be established through soft governance between HTA and European regulatory processes of pharmaceuticals?*

METHODOLOGY

The role of soft governance in structuring HTA cooperation within the EU framework will be examined through the prism of network analysis. As outlined above, networks are a central feature in European HTA cooperation and are considered by the EU as an adequate forum to pursue specific policy objectives via soft governance modes and instruments. To this end, a research framework has been developed upon the concepts of 'governance networks', 'metagovernance' and 'network governance' and comprises specific soft-governance-related factors potentially impacting governance networks' typologies and network governance effectiveness.

Empirical data has been gathered through the examination of the academic literature, grey literature, semi-structured personal interviews, written contributions of key-actors in the field and personal observations during attendance of international conferences organised by HTA Networks and/or the European Commission. The data gathered will be presented in part B of the thesis. Data related to the development of HTA networks has been structured according to the five stages of a policy cycle, as defined by Howlett, Ramesh and Perl (2009). Structuring this data by means of the five stages of a policy cycle allows for a systematic presentation of both the developments taking place in the HTA arena as well as in EU health policy and which can then be related to one another. Data related to specific developments taking place on an EU institutional level has been presented according to three policy streams: the EU health policy stream, the pharmaceutical policy stream and the social policy stream.

In Part C, the data will be examined through a systematic network analysis based on the research framework. This analysis should allow us to answer the research questions in a comprehensive and argumentative way by addressing the specific domains defined in the three sub-research questions regarding governance practices in European HTA cooperation: 1) convergence and harmonisation of HTA tools, methodologies and practices, 2) uptake of joint work in national regulatory processes and 3) synergies between HTA and EU market access regulation of pharmaceuticals. The examination of these issues through the three sub-research questions will permit to address the overarching research question regarding the role of soft governance in structuring HTA cooperation within the framework of the European Union.

The thesis is composed of three parts. Part A establishes the theoretical and research framework. As the topic of this research finds itself at the intersection of two different academic fields – health policy and EU governance - contextualisation of the topic in these fields is necessary. As such, the first chapter will define our understanding of HTA cooperation and how it relates to national and European regulatory processes (e.g. market authorisation and pricing and reimbursement decisions). It will also examine the literature on HTA cooperation processes and seek to identify any research gaps. Chapter 2 aims at contextualising HTA cooperation in the EU health policy and governance architecture. The allocation of competences is a central feature herein as it determines governance modes available to specific health policy fields such as HTA. This chapter will in particular focus on the implementation of soft governance through the so-called New Modes of Governance (NMG) developed since 2001 in the EU governance architecture. One of the approaches used by the EU in the implementation of NMG is networking. Recourse to networks as a means to implement soft governance modes and instruments will be examined in chapter 3. This chapter will explore how networks relate to national and European governance and policy-making approaches. It will then identify key-concepts related to networks such as: governance networks, meta-

governance and network governance. The research framework designed in chapter 3 will be based on these key-concepts and will focus in particular on the typology of networks and the effectiveness of networks. Effectiveness being defined here as 'goal attainment'. Through the examination of the literature, soft governance-related factors affecting typology and network effectiveness have been identified and will be used as tools to answer the research questions defined above.

Part B outlines the findings of the empirical research on European HTA cooperation. It is structured according to the three development periods outlined above. Chapter 4 regards the development of the early cooperation projects which have taken place from 1992 to 2001. Chapter 5 is focused on the 'interlude' period from 2001 to 2006 and addresses in particular the developments regarding EU health policy and which have laid the basis of the future HTA cooperation processes. The examination focuses on three different policy streams affecting HTA cooperation: the EU health policy stream providing the institutional frame-work of HTA cooperation; the social policy stream, providing soft governance instruments in HTA cooperation and the pharmaceutical policy stream, providing key content to HTA cooperation. Chapter 6 regards the period since 2006 with the creation of HTA networks such as EUnetHTA and the EU HTA Network and the attempts of the European Commission to embed HTA cooperation in an EU regulatory framework.

Part C regards the critical examination of the empirical findings by applying network analysis based on the research framework of chapter 3. Chapter 7 is therefore divided in three sec-tions. The first, based on the concept of governance networks, seeks to identify the typolo-gies of the various European HTA cooperation initiatives. The second, based on network governance, regards the effectiveness of these networks in reaching the objectives set. A third section addresses the question whether in European HTA cooperation, metagovernance has been identified, The outcome of this examination will permit to relate the findings to the research questions which will be answered in chapter 8 drawing the final conclusion of the thesis. This concluding chapter will furthermore highlight the strengths and weaknesses of the research, its limitations as well as topics requiring further research and policy recom-mendations.

CONTRIBUTION TO RESEARCH

The contribution the research will make to the academic literature is three-fold. First, to date, no exhaustive account exists on HTA cooperation in Europe by examining the subject from an EU governance perspective. Most publications either present HTA practices and their impact in individual countries or highlight main development stages of HTA networks and

their contribution to HTA collaboration in Europe (see also section 1.4.). However, to my knowledge, no systematic analysis exists whereby the general internal HTA networks' governance processes are brought into relation with EU health policy. Moreover, many publications only briefly refer to the initial HTA networks and posit the start of the collaboration in 2006. Consequently, there is a tendency to disregard on the one hand the connectivity between the networks since they originated and on the other hand the connectivity between EU health policy and HTA cooperation. Indeed, the latter is rooted in the initial cooperation initiatives and is further developed in the 'interlude' period from 2001-2006.

Second, though networks, by their intrinsic characteristics, become a favourable forum for the development of soft governance, few publications examine soft governance through the prism of *network analysis*. Most often, particular soft governance instruments will be examined as to their role and effectiveness in (EU) policy-making (e.g. Scott and Trubek 2002; City and Rhodes 2007, Héritier and Lehmkuhl 2011a, Schmidt 2006, Follesdal 2010). Proceeding through network analysis in the examination of soft governance, permits to combine knowledge rooted in different academic disciplines and herewith provide innovative insights on the subject.

Finally, by retracing the process of HTA cooperation since its origins till the proposal of an EU Regulation in this area, this research also gives account of the emanation of a new EU policy area and of the development of new EU legislative tools in a domain of restricted EU competences.

PART A

THEORETICAL FRAMEWORK

1 | Health Technology Assessment in Europe

"When one undertakes any action, one must not speculate about whether it will succeed."
Jean Monnet, Memoirs

1.0.   INTRODUCTION

European cooperation in Health Technology Assessment (HTA) reflects a dynamic interplay between two distinct processes: the organisation and financing of national health systems and European integration. Examining the development of European HTA cooperation processes requires to have a good understanding of the place of HTA in national health policy processes as well as of the development of European health policies. This chapter aims to situate HTA cooperation within the national and European health policy contexts. It also examines which attention it has received in the academic research and which aspects still remain under researched.

The first section of the present chapter will address what is understood by Health Technology Assessment. The second section will develop the role of HTA in domestic health policy processes and how it has been developed in diverse ways across the EU Member States in terms of content, methodology and weight in regulatory processes. This diversity of approaches underpinned the cooperation initiatives among HTA agencies seeking to reinforce and develop their activities. Section three of this chapter will outline the broad stages of the HTA cooperation process in Europe having triggered attention and support of the European Commission. It will also address the numerous challenges faced in the quest to elaborate common European approaches and methodologies in HTA.

The literature review, set out in section four, brings to the fore how European HTA cooperation has been discussed in the academic literature. Three main strands in this regard have been identified. The first concerns publications elaborating on the general developments of HTA in Europe and the different (institutional) approaches that have been chosen in various countries. The second strand highlights diversity in methodological and policy aspects regarding HTA in Europe and discusses to which extent and how challenges could be addressed. The third strand of the literature discusses European HTA cooperation initiatives by presenting the various projects and their outputs and outcomes in this field. This review also allows to identify several gaps in the literature on European HTA cooperation initiatives which will be discussed in section five.

1.1.   HEALTH TECHNOLOGY ASSESSMENT DEFINED

To address the problem of rising health care expenditures and ensuring access to safe and efficient health care, EU Member States have developed since the late 1980s so-called 'Health Technology Assessments' (HTA) as an aid to decision-making (Raftery 2011). Health Technology Assessment (HTA) refers to" the systematic evaluation of properties, effects, and/or

impacts of health care technology" (www.inahta.org). As such, "it summarises information about medical, social, economic and ethical issues related to the use of a health technology" (Kristensen 2006). Health technology has been defined as "the application of scientific knowledge in health care and prevention" covering a wide range of aspects of the health care system ranging from pharmaceuticals, medical devices, medical and surgical procedures, diagnostic and treatment methods, rehabilitation and prevention methods as well as the management of systems where health care is provided (Banta 2003:122; Nielsen, Santamera, Vondeling 2008: 20; www.inahta.org).

HTA is linked to policy-making since it is aimed at giving input into decision-making processes, such as, pricing and reimbursement of health technologies, clinical guidelines and hospital investments which makes it also a highly politicised process (O'Donnell et al. 2009; Thatcher 2010). The HTA process of pharmaceuticals differs from other health technologies as it can take place only after EU market authorisation through the European Medicines Agency (EMA) has been obtained. This authorisation is based on the (centralised) evaluation of data regarding the safety and efficacy profile of the product (benefit-risk assessment). Once the EMA has issued a positive recommendation, the European Commission will authorise to market the product in the EU (www.ema.eu). Following this process, products will enter an assessment process on a national or regional level which will further evaluate the products as to their safety profile, effectiveness compared to other available products on the market as well as to aspects related to cost-effectiveness, legal, social and ethical matters. The outputs of these assessments can be used in decision-making processes regarding pricing and reimbursement of the assessed products.

The HTA process of medical devices differs in many regards from the one of pharmaceuticals. These differences are related to the regulatory environment, the pre-marketing evaluation assessments, the characteristics of medical devices[2], the life-cycle of medical devices[3] as well as the industrial development environment[4]. Conversely to pharmaceutical products, no harmonised approach exists for medical devices regarding EU market approval. For a device to be marketed in the EU it needs to obtain a CE mark. This decentralised process involves

---

2   Unique characteristics of medical devices are for example: the incremental innovation of a devices leading often to a short lifespan, the device-operator interaction (learning curve and handling), level of risk, economic or organisational implications etc. (Rummel, Hawlik,and Wild 2016:20)

3   Medical devices evolve rapidly, often due to incremental innovations leading to product modifications. The latter can have an impact on the assessment process as well as on the (clinical) studies related to them (Rummel, Hawlik,and Wild 2016:21).

4   The majority of medical devices companies are Small and Medium sized Enterprises (SMEs), whereas the pharmaceutical industry is characterised by large multinational companies (Rummel, Hawlik,and Wild 2016:23; Medtech Europe 2015).

pre-marketing evaluation through competent authorities and their designated Notified Bodies. Once the CE mark has been acquired, the product can enter the market and national assessment processes can take place. These processes differ however highly amongst the EU Member States as to the level of clinical evidence requested, the timing of an assessment and the methodologies applied (Rummel, Hawlik,and Wild: 2016). Although several EU Directives adopted in the 1990s created a framework to regulate safety and marketing of medical devices, the rapid development of devices as well as events pointing to safety concerns of some of them, has led to the adoption in 2017 of a new EU Regulation on Medical Devices and In Vitro Diagnostics (Regulation EU 2017/745 and Regulation EU 2017/746). The aim was to strengthen pre-market conformity assessments, post-marketing control and supervision and offer the possibility to trace devices throughout the life cycle.

Hence, the introduction and prescription of health technologies in European Member States follows a particular path which differs from other products which can be marketed in the European Union. Indeed, although resulting from an industrial process, health technologies may have a potential impact on health care and, as such, fall under the health policies of the Member States. Health policy contains multiple facets and regards besides sanitary measures also economic, fiscal, budgetary and social concerns. The market authorisation and diffusion of health technologies reflect all these issues as besides the assessment of the quality and safety of the products, their prescription and use will also be based on assessment of the technologies related to other policy aspects (e.g. economic, social, legal, ethical).

No uniform approach regarding health policy and the organisation of health systems exists in Europe as the latter depends on the underlying social security structures as well as on social, legal, fiscal and economic policies of each Member State. Similarly, although market authorisation for pharmaceuticals has been centralised at the EU level, the process for other technologies as well as the pricing and reimbursement policies of all health technologies still differ across the EU and fall under the exclusive competences of the Member States. The way health care funding is organised also differs highly in the EU but, most commonly, health care systems function either on a tax-based funding system or a social health insurance system (Saltman 2004:16)[5].

Most EU Member States strive to base the reimbursement decision-making process of a health technology on an assessment which examines short and long-term consequences of

---

5   General taxation systems can be found in countries such as the United Kingdom, Finland, Sweden, Spain, Portugal, Italy and Greece. Social Health Insurance Systems can be found in countries such as Austria, Belgium, Croatia, Czech Republic, Estonia, France, Germany, Hungary, Latvia, Lithuania, Luxembourg, the Netherlands, Slovakia and Poland (Saltman 2004:3)

the diffusion of that technology. Hence, besides quality and safety issues, HTA can address also other domains such as the effectiveness of a product compared to similar products on the market (relative effectiveness assessments, REA), the costs of a product compared to its effectiveness (cost-effectiveness assessments), the impact of the product on the health budget as well as societal, ethical or legal implications linked to the introduction of the product on the national market (Banta 2003; Jonsson and Banta 2009).

The goal of health technology assessment is to provide policy-makers with information on policy alternatives and thus to support decision-making in the health sector by a systematic assessment of health technologies under medical, economic, social and ethical aspects (Banta and Oortwijn 2000; Banta 2009). HTA is often also considered as a bridge between research and decision-making (Batista and Hodge 1995). Indeed, HTA has been developed by building further on knowledge stemming from different methodological streams such as policy analysis, evidence-based medicine, health economic evaluation and social and humanistic sciences (Kristensen 2009: 336).

By systematically assessing health technologies, efficient and equitable resources allocation may be achieved in health care, improving herewith also cost-controlling strategies. Moreover, the fact that the HTA covers many different domains also permits to identify underutilisation or overutilisation of some products and can have, as such, an impact on price-setting (Cookson and Maynard 2000). Price regulation and reimbursement decision-making processes are often interrelated and HTA can give input to both type of processes. For example, the analysis of the target population, the incidence of the disease on the overall population and the availability of alternative treatments allows to assess which consequences reimbursement of the product would have on the health budget depending on the price set.

Whilst HTA has received a lot of attention in the framework of regulatory processes of pharmaceuticals or medical devices, it is important to understand that it concerns a wide range of different health technologies which all affect the health systems and are thus concerned by health policy and the organisation of health care in a country aiming to improve public health. For example, screening policies or medical and surgical procedures as well as the organisational and supportive systems within which such care is provided can be subject of an HTA (Banta 2003: 122). Hence, when examining HTA cooperation processes, it is important to keep in mind that HTA encompasses both health technologies and health interventions[6].

---

6   Health Technology Assessment has originally been developed in the Office for Technology Assessment in the US, assessing a broad range of other technologies. This can explain the broad scope of technology assessment in health care (see further 1.4.1. and 4.1.1).

As the aim of HTA is to inform health care decision-making, there exists a clear relationship between HTA and public health policies as the latter target the overall population and regard the management of collective health (Brooks 2012). As underscored by Acheson (1988), public health can be defined as the "art and science of preventing disease, prolonging life and promoting health through organised efforts of society". In this sense, HTA can be considered as a tool for knowledge management and permits to inform decision-making processes seeking to promote public health. This can be translated in pricing and reimbursement processes, as outlined above, but HTA can also inform the development of clinical guidelines, treatment decisions or public health strategies (e.g. prevention) (Røttingen, Gerhardus and Garrido 2008). As underscored by Garrido, Zentner, and Busse (2008), "In general, HTA can be applied: first, to all interventions supplied by the health system (e.g. medical services, drugs, diagnostics, etc.), second, to interventions into the health care system (e.g. organisation of service delivery, financing of the system, etc.) and third, to health interventions outside the health care system (e.g. environmental policies that aim at healthy living conditions)".

Several definitions have tried to encompass the many aspects covered by HTA. Two of them stand out in the academic literature. One has been developed by the International Network of Agencies for Health Technology Assessment (INAHTA) which describes health technology assessment as "a multidisciplinary field of policy analysis. It studies the medical, social, ethical and economic implications of development, diffusion, and use of health technology" (www.inahta.org). In the European context, another definition defines HTA as a "multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. The aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value" (Kristensen 2006).

Most recently scholars have published yet another definition of HTA seeking to encompass all dimensions of the process. This definition comprises also four explanatory notes[7]. It defines HTA as "a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system" (O'Rourke, Oortwijn and Schuller 2020).

Most definitions of HTA underscore the multidisciplinary aspect of HTA which we find back in the three definitions given above. However, while they highlight the multidisciplinary aspects in a similar way, the second and third definitions presented above are more explicit in defining the aim of HTA by underscoring that the essence of an HTA is to inform the formulation of health policies. HTA in this thesis will be understood as defined in the second definition, which is, to date, also the HTA definition used by the European Commission (European Commission 2018; 2018a). The third definition having been published at the end of the research process could not have been taken into account in the research process. However, the manner in which HTA is understood in this dissertation is fully consistent with the latest definition published.

1.2. HTA AND NATIONAL POLICY PROCESSES

1.2.1. Diversity in methodologies, assessment domains and their inclusion in HTA

By seeking to inform decision-making processes, HTA plays a particular role in health policy processes. Health policy responds to many different definitions which often reflect various

---

7   The four accompanying notes are: "Note 1: A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system (definition from the HTA Glossary; http:// htaglossary.net/health+technology).
Note 2: The process is formal, systematic, and transparent, and uses state-of-the-art methods to consider the best available evidence.
Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.
Note 4: HTA can be applied at different points in the lifecycle of a health technology, that is, pre-market, during market approval, post-market, through to the disinvestment of a health technology" (O'Rourke, Oortwijn and Schuller 2020).

underlying interests or goals pursued by policy-makers. As such, according to Busse, Mays and Walt (2012:7), from an economic point of view, one can underscore the role of health policy in allocating scarce resources available for health. From an organisational point of view, one can highlight the policies permitting to influence the determinants of health to improve public health. From a medical point of view, one can focus on the health services delivered to individuals. One could also add to these, the social and ethical dimensions concerned by health policy. HTA contributes to all these different facets of health policy and should therefore not be reduced to only its cost-containment dimension, as it also permits to take into account the other facets of health policy mentioned above (e.g. medical, organisational, social, ethical). Indeed, HTA, as aforementioned, seeks to contribute to the formulation of health policy by providing (evidence-based) information and as such plays a role in the way health care priorities are set and service provision is delivered.

Although HTA is primarily targeted at decision-makers, it concerns a wide range of stake-holders as it can have an influence in the access and timing of availability of new technolo-gies to patients. Hence, it regards those that decide upon the availability of the technology on the market (e.g. health policy decision-makers), the end-users (e.g. patients), the ones that will prescribe the technologies (e.g. health care professionals), organisations that will reimburse (partially) the technology (e.g. social security system, private insurance companies) and of course those that have developed and will sell the technology (e.g. industry). All stakeholder groups are potentially concerned by HTA which could contribute to a timely and cost-effective marketing of new effective and safe health technologies permitting to improve the general delivery of health services in a given state.

Besides safety and effectiveness aspects, attention for HTA on behalf of decision-makers stems from its potential impact on the health budget. As the health budgets in EU Member States' have increasingly come under pressure, HTA is often associated with cost-containment policies. Health systems decision-makers need to ensure that effective and safe health tech-nologies are available on the market at a given price, offering so-called 'value for money', justifying coverage and which will not undermine the budget allocated to health care costs. The price should thus respond to the needs of patients, 'payers' and manufacturers. Hence, often decisions will be based on the incremental value of the technology and on the 'value for money' associated with the use of the new technology compared to current practice in the health system (Henshall and Schuller 2013:3).

To ensure a technology responsiveness to real-world challenges of the health systems, the notions of '(incremental) value' and 'value for money' often underpin decisions made by policy-makers, insurance companies or even health care institutions (e.g. hospitals). New technologies brought on the market need to respond to both notions, hence the need to

develop methods and analytical approaches permitting to identify them. HTA, in its large understanding - as outlined in the two aforementioned definitions - permits to assess both 'value' and 'value for money'. The notion of 'value' can be considered in a broad sense by taking into account what 'value' represents to patients, caregivers, society as well as decision-makers. As such, HTA represents a link between innovation and assessment of value (Henshall and Schuller 2013). However, as many interpretations can be given to the notion of 'value', many methodologies have also been developed to assess this notion in HTA.

Value for money is often a criterion brought to the fore by health care package decision-makers and other so-called 'payers' of health care expenditures (e.g. insurance companies). However, this notion should not be reduced to the sole cost analyses or cost-benefit analyses (CBA) (measuring the effects of the introduction and diffusion of a technology in monetary units). Drawing upon health economics, value for money can also be expressed in cost-effectiveness analyses (CEA) (measuring the effect in clinically relevant parameters or health benefits in natural units (e.g. costs per life saved or costs per avoided stroke). Often these CEA apply a so-called 'incremental cost-effectiveness ratio' (ICER) using decision-analytic modelling based on quality-adjusted life years (QALYs). In most cases, CEAs seek to inform a particular decision by identifying possible alternatives that could be taken to improve health of a patient facing choices between mutually exclusive alternatives (Drummond et al. 2015).

Hence, assessing health gain requires being able to measure health effects both in a positive as in a negative way (main health outcome and side-effects which can have an impact on health-related quality of life). Lately, the idea of 'real world effectiveness' (RWE) has become more widespread and used increasingly in health economic analyses. This approach is based on the use of data generated by real-world settings (e.g. data of registries) additional to, for example, clinical studies based on Randomised Controlled Trials (RCTs) often used in CEAs. Hence, different health economic approaches exist across Europe and no standardisation of methods in this regard is being developed. Moreover, economic analyses are not always part of HTAs as some countries prefer not to include them in the assessments. However, as they permit to take into account the notion of 'value for money' in its different interpretations and, as such, can inform decision-making on price-setting and reimbursement packages, an increasing number of countries do include economic assessments, at some point, in the assessment procedure of health technologies. For some countries this approach can even represent the core and most essential part of the HTA process.

Besides the assessment of value, other aspects are also frequently part of an HTA. No uniform approach exists however regarding the elements to be assessed in an HTA. The EUnetHTA network has developed a so-called HTA 'Core Model', including nine domains which can potentially being included in an HTA and which are increasingly considered in HTA processes.

These domains comprise: 1) Health problem and current use of technology; 2) Description and technical characteristics of technology; 3) Safety; 4) Clinical effectiveness; 5) Costs and economic evaluation; 6) Ethical analysis; 7) Organisational aspects; 8) Social aspects; 9) Legal aspects (www.eunethta.eu). Hence, when discussing HTA, it is important to examine first which domains are concerned in the assessments, as the approach can highly vary across agencies and countries. Some will encompass in their assessments all domains or will high-light the importance of costs- and economic aspects, whilst others will consider only the first four domains as essential. Moreover, methodologies used to assess the different domains show many disparities across the European agencies carrying out an HTA.

The first four domains - also considered as the *clinical* aspects of the assessments - are most commonly being considered in an HTA. Indeed, to assess a new or existing technology, one needs to place it in its context. The first domain therefore focuses on the health problem and population targeted, the epidemiology as well as the burden of the disease on individuals and on the society. Moreover, it gives a description of the availability and patterns of use of the technology and the alternatives available on the market. The second domain gives an overall understanding regarding the technical aspects of the technology and its function-ing including investments and information needed for use. The third and fourth domains regarding clinical efficacy and safety, are often based on RCTs and describe the efficacy or effectiveness of the technology in terms of health outcomes, function and patients' quality of life. They also look at potential direct or indirect harm that can result from use of the technology or from particular patient characteristics (EUnetHTA 2016a).

The inclusion of the fifth domain, assessing costs and economic impacts highly varies among EU countries and is still a controversial issue in many debates on HTA and even more so on HTA cooperation and convergence of practices. Indeed, the domain is closely linked to economic and fiscal policies as it can have a direct impact on pricing and reimbursement negotiations and decisions. Moreover, this domain is considered as being highly context specific. As aforementioned, methodological approaches regarding cost effectiveness differ across agencies and countries and bear the potential to influence outcomes of the assess-ments (e.g. specific criteria/endpoints used; choice of comparators; calculation methods) (Eddy 2009; Angelis, Lange and Kanavos 2018).

The last four domains (ethical analysis, organisational, social and legal aspects), although regularly recognised as important and justifying the context-specificity of HTA, bear often the least weight in many HTAs and are still under-researched in terms of HTA cooperation (Lehoux and William-Jones 2007; Lysdahl et al. 2016). Indeed, since the early days of HTA development, it has been considered that HTA should encompass not just clinical and eco-nomic issues but also ethical and social implications (Banta and Perry 1997). These domains

are however also subject to controversy which may explain the limited inclusion of them in HTAs (e.g. in vitro fertilisation, preimplantation genetic diagnosis). Moreover, the need to assess social and ethical issues can differ according to the country in which it is - or seeks to be - introduced (Lehoux and William-Jones 2007).

1.2.2. Diversity in policy approaches towards HTA

We have seen above how approaches regarding methodologies and domain inclusion in HTAs vary among different HTA agencies, even between those operating within the same country. As HTA has developed in numerous ways in the EU Member States and reflects still today a high variety in the way it is structured, no standardised practices exist regarding HTA. Hence, whilst the assessments are based on solid scientific approaches, different HTAs done on the same technology in different countries can result into different conclusions (Nicod and Kanavos 2016). This is however not the only diversity in approaches towards HTA. The manner in which the assessments are considered in the decision-making processes regarding health technologies also presents dissimilitude.

The understanding of the notions of *assessments* and *appraisal* play a role in the divergence of policy approaches regarding HTA. Stevens and Milne (2004:11) define the former as "the analytical process of gathering and summarising information about health technologies" and he latter as "the political process of making a decision about health technologies". Hence, assessments in this perspective, refer to a scientific process based on different methodologi-cal streams (e.g. evidence-based medicine, health economic evaluation, policy analysis, social and humanistic sciences) while appraisal refers to the role of policy-makers in making a decision based on the assessment (Kristensen et al. 2009:33). Others, underscore that "appraisal is a consideration of the outputs of the assessment process within the context of additional information supplied by relevant parties" (Oortwijn et al. 2013). In this perspective, the appraisal of the product and how this will find its place in the given health system is context specific and explains national differences, even if they are based on the same HTAs. Hence, even if manufacturers develop their products to be marketed globally, technologies will still have to undergo separate assessments and appraisals in each (national) market.

The disparity in approaches is also reflected in the literature where the boundaries between assessment, appraisal and decision-making are not always established at the same levels. As such, some will consider domains dealing with social and ethical issues as part of the appraisal process, while for others this is still part of the assessment process. Similarly, some will consider some aspects of the cost-effectiveness assessment as part of the decision-making process whilst for others this is either part of the assessment or the appraisal process (or both). This confusion can be related to the weight and value given to each of the domains in respectively the assessments, appraisal and decision-making process.

Thatcher (2010:4) underscores how sometimes processes referring to assessment, appraisal and decision-making take place within the same institutions whereby boundaries can somehow be blurred. Conversely, in some countries these processes can take place across different (public and private) institutions/agencies. Moreover, blurred boundaries between assessment, appraisal and decision-making can also result from the fact that they are, to a certain extent, intrinsically linked. The setting of endpoints in clinical studies, for example, can be related to the appraisal phase which will value whether these endpoints are relevant in a specific case and as such have an impact on the decision-making. Similarly, an appraisal process can implicitly give more weight to certain assessment domains (e.g. what is prevailing in a particular case: cost-effectiveness or social/ethical issues?) Moreover, the appraisal and decision-making processes can also add issues not included as such in the assessment processes (Garrido, Zenter and Busse 2008:61). As such, separating assessment from appraisal remains to a certain extent debatable and no generally accepted definitions about the concepts exists to date (see also e.g. Van der Wilt, Gerardus and Oortwijn 2017).

The absence of consensus regarding the understanding and definitions of assessment and appraisal infers in political debates regarding European HTA cooperation as it touches upon competence issues of Member States. By separating assessment from appraisal, the division of competences between the EU and the domestic level is indirectly addressed. Indeed, considering *assessments* in the sense of providing scientific information about the selected HTA domains and serving as input in decision-making processes (which would handle the appraisal process of HTAs) detaches them from domestic decision-making procedures, falling under the exclusive Member State competences. Hence, as the debate about assessment and appraisal is still ongoing it bears the potential to influence European HTA cooperation because of competencies' related issues.

According to Garrido, Zenter and Busse (2008:61), decisions regarding health technologies need to be based on information regarding context-free factors of the technology as well as on context-dependent factors. "An assessment (i.e. HTA report) can provide such information as it is a summary of the relevant research on context-free and context-sensitive evidence". However, context sensitive information is not always available in research and needs to be brought into the process in the decision-making processes (by Garrido, Zenter and Busse 2008:61). Hence, the importance to always take into account contextual factors when analysing HTA and in particular cooperation between HTA agencies (Hutton, Trueman and Facey 2008; Barron et al. 2015).

Although designed to be politically 'neutral' and based on a solid scientific approach, HTA can become politicised as it can feed into specific policy processes on a particular issue (e.g. ethical issues, political pressure). We have seen above how health policy is linked to

other policies (social, fiscal, financial and economic). The weight of the health sector on the European economies represents almost 10% of the GDP (Garrido 2008:162). With the rapid technological developments, policy-makers face not just budgetary constraints, but are also confronted with pressure from stakeholder groups (e.g. patient organisations) seeking to have fast access to these new technologies (Garrido et al. 2009:46). Hence, trade-offs need to be made between health concerns (safe and efficient medicines), budgetary concerns (affordability of health technologies and sustainability of the health system) and economic concerns (development of the industry as driver of the economy).

As such, HTA finds itself in various policy processes and involving the many stakeholders concerned by the policy. Moreover, instead of being used in a neutral manner based on scientific research, HTA can be used "as ammunition in political debates" (Nielsen, Santamera, Vondeling 2008:23-24). Increased stakeholder participation and request for more transparency, sometimes also results in increased pressure on regulatory bodies who seek to gain trust from the wider public to ensure their legitimacy. Especially in fields such as genetics or stem cell research appraisal, the conflicting perspectives of patient groups, industry, scientists or religious groups can impact decision-making (Blume 2008). As such, HTA conclusions can be used either to post-pone action or at the contrary to support implementation of the new technology.

The challenge for HTA is thus to provide information which is based on solid scientific (e.g. evidence-based) methods permitting to estimate future benefits and risks for both the health system as the end-users of the technology (Henshall and Schuller 2013:5). As it can find itself at the cross-roads of different policy areas, the assessment, appraisal and decision-making processes based on HTAs can become politised. No uniform methodological approach to HTA exists in Europe and even within a single Member State, different methods can be used in different agencies. As such, to date, when a manufacturer develops a new health technology for the EU market, a separate HTA will be realised in each Member State. As HTA is a time-consuming and costly exercise, avoiding duplication of assessments may be beneficial for all stakeholders. This observation has led to the cooperation efforts among HTA agencies which have started in the 1990s. In the next section we will outline the development of the different collaboration initiatives and the challenges faced by these.

1.3. HTA AND EU COOPERATION INITIATIVES

HTA has been introduced in Europe in the mid-1980s and was based on the work initiated in the Office for Technology Assessment which had been created in 1972 in the USA (Banta 2009; Thatcher 2010). Since HTA was a very young discipline, representatives of agencies

from all over the world gathered in international societies (e.g. ISTAHC, INAHTA) and sought to exchange their knowledge and experiences. The first European cooperation initiatives among HTA agencies were born inside these international societies and took place almost simultaneously with the setup of the first HTA agencies in Europe (Boehm and Landwehr: 2013:15). The aim was to enhance the quality of the assessments and to develop HTA in countries where it did not yet exist. The underlying idea was that enhancing the quality and the quantity of HTA would allow for a better uptake of HTA in the national decision-making processes and also permit the development of HTA in countries having limited experiences in this field (personal interview 2).

The first cooperation initiatives at a European level coincided with an increased attention for HTA on a national level due to the rapid development of new technologies, procedures and care pathways impacting the national health care budgets (Henshall and Schuller 2013). Considering the diversity of approaches in HTA, the numerous duplication of assessments made on the same technologies, as well as the need for HTA capacity-building, questions were raised on what should be considered as best practices in HTA as well as on the manner to develop 'joint HTAs' between several HTA agencies across various countries. The idea to 'harmonise' HTA permitting to cooperate better and avoid duplications has been present from the start. However, as underscored by Hutton,Trueman, and Facey (2009: 455), harmonisation can refer to different elements. It can concern 1) the harmonisation of approaches and processes, 2) the harmonisation of methods and evidence requirements or 3) the harmonisation of decisions.

Harmonisation of decisions has never been the objective of the cooperation efforts as this is intrinsically linked to domestic health policy-processes. However, increased standardisation of HTA methods and procedures has always been one of the prime objectives allowing "a wider range of HTAs in Europe to be undertaken and also help improve links between technology assessment and decision making" (Kristensen 2006). The challenge was thus to streamline methods and practices of various HTA agencies in Europe which applied different criteria in HTA regarding issues, such as, technologies to be assessed, data requirements and analytical designs (Boehm and Landwehr 2013:15). Moreover, according to those considering assessments and appraisal as two distinct processes, convergence in assessments would still leave room for individual domestic appraisals of the assessments, taking into account context-specific elements on a national or regional basis.

The more the cooperation process evolved, the more the issue of 'transferability' came to the forefront as a key-concept regarding convergence in HTA practices. Gradually, it became clear that the feasibility to transfer work done jointly on a European level to the national context depended on different factors such as the HTA domains concerned. As such, the transfer-

ability potential of joint work seemed the highest in the first four domains often referred to as 'Relative Effectiveness Assessments' or 'Clinical Assessments'[8] whereas it seemed rather problematic in the five remaining domains: Cost and economic analysis; Ethical analysis; Organisational aspects; Social aspects; Legal aspects (see further chapter 6).

Moreover, streamlining methodologies and practices required to overcome challenges linked to other important aspects of HTA in Europe. The latter regarded, amongst others, organisational approaches and policy-making aspects. Indeed, some countries having organised HTA by adopting a centralised approach where HTA is being carried out by one central agency (e.g. France). Other countries having organised HTA in a decentralised way where HTA are realised by several independent agencies (e.g. Spain, the Netherlands). Agencies can be public or private and can provide information for decision-making either on a national basis or on a regional basis (Garrido et al. 2008:32; see also Dragborg et al. 2005 for an overview).

Moreover, as mentioned above, disparities amongst Member States' HTA agencies also reside in the nature of the agencies, some conducting both assessments and appraisals (e.g. France), while in other countries the processes are separated (e.g. UK, the Netherlands). As such, methodological differences can be observed amongst them as well as across agencies in a single country. Some agencies focusing on clinical effectiveness and may or not include costs-effectiveness. Other, considering ethics and the social impacts of the diffusion of the technology in their assessments (Garrido et al. 2008: 40). The variety of approaches, partly finding its origins in the variety of health systems functioning and organisations can have an impact on the uptake of HTA in decision-making processes[9] (Garrido et al. 2008:83).

Although consensus exists within the HTA arena regarding the fact that HTA should be firmly rooted in scientific research, opinions differ as to the scientific methods that should be used in HTA. Moreover, methodology is often related to uptake in decision-making processes. Indeed, whether decisions will be considered legitimate, partly depends on the validity of the assessments results. The latter will depend on the methods used. To date, no consensus exists on what an 'optimal HTA' should refer to (Cookson and Maynard 2000), neither on the adequacy of the methods used. Relatively little controversy exists regarding the need to prioritise health technologies candidates for evaluation, as it is not feasible to assess all new

---

8   The first four domains are: 1. Health problem and current use of technology; 2. Description and technical characteristics of technology; 3. Safety; 4. Clinical effectiveness (www.eunethta.eu).

9   Some studies have highlighted the variety of criteria applied in coverage decision-making such as appropriateness, budget restraints, cost-effectiveness, innovation or need. No strict guidelines exist, however, on how to operationalise these criteria or to weigh them against one another (Manjusha, Bending and Hutton 2009; Garrido et al. 2006).

technologies entering onto the market. However, differences in approaches to prioritisation still exists. Methodologies used in economic evaluations represent maybe the area where divergences across countries and agencies and (health) economists are the highest, as they play an important role in the domestic decision-making process and are intrinsically linked to value attribution (see above). Moreover, the timing of doing an HTA is a matter of debate, as positions range from assessing a new technology as early as possible, to post-marketing assessments (so as to inform on whether a product should remain available and be reimbursed or be withdrawn from the market or removed from reimbursement baskets).

Despite these differences, significant progress has been made in finding common methodological approaches since first the cooperation projects. Today, several tools have been developed to establish a common basis for cooperation such as a European 'core HTA model', guidelines and other tools (e.g. databases). These objectives have not been achieved overnight and result from a long and still-ongoing cooperation process which has started in 1994 with the EUR-ASSESS project (1994-1997). This project was the first in its kind and was followed-up by two other projects HTA-Europe (1998) and ECHTA/ECAHI (1999-2001). These projects permitted to exchange information and experience regarding HTA on emerging technologies and priority-setting. From the start, one of the objectives regarded the establishment of 'joint assessments' and the coordination of the findings and resources necessary to carry out an HTA (ECHTA/ECAHI 2001:8). Moreover, the establishment of a permanent network structure was considered to be the most appropriate way to conduct the cooperation efforts.

The European Commission has very soon recognised the potential impact of HTA on the national health system. As such, it has given its financial support to the first cooperation initiatives. In 2003, it included HTA in the High Level Process of Reflection on Patient Mobility and Healthcare, permitting the topic to enter onto the EU political agenda and be discussed on the highest expert level. The experts recognised the importance of HTA cooperation in Europe and invited the European Commission to reflect upon the establishment of a sustainable network of HTA (European Commission 2003a:6). To take the recommendation of the high-level reflection process further, the European Commission established the High Level Group on health services and medical care (HLG) in 2004. This HLG developed a new project called the 'EUnetHTA project', which continued the work began in the early cooperation projects. This project further developed in three so-called 'Joint Actions' between the newly establish EUnetHTA network and the European Commission.

All projects aimed at the establishment of a sustainable structure for HTA cooperation which could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTA in Member States (EUnetHTA 2009). As such,

the different projects of EUnetHTA sought to reduce overlap and duplication of efforts and promote a more effective use of resources. The latter should also contribute to increase uptake of HTA in national decision-making processes, strengthen the link between HTA and health care policy and develop HTA in countries with limited experience in the matter (EUnetHTA 2009). Many different tools have been developed throughout the different Joint Actions focusing on the establishment of joint work (methodologies, tools[10]), uptake (re-use of joint work and impact on decision-making processes) and adopting a life-cycle approach (priority setting/Horizon Scanning, evidence generation and so-called Early Dialogues seeking to streamline evidence required for regulatory purposes and HTA purposes).

The adoption of a Cross-Border Health Care Directive (2011/24/EU) has permitted to take further the HTA cooperation process in Europe as the Directive created a legal basis for HTA cooperation between EU Member States. Building upon the provisions laid down in the Directive, the European Commission established a new EU HTA Network in 2014 which gathers national authorities responsible for HTA. Its focus is on the strategic and policy coordination of HTA relevant issues in the EU. The EUnetHTA network would since continue to operate as the scientific and technical arm of the EU HTA Network until 2020, after which a new sustainable (financial and organisational) structure should be implemented to support EU cooperation in the field of HTA.

Despite the efforts and progress made, duplication of assessments still take place and uptake of joint assessments in national decision-making processes is rather low. Barriers which have been identified so far point to issues such as methodology, resources and national regulatory processes (legal conditions) (Kleijnen et al. 2015; Garrido et al. 2009:44-45). Cultural differences are also sometimes mentioned as a barrier to uptake and harmonisation of methods in the wider sense (Lux and Karner 2013). Moreover, some reports are context-specific and their transferability to other contexts seems problematic. Similarly, sometimes legal and ethical information can be context-specific and difficult to adapt in another setting (Garrido et al. 2009:45). Trust seems to be another important aspect in the reluctance of national policy-makers to base their decisions on assessments that have been done on a cross-border basis. Finally, the quality and timely availability are brought to the fore as critical success factors to ensure a better uptake of joint work (Kleijnen et al. 2015). Hence, despite potential costs- and time savings, in practice, many countries continue to develop HTA according to domestic approaches.

---

10   As methodologies and tools developed by EUnetHTA we can cite: a core HTA model common reporting standards; a model to implement joint assessments; adaptation tool kits to use HTA done by other agencies and adapt it to the local requirements; tools to monitoring the development of HTA in countries with limited experience, databases to share HTA data and results.

To overcome the problems of insufficient uptake of joint work and to boost cooperation amongst EU Member States, the European Commission has made in January 2018 a proposal for the adoption of a new EU Regulation on HTA. This proposal aims at providing the basis for permanent and sustainable cooperation at the EU level. It proposes 'the use of common tools, methodologies and procedures in four areas: 1) on joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients; 2) on joint scientific consultations whereby developers can seek advice from HTA authorities; 3) on identification of emerging health technologies to identify promising technologies early; and 4) on continuing voluntary cooperation in other areas" (European Commission 2018). This proposal stipulates that for the pharmaceutical products and medical devices where a joint clinical assessment has been made, Member States cannot organise a similar assessment on a national level. Assessment of non-clinical (e.g. economic, social, ethical) aspects of health technology is in this proposal still conceived as individual EU Member State exercise leaving the possibility for cooperation and uptake of the results on a voluntary basis. The decision-making processes on pricing and reimbursement fall outside the scope of this proposal as this remains an exclusive competence of national Member States. The proposal can only enter into force and be applicable if it will be accepted by the EU Parliament and the Council of Ministers.

Although initiated from within the HTA community itself, the European Commission's implication in the European HTA cooperation process has been determinant for its course of action. From granting only financial support in 1994 to becoming a full-fledged partner in the HTA Joint Actions, the Commission has gradually taken the driver's seat and steered the developments in this field. Moreover, several initiatives launched by the Commission have permitted to lift HTA cooperation to an EU institutional level. The most recent proposal for an EU Regulation in the field of HTA cooperation is another example of the role of the EU in seeking to establish a sustainable European cooperation in health technology assessment.

In the following section we will examine how these HTA cooperation processes in Europe have been examined in the literature. We will proceed by first looking at publications about the general development of HTA in Europe before addressing literature specifically examining European HTA cooperation processes.

1.4. RESEARCH ON EUROPEAN HTA COOPERATION: LITERATURE REVIEW

If one leaves out the scientific publications reporting on the results of a specific HTA made on a health technology, the literature on HTA remains rather limited[11]. Focusing essentially on the publications which have examined HTA cooperation in Europe, the literature becomes even more scarce and is being addressed predominantly by the HTA arena itself. Most publications focus on a few central issues such as the (historical) development of HTA and the relationship between HTA and policy-making/regulatory issues (in particular pricing and reimbursement). Another important part of the literature is dedicated to individual or multi-country reports on the state of HTA and its impact on decision-making. Methodological issues of HTA are also increasingly being debated in the academic literature and mostly regard evidence-based decision-making and economic evaluations.

HTA related to pharmaceuticals receive most attention followed by research done on HTA and medical devices (e.g. Siebert, Clauss and Carlisle et al. 2002; Altenstetter and Permanand 2007; Sorenson and Kanavos 2011; Kirisits and Redekop 2013; Fuchs et al. 2017; Olberg et al. 2017). Little attention is given to other types of health technologies. Other issues such as HTA and priority setting (e.g. Oortwijn 2000; Anell 2004; Oliver, Mossialos and Robinson 2004) and the participation of stakeholders in HTA have also received attention in the academic literature but to a much lesser extent (e.g. Nielsen et al. 2009; Gauvin et al. 2010; Houÿez et al. 2011; Gorry et al. 2015; see further section 1.4.2).

In this section we will briefly outline the key-aspects brought forward in the literature on HTA. The aim here is not to present an exhaustive overview of the literature but to highlight the main topics and positions discussed in relation to EU HTA cooperation initiatives. As such, in the examination of the literature, we have identified three main strands which we will outline hereafter. The first part of this section will regard publications on the general development of HTA in Europe. The second sub-section will be focused on methodological and policy aspects brought to the fore in the literature related to HTA cooperation in Europe. The third sub-section will examine publications that have treated more specifically the HTA cooperation processes in Europe. The final sub-section will highlight the gaps in the literature as regards EU cooperation in HTA.

---

11 As this thesis will focus on the governance aspects of HTA cooperation, this non-exhaustive overview of the literature will not treat individual HTA reports.

1.4.1. Development of Health Technology Assessment

Early publications on the development of HTA aimed at underscoring the role of HTA as a valuable tool for decision-makers to assess safety, (cost-)effectiveness, quality of care and patient outcomes. Most publications draw back on the establishment of HTA in the Office for Technology Assessment (OTA), which closed in 1995 (e.g. Battista and Hodge 1999: Banta and Oortwijn 2000b; Jonsson 2002; Stevens Milne and Burls 2003; Banta 2003; O'Donnell et al. 2009). The OTA had been established upon request of the American Congress to respond to the need of policy-makers regarding information on the rapid development of new technologies and their intended and unintended impact on society. Health technology has been included in this approach. Against this background HTA has been first conceptualised in 1976 (Banta 2003; 2009; O'Donnell et al. 2009; Meneu 2015).

Many publications elaborating on the general developments in the field of HTA outline how from the US, the concept of HTA has been established and further developed in many other countries across the world such as Canada, Australia, Europe and later to Asia and Latin America (e.g. Perry, Gardner and Thamer 1997; Stevens Milne and Burls 2003; Banta 2003, Garrido and Busse 2005; Blume 2009; O'Donnell et al. 2009). Sivalal (2009) underscores how the development of HTA has been most successful in developed countries whereas less developed countries would maybe even need HTA the most. Whilst HTA became increasingly recognised as tool for policy-makers in decision-making processes, no uniform model of HTA existed across the continents. Several analytical accounts have sought to highlight the similarities and differences between HTA agencies (e.g. Banta et al. 1995; Perry, Gardner and Thamer 1997; Dragborg et al. 2005; see also the multi-country analyses below).

Most often however, these publications regard the presentation of individual countries or present a multi-country comparison. In the literature, the United Kingdom (UK) stands out in terms of academic attention received. The National Institute for Health and Clinical Excellence (NICE) established in 1999 in the United Kingdom is indeed one of the most researched agencies. This can partly be explained because of its role and weight in the domestic decision-making process as the National Health Service (NHS) has to implemented recommendations made by NICE (e.g. Woolf and Henshall 2000; Stevens and Milner 2004; Milewa 2006; Schandler 2007, Sorenson et al. 2008; O'Donnell 2009; Drummond and Sorenson 2009; Drummond 2009; Longworth et al. 2013). The Swedish model is also often presented, focusing on the Swedish Agency for HTA (SBU) established in 1987 as one of the first European HTA agency (together with the Catalan Agency for HTA) (e.g. Carlsson et al. 2000; Jonsson, Banta and Scherstén 2001; Carlsson 2004; Schwarzer and Siebert 2009; O'Donnell et al. 2009; Jonsson 2009). Finally, the Canadian experience in HTA is also often used as a reference in international comparisons (e.g. Menon and Topfer 2000; Borowski, Brehaut, and Hailey 2007; Battista et al. 2009; Menon and Stafinski 2009).

Many publications have presented the role and impact of HTA in specific countries. As it is not our aim to give an exhaustive list of these, we will just highlight a few of them. Multi-country analyses have been made by scholars such as Banta and the US Congress (1995) outlining the development of HTA in Australia, Canada, France, Germany, the Netherlands, Sweden and the United Kingdom. Chinitz (2004) focuses his research on the UK, the Netherlands, Sweden and France, Dragborg et al. 2005 presents a multi-country review including Denmark, Sweden, the Netherlands, Norway, the United Kingdom, Canada, Australia and the USA. Schwartzer and Siebert (2009) include Germany, the United Kingdom, France, and Sweden in their research. An analysis of HTA in central and eastern European countries has been made by e.g. Sorenson, Kanavos and Karamalis (2009). Other publications presenting a multi-country approach are e.g. Healy and Pugatch 2009 (Australia, Canada, Germany and UK); Kanavos et al. 2010 (Canada, England, Australia, Sweden, France and Scotland); Oortwijn et al. 2013 (comparison HTA in middle-income countries (e.g. Brazil, India, Malaysia) with Australia, Canada, and United Kingdom); Del Llano-Señarís 2015 (France, Germany, Spain, Sweden, United Kingdom); Fisher, Heisser and Stargardt 2016 (Germany, England, Scotland and Australia).

An important strand of the HTA literature regards analyses of individual countries, such as, *Australia* (Bulfone, Younie and Carter 2009; Hailey 2009b): *Austria* (e.g. Wild 2006; 2009); *USA* (e.g. Sullivan et al. 2009; Luce and Singer Cohen 2009); *Belgium* (e.g. Cleemput and Van Wilder 2009*); Denmark* (e.g. Sigmund and Kristensen 2002; 2009); *Finland* (e.g. Lauslahti et al. 2000; Mäkelä, and Roine 2009); *France* (e.g. Chevreul and Durand-Zaleski 2009; Weill and Banta 2009; Orvain and Matillon 2004; Barron et al. 2015), *Germany* (e.g. Gerhardus 2006; Nachtnebel et al. 2015; Nasser and Sawicki 2009; Perleth, Gibis and Gohlen 2009, Schwarzer and Siebert 2009); *Hungary* (Gulacsi et al. 2009); *Italy* (e.g. Favaretti et al. 2009); *Norwa*y (e.g. Mørland 2009); *Spain* (De Sola-Morales and Granados 2009); *The Netherlands* (e.g. Banta, Oortwijn, and Van Beekum 1995; Bos 2000, Berg, Van der Grinten and Klazinga 2004; Banta and Oortwijn 2009); the *UK* (Woolf and Henshall 2000; Stevens and Milner 2004; Schandler 2007; Sorenson et al. 2008; Drummond 2009; Longworth et al. 2013).

The research done on HTA in the individual countries brings to the fore both similarities and disparities in the development and institutionalisation of HTA. Most agencies have been created and have developed their activities in a rather depoliticised manner and receiving state aid or other types of institutional funding and support in the production of HTA reports. However, as the financial pressure on the national health budget increased overtime, the need for HTA also increased and more emphasis was put in the publications on the relationship between HTA and cost-containment. Chinitz (2004) underscores how this situation has impacted the political accountability of the agencies in many countries.

One of the striking differences between the HTA agencies regards their (institutional) status and role in the decision-making process. In some countries a decentralised approach (e.g. Sweden, Italy) has been adopted whereas in other countries it is characterised by a more centralised control (e.g. France[12]). Research has underscored how a centralised control is often more associated with an enhanced role in decision-making whereas a decentralised organisation of HTA agencies reduces their impact and can lead to competition among them (Chinitz 2004:57). However, the degree of centralisation or decentralisation can vary depending on whether one looks at the assessment process of HTA and the appraisal process. As such, in one country (e.g. England) assessment can be organised in a decentralised way (several HTA agencies conducting assessment and delivering a report) but the appraisal process will be centralised. Conversely, in other countries (e.g. France) the assessment phase will take place in a single entity whereas the appraisal and decision-making processes will take place in several institutions[13]. Moreover, in some countries, recommendations of HTA agencies will be binding whereas in others this will not be the case.

As underscored by several scholars (Garrido et al. 2008; Barron et al. 2015), the organisation of HTA is often related to the organisation of the health systems in general which display a high degree of variation across the EU countries. These disparities stem from their genesis and development and lead to differences in the way financial resources are obtained and distributed. It also impacts on the manner in which service provision is organised and who participates in that process (Garrido, Zenter and Busse 2008:55). All systems however have in common the need to decide upon health technologies and their availability to patients. Sola-Morales and Granados (2009:88) point to the fact that the introduction of "HTA in decision-making processes is unique and linked to the local context".

1.4.2. Methodological and policy approaches in HTA

Besides institutional and organisational aspects, other disparities between HTA agencies exist and regard, in particular, methodological and policy approaches related to HTA. As such, the scope (domains, processes and methods used), dissemination (diffusion and reaching the policy area for decision-making) and implementation (impact on the population and society) of HTAs can vary amongst countries and even amongst agencies within a country (Schwartzer and Siebert 2009). Differences in the organisation and financing of the health

---

12 In France the Haute Autorité de Santé (HAS) plays a central role in the HTA process regarding assessments and excluding cost-effectiveness analyses. However, other institutions such as the Commission de Transparence (TS), the Comité Economique des Produits de Santé (CEPS) and the Union Nationale des Caisses d'Assurance Maladies (UNCAM), la Commission d'Evaluation Economique et de Santé Publique (CEESP) play an important role in the pricing and reimbursement process.

13 See footnote 8.

systems also impact the role of HTA in a given country. Similarly, the role of HTA can also affect the methodology and dissemination of the assessments. As such, agencies will have different requirements regarding the information needed to conduct the assessments and may also differ in the way evidence is being interpreted (Dragborg et al. 2005; Kanavos et al. 2010).

As regards the scope and methodologies used, whilst most agencies include clinical aspects and, to a lesser extent, economic aspects, real differences exist regarding the inclusion of HTA domains related to social impact, ethics, psychological reactions of patients (Dragborg et al. 2005; Duthi and Bond 2011; Lehoux and William-Jones 2007). Moreover, not all agencies apply the same standards to the process. As such, criteria to include clinical evidence in the assessments differ as do the methods used in the calculation of cost-effectiveness (e.g. Eddy 2009; Weatherly et al. 2009; Angelis, Lange and Kanavos 2018). Moreover, the weight of the different domains is not always the same across the agencies and reflects to a certain extent societal (and political) norms and expectations. Some (e.g. Sweden (TLV), France (HAS), Germany (G-BA)) emphasize quality and safety issues in appraisal and decision-making processes whereas others (e.g. UK (NICE)) also give important weight to cost-effectiveness issues in those. Finally, the choice of comparators can also vary. Some agencies including the current best alternative, others the cheapest available comparator and others use a comparison with placebo (Chalikidou et al. 2009; Kanavos et al. 2010; Angelis, Lange and Kanavos 2018).

Methodological issues have been widely discussed in the literature (e.g. Cookson, R. and A. Maynard 2000; Kristensen, Hørder and Poulsen 2001; Busse, Orvain, Garrido et al. 2002; Draborg and Andersen 2005, Drummond et al. 2015; Kanavos and Efthymiaou 2017). Several publications address the development of models facilitating the prioritisation of health assessment topics (e.g. Oortwijn 2000; Oliver, Mossialos and Robinson 2004). Many elaborate on techniques permitting to assess expected costs and benefits of health interventions. Although, as aforementioned, not all HTA agencies include in their assessment economic analyses, an important part of the publications discussing methodological issues will focus their attention on this domain. 'Value for money' is a central concept underpinning these publications and the methodologies being discussed (e.g. Davies, Drummond, Papanikoloau 1999; Drummond and Sculpher 2005; OECD 2005; Sorenson, Drummond and Kanavos 2008; Henschke, Sundmacher and Busse 2013; Henshall and Schuller 2013; Shah et al. 2014; Barron et al. 2015; Culyer 2015). Some publications underscore how the need to display 'value for money' is mostly present in high income countries so as to demonstrate that public money was spent appropriately. However, cost-effectiveness concerns are also represented in middle-income countries (Gulasci et al. 2009; Sorensen, Kanavos and Karamalis 2009). Moreover, in this strand of the literature, the use of relative effectiveness in HTA has also been increasingly addressed (Eichler et al. 2010; Sorenson 2010; Kleijnen et al. 2012; 2015.)

Within the literature strand on methodological issues, the use of multiple criteria decision-analytic modelling in HTA occupies an important place. Multiple criteria decision analysis (MCDA) aims to offer a support framework for decision-making in areas where multiple (and sometimes conflicting) criteria need to be considered (and weighted) and its use in HTA has significantly increased over the past decade. The aim is to offer a more systematic approach and address shortcomings in HTA (Angelis and Kanavos 2016). This has led to the development of guidelines for best practices and the development of specific models of assessments in this regard. However, these models can differ as to their structure, use of data and consistency (Philipps 2006; Abellán-Perpiñán 2015; Drummond et al. 2015; Angelis and Kanavos 2016; Marsh et al. 2016; Marsh et al. 2017; Angelis, Lange and Kanavos 2018).

In the literature on HTA, many publications address policy and regulation issues, as methodologies regarding economic evaluations are commonly targeted to inform reimbursement decisions. Many scholars therefore underscore the need to consider the link between HTA and the decision-making process (e.g. Harris et al. 2001; Marinoni 2012; Drummond et al. 2008; Drummond 2015, Meneu 2015; Del Llano-Señarís, and Campillo-Artero 2015). The use of evidence for pricing and reimbursement purposes receives growing attention in the literature on HTA and regulatory issues. (e.g. Garattini, Cornago and De Compadri 2007; Hutton, Trueman and Facey 2008; Drummond et al. 2011; Drummond 2012; Akehurst 2017). Although HTA and coverage or regulatory processes have different missions, some scholars examine whether communication and cooperation between both areas could be improved to facilitate timely patient access to innovative treatments (e.g. Henshall et al. 2011; Frønsdal et al. 2012; Berntgen et al. 2014).

Similarly, the issue of 'uncertainty' has been a central feature in many publications, as is the concern for transparency and validity of the results (Porzsolt et al. 2005; Philipps et al. 2006; Hutton, Trueman and Facey 2008; Richardson 2016; Brixner et al. 2017; Akehurst et al. 2017). In this regard, conditional reimbursement to address innovation and (early) access to health care intervention, is increasingly present in the academic debate. Indeed, when innovative and 'promising' therapies enter the market, their impact on health and the health system may still be uncertain. Additional data may therefore be needed from a real-world perspective. Several publications address the need to develop framework and international guidelines to address this issue (e.g. Chalkidou et al. 2008; Quentin et al. 2009; Carbonneil, Quentin, Lee-Robin 2009; Henshall and Schuller 2013; Makadi et al. 2016; Kanavos et al. 2017).

Akehurst et al. (2017) underscore the variation between HTA and reimbursement processes in Europe and highlight the influence of particular sources of information which can impact decision-making differently. Similarly, Nicod and Kanavos (2016) underscore how the

variations observed in HTA recommendations based on the same technologies could lead to different coverage decisions and, as a result, to unequal access to medicines across countries. Moreover, it could also reflect weaknesses in HTA methodologies. The scholars have sought to identify criteria which would explain the variations in decision-making processes and proposed a methodological framework aiming "to account for (part of) the unexplained heterogeneity in HTA recommendations across settings" (Nicod and Kanavos 2016:44). Similarly, Allen et al. (2017) have examined HTA and reimbursement decisions over four countries[14] and brought to the fore how differences in activities could be explained by the different mandates of the agencies and the unique political, social and population needs. The difference in recommendations made was related to the risk perception of the agencies and the choice of comparators in clinical and cost-effectiveness studies.

1.4.3. Convergence of HTA practices

To address this important diversity in methodology and practices, some argue for a harmonised EU approach of (economic) evaluation methodologies (e.g. Cookson and Hutton 2002). As underscored by Hutton, Trueman and Facey (2008:511; 513), "Harmonisation has the potential to avoid duplication of effort for both manufacturers and HTA bodies involved in preparing and reviewing HTA submissions for innovative technologies. However, it also carries risks of loss of local control over decisions, the application of general data standards which are not universally accepted and slowing the rate of development of innovation in the analytical disciplines supporting HTA. (…) Therefore, whereas some aspects of economic evaluation remain highly context-specific, there is scope for further exploration of harmonisation of others".

Since the implementation of the EUnetHTA project (2006-2008), the topic of harmonisation of HTA has received increased attention. Many publications examine the outputs and outcomes of the European projects. They outline the different tools, guidelines and methodologies having been developed within different European collaboration initiatives (e.g. Kristensen et al. 2009a, Kristensen et al. 2009b; Lampe et al. 2009; Pasternack et al. 2009, Kristensen 2012; Boehm and Landwehr 2013; Huic et al. 2013; Gillespie, and Cerbo 2014; Woodford, Huic and Teljeur 2014; Kristensen et al. 2017). As such one can mention the HTA Core Model developed by EUnetHTA and offering a standard structure composed of the HTA ontology, methodological guidance and a common reporting structure. This model, available as a full model or as one focused on rapid effectiveness assessment, covers besides safety, effectiveness and economics also domains covering organisational, patient, social and legal aspects (Kristensen et al. 2017: 244). European harmonisation regarding relative effectiveness assessment is another issue which has been examined by several scholars seeking to

---

14   Australia, Canada, England and Scotland (Allen et al. 2017).

identify barriers and success factors for international collaboration in the field (e.g. Kleijnen et al. 2015; Kleijnen 2016).

In this regard, one can mention the publications related to other EU funded projects in the field of HTA such as the AdHopHTA project, focusing on collaborative efforts to produce HTAs for hospitals. The publications highlight progress made in this sector but with still disappointing results as to the impact of HTA on hospital-based decision-making (e.g. Gagnon et al. 2014; Cicchetti et al. 2015; Halmesmäki, Pasternack and Roine 2015; Kidholm et al. 2015, Sampietro-Colom and AdHopHTA 2015). The Integrate-HTA project has also received some attention in the academic literature. This EU funded initiative aims at developing concepts and methods to make patient-centered assessments of complex health technologies. It challenges the idea that assessment, appraisal and decision-making should be considered as distinct processes. The authors also critically assess attempts of frameworks that seek to integrate these to some extent (e.g. some forms of Multi Criteria Decision Analysis). Publications related to this project bring to the fore alternative methods permitting to develop an integrated approach of HTA. The latter underscores that collection of facts and evidence should not be detached from the aim of the overall the evaluative exercise, "which is to explore how health technologies help, or prevent, us from realising final ends or basic human good" (e.g. Van der Wilt, Gerardus and Oortwijn 2017; Lysdahl et al. 2016; Bond and Weeks 2017; Wahlster et al. 2017, Bijlmakers et al. 2017; Lampe and Schnell-Inderst, 2017) Another example of an EU-funded HTA project presented in the academic literature is the Advance-HTA project which seeks to develop methodological tools and practices related to the application and implementation of HTA (e.g. Nicod et al. 2017).

Hutton, Trueman and Facey (2008:514) are the authors of one of the few publications referring to other attempts of HTA harmonisation across the world. They cite for example efforts made in New Zealand, Canada and in the USA where guidelines have been developed by the Managed Care Pharmacy (AMCP) generating a common standard for HTA formulary submissions. The Canadian experience is more often cited in relation to EU cooperation in the field of HTA. Indeed, the work accomplished by the Canadian Agency for Drugs and Technologies in Health (former Canadian Coordinating Office for Health Technology) has been underscored by several scholars and cited as an example for the EU cooperation (e.g. Sanders 2002; McDaid 2003; Hailey 2007; Menon and Stafinski 2009).

Hutton, Trueman and Facey (2008) make a distinction between different aspects of HTA where perspectives of convergence of practices are not the same. Indeed, more consensus is to be found regarding the feasibility for harmonisation of clinical evidence which is less context-dependent and more easily transferrable than economic evidence which is more context-sensitive. Ethical, social and legal issues in HTA are under-researched and it remains

unclear to what extent harmonisation in these fields can take place (see also Sacchini et al. 2009; Den Exter, Santuari and Sokol 2015; Abrishami, Oortwijn and Hofmann 2017). Whereas decision-making processes are still highly diverse in the EU, some believe convergence regarding the conceptual stages of decision-making could be made.

Harmonising practices regarding uptake of HTA in decision-making processes is still often considered as being far-fetched. (Schwarzer and Siebert 2009). As aforementioned, countries adopt various policy approaches regarding HTA. Whether the recommendations are used in decision-making processes depends on several factors. Kanavos et al. (2010) brings to the fore that the differences in impact of HTA can be related to national priorities, responsibility and membership of HTA bodies, differences in processes and timeframes, implementation or not of HTA recommendations or the ability to engage in price negotiations (Kanavos et al. 2010). Impact on decision-making processes can also be affected by the bodies and stakeholders participating in the assessment and appraisal process. Moreover, the extent to which stakeholders are involved in the process varies. The latter has received increased attention in the literature over the past decade. However, publications on this issue mostly concern involvement of patients and to a lesser extent the industry (Schubert 2002; Hivon et al. 2005; Sorenson et al. 2008; Nielsen et al. 2009; Gauvin et al. 2010; Bowman-Busato 2011; Facey 2011; Cavazza and Jommi 2012; Gorry et al. 2015. Houÿez et al. 2011; Hansen and Lee 2013; Tantchou Dipankui 2015; Abelson et al. 2016).

Gerhardus and Dintsios (2005) underscore the difficulty to assess impact on decision-making processes and the need to develop study designs and methods permitting a valid assessment of the issue. Indeed, so far only few studies have been made, displaying a disparity in the results and methodological flaws, making it difficult to draw solid conclusions related to the impact of HTA on decision-making processes. Some scholars underscore how the impact of HTA in policy processes depends on effective and timely applications in decision-making processes and on the overall transparency of the HTA process (Sorenson et al. 2008). Moreover, the need to develop better methodological approaches to well align problem definitions between HTA agencies, policy-makers and end-users has also been addressed by several scholars (Moret-Hartman, van der Wilt, and Grin 2007; Atienza Merino and Varela Lema 2008; Henshall et al. 2013).

Hence, attention given to European cooperation in the field of HTA has addressed several important issues related to the convergence of practices, methodologies and policies. Most publications have done so by underscoring the differences and similarities between countries and agencies. Particular attention has been given to methodological issues, especially regarding cost-effectiveness assessments of medicines. This has often been used as input in the debate about regulatory aspects of pricing and reimbursement and countries specificities in

this regard. An increasing amount of publications have addressed the cooperation efforts made in the EU context relating mostly on the objectives and outputs of the projects. Little attention is given however to the governance aspects of this cooperation process which has been set in motion some twenty-five years ago.

1.4.4. Research gap in the literature on European HTA collaboration

As discussed in the previous section, EU cooperation in the field of HTA has received some attention in academic research. Most publications however were focused on methodological and regulatory issues or presented outputs and outcomes of cooperation initiatives such as the EUnetHTA network and its predecessors (EUR-ASSESS, HTA-Europe, ECHTA/ECAHI) and related initiatives (e.g. AdHopHTA, INTEGRATE- HTA, Advance HTA, MedtechHTA). Whilst the support and participation of the European Commission is often mentioned, little research has examined in depth the role of the European Union in structuring the cooperation process.

Health Technology Assessment, whilst being a scientific exercise is, as outlined above, also strongly linked to wider policy processes on the European and Member State level. Use of HTA in decision-making and regulatory processes and its impact on the organisation of the national health system turns HTA into an issue of public policy and becomes subject of governance processes both at the EU and the domestic level. Moreover, the increased participation of stakeholders in the process underscores how HTA is not solely a scientific exercise but also undergoes influence from political, economic, industrial, civil and public policy actors. Although research has increasingly been focused on the relationship between HTA and policy-making since the appeals of scholars in the early 2000s (e.g. Oliver, Mossialos and Robinson 2004), few have focused on the role of the EU in this process and even less on the role of HTA in EU health policy which have developed almost simultaneously with the uptake of HTA in Europe.

Interest for and implication in HTA cooperation on behalf of the European Commission has been underscored in several publications relating about the European projects (e.g. Jonsson 2002; Banta 2003; Kristensen et al. 2009; Nachtnebel et al. 2015). Whilst pointing to the role of the European Commission in this process, no analysis is made of the underlying governance mechanisms steering HTA cooperation in Europe and allowing the European Commission to play an important role herein. Boëhm and Landwehr (2013) underscore how the European Commission has promoted the emergence of HTA as an EU new policy field and how temporary projects develop into a more lasting network structure with a solid organisational basis. However, they remain dubitative about the potential of convergence in this field. Indeed, they believe that "given this long list of context-specific characteristics and countless tiny setscrews of health technology assessments it becomes clear that the

Europeanisation of HTA is unlikely to result in convergent outcomes" (Boëhm and Landwehr 2013: 16).

Gorry et al. (2015) give a brief overview of how HTA has been promoted by the European Commission at the EU level. They underscore how it has supported the early EU HTA cooperation projects and recognised HTA as a 'political priority' in 2004. The inclusion of HTA cooperation in the Directive on Cross-Border health care (2011/24/EU) has permitted to further develop HTA cooperation as a new policy objective of the EU. They also highlight how, since 2008, the EMA has been officially authorised to work with HTA bodies. These developments have led to a repositioning of the various actors in the field of HTA. They point to the fact that whilst, till recently, HTA was a rather depoliticised field, this may change in the future. They also underscore how most publications do not refer to the exact role and position of the pharmaceutical industry in this. Moreover, in their opinion, mobilisation around HTA at the EU scale will impact upon national systems of pricing and reimbursement and tensions over 'sovereignty' remain present (Gorry et al. 2015: 130-131). Hence, according to the authors, the discussion on HTA cooperation is two-fold. One level is concerned by scientific knowledge and its transferability. The second level is concerned with the how such a system of pooled assessment data would fit national appraisal. "many actors fear that an EU-scale assessment system will inexorably threaten national modes of appraisal" (Gorry et al. 2015: 132).

Given the specificity of Health Technology Assessment, publications regarding European cooperation processes have been mostly present in academic literature strongly related to medical and health policy matters. Review of the subject in the European governance literature shows that, besides the publications mentioned above, very few other scholars from this academic field have given attention to HTA cooperation from a European governance perspective. Similarly, our research has not been able to identify attention for the governance aspects of European HTA cooperation processes in literature emanating from other academic schools such as public policy, management or administration studies. In this regard, it is however interesting to underscore the publication of Fierlbeck, Gardner and Levy (2018), examining HTA cooperation in the Canadian context from a New Public Governance (NPG) perspective. The authors come to the conclusion that the governance instruments recommended by NPG have contributed to the development and integration of HTA in Canada., As some of these soft governance instruments resemble those used in the European context, this approach can be of real interest for our research. However, the analysis is exclusively based on the Canadian context and does not address governance of the European HTA cooperation process.

This research will aim to fill what we have identified as a gap in the literature, and which refers to the governance of European HTA cooperation processes. We will focus our research on the examination of governance modes used by European HTA networks and by the European Commission and try to understand how the interaction between both policy levels has structured HTA cooperation in Europe.

1.5.   CONCLUSION

This chapter has outlined the development of Health Technology Assessment in its general and European contexts. As a multidisciplinary process, HTA seeks to summarise information about medical, social, economic and ethical issues related to the introduction and diffusion of a health technology in a given market. Aiming to inform decision-making processes and the formulation of safe and effective health policies, HTA relates to health policy processes. How the two areas are articulated in a country varies according to organisation of the health system as well as to other context-specific factors. Moreover, HTA responds to many different approaches regarding scope, methodologies and practices implemented. The assessment, appraisal and decision-making processes related to an HTA will also differ across agencies and countries which explains why several assessments made on a single technology can lead to different outcomes.

Faced by increased budgetary constraints, an aging population and a rising number of innovative and expensive technologies being developed, HTA agencies in Europe have sought to establish cooperation mechanisms. These would allow them to exchange experiences and develop best practices, avoid duplication of assessments and develop HTA in countries where it was not present. Support of the European Commission has been given first essentially through financial support to different projects in the field and later also as a partner in Joint Actions on HTA. The Directive on Cross-Border Health Care (2011/24/EU) adopted in 2011 has given a legislative basis to establish a sustainable cooperation mechanism in the field of HTA. In 2018, the European Commission introduced a Proposal for a Regulation on HTA cooperation in Europe as another step to reach this objective.

The developments outlined above, show the EU implication in the development of HTA cooperation processes. Although a lot of attention is given in the literature on HTA to the challenges of HTA cooperation and convergences of HTA methodologies and practices, little attention has been given to governance mechanisms steering these cooperation processes. Whilst most publications do highlight the role of the European Commission in this process, so far, no research has been done on the governance modes used to steer HTA cooperation and how these are related to the wider EU health policy developments.

This research aims to fill this gap by examining HTA cooperation from an EU governance perspective. Situating HTA cooperation in the wider EU health policy requires however to have a good understanding of the particular developments in the field of European health policy on the one hand as well as of the governance modes applied in EU policy-making processes on the other. The next chapter will therefore seek to contextualise HTA cooperation in the EU health policy and governance architecture.

2 | HTA Cooperation in the EU health policy and governance architecture

"To achieve success, we shall need a great deal of tenacity and patience, both within our own countries and in negotiations between the Governments themselves."
Robert Schuman, Council of Europe 10th December 1951

2.0.   INTRODUCTION

HTA cooperation is an initiative that stems from the HTA arena itself and has been launched to promote HTA in Europe and enhance the quality of the assessments to ensure their uptake in national policy-making processes. The first initiatives launched in the early 1990s were project-based and gathered HTA experts from different European countries. No specific connection with EU health policy was to be made at the launch of the initiative apart from funding that had been requested and obtained through a specific EU research programme. The first cooperation initiatives however coincided with the launch of a dedicated EU public health policy which took off with the insertion of an article on public health in the Maastricht Treaty (1992).

The attention and support for HTA cooperation by the European Commission would grow simultaneously with the advancement of the EU public health policy. In the first HTA cooperation projects, the EU support would be limited to financial aid. However, gradually, HTA has been identified by the European Commission officials as bearing the potential to play an important role in the development of the EU health systems. The Commission's role and involvement in the cooperation process would then profoundly change. As the development of HTA cooperation and EU health policy have progressively become intertwined, a good understanding of the EU governance processes and EU (public) health policy is of prime importance. At the core of these processes lays the issue of the division of competences between the EU and the Member States which defines the governance modes and instruments available to the EU. This division will also play a role in HTA cooperation seeking to establish convergence in the development of tools, methodologies and practices.

The EU competences in the field of health care are defined by the Treaties and based on a division of competence between the EU and the Member States. Although they have evolved over the years, the EU competences are limited and distributed over different policy areas (e.g. public health, environment, Internal Market, employment). Member States remain the key actors when it comes to health policy in Europe and often enjoy exclusive competences in a health policy related field. Management of health services and medical care for example falls entirely under the responsibility of the Member States. As such, the EU cannot interfere in the definition of domestic health policies which comprises HTA (Art 168 TFEU).

Despite the very restrictive definition of competences regarding health policy, the EU has nevertheless been able to exert some influence over public health issues in the EU Member States. This has resulted on the one hand from so-called 'uninvited Europeanisation' of health policies stemming from a 'spill-over process' of Internal Market policies (Greer 2006; 2009) and on the other hand by means of soft policy instruments. HTA cooperation is

primarily being concerned by the latter. Indeed, in policy areas which fall under the exclusive competences of the Member States, the EU institutions can often only make use of soft policy instruments to promote cooperation between Member States.

To well understand the role of soft governance in structuring HTA cooperation in the EU, we will need to situate the latter in the wider environment of EU health policy and the governance modes used in this policy area. The present chapter will therefore first set out the broad development stages of EU health policy and outline the different governance modes available to the EU institutions in this area. The second part of this chapter will focus more specifically on the so-called New Modes of Governance which have been introduced by the European Commission in the 2000s and consists of soft governance instruments to promote European integration processes. EU health policy and thus also the EU support to HTA cooperation have been structured according to these innovative governance modes, which comprise networking.

2.1. HTA COOPERATION CONTEXTUALISED WITHIN EU HEALTH POLICY

2.1.1. The Development of EU Health Policy

Because of the highly diverse organisation of health systems in the EU Member States, as well the high interdependency between health care, economic, fiscal and social policies, a need for convergence of health policy at a European level has never really been considered feasible nor desirable. No reference to health policy is therefore to be found in the founding treaties of what is today the European Union (EU). The failed attempt to create a European Health Community in 1952-1954 (Davesne and Guigner 2013), underscores how, already in the early days of the EU integration process, Member States were reluctant to pool competences in this field at a European level.

Although the underlying reasons holding back Member States from shifting part of their health policy competences to the supranational level have varied in the course of the EU integration process (see for an extensive account of the project Davesne and Guigner 2013; Vollaard et al. 2016), the predominant feature is that no significant powers would be given to the EU in the field of health policy. The competence allocation as codified in the Lisbon Treaty states in this regard that*: "The Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them"* (Art 168 (7) TFEU).

Despite the fact that the organisation of Member States' health systems remains an exclusive national competence, a specific European health policy has nevertheless emerged and has grown in importance over the years, becoming an official EU policy field since the insertion of a specific Public Health Article in the Maastricht Treaty (1992). Small but not insignificant revisions in subsequent treaties, reveal the gradual extension of EU's competences in this policy area which hasn't been the result of 'classic integration policies'. Instead, the expansion of specific European health policies has emanated from different political, economic and legal processes in other policy areas which have also shaped the diverse policy modes adopted by the EU in the health policy field (Greer 2009, Mossialos et al. 2010).

In particular, public health threats (e.g. the BSE crisis[15]) have been identified as having acted as catalyser for an increased EU involvement in health policy (Randall 2000b). Public health concerns related to the uptake of diseases such as cancer and HIV/AIDS as well as drug dependency in the 1980s and 1990s had led to the awareness that a coordinated action on EU level might be necessary and possible. Common European actions such as the "Europe against Cancer" campaign launched in 1985 have contributed to increased salience for the issue and its appearance on the EU political agenda (Randall 2000; Greer et al. 2014:38). The Maastricht Treaty has created the opportunity to formalise the new EU approach on Public Health by inserting a dedicated article (art. 152 TEU) on public health in the Treaty (Randall 2000a; 2000b; Greer et al. 2014: 38-40).

The first legal provisions on EU health policy bear traces of what could be considered to be a 'political insertion'. Indeed, four out the eight areas allocating competences to the EU reflected domains in which cooperation on a European level had been developed despite the absence of formal competences attributed to the Union in these areas: drug dependence, cancer, AIDS and other communicable diseases and health promotion. The four new spheres of EU influence targeted the monitoring and surveillance of disease, injury prevention, pollution-related diseases and rare diseases (Randall 2000a:140). Still, the provisions referred to in article 152 TEU lay worlds apart to what is commonly understood by 'health policy' on a national level. Hence, the impact of this article on health policies, would it be on a national or European level, will remain very limited.

Notwithstanding the restrictive basis for EU action in the Treaties, a European dimension of health policy has nevertheless developed, increasingly affecting the organisation of domestic policies. In the literature, scholars have explained this by pointing to the (unintended) effects of Internal Market related policy decisions and rulings of the Court of Justice of the European Union (CJEU) on domestic health policies (e.g. Greer 2009; Randall 2000b; Hervey and

---

15   BSE stands for 'Bovine spongiform encephalopathy', also called 'mad cow disease'.

Vanhercke 2010). Greer (2006) qualifies these developments as "uninvited Europeanization" in health policy, hereby basing his observations on the so-called neo-functional "spill-over effect" as identified by Haas (1958). Indeed, since the Single European Act, the application of the principle of free movement of people, goods, services and capital has led the CJEU to pronounce itself on health policy related issues, using an 'Internal Market-based' approach in the assessment of the cases.

A striking example of this is cross-border health care which has received increased attention since the *Kohll* and *Decker* cases in 1999. The subsequent CJEU decisions on similar cases of health care services or goods pursued by patients outside their state of social security affiliation, have progressively shaped specific EU patient mobility provisions. By establishing as such a 'parallel route' to reimbursement of cross-border health care, already regulated by the Regulations 1408/71 and 883/2004, tensions inevitably aroused, creating the need for legal certainty on the issue. It took however almost a decade before a new Directive on "Patients' Rights in Cross-Border healthcare" (2011/24/EU) has been adopted (commonly referred to as the Cross-Border Health Care Directive; see also Nys and Goffin 2011, Palm and Glinos 2010; Sauter 2008; Wismar et al. 2011).

In the literature, detailed accounts are given of similar situations where domestic health care provisions have been impacted by European policy decisions taken in another policy area. Considering the specific nature of health policy, the implementation of provisions can be sometimes problematic and often creates a need for further clarification and coordination on a European level. This can involve rulings of the CJEU applying (market) integration policies in health policy areas, whereby its decisions become European jurisprudence, having effect in all Member States (as for example in cross-border patient mobility).

This inevitably raises questions on the role of the Court pronouncing itself on sensitive (ethical) issues in policy domains falling traditionally under Member States' competences (see further McKee and Mossialos 2006). Hence, applying Internal Market provisions in health policy related fields seems to be a rather delicate and contentious exercise. All too conscious about the far-reaching consequences its jurisprudence in health matters can have, the Court sometimes opts not to pronounce itself on specific issues. This was for example the case regarding quality and safety standards in professional mobility of health professionals, when the Court refrained to legislate on the issue, leaving it up to the Member States to deal with the subject (see e.g. Nickless 2001:82; Peeters, McKee and Merkur 2010:632; Greer 2006:142).

Similarly, the development of a specific European social policy (in particular since the adoption of the Social Charter in the Amsterdam Treaty (1997)) has impacted EU's involvement in

health-related issues. The impact of the Working Time Directive on the organisation of hospital practices is another example of how a decision taken in one policy field can have direct consequences on domestic health care settings (see e.g. Greer 2006: Greer 2009: 45-46). Another sensitive question regards the application of competition law and public procurement provisions to the health sector. In this area too, tensions have arisen on the national level where the support of health care institutions is considered as a core-component of the national welfare state and should not be confused with state aid (for a detailed account on this topic see e.g. Mossialos and Lear 2012: Prosser 2010: Hatzopoulos 2010).

Finally, the EU treaty provisions also call for a high level of health protection in the definition and implementation of all Union policies and activities (Article 168 TFEU). Although this ambitious aim may not always be easy to implement, it has led, in some cases, to legal provisions such as the Product Safety Directive (2001/95/EC) which creates a framework for safety requirements for consumer products (including medical devices). Another example is the 'Horizontal' Liability Directive (89/374/EEC) aiming to protect consumers against defective products. Protection of human health has also been underscored in Article 9 TFEU. Finally, the Charter of Fundamental Rights, which has become binding since the adoption of the Lisbon Treaty (2007) foresees some provisions which are indirectly related to health matters. The most important in this regard is Article 35, which refers to the right of "access to preventive health care and the right to benefit from medical treatment under the conditions established by national law and practices"[16].

Hence, as underscored by many scholars (e.g. Mossialos et al. 2010; Brooks 2012; Greer et al. 2014), European health policy is characterised by what Scharpf (2002) has called a "constitutional asymmetry" referring to the fact that the EU is promoting on the one hand market-efficiency policies and on the other (often national-based) social protection policies. The former being predominant in comparison to the latter. Moreover, as we have seen above, and as underscored by Mossialos et al. (2010:4-5), a "fundamental contradiction" lays at the core of EU health policy. On the one hand the European Treaties state that health is an exclusive competence of the Member States, but on the other hand, as the domestic health systems are concerned by people, goods and services, they become also directly or indirectly subject to EU law and policies.

---

16   Other articles in the European Charter of Fundamental Rights referring indirectly to health matters are: the right to human dignity (Article 1), the right to live (Article 2), the right of persons with disabilities (Article 26) the right to the protection of personal data (Article 8), the right to freedom of conscious (Article 10) (potentially affecting professionals in the medical field.

This leads thus to the delicate question of the allocation of competences between the EU and the Member States. Moreover, although health represents a core component of the welfare provisions in all EU Member States, these countries highly differ in their organisation, financing and governance of the domestic health system (Brooks 2012, Steffen 2005). Finally, would it be on a national or European level, the governance of health policy is often not centralised but can be fully or in part governed on multiple levels. In countries such as Spain, regions play an important role in the definition and implementation of health policies. Similarly, as health touches upon many other policy areas, on a European level too, decisions affecting national health systems can be dealt with in different Directorate Generals (DG) of the European Commission, despite the existence of dedicated DG to Health DG Santé (formerly DG Sanco) [17].

Health governance in Europe is thus characterised by a high diversity of governance systems, involving multiple levels and players. Considering its high interdependency with financial, social and economic policies, it can be affected by decisions taken outside the health policy area. Especially on the European level, this has led to the situation where health-related matters indirectly became subject to European law and policies leading gradually to an extension of EU's involvement in health policy. The role of the CJEU should be underscored here. Indeed, by basing itself on the Treaties it has seized the opportunity to create new legal provisions affecting domestic health policies and hence 'interfere' legally in what is in many health-related issues considered to be domestic affairs. Consequently, this has raised the question of the allocation of competences in health policy and it seems that the line, as it has been drawn in the European Treaties underscoring the exclusive competences of the Member States, is more and more blurred.

The allocation of competences and governance modes are interrelated in the EU governance setting. Indeed, the level of competence in a given policy field will determine the governance modes available to the EU. As such, the European Union can have exclusive competence in some fields (e.g. customs union, competition policy, monetary policy, commercial policy) (Art. 3 TFEU). It can however also share its competences with Member States (e.g. Internal Market, social policy, consumer protection agriculture and fisheries, some aspects of public health) (Art. 4 TFEU). Finally, as defined by article 6 TFEU, in some areas the EU has only the competence to support, coordinate or supplement actions of the Member States (e.g. human health, industry policy, culture, tourism, education).

---

17   Randall (2000) had already underscored the diversity of health issues in which one can detect EU engagement where health policy matters are spread over many different DG (18 out of 24 in 2000).

A variety of governance instruments exists at the EU level. Their application will however depend on the competences allocated to the governing body. In the following section we will therefore outline the different governance modes used in EU health policy and see how these relate to the competences conferred to it in the different health policy sub-areas. This will permit a better understanding of how the introduction of soft governance modes have created an opportunity for the EU to further extend its powers in the field of health policy and why these innovative governance instruments have been used to support HTA cooperation in Europe.

2.1.2. The allocation of competences and governance modes in European health policy

Although codified by the Treaties, the allocation of competences between the EU and Member State level is an evolutionary process in which actors seek to strike a balance between "high politics" of the EU and "functional appropriateness" of a policy mode (Wallace 2010:90). Hence, the challenge is to define a governance mode respecting the allocation of competences as defined by the Treaties and permitting to define objectives and secure outcomes as commonly agreed upon by twenty-seven Member States each responding to distinctive socio-economic conditions, policy practices and legal frameworks (Wallace 2010).

As Europe moved further along the path of integration, different policy instruments and mechanisms have been implemented by the European institutions ranging from the classic 'Community method', the EU regulatory mode, the distributional mode to "intensive trans-governmentalism" and 'open policy coordination' (for an extensive overview see e.g. Wallace 2010; Nugent 2010). It is the variety of policy modes and the way they co-exist across the different EU policy sectors that makes the European policy-making system so singular. As EU's involvement in health issues has mostly resulted from the extension of policies originally designed in and for other policy areas, the health sector too is characterised by a "hybridization of policy modes" (Wallace, Pollack and Young 2010:484) where a variety of governance modes are structuring health policy on a European level and are affecting domestic health systems.

The heterogeneity in EU governance practices can partly be traced back to the different levels of competence which are conferred to the European institutions as codified in the European Treaties. According to the principle of conferred powers (Art. 5 TFEU) the EU institutions can act only in those areas where the Treaties give them power to act. Hence, specific governance modes will be adopted at the European level depending on whether a policy field falls under the exclusive competences of the EU (Art. 3 TFEU), shared competences between Member States and the EU (Art. 4 TFEU) or under the main competence of the Member States (Art.

6 TFEU). As outlined above, in case of the latter, the EU has only the power to support, coordinate or supplement Member States' actions (Art. 6 TFEU).

Although, health policy issues can be affected by EU decision-making processes taken in an area where the EU has exclusive competences, health policy taken *stricto sensu* is concerned only by the last two categories. Indeed, the EU Treaties stipulate that only certain aspects of public health policy fall under the *shared* competences of the EU and others (e.g. organisation of the health systems) fall under the *exclusive* competences of the Member States. For example, in cases regarding the protection and improvement of human health, "the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States" (Art. 6 TFEU).

The latter also implies that the 'subsidiarity principle' should be applied as stipulated in article 5 (3) of the Treaty of the European Union (TEU). The subsidiarity principle refers to the fact that "in areas which do not fall within its exclusive competence, the Union shall act only if and so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at a central level or at a regional and local level, but can rather, by reason of scale or effects of the proposed action, be better achieved at Union level".

Even though the insertion of a dedicated public health article in the Maastricht treaty has represented a big step forward in shaping a European health policy, the competences conferred to the Union in this policy field remain however quite limited. Article 168 of the Lisbon Treaty (replacing the public health article of the former treaties) still clearly stipulates that EU action in health policy shall come "as a complement" to national policies. It furthermore delimitates EU action to "encouragement policies" and "support-lending policies" in particular in cross-border cooperation.

Some amendments in the Lisbon Treaty have nevertheless created an opening to further extend the EU's competences by introducing soft policy instruments at the disposal of the Commission to promote the coordination of policies and programmes between Member States (Art. 168 (2)). This is in line with article 6 TFEU (EU competence to support coordinate or supplement actions of Member States). These policies can be shaped through the establishment of guidelines and indicators, the organisation of exchange of best practices and specific monitoring and evaluation mechanisms. It is on the basis of these governance instruments that HTA cooperation will be structured by the EU institutions.

2.1.3.   EU governance modes and European HTA cooperation

EU cooperation in Health Technology Assessment finds itself at the cross-roads of different domestic and EU governance modes. HTA enters the public policy arena after a health tech-

nology has been accepted on the EU market and before it is being considered in domestic decision-making processes regarding the price and reimbursement of this technology[18]. In the case of pharmaceuticals, market authorisation is an exclusive EU competence since medicines are being considered as goods which fall under Internal Market regulations. Assessments of the products are made based on safety and efficacy criteria developed by the European Medicines Agency (EMA)[19]. The EMA, as an EU regulatory agency, is the only authority in the EU entitled to authorise commercialisation of medicines in the EU.

Once a pharmaceutical product has received EU market authorisation, it can undergo a 'domestic' HTA process. As we have outlined in the previous chapter, the outcome of the assessment will be used in national pricing and reimbursement decision-making processes. The latter falls under the exclusive competences of the Member States and domestic governance modes as it regards the domestic organisation of health systems. As such, use of HTA as input in domestic regulatory and decision-making processes lays outside the EU scope. Hence, the EU cannot not interfere in pricing and reimbursement policies regarding health technologies that enter or are already on the market. In this regard it is important to keep in mind that pricing and reimbursement of health technology bear, besides a public health concern, also economic, legal and fiscal aspects for which national governments wish to remain in full control.

Reimbursement policies (and the related pricing policies) are organised in a variety of manners across the EU. As underscored by Saltman, Busse and Figueras (2004: xiii), "different nations with different histories, cultures and political experiences, have long since constructed different institutional arrangements for funding and delivering health services". As such, health care systems differ for example in the type of revenue generation, some functioning via private insurance, others via taxation (either direct or indirect, national or local, general or hypothecated), social health insurance or charges and co-payments (Saltman 2004). Funding can be either private or public (or a mix of both) which corresponds to different underlying principles since public funding will seek to 'redistribute resources across the population" and private funding will serve individual needs (Robinson 2011:44).

---

18   Assessment processes linked to market authorisation of pharmaceuticals given by the European Medicines Agency or those linked to CE marking given by Notified Bodies, could to some extent be considered as part of an assessment process of a health technology. The present research will however consider these processes as being dissociated from the assessment process taking place on a national level after market authorisation is given.

19   This Agency has been created with the strong backing of the industry which invoked the Article 100A of the Maastricht Treaty, designed to facilitate completion of the Internal Market through the harmonisation of national laws (Permanand and Mossialos 2005:74).

HTA needs to inform the decision-making processes regarding pricing and reimbursement policies of technologies. Besides public health considerations, these processes will also be based on economic, social, political, legal and ethical issues. As Member States organise their health systems differently, decisions using HTA input may also vary. Harmonising these decisions is thus generally not considered feasible nor desirable. HTA cooperation in Europe does not seek harmonisation of decision-making regarding pricing and reimbursement in Europe for the reasons explained above. However, convergence of practices and methodologies regarding the assessments themselves is an aim shared among many actors in the field and has triggered the first cooperation efforts as we will outline in part B of this thesis. The aim here is to upgrade the quality of HTA and consequently its uptake in national decision-making processes. Although the use or not of HTA outputs, as such, falls under Member States' competences, the EU does have the right to lend support to the cooperation efforts in this area. The governance mode available to this competence is based on Article 6 TFEU and refers to so-called 'open coordination policy'.

This governance mode based on 'OECD techniques' was originally intended as a "mechanism of transition from nationally rooted policy-making to an EU collective regime" (Wallace 2010:98-99). In this mode, the Commission can act "as developer of networks of experts or epistemic communities, or of stakeholders and/or civil society, and accumulating technical arguments in favour of developing a shared approach to promote modernization and innovation" (Wallace 2010:99). The Commission can also have recourse to independent experts or convene high-level groups of national experts and ministers to develop policy options. Techniques such as peer pressure, 'benchmarking', and policy comparisons are being implemented and are considered to encourage policy learning. Dialogue with specialist committees and soft-law commitments are also features that characterise this governance mode (Wallace 2010:99). From an initially transition mode, this coordination mode has been developed into a policy mode of its own right, and falls under the so-called 'New Modes of Governance' (NMG) (Wallace 2010:99; European Commission 2001).

NMG have been implemented in many different policy areas with mixed results (see e.g. Idema and Kelemen 2006; Héritier 2006; Kröger 2009; Diedrichs 2008). Research has shown that these innovative governance means, also called soft governance modes, have been implemented in particular in areas where Member States agree that common action is required but where decision-making powers lay mostly on the domestic levels (e.g. research policy, environmental reform, social policy) (Shaw 2008). Implementation of soft governance modes is also observed in sensitive areas where the Community method encounters sovereignty concerns and where Member States seek to protect their autonomy and domestic legacies from EU interference. Moreover, uncertainty over EU decision-making has also triggered the resort to soft governance instruments (Diedrichs, Reiners and Wessels 2011:29).

NMG do not come as a substitute to the more traditional governance forms but are often added to the existing hybrid decision-making structure of the EU which is characterised by the co-existence of different governance modes (Diedrichs, Reiners and Wessels 2011:45; Héritier 2006:21). The manner in which NMG find their place in the EU governance architecture varies, as different patterns of change in governance modes can be observed. As such, a shift from traditional governance means to innovative forms of governance can take place. The opposite, however, has also been observed in cases where NMG have failed to produce policy decisions. Finally, traditional and innovative soft governance modes can be operating simultaneously. The outcome of the latter varies. Either the different governance modes reinforce or complement each other. They may, however, also undermine each other or have no effect on each other (Héritier and Lehmkuhl 2011:62).

Open coordination policy and soft governance modes - which are in the case of European HTA cooperation the only EU governance modes available - have triggered much discussion as to their role in the EU integration process. As they are being implemented in sensitive areas or areas falling outside the EU exclusive competence, the question of EU competence extension via NMG has been raised. Indeed, if no regulatory authority exists in a certain area to bring about 'hard law' favouring EU integration process, soft law procedures may well be an alternative to bring the EU integration efforts further. To get a profound insight of the role of soft governance in structuring HTA cooperation in Europe, it is therefore of prime importance to well understand what these innovative governance modes refer to and what role they play in the broader EU governance architecture and EU health policy-making. The next section will outline these issues permitting us to contextualise HTA cooperation in the wider EU context.

2.2. DEVELOPMENT OF NEW MODES OF GOVERNANCE IN THE EU GOVERNANCE ARCHITECTURE

2.2.1. Multiple understandings of 'governance'

'Governance' is a concept responding to many different definitions and can be used in a public private or international setting. Some have examined it as a means to reduce state intervention by, for example, establishing new regulatory bodies (Stoker 1994). Others refer to the notion in a corporate environment where new steering activities have been developed based on principles such as open access to information or accountability of individuals (Rhodes 1996:654). Governance can also be understood as ' New Public Management' based on private sector management methods applied in the public sector, (Osborne and Gaebler 1993; Aucoin 1995; Hood 1983). In international institutions, 'governance' is also often related to the notion of '*good governance',* responding in itself to many different terminolo-

gies referring to notions, such as, effective public management, transparency, accountability, democratisation, anticorruption policies and respect of human rights[20] (Maldonado 2010; Rhodes 1996; Punyaratabandhu 2004: 2).

Governance can be related to governmental activities but can also imply participation of formal governmental organisations as well as informal non-governmental mechanisms. To Rosenau (1992:3-6), one can speak about "governance without government when there are 'regulatory mechanisms' in a sphere of activity which function effectively even though they are not endowed with by formal authority". Kooiman (1993:258) considers governance as "the pattern or structure that emerges in a socio-political system as 'common' result or outcome of the interacting intervention efforts of all involved actors". He underscores how, in this pattern, social self-organisations are complimentary to traditional hierarchical governing organisations. Moreover, public and private actors share the responsibility and accountability of interventions.

The different notions of governance as outlined above either put the accent on a distinctive mode of government or refer to the coordination of individual activities or any form of social order. Governance analysed within the European context also brings to the fore the various understandings of 'European governance'. Saurugger (2009:236) identifies three conceptualisations of European governance: multilevel governance, networking governance and the New Modes of Governance. Although distinct they are all three somehow connected. The three understandings underscore the relatively weak formalisation of decision-making processes characterising EU decision-making processes where public policies are being developed and implemented at different levels within the system.

According to Saurugger (2009: 233-236), these processes are characterised by the interaction of multiple state and private actors as well as by the complexity of the negotiation processes which take place on different levels. Instead of hierarchical or subordinated relations between actors, the European governance approach refers to a system of exchange between equal actors seeking a common solution for their problems. Governance within

---

20   The terminology first appeared in a World Bank report of 1989 regarding sustainable growth in Africa: "Sub-Saharian Africa, from Crisis to Sustainable Growth" (Maldonado 2010: 4; http://web.worldbank.org). Initially the concept of 'good governance' has been defined in 1992 by the World Bank as "the manner in which power is exercised in the management of a country's economic and social resources for development" (Santiso 2001:3). As such the concept referred to public sector management, accountability, legal development frameworks and transparency (Maldonado 2010: 5-10). However, progressively the understanding of the term 'good governance' has broadened to include other issues such as anti-corruption policy or participation. It is often associated to liberal economic perspectives adopted in international institutions ((Maldonado 2010; Rhodes 1996).

the European context, in this perspective, is based on cooperation mechanisms between all concerned actors as well as on learning processes rather than competition.

Jachtenfuchs and Kohler-Koch (1999) consider EU governance as an interaction of state and social actors in a multilevel organisational structure, seeking common solutions to what is considered problematic or a desirable goal to achieve. However, her definition also includes the notion of unitary action and compliance. Hence, to Jachtenfuchs and Kohler-Koch (1999:14) "'governance' is about the way and means in which the divergent preferences of citizens are translated into effective policy choices, about how the plurality of societal interests are transformed into unitary action and the compliance of social actors is achieved. The essence of governance just like that of government is to reach binding decisions".

Jachtenfuchs and Kohler-Koch's definition shares some traits with the one set out by the World Health Organisation (WHO) which considers governance as a political process which requires to balance competing influences and demands. Focusing on the health sector, the WHO understands by governance "a wide range of steering and rule-making related functions carried out by governments/decisions makers as they seek to achieve national health policy objectives that are conducive to universal health coverage" (www.who.int). Moreover, the WHO underscores that governance comprises collaborating with other sectors, including the private sector and civil society, to promote and maintain population health in a participatory and inclusive manner.

In the present research we will understand governance in the sense described by Jachtenfuchs and Kohler-Koch and the WHO, highlighting the importance of the interaction between state and non-state actors in translating societal influences and demands into effective policy choices taken and implemented in a participatory and inclusive manner by the actors involved. In the sections below, we will examine how each of these aspects (i.e. inclusiveness, deliberative decision-making, multi-level participation, compliance) are also inherent to New Modes of Governance, introduced in the EU at the turn of the Millennium and underpinning EU health policy.

2.2.2. European political and economic developments preparing the governance turn

Besides developments in public management on a national level[21], the emergence of innovative governance modes could be explained by political and economic developments that have affected the EU integration process at the turn of the millennium. On the one hand, the EU faced the challenge of completing the European Monetary Union (EMU). On the other hand, it had to prepare the enlargement of the Union to candidate countries from Central and Eastern Europe. The project of adopting a new EU Constitutional Treaty sought to respond to the many challenges faced by the EU, in particular the low rate of economic growth, a high unemployment rate and a weak global competitiveness position (Héritier and Rhodes 2011:49; Bermeo 2001; European Parliament 2010).

Moreover, EU governance practices came under strong public scrutiny with the resignation of the Santer-Commission in 1999 which had been accused of fraud, nepotism and financial mismanagement (Judge and Earnshaw 2002). The sudden departure of all European Commissioners was an unprecedented event and seriously undermined public confidence in the institution. The legitimacy of the Commission's practices and decisions was openly being questioned. Calls for more *transparency* in the governance practices of all EU institutions were increasingly heard in both public as academic debates. This quest for more transparency in EU institutional practices came on top of an already ongoing debate regarding the

---

21   Since the 1980s, several movements emerged seeking to bring about administrative reform. These reforms have led to the introduction of new governance instruments in the US and in EU Member States (e.g. 'management by objectives; performance measures). The 'New Public Management' (NPM), can be cited as an example hereof (see further on NPM: Aucoin 1990; Hood 1991; Osborne and Gaebler 1992; Gray and Jenkins 1995, Dunsire 1995).

so-called '*democratic deficit*' of the Union (De Schutter, Lebessis and Patterson 2001: 4; Lebessis and Paterson 2001:15)[22].

Hence, the serious economic and political challenges faced by the new Prodi Commission appointed in September 1999, required in a certain sense to depart from the previous governance practices and develop adequate policies to successfully take up the gauntlet. Implementing "New Modes of Governance" becomes the first and most important EU strategic objective as defined by the Prodi-Commission (European Commission 2000a). In its official communication on the subject, the Commission highlights how the other three objectives (enhance the voice of the EU in world affairs, create a new economic and social agenda and enhance the quality of life) depend on de governance forms chosen (European Commission 2000a).

These NMG were not entirely new to the Commission as 'open coordination policies' inspired by national developments related to new management modes had already been tested in two EU policy areas. The first regarded the "Broad Economic Policy Guidelines (BEPG)" which had been established in the light of completing the EMU and which primarily served to coordinate the economic policies of the Member States (Nugent 2010: 297). Soft policy coordination instruments had also been implemented in the European Employment Strategy (EES) emanating from new provisions in the Amsterdam Treaty establishing a European Employment Policy (art 125-130) (see further Goetschy 1999; Vellutti 2010).

---

22   The concept of democratic deficit which has become a key-aspect of the discussions regarding the need for governance reforms of the EU, failed to respond to a commonly accepted definition and still gives way to many different understandings (Weiler et al. 1995; Follesdal and Hix 2006; Bellamy and Castiglione 2000; Moravcik 2002; Majone 1998). Critical assessments on the democratic practices within the EU point for example to the lack of parliamentary control on the executive (Council, Commission) and the weak powers of European Parliament (Follesdal and Hix 2006: 534-537). Some (e.g. Reif and Schmitt, 1980) also underscore the lack of real party politics and European election campaigns serving as "second-order national contests" expressing often protest-votes regarding domestic policies (see further Hix, 1999; March 1998; Marks et al., 2002; Kousser, 2004; Hix 2002; Hix and Marsh, 2005). Others point to the technocratic policy-making processes taking place in a complex institutional architecture which create a distance between the EU institutions and ordinary citizens (Wallace and Smith, 1995). Finally, others underscore how policy decisions do not necessarily reflect voters' preferences. The latter can potentially lead to a 'policy drift' where domestic decision-makers choose the EU level to pursue their policies so as to circumvent the national control of parliaments, courts and civil society (Scharpf 1999; Follesdal and Hix 2006:537). The multitude of perceptions adopted around the notion of democratic deficit nourished the debate on the need for governance reforms.

NMG aimed enhancing citizens' participation in European affairs, increase effectiveness and transparency of the European institutions and build new forms of partnerships within a multilevel European governance structure (Lebessis and Paterson 2000). The importance given to open coordination policies was also underscored in the Lisbon Agenda launched a few months after Prodi's Communication on the Strategic Objectives of the EU. This important document cites innovative forms of governance as a mean to achieve the new goal set by the European Council: making the EU "*the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion*" (European Council 2000).

The manifestation of the Commission's governance turn can be found in its *White Paper on European Governance* (European Commission 2001l) issued a year later, but already announced in Romano Prodi's first speech before the European Parliament in February 2000. According to the newly elected president, New Modes Governance should respond to the needs of an enlarged Union and revise the division of labour between the EU institutions, hereby offering "a new and more democratic form of partnership between the different levels of governance in Europe" (European Commission 2000b). In other words, NMG were considered to be the means to address the most critical issues the EU had to address in the early 2000s.

The introduction of NMG does not mean however that the EU abandoned the traditional governance modes. All the contrary, an important part of the White Paper on Governance (2001) still concerns the classical community mechanisms which – though they need to be improved - are considered by the Commission as the preferred governance models to pursue EU integration (European Commission 2001; Scott and Trubek 2002:8). Moreover, the White Paper explicitly states that NMG "should not be used when legislative action under the Community level is possible" (European Commission 2001:22).

The Commission also underscores in this document how "[e]ffective decision-making also requires the combination of different policy instruments (various forms of legislation, programmes, guidelines, use of structural funding etc.) to meet Treaty objectives" (European Commission 2001:16). This approach is consistent with the "hybridization of policy modes" (Wallace, Pollack and Young 2010:484) characterising the European policy-making system as we have seen above. This *governance mix* does not regard only the *modes* used but also, as underscored by Börzel (2010:191), the *levels* (regional, national and European) concerned.

2.2.3. Innovative governance Instruments

New Modes of Governance can be implemented by using various governance instruments ranging from framework Directives, voluntary agreements, co- and self-regulation and

networks. As underscored by Scott and Trubek (2002) a certain number of characteristics distinguish NMG from traditional hierarchical forms of governance. NMG for example are expected to show a higher level of deliberation and power sharing with stakeholders, coordination between multiple governance levels and informal guidelines allowing for diversity and flexibility (see also Idema and Kelemen 2006:110). These traits characterising NMG show many similarities with the management approach implemented in New Public Management in particular regarding the importance given to notions of inclusiveness, accountability, efficiency, effectiveness and deliberation among actors operating in multiple settings.

The White Paper on European Governance (European Commission 2001) outlines how the innovative governance practices should be implemented in an EU setting. It highlights in this respect the need to establish a stronger link between institutional and non-state (national) actors by means of consultation methods, partnership agreements, networking, risk assessment and risk management (through expert committees). Developing a culture of evaluation and feed-back is another objective pursued by the implementation of NMG. As such, soft governance methods should encourage voluntary co-operation, exchange of best practices, defining common targets and guidelines for Member States.

A particular EU approach of co/self-regulation has been developed by means of the so-called "Open Method of Coordination" (European Commission 2001:19-22). The latter refers to an iterative process comprising interrelated stages whereby Member States agree to cooperate on a voluntary basis. These stages include: the joint diagnosis of a problem; the establishment of objectives to overcome the problems; the agreement on guidelines on how to achieve the objective; the establishment of (quantitative or qualitative) indicators and benchmarks as means to compare best practices; monitoring and periodic evaluation using in particular peer review to favour mutual learning processes (European Council 2000; De la Porte, Pochet and Room 2001:293).

Benchmarking refers in open coordination policies to "a process of mutual learning and continuously improving performance by exchanging information and good practice and identifying excellence according to objectives to which the parties have committed themselves". It is closely related to peer review of the procedures for coordinating national policies and the comparability of data and transparency of indicators. Indeed, based on indicators or common reference factors, quantifiable objectives can be set permitting to evaluate the performance of participating actors and ensure an effective multilateral monitoring or coordination (European Commission 2002: 202).

In this new governance architecture as outlined in the White Paper on European Governance, networks play an important role. They are considered to be a mean to achieve the wider

goals of the Commission: increase public participation and upgrade EU policy-making and, in this sense, contribute to enhance effectiveness and legitimacy of the EU integration process. According to the Commission, "networks link businesses, communities, research centres, and regional and local authorities at a European or even global level. These networks can enhance the success of Community policies. The Commission will work more closely together with them to enable them to contribute to decision shaping and policy execution" (European Commission 2001; Schout and Jordan 2003: 4-6).

Moreover, networks play directly a role in the Commission's desire for more consultation and are also often representing a network of national agencies within the European agencies. Even in the benchmarking exercises promoted as a new governance mode in the White Paper, networks do play a prominent role. Hence, in the Commission's vision of governance, giving significant weight to notions as 'decentralisation' and 'partnerships', networks permit to facilitate and complement these new policy objectives (European Commission 2001; Schout and Jordan 2003:7).

Although the importance of networks has been underscored in the White Paper, experts focusing on this issue, acknowledged that "at the European level, we are only at the start of the learning curve with respect to the use of networks as tools for public policies" (European Commission 2002: 252). Indeed, in the preparatory phase of the White Paper, a separate working group on "coherence and cooperation in a networked Europe" had examined the role of networks in the new governance architecture (European Commission 2002: 198). The mission of this working group was to identify a typology of networks and recommend architectures and management practices for ensuring network efficiency, inclusiveness, representativeness, transparency and accountability (European Commission 2002: 251).

The White Paper on European governance does not give an explicit definition of networks, nor clarifies their role or operational modes (Schout and Jordan 2003:8). However, the working group preparing the White Paper has identified four types of networks interacting with the European Union: 1) networks for information and assistance to citizens and organisations on Commission policies or programmes; 2) networks for consultation when defining or reviewing a policy or programme; 3) networks for implementing and adapting EU policies such as programmes or legislation; 4) networks for developing policies/policy-making (including regulation) (European Commission 2002: 255).

Networks are in this view considered as potential instruments to develop public policies in Europe or even as "a powerful tool to help solve many of the problems inherent in European governance". Indeed, experts regard them as being able to "provide the flexibility required to deal with the wide diversity and sometimes fundamental differences existing between

administrative cultures and structures in Europe" (European Commission 2002: 254). The report underscores how networks permit in particular to address major challenges of the EU: maintain the democratic nature of the EU and its legitimacy and make the subsidiarity principle operational (European Commission 2002:254).

Although aiming to enhance democratic legitimacy, accountability, participation and effectiveness of European governance, no consensus exists whether the open and decentralised approach of coordination actually reaches that goal (e.g. Kröger 2009; Citi and Rhodes 2007; Héritier and Lehmkuhl 2011; Schmidt 2006). Networking is in this regard too, considered as a mean to ensure transparency, inclusiveness, accountability "by a systematic sharing of information and experience, coordination of actions undertaken, and simplification of procedures" (European Commission 2002: 204). We will examine in part B to which extent this can be verified in European HTA cooperation which has been predominantly developed by means of networking. To understand why the European Commission has chosen this soft governance approach to support HTA cooperation in Europe, it is important to understand the how this approach relates to European integration policies in the wider European governance architecture, as explained in the following section.

2.3. ROLE OF NEW MODES OF GOVERNANCE IN THE EU GOVERNANCE ARCHITECTURE

Many academics have analysed whether and how NMG have an impact on the effectiveness of EU policy-making. Some stressing their role to find solutions in situations of political deadlock through the inclusion of stakeholders while respecting the autonomy of Member States. In this respect some believe soft governance procedures to be durable and eventually even preparing for hard-law solutions. Others, however have a more critical view on the effectiveness of NMG and underscore the difficulty to ensure compliance in decision-making processes as participation is based on voluntarism (Kröger 2009; Citi and Rhodes 2007:21).

Similarly, NMG are considered by some to positively impact the democratic legitimacy and transparency of the EU decision-making processes. They point to the level of inclusion and participation from the conception to the implementation of various actors concerned by a policy. In particular, the role of expert networks to establish common agreements would positively impact decision-making and develop an environment of interaction leading to the establishment of trust and confidence among the different stakeholders involved. This inclusive approach of NMG has however also raised criticism as to whether these new governance modes would not present a way to circumvent traditional legislative and political

decision-making and thus put at stake, rather than increase, the democratic legitimacy of the EU (e.g. Héritier and Lehmkuhl 2011; Schmidt 2006).

Finally, some have underscored how NMG could have a positive impact on policy-making by favouring discourse and learning processes which lay at the heart of political processes and could induce policy change (e.g. De la Porte and Pochet 2002; Scharpf 2002; Knill and Lensshaw 2003). Different academic schools have examined in this respect the importance of values and beliefs in the development of policy-making processes (Schmidt and Radaelli 2004; Haas 1990). Innovative governance modes would also favour learning processes, producing information, support problem-solving and establish best practices (Eberlein and Kewer 2004; De la Porte, Pochet an Room 2001; Trubek and Mosher 2003). Discourse and the use of argumentation would also serve to "disentrench settled practices" and permit to "reconsider the definition of group, institutional and even national practices" (Sabel and Zeitlin 2008).

Guigner (2007) has examined the impact of soft policy instruments such as the Open method of Coordination (OMC) in the field of EU health policy (e.g. health information policy) (see further on OMC e.g. Borras and Jacobsson 2004). He underscores how exchange of ideas and experiences in formal and informal fora (e.g. European Health Forum, 'comitology', expert working groups) can lead to the Europeanisation of EU health policy. His research underscores how by means of socialisation and 'argued persuasion' actors can gradually adopt new ideas and practices. He refers to the latter as "constructivist cognitive Europeanisation" which according to him can have an important influence on the health policy-making processes in Europe (Guigner 2007:274-279). Critical assessments as regard the virtues of NMG through discourse and learning underscore, however, how the impact of the latter remains difficult to assess (e.g. Scharpf 2002; Héritier 2003; Rhodes 2005; Trubek and Trubek 2005).

Hence, NMG have been implemented by the EU institutions as means to improve effectiveness, transparency and democratic legitimacy of the EU. These innovative governance modes are characterised by the interaction mechanism, voluntary and non-binding decision-making procedures and the importance of discourse and learning mechanisms among the participating actors. As outlined above, the White Paper on European Governance underscored how these NMG should reinforce the principle of proportionality and subsidiarity. The latter is of major importance in areas of exclusive competence of the Member States such as HTA. In the next section we will therefore examine the relationship between soft governance modes in the EU and the principle of subsidiarity and why this may have an impact on the distribution of competences between the EU and the Member States.

2.4. NEW MODES OF GOVERNANCE AND THE SUBSIDIARITY PRINCIPLE

2.4.1. Subsidiarity responding to multiple interpretations

Besides striving for more effectiveness, transparency and democratic legitimacy, the governance reforms proposed in the White Paper on European Governance were also designed to address the issue of proportionality and subsidiarity inherent in EU policy-making processes. According to the Commission, the political principles underpinning the overall EU governance architecture should reinforce the principles of proportionality and subsidiarity from the conception of the policy to the implementation. Hence, the Commission underscores here the importance to systematically check whether (a) (…) "public action is really necessary, (b) if the European level is the most appropriate one; and (c) if the measures chosen are proportionate to those objectives" (European Commission 2001:8).

Referring to the principle of subsidiarity within the framework of New Modes of Governance is as such not astonishing since, as outlined above, open coordination as governance practice is considered to be particularly appropriate in politically sensitive policy areas where Member States often hold exclusive competences, and which should be governed within the respect of the subsidiarity principle. However, referring to the principle of subsidiarity within the framework of NMG is politically not completely neutral since the concept comprises a strong political dimension (Van Kersbergen and Verbeek 1994; 2004). One of the reasons for that lays in the multiple understandings and definitions that have been attributed to the notion of subsidiarity.

The subsidiarity principle in an EU understanding has formally been introduced Maastricht Treaty (1992). The numerous debates that took place prior to the treaty insertion of this concept, failed to adopt a commonly accepted European understanding of subsidiarity (Van Kersbergen and Verbeek 2004: 151). To some, it is even the ambiguity in interpretation that has permitted to turn this principle into a treaty-based provision (e.g. Endo 1994; Van Kersbergen and Verbeek 2004). Although support for the introduction of the concept in the Treaty was given by most political leaders, their views regarding the exact definition

of subsidiarity differed[23] (Van Kersbergen and Verbeek, 1994, 221–226). The absence of a uniform understanding of one of the key concepts in the European decision-making architecture can however have far reaching consequences in EU policy-making. In particular in the field of NMG these different understandings may allow for a transfer in the allocation of competences between the EU and the Member States (Scott and Trubek 2002: 6-8; Van Kersbergen and Verbeek 2004; Tholoniat 2010).

The principle of subsidiarity has been defined in Article 3b of the Maastricht Treaty its definition has not changed since: *"The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein. In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community. Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty"* (Art 5 TEU).

Depending on the analytical framework used, different meanings have been attributed to the principle of subsidiarity. Most often a distinction is made between so-called positive or negative concept of subsidiarity (Endo 1994). Subsidiarity as a positive concept refers to the fact that a (higher) entity has the possibility or obligation to act towards a (lower) entity, if the lower entity cannot accomplish its objectives in a satisfactory way or if the higher entity is assigned to intervene. Subsidiarity understood within a negative interpretation points to the fact that a (higher) entity has not the right to intervene in the affairs of the lower entity if the

---

23   Van Kersbergen and Verbeek (2004:152) identify three different varieties of the philosophy of subsidiarity represented among the European leaders in 1992. The first, supported by the Christian democrats, considered subsidiarity "as a flexible criterion in order to determine the extent to which the state can legitimately interfere in society". The second emanated from a (German) legalistic view of subsidiarity, embraced the idea that responsibility should be bore by decentralised public (rather than private) authorities (see also Goetz, 1995: 102). The third variety of subsidiarity (partly supported by the British Conservative Party) "referred to the legitimization of state intervention in order to protect the state's citizens from unwanted effects of capitalism".

lower entity can reach its objectives by itself, or if the higher entity has not been assigned to intervene (Endo 1994)[24].

No clear criteria exist indicating when the higher or lower level are considered capable of accomplishing objectives in a satisfactory way. Interpretation of the latter could be based on goal attainment, efficiency or necessity criteria. However, the lack of objective appraisal of these criteria makes the application of the subsidiarity principle a challenging exercise and politically charged. In this sense, subsidiarity is considered by some as a mean to strengthen EU integration policies in cases where the EU level would be considered to be more appropriate to establish policies in a certain field (Scott and Trubek 2002; Van Kersbergen and Verbeek 2004). In the next section we will highlight how associating the subsidiarity principle to New Modes of Governance further triggers questions as regard the competence extension from the Member State level to the EU.

2.4.2. Competence extension through NMG and the application of the subsidiarity principle

By introducing the possibility to have recourse to New Modes of Governance in policy areas where competences are either shared or fall exclusively under the responsibility of Member States, the Commission has added new governance instruments to its arsenal. Ambiguity exists however as regards the role these soft governance modes play in EU policy processes. Some considering them as a mean to favour integration policies while others regard them as a mean to safeguard Member States' control of EU policies (Diedrichs, Reiners and Wessels 2011:22-23). Similarly, the principle of subsidiarity can be considered either as a way to safeguard Member States' interests and decision-making powers or as a means to enhance EU competences in new policy fields. The relationship between the subsidiarity principle and NMG brings to the fore two aspects which may influence governance processes taking place in the EU.

---

24 The dual positive or negative interpretation of subsidiarity as an organising principle of the relations between State and society was already present in the early works on subsidiarity such as the encyclical "Quadragesimo Anno" of Pope Pius XI published in 1931 and considered to be the first publication where subsidiarity as function has been explicitly mentioned (Endo 1994). In this encyclical, the Church sought that subsidiarity should function as a mean to restrict state intervention in associations. In this sense it gave a negative interpretation of the concept. However, as underscored by Endo (1994:624), the encyclical also underscored the duties of the state intervention and did built further upon the encyclical "Rerum Novarum" written four decades before by Pope Leo XIII underscoring the obligation of the State in the field of social reform. The latter could be interpreted as a positive understanding of the subsidiarity principle (Endo 1994:624).

First, it seems that the combination of two politically ambiguous concepts (i.e. NMG and Subsidiarity principle) may influence the outcome of governance processes. Due to the "room for manoeuvre" offered by NMG to the Commission, 'windows of opportunity' may appear, permitting the extension of the Commission's influence in sensitive areas (e.g. health care). Having recourse to NMG in the implementation of supportive and coordinating measures, offers the Commission the possibility to take action in policy areas where, according to the treaties, it has no specific competences, while fully respecting the subsidiarity principle. Hence, since both the subsidiarity principle and NMG find support by those fostering further integration as well as by those seeking to limit it, the Commission's actions may be implemented without hindrance.

The second rapprochement which can be made between subsidiarity and NMG regards the envisaged aims of the latter as underscored in the Lisbon Agenda and White Paper on Governance (i.e. increasing efficiency and effectiveness of EU's (integration) policies and transparency). By implementing an open coordination policy in areas of exclusive or shared competences, the Commission's actions are limited to promoting cooperation policies and lending support to those policies. Since the Member States remain in full possession of their competences, the Commission does not trespass its powers as defined in the Treaties. However, the promotion and support of cooperation activities are often facilitated through the allocation of financial and administrative support. Hence, in a certain policy area, specific network activity can be financed through EU programmes (e.g. through grants or in kind) or support activities within related DGs. Via these kinds of mechanisms, the Commission has the potential to progressively become a key-player in the policy-making process since the boundaries between 'coordinating' Member States' policies and 'steering' their policies in a certain area become increasingly blurred.

A possible outcome stemming from this dual relationship between NMG and the subsidiarity principle is that through the implementation of NMG, the action of the Commission could *in practice* alter the allocation of competences and enhance its own influence on a particular policy domain. A two-fold explanation could be given in this regard but should however be further examined. First, by being in the situation permitting to determine which actions to support or not, the EU institution can adopt a steering function in particular policy areas. The more support for coordinated action, the more chance that Member States will develop a similar/coherent approach to particular policy problems. Through dialogue and learning processes underpinning NMG, Member States' policies could slowly but certainly converge. If harmonisation was not the aim envisaged at the beginning of the policy coordination process, it can in the end result in policy actions which could *de facto* be assimilated to convergence policies.

Second, in those situations where a certain degree of convergence has been attained as a result of EU's support to cooperation initiatives, it will become particularly difficult to determine which level is the most appropriated to deal with the particular policy, especially considering the role of the Commission as key-player in the coordination of policies. As the coordination is already being steered by the supranational level, it takes only one more step to determine that that level is the most appropriated level to undertake action. Conversely, it will be hard to argue that Member States are in a better position to bear that responsibility. This is the second point where the application of New Modes of Governance impacts the application of the subsidiarity principle.

In conclusion, the NMG emerged as a strategic objective of the new Prodi Commission and as instruments to attain the objectives of the Lisbon Council. As such, they became formal policy instruments of the EU with the intention to strengthen the transparency of the Union's policies through an inclusive governance approach; insure effectiveness and efficiency through new and flexible governance instruments; and reinforce the subsidiarity principle by the establishment of new mechanisms in the policy process facilitating the exchange of experience and permitting the achievement collectively of context-specific solutions on complex policy issues (Lebessis and Paterson 2001:8). In the following chapters we will examine how these soft governance policies have been implemented in the field of HTA cooperation and to which extend they have favoured or not convergence of practices.

2.5.   CONCLUSION

We have seen in the first part of this chapter how EU health policy has been developed either through a spill-over of Internal Market-based policies or by means of soft governance. The competences of the EU in the field of health policies are laid down in the treaties (e.g. Art. 4, 6 and 168 (TFEU)). The use of HTAs in national decision-making processes is considered as falling under the exclusive competences of the Member States. Although the EU has no say in the input of HTA into domestic pricing and reimbursement decision-making processes, it may lend support to HTA cooperation within the European Union. The public health article in the Lisbon Treaty (Art. 168 TFEU) underscores how soft governance modes can be used in these kinds of situations while respecting the subsidiarity principle.

The second part of this chapter has outlined the development of innovative governance modes in the EU and which comprise the recourse to networks. These New Modes of Governance have been developed to address the challenges of enhancing the effectiveness, participation, and democratic legitimacy of EU governance practices. NMG intrinsically bear the potential to become heavily politicised as they may be used by the Commission as a

mean to extend its jurisdiction. In particular when relating NMG to the subsidiarity principle, impacts on the division of competencies between the EU and the Member State level may occur.

HTA cooperation in Europe has taken place within this context of EU integration challenges and governance modes developed to address those. Having outlined EU health policy developments and governance instruments available in this area will permit us to better situate HTA cooperation processes and the governance modes applied in them. Indeed, HTA cooperation in Europe has been structured by means of networks. The EU has played a major role in supporting and developing these networks and has even integrated HTA cooperation as one of its own policy objectives. The development of HTA cooperation in Europe and the development of EU health policy have progressively been intertwined and have been structured on the basis of the new governance approach launched at the turn of the century. Networking has played a major role in these processes.

Getting a profound insight of the governance of HTA cooperation in Europe requires thus to situate these cooperation processes into the broader EU governance developments as they have had a profound impact on them. New Modes of Governance and in particular networking have been chosen to develop HTA cooperation processes in Europe. In the next chapter we will examine how soft governance can be implemented in governance networks and how these relate to national and European policy-making. Based on our findings in de literature we will design a research framework allowing to explore, through network analysis, how soft governance has structured European HTA cooperation within a EU framework.

3 | Research design

"Everybody is ambitious. The question is whether he is ambitious to be or ambitious to do."
Jean Monnet, Memoirs

3.0.   INTRODUCTION

In European HTA cooperation, the conjunction between the HTA arena and the EU institu-
tions takes place within networks. For the HTA arena, uniting in the form of a network is
a means to achieve the objectives of enhancing the quality, quantity and uptake of HTA in
national decision-making processes regarding health technologies. For the EU institutions,
lending support to European HTA networks and coordinate their activities, is a mean to de-
velop EU health policy and have an influence on the national health systems. The HTA arena
needed the EU support to develop its activities. The EU arena needed the HTA networks to
enter the domestic health systems. The governance processes of the HTA networks have,
since the beginning, been based on voluntary cooperation and soft governance modes. This
approach perfectly matched the New Modes of Governance available to the EU in health
policy-making.

From the outset, HTA cooperation has developed through the setup of specific project-based
networks aiming to establish a sustainable European HTA cooperation framework. These
networks have responded to different forms of composition and governance structures and
practices. Although they have emanated from an HTA expert community, they have gradu-
ally been integrated into EU health policy-making processes. Hence, HTA networks have
undergone influence of management and governance procedures laying within and outside
the EU-scope. Networking has been a means for HTA actors to unite their competences and
knowledge for specific HTA-related objectives. Salience for this matter has been developed
within the EU Commission which has supported and, in a later stage, coordinated these
cooperation initiatives, partly to develop broader EU health policy objectives.

In this chapter we will highlight the interplay between soft governance and networks in the
EU governance architecture. Although various governance modes can be implemented in
networks, these structures intrinsically present characteristics favouring the implementation
of soft governance instruments. As such, they are often considered by the EU as an adequate
forum to pursue specific aims in sensitive policy areas where its competences are limited.
Yet, EU recourse to networks is not restricted to areas of soft governance, as governance
based on networking can take place in all other EU governance modes (e.g. Börzel and
Heard-Laureote 2009). Similarly, and as underscored above, whilst soft governance can be a
privileged mode in networks, other governance practices can be observed in networks (e.g.
Klijn and Koppenjan 2016).

Hence, networks, can intrinsically function as a medium through which various soft gover-
nance instruments can be diffused. We have seen in the previous chapter how soft gover-
nance could, for example, avoid political deadlock through voluntarism, inclusiveness and

participation and establish favourable conditions for hard-law decision-making. Applied to networks, these elements will relate to a network's membership structure. Moreover, actors' incentives, rationality and preferences for particular policy choices can be influenced by learning processes and shared values and understanding. These elements will come forward in network formation and network socialisation. Similarly, horizontal coordination, importance of legal certainty, policy entrepreneurs and the presence of a shadow of hierarchy have been brought to the fore as playing a role in the effectiveness of soft governance. These features will find their expression in network governance. Hence, soft governance can be examined through the prism of networks. Networking being considered here as an instrument of soft governance and networks as a medium through which other forms of soft governance instruments can be applied. Adopting this approach in our research offers the possibility to associate HTA cooperation networks with EU soft governance modes and examine the role of soft governance in structuring HTA cooperation within an EU framework.

In order to better understand the governance processes of HTA cooperation through networking, this chapter will first address the role of networks in national and European policy-making processes and outline the concepts of governance networks, metagovernance and network governance. Our research framework will be built upon these concepts representing the external structure of the research framework. To understand *how* governance networks have been governed both from the 'inside' (network governance) as from the 'outside' (metagovernance), the framework addresses two particular aspects of governance networks and network governance: network typologies and network effectiveness. Both will be examined within the scope of soft governance. These concepts represent the inner structure of the research framework.

This chapter is organised according to the key-concepts of the research framework. The first section will set out what is understood by *governance networks* and will outline how they operate in national and European policy-making processes. The second section will elaborate on the 'governance of governance networks' by external actors, also referred to as '*metagovernance*'. Of interest here is to examine how this concept is applicable to the EU setting. The third section will turn to the governance of networks from a network perspective and outline operational aspects of *network governance* rooted in soft governance modes. It will explain how network governance can touch upon network characteristics (network typology) as well as on network effectiveness. The notion effectiveness and how this relates to network governance in our research will be explained in this section as well. The last part of this chapter will be focused on constructing the research framework based on the central concepts outlined above. This research framework will be used to examine the empirical data outlined in Part B. The latter should allow us to answer the research questions as defined in the introduction of the thesis.

3.1. GOVERNANCE NETWORKS

3.1.1. Governance networks in national policy-making processes

Networks have been studied across different academic schools such as political science, policy analysis, and organisational studies (Sandström and Carlsson 2008: 497). This explains the important variety in approaches and comprehension of what networks refer to. Many different concepts of networks have been developed across these academic fields such as 'advocacy coalitions' (Sabatier and Jenkins-Smith: 1993), 'implementation structure' (Hjern and Porter, 1993), 'Iron triangles' (Jordan and Schubert, 1992), 'issue networks' (Heclo 1978), 'policy communities' (Jordan 1990) and 'subgovernments' (Rhodes 1990). Networks used as resources for policy development and implementation can also be referred to as 'governance networks'.

Governing by having recourse to networks differentiates itself from the more traditional forms of governance also known as "buy, make or ally" (Williamson 1985) referring to *market regulation* (characterised by competition rules), *state regulation* (characterised by hierarchical command and control forms of governance) and *cooperation mechanisms* (characterised by negotiations and trust) (Provan and Kenis 2008). Instead, public policymaking, implementation and service delivery could be achieved "through a web of relationships between autonomous yet interdependent government, business and civil society actors" (Klijn and Koppenjan 2016:11).

The concept of 'governance networks' is closely related to the one of 'policy networks' developed in the 1980s and associated to state and public-policy reforms (Rhodes 1997, Smith 1999, Stoker 2000, Smith 2002). It has been argued that policy networks have developed following the neoliberal turn of the 1980s and the introduction of New Public Management. The latter, operating often via 'agentification' and outsourcing service delivery, had created a fragmented public sector, generating the need for horizontal coordination among public and private actors (Torfing and Sorensen 2014:332). Hence, due to an increased complexity in policy issues and policy processes including a variety of actors and institutions at multiple levels, some considered that so-called 'wicked problems' could not adequately be solved through either a state-only or a market-only approach. Policy networks have been presented as a third way permitting to compensate for limitations of both state and market regulation

and respond to societal changes creating new dynamics[25] (Kooiman 1993; Jessop 2002; Klijn and Koppenjan 2004; Sorensen and Torfing 2007).

The concept of *governance networks* draws a lot on the understandings of policy networks but has developed as a separate research agenda. From a political science perspective, Torfing and Sorensen (2014) have presented four different approaches on governance networks being developed within the new institutionalism school of thought. All four approaches underscore the presence of specific elements which can be related to soft governance. From a historical institutionalism perspective, some researchers (Jessop 1998; Kickert et al. 1997, Rhodes 1997), underscore how networks serve as a medium for interest mediation between interdependent actors whereby networks are constituted following strategic calculations of self-interested collective actors. Governance networks are formed through an incremental bottom-up process and allow actors to find "joint solutions to joint problems" (Torfing and Sorensen 2014: 337). Networks can be used by public authorities to pursue specific objectives. Mutual interdependence and the development of common norms, values and perceptions underpin negotiation processes, learning and compromise formation whereby interests and objectives of public and private actors can be transformed (Torfing and Sorensen 2014: 337).

Researchers adopting the perspective of rational choice institutionalism (e.g. Kooiman 2003; Mayntz 1993; Scharpf 1994), will consider governance networks as "arenas for horizontal coordination between autonomous actors who interact in and through different negotiation games" (Torfing and Sorensen 2014: 337). Network formation follows a functional response to changes in society and traditional governing approaches. Governance networks are considered as "game-like structures" functioning by anticipation of potential gains from the network through pooling resources and the build-up of mutual trust. Incentive structures facilitate collective action and conflict-resolution. Moreover, network formation can result from either the objective to avoid potential problems or situations ('negative coordination')

---

25   The term 'policy network' has been introduced in the 1990s as a generic label to describe various forms of interest mediations (March and Rhodes 1992). Policy networks were categorised in terms of participants, stability and internal consensus. According to Börzel (1998:260), "a policy network includes all actors involved in the formulation and implementation of a policy in a policy sector. They are characterised by predominantly informal interactions between public and private actors with distinctive, but interdependent interests, who strive to solve problems of collective action on a central, non-hierarchical level". To some (e.g. Rhodes 1994), the proliferation of networks would lead to a "hollowed-out state" as there would be an increased need of the state to rely upon other organisations for the delivery of services. Others, however, have pointed to a transformation of state power, exercised in new ways as a result of the development of partnerships and networks (Pierre and Peters 2000; Torfing and Sorensen 2014:335).

or from the search for common solutions to a particular problem through mutual engagement and interactions ('positive coordination') (Torfing and Sorensen 2014: 337).

Normative institutionalism approaches will underscore how actors can be normatively integrated through a new set of rules, norms, values and perceptions that may be developed in a governance network which will contribute to developing a shared logic of appropriate action (March and Olson 1995, Powell and Di Maggio 1991). This theory also adopts the perspective that networks are created through a bottom-up process and are further developed on the basis of institutional logics of appropriateness and interdependencies. Adjustments can take place as a result of mutual learning process. Actor interaction will be based on a shared logic of appropriate action and conflicts can be resolved through solidarity and commonly adopted rules (Torfing and Sorensen 2014: 338; March and Olson 1995: 45-89).

Finally, the governmentality theory, developed by scholars, such as, Dean (1999), Foucault (1991) and Rose and Miller (1992), consider governance networks as means for self-regulation of actors in a particular policy field which act, however, within an given institutional framework and respond to specific regulatory norms , performance standards and practices in adequation with overall (institutional) policy objectives. In this sense, governance networks are considered as a mean for government "to recruit social actors as vehicles of the exercise of power". Actors may however resist and oppose these "normalising power strategies" which can lead to the development of conflicts (Torfing and Sorensen 2014: 338)

What characterises governance networks and which is underscored in most approaches, is the presence of multi-level interactions among network actors and between the network and external actors. Huppé et al. (2012:2), for example, underscores how the combination of diverse participants from different levels (local, national, global) and sectors not only "aggregate resources, but are structured to take advantage of the fact that each participating sector brings different resources to the fore". More recently, Klijn and Koppenjan (2016:11) define *governance networks* as "more or less stable patterns of social relations between mutually dependent actors, which cluster around a policy problem, a policy programme, and/or a set of resources and which emerge, are sustained, and are changed through a series of interactions".

Hence, participants in a governance network rely upon each other but their relationship is not structured around a hierarchical command and control model and no superior-subordinate relationship exists among the participating organisations (see also O'Toole 1997; Keast, Mandell and Brown 2006). The network partners are not necessarily equal in terms of authority and relationships (Klijn 2008). Negotiations contain elements of bargaining but are linked to a "wider framework of deliberation that facilitates learning and common understanding"

(Scharpf 1994; Sorensen and Torfing 2007:10). The aim of the network is to regulate a particular policy field, but it does necessarily operate in a specific political and institutional environment which "both facilitates and constrains their capacity for self-regulation" (Sorensen and Torfing 2007:10).

No uniform understanding of the concept of *governance networks* exists. However, the definition of Sorensen and Torfing (2007:9) covers most aspects highlighted in the different schools of thoughts. In this definition, governance networks are qualified as "1. a relatively stable horizontal articulation of interdependent, but operationally autonomous actors; 2. who interact through negotiations; 3 which take place within a regulative, normative, cognitive and imaginary framework; 4. that is self-regulating within limits set by external agencies; and 5. which contributes to the production of public purpose".

Combining this definition with other aspects of governance networks highlighted above brings us to the following list of characteristics of a governance network:

Characteristics Governance Networks
More or less stable pattern of relationships of social actors clustering around policy problem/resources, emerging, sustaining and changing though interactions[1]
Stable horizontal relations of interdependent, autonomous actors (public private, civil society), not necessarily equal in authority and relationships[2, 3]
Interaction through negotiations based on deliberation, learning and common understanding[2]
Interactions in regulative, normative, cognitive and imaginary framework[2]
Self-regulating within limits set by external agencies[2]
Actors aggregate different resources[4]
Contributes to public purpose[2,3,4]

Table 3.1. General characteristics governance networks
[1]Klijn and Kloppenjan (2016), [2]Sorensen and Torfing (2007), [3]Klijn (2008), [4]Huppé, Cneech and Knoblauch (2012)

These attributes allow to determine whether a network could be qualified as governance network. However, different networks although responding to the characteristics of a governance network could also present distinct features which would further characterise them. As such, governance networks could respond to different reasons of establishment, different membership structures, resources and governance modes. The combination of these characteristics in one governance network can be considered as a specific network's typology. Examining *governance network typologies* allows us to better understand how specific networks have been created according to which incentives, strategic calculations or specific support or constrain measures received (Herting 2007; Klijn and Koppenjan 2016, Rhodes and Bevir 2007). Moreover, the membership of a governance network may impact

the strategic directions decided upon or may explain why certain objectives have or not been reached. The composition of a network also gives information about the background of its members (public, private, non-profit), whether the membership structure will be homogeneous or heterogeneous or will be open to new members or not (Koliba 2011Agranoff 2007;Schaap 2007; Peters 2007; Sandström and Carlsson 2008). Similarly, use of available resources will also characterise network governance and will have an influence on management and implementation strategies and choices (Koliba 2011). Finally, power distribution within a governance network will be a consequence of a specific network governance approach and can vary according to for example horizontal, asymmetric or centralised power distribution (Börzel and Panke 2007; Sorenson and Törfing 2007; Provan and Kenis 2007; Schout and Jordan 2003).

Hence, although networks can respond to specific characteristics which would qualify them as governance networks, each network itself will respond to a specific typology referring to its establishment, memberships structure, resources and governance modes. As these features will differ in the various governance networks and relate to various soft governance instruments used. The way networks will function in a specific environment and the manner in which they will set specific objectives and seek to attain them may also vary. In this sense, network typology at one hand can have an influence on the governance practices of a network and at the other hand can be a part of a governance strategy itself (e.g. determining membership, governance modes). For analytical purposes we address the typology of networks as part of characteristics of governance networks whilst recognising the role it plays in *network governance*, concept we will outline below.

3.1.2. Governance networks in European policy-making processes

Following general changes in domestic policy-making processes as outlined above, EU policy-making too becomes characterised by the interaction of multiple state and private actors as well as by the complexity of the negotiation processes. Policy networks will increasingly play a key role in these processes as they are considered to be a means to respond to the needs of private interest groups as well as European, national and sub-national interests (Marks 1993:392; Saurugger 2009:233-236). This new style of policy-making within the EU, corresponds, according to some observers, to a "transformation of governance" (Hix 1998:40; Jachtenfuchs and Kohler-Koch 1999). The inclusion of non-state actors in the governance process of the EU is being referred to by others as a genuine 'governance turn' in the EU (e.g. Kohler-Koch and Rittberger 2006; Rhodes 2012). The 'White Paper on European governance' published in 2001, integrates these practices in the official governance approach of the EU, as we have outlined in chapter 2. Recourse to soft governance instruments is a major constituent in this new strategy.

The new governance approach within the European context is based on cooperation-mechanisms between all concerned actors as well as on learning processes rather than competition (Saurugger 2009:236). Networks play a particular role in this governance architecture in which emphasis is made on the non-hierarchical modes of interaction between state and non-state actors, interdependent relationships between public and private actors as well as the importance of expertise and discourse and the problem-solving capacity of network governance. Whereas decisions are still being made on specific levels in the EU decision-making systems, networks modify actor's preferences and bring new issues on the agenda (Saurugger 2009:243-245).

As the inclusion of private actors and networks play an important role in the definition and implementation of EU policies (Kooiman 1993; Rhodes 1997; Mayntz 1998), some researchers have tried to clarify whether "the EU could be conceptualised as a form of governance by networks or governance in networks" (Börzel and Heard-Laureote 2009:139). Governance *by* networks referring here to a system where authorative allocation is being negotiated between the state and societal actors. The governance *in* networks approach considers that the EU decision-making system is being dominated by governmental actors. To elucidate this question, Börzel and Heard-Laureote proceeded by looking at the functional aspects of networks in the EU policy process and their normative implications.

Although they do recognise that, since the inception of the EU, networks have played a part in policy formulation and implementation, they believe that relationships between networks and EU institutions are asymmetrical and do not correspond to governance *by* networks (Börzel and Heard-Laureote (2009:139). They point to a "shadow of hierarchy" (See also Héritier 2011) present in EU decision-making which should therefore call for caution not to overestimating the role of private actors in the EU. Hence, according to Börzel and Heard-Laureote, governance *in* networks corresponds to a better conceptualisation of EU governance as "Instances of network governance are rare compared to forms of governance entailing combinations of supranational hierarchy, intergovernmental negotiations and market competition" (Börzel and Heard-Laureote (2009:140)

The scholars also underscore that networks have proliferated in the EU and have been used by private actors to seek access and influence at the EU institutional level by offering expertise and support. Drawing upon work of Obradovic and Vizcaino (2007), they also point to the fact that "the European Commission has made strategic use of them to strengthen their position in EU policy-making. Networks lend significant power to the European Commission, which often acts as a broker drawing on the resources provided by private actors (expertise, acceptance) to shape the formulation and implementation of EU policies according to its interests. While it takes advantage of private actor resources to increase its action capac-

ity, the Commission seeks to preserve its autonomy and has little interest in extending the involvement of private actors beyond consultations" (Börzel and Heard-Laureote 2009:140).

Hence, as underscored by Börzel and Heard-Laureote (2009:146), "networks have the potential to support all the forms of governance in the EU, ranging from supranational hierarchy, intergovernmental negotiations to market competition and rare forms of genuine network governance". The authors point to the White Paper on European Governance (2001) which underscores the importance of networks in the implementation of New Modes of Governance as they permit to establish relationships between multiple actors on multiple levels. According to the Commission, these networks can enhance the success of Community policies (European Commission 2001b). By working more closely with networks through the use of soft governance instruments and "enable them to contribute to decision shaping and policy execution", the Commission seeks to increase public participation and enhance effectiveness and legitimacy of the EU integration process (European Commission 2001b; Schout and Jordan 2003: 4-6). Through 'decentralisation' and 'partnerships', networks permit to facilitate and complement these new policy objectives (European Commission 2001b; Schout and Jordan 2003:7).

Although the very notion of networks is clearly present in the White Paper on governance, no explicit definition of these can be found. Moreover, as underscored by Schout and Jordan (2003:8), very little attention is given to the difficulties of creating and managing transnational networks. It seems that the governance network approach is mostly based on national experiences of the kind. Moreover, the role (support policy-making/participate in policy-making) and operational modes (self-steering/active steering by EU) of networks has not been clarified. Nevertheless, in the course of the years the EU will have recourse to governance networks in various ways mainly to support and develop specific policy objectives. The manner in which it does so could be related to so-called meta-governance which will be outlined in the section below.

3.2.   METAGOVERNANCE

Governance networks operate within a broader system as they relate directly or indirectly to public policy-making. Hence, interaction between governance networks and public institutions is often taking place either on a national level and/or on an international level depending of the nature of the policy issue. Analysing governance networks requires thus to distinguish two levels of analysis: the network-level (network governance and management) and the so-called 'meta-governance'-level (governance of governance networks). The latter

can refer to a domestic institutional setting or can involve an international institutional level such as the EU institutions.

Many scholars have examined governance networks from the perspective of autonomy and self-management (e.g. March and Olsen 1995; Jessop 1998, cited in Triantafilou 2007:190). As underscored by Triantafilou (2007:190), often in these perspectives, autonomy equates insulation from state power. Strong interdependencies between state and governance networks however often exists (e.g. manpower, expertise and finance) and autonomy could be actually considered "as a specific constellation between the exercise of power and the exercise of freedom" (Triantafilou 2007:190). As governments can and often have recourse to networks for service delivery or policy implementation or any other reasons, the question arises who actually governs the networks' actions, the state or the network? (Triantafilou 2007:190).

The answer is not a clear-cut one and no standard model of metagovernance exists. The question is directly related to the development of governance networks which, as outlined above, are rooted in public sector reforms where the state delegated tasks and policy implementation to networks. As governance networks are concerned by policy formulation and implementation, it is not astonishing to find strong relationships between public authorities and governance networks. Some scholars consider that when it comes to public policy, the state remains the central actor but uses a new mix of policy instruments. Instead of resorting to coercive regulatory instruments it will in particular cases or policy areas use a soft governance approach. In this new policy-mix, networks will "offer the state new capacities to govern by the use of indirect control instruments" (Bevir 2011:186 drawn upon Pierre and Peters 2000; Davies 2002, Jessop 2003).

The perspective that states can govern through governance networks refers to the concept of 'meta-governance'. Whilst many scholars point to the interrelationship between public authorities and governance networks, no uniform comprehension of the concept 'metagovernance' exists. Some consider this as state coordination though informal modes of steering. Bevir (2011: 186) for example considers that "the state increasingly steers and regulates sets of organisations, governments and networks. These other organisations undertake much of the work of governing: they implement policies, provide public services, and at times even regulate themselves. The state governs the organisations that govern civil society – the governance of governance."

Although metagovernance is often related to state actors, some scholars (e.g. O'Toole 2007; Klijn and Edelenbos 2007) underscore how metagovernance should not be strictly associated to public authorities as other societal actors also could fulfil this role by setting rules of a

game producing specific outputs and outcomes. Whilst O'Toole (2007:223) does not relate metagovernance exclusively to state actors, he does underscore that governments "have a major point of leverage that can shape what happens via networks: public policy". Influence of governments or international institutions on networks can take place through informal instruments that can affect coordination of positions of network actors. They can also play a role in information diffusion in the network regarding e.g. motives and commitments of network members or partners. These moves are not always transparent but can play an important role in the functioning and output of the network.

In case of discordance within a network regarding policy options, governments and international institutions can build connections between actors which did not necessarily exists before or can act as a broker in the achievement of policy objectives set by the policy network (O'Toole 2007; Huppé, Cneech and Knoblauch 2012:21). New options can evolve, or others can become acceptable. In this sense, governmental action can direct the choices of governance networks. Finally, through monitoring and enforcement mechanisms, governmental authorities or international institutions can influence commitment which have been collectively recognised as in the interest of the network. Hence, metagovernance "can be important in inducing the production of network outputs and outcomes desired by a government" (O'Toole 2007:226).

When preferences of a governance network are aligned with the agenda of the government or international institutions, action of public authorities can help shape network results appropriately. Instruments used can be persuasion and incentives. Authorities can in these cases also persuade network participants "of the value to them of long-term stable cooperation rather than short-term, narrowly self-interested calculus" (O'Toole 2007:227). These persuasive efforts will be accompanied by notions such as trust, reciprocity, commitment and good faith, which play a role in sifting participants' perceptions and choices and favour the development of stable and durable network solutions. Therefore, the role of public authorities in promoting these norms in a network should not, according to O'Toole, be underestimated (O'Toole 2007:227).

The research on metagovernance is still relatively young and not many definitions of it have been given to date. Sorenson and Torfing (2007) define metagovernance as "a reflexive, higher order governance involving 1) the production and dissemination of hegemonic norms and ideas about how to govern and be governed; 2) political normative and context-dependent choices among different mechanisms of governance or among different combinations of governance in order to prevent dysfunctions and advance particular goals". They also point to the fact that in case of network failure, often some kind of metagovernance will be used to resolve the problem (Sorenson and Torfing 2007a:110).

If some form of public authority steering can be observed in many cases of governance networks, Triantafilou (2007:195) warns not to exaggerate "the ability of meta-governance to control the outcomes of political processes of networks". In his understanding, the concept of metagovernance should not be reduced to a unitary governor standing above network governance, as network governance cannot be reduced to the intentions or will of that governor. Whilst no uniform definition about metagovernance exists, the various contributions in the literature do highlight the complex relationship between metagovernance and networks where state authorities and networks need to adjust to each other and can mutually influence each other.

As outlined above, metagovernance can be considered beyond the conception of state or other public authorities. In our research on HTA cooperation, we will consider metagovernance only from the perspective of governmental authorities, by encompassing herein the European institutional level as this may broaden the analytical perspective of EU support-lending and coordinating policies in the case of European HTA cooperation. We have highlighted how metagovernance can be exercised through soft governance means (e.g. persuasion, discourse, diffusion of norms and ideas). Incorporating metagovernance in our research framework permits to add a dimension in our network analysis aiming to assess the effectiveness of soft governance in HTA cooperation and explore the role of the EU institutions herein. Having explained the concepts of governance networks and metagovernance, the following section will focus on network governance and how this can be operationalised to examine HTA cooperation networks in Europe.

3.3. NETWORK GOVERNANCE

The concept of g*overnance networks* should be distinguished from the closely related concept of *network governance.* The latter refers to "the set of conscious steering attempts or strategies of actors within governance networks aimed at influencing interaction processes and/or the characteristics of these networks" (Klijn and Koppenjan 2016:11). This definition is characterised by a holistic view of network governance and touches upon both the typology of the networks and the effectiveness of the networks in defining and reaching a specific goal with given actors. In the section on *governance networks*, we have seen how typology is indeed interrelated with *network governance* as the latter can influence the characteristics of a network during its development process. As such, typology can have an influence on the effectiveness of a network in reaching set objectives. However, as outlined above, for analytical purposes we will address the typology of networks under the concept of *governance networks*, recognising however the interrelationship of 'typology' of governance networks and *network governance*.

Focusing on *network governance* points to a network level analysis and relates to the strategic objectives of the network. Network governance is often linked to *network management* which can be defined as "the deliberate strategies aimed a facilitating and guiding the interaction and/or changing the features of the network with the intent to further the collaboration within the network process" (Klijn and Koppenjan 2016:11). Networks are established with a certain purpose, in the case of governance networks, this purpose is often related to a public policy. For a comprehensive approach of network governance, the analysis requires to go beyond decision-making structures and processes and englobe the operational aspects of a governance network as well as external factors potentially affecting the network in its *effectiveness* to reach the objectives set.

As the term 'effectiveness' may refer to various conceptualisations, we will frame the notion of effectiveness of network governance as we understand it in the present research, before developing the research framework in section 3.4.

3.3.1. Defining the notion of effectiveness

We have outlined above how governance networks can distinguish themselves, in terms of governance, from more hierarchical or market based steering principles. A common aspect among governance networks is the use of soft governance modes to reach their goals. As aforementioned, New Modes of Governance offer to the EU institutions a means to develop or implement specific policy processes through governance networks. Hence, besides analysing the development and the composition of networks, it is important for our research to examine what affects the effectiveness of governance networks operating by means of soft governance.

To identify factors that have the potential to affect the effectiveness of a governance network, requires first to delimitate the notion of effectiveness as besides the relatively few studies made in this regard, various interpretations can be found. As such, one strand in the literature, considers that effectiveness should be examined by focusing on internal processes, as negotiation between public and private actors forms the basis of a network's operations aiming to formulate and implement policy options. As such, some scholars consider effectiveness in the light of a network's capacity to adapt to changes based on learning processes (e.g. integration theory) (Sorenson and Torfing 2007a). Exploring the internal processes of negotiation and interaction between network actors, brings to the fore the importance of elements such as social capital, trust, single or double-loop learning, shared values and understanding and exchange of knowledge for an effective functioning of the network (e.g. Peters 2007; Provan and Kenis 2008; Huppé, Cheech and Knoblauch 2012). Effectiveness can also be assessed by examining elements of network failure. In this perspective, Rhodes and Bevir (2007) identify the degree of closeness/openness in terms of network participation

as well as conflict-resolution or private or public interest serving as elements influencing the effectiveness of (social) processes taking place in governance networks.

Effectiveness in governance networks does not respond to a uniform definition and can be regarded in various ways depending on the perspective one takes. It is important to highlight here that, as underscored by Jessop (2002:236), effectiveness of governance networks cannot be defined and measured as the effectiveness of the governance of state and markets. Moreover, in the literature on networks, the issue of effectiveness is being examined mainly through three different angles. These distinguish themselves by the fact that they consider effectiveness by focusing either on aspects of *process*, *output* or *outcome* (or a combination of two or three aspects).

We have seen above that one of the reasons brought forward to explain the emergence of governance networks relates to the presumption that by combining resources and knowledge, governance networks may be more effective in achieving desired results. Within this perspective, effectiveness is often considered in the light of *outputs*. The latter differ from so-called *outcomes* in the sense that they can be measured as concrete, desired and targeted 'products' of the collaboration efforts. Measurement will here be done by comparing the results of the collaboration to the original goals set or needs expressed. Hence, effectiveness in this perspective is understood in terms of goal attainment or demand satisfaction (Börzel and Panke 2007). Considering networks as a mean for service delivery is another example of a viewpoint that will give significant attention to outputs in its assessment of network effectiveness, even though the process aspects will not be ignored (e.g. Milward and Provan 2000; Agranoff and Mc Guire 2003).

It is important to highlight here that the notions of *output* and *outcome* are sometimes used interchangeably in the literature on effectiveness of networks. In our understanding we make a distinction between the two notions. *Outcomes* referring to the (un)desired effects of the cooperation efforts which explains why they are indeed closely related to process and output. An outcome can for example be a new political or social situation evolving as a result of a specific policy implementation by a governance network. The nature of outcomes can thus be very diverse. Some theoretical schools will for example consider as outcome a network's problem-solving capacity (e.g. governability theory) or its horizontal coordination capacity (across institutions, levels and actors) (Sorenson and Torfing 2007a).

In their efforts to assess effectiveness in terms of *output* or *outcome*, many scholars focus on the management or governance aspects of networks. Factors favouring effectiveness in this sense will be, for example, management competences, governance procedures and resource availability (e.g. Klijn, Steijn and Edelenbos 2010). The specific skills needed to manage or

steer a governance network will differ from those needed in a private (business) or public (administration) environment because of the specific structure and actor composition of the network (Klijn 2008: 519). Several researchers have found "strong correlations between network management and good outcomes" (e.g. Meier and O'Toole (2001, 2007) Agranoff and Mc Guire 2003; Edelenbos and Klijn 2006, cited in Klijn 2008:519).

Evaluating effectiveness can thus be done by exploring *processes*, *outputs* and *outcomes* of a governance network. Each of these aspects can be considered in isolation as different factors may impact them separately. However, although distinct, they are also interrelated since they are elements of the same dynamics of goal pursuit inherent to a governance network. The *processes* may have an impact on the *outputs* produced and both the processes and the outputs may influence the *outcomes* of a cooperation process. *Process* and *output* are aspects that lay within the organisational structure and can be influenced by the interaction of network actors and network governance and management processes. Being a consequence of the former two aspects, the *outcome* lays outside the network's organisational and governance scope and cannot necessarily directly be influenced by the network actors and the network organisational and governance processes.

As discussed in the section above, a governance network is setup for a specific purpose. This purpose – the network's *raison d'être* - will define its overarching goal(s). Particular means will be developed permitting the network to attain this/these goal(s). The network's goal attainment can be analysed in terms of process, output and outcome. Each of the means developed and implemented to reach that overarching goal, can in itself be considered or defined as 'sub-goals'. Hence, the sub-goals become a pre-requisite to attain the ultimate goal of the governance network. Moreover, attainment of one sub-goal permits the definition of the next goal necessary to reach the overarching network's goal. These dynamics of goal pursuit, inherent to a governance network, could also be pictured as a 'chain of goal attainment'. Every (sub)goal is a mean to attaining the next (sub) goal which in the end permits the network to reach its overarching goal(s).

Effectiveness of a governance network could thus be considered as the capacity of a network to reach its overarching goal(s)s which is being pursuit through a 'chain of goal attainment'. Goal attainment is understood here as "the action or fact of achieving a goal towards which one has worked" (Oxford dictionary). In our understanding, goal attainment encompasses goal setting and goal achievement.

3.3.2. Application of network governance effectiveness as 'goal attainment'

The overarching research question of this thesis regards the extent to which soft governance has structured HTA cooperation within the framework of the European Union. To delimitate the scope of this question, we have formulated three sub-research questions. The first sub-research question regards the possibility to reach convergence and harmonisation of HTA tools, methodologies and practices through soft governance principles. The second refers to the uptake of the common tools, methodologies and practices in national decision-making processes. The third regards the impact of soft governance in creating synergies between HTA cooperative bodies and European regulatory processes (i.e. market authorisation of pharmaceuticals).

What these sub-research questions have in common is that they all examine whether in European HTA cooperation efforts, a specific goal can be attained by soft governance modes. These goals are: SRQ 1) development of common tools, methodologies and practices; SRQ 2) uptake of these in national settings, SRQ 3) synergies between HTA and European regulatory processes. All of them bear thus an element of effectiveness which could be considered in the sense of *goal attainment*. In all three cases, these goals can be examined through the scope of *process*, *output* and *outcome*.

The first sub-research question regards the possibility to reach convergence and harmonisation of HTA tools, methodologies and practices through soft governance principles. The *output* would refer to the realisation of common tools, methodologies and practices which can be measured (e.g. common guidelines, joint tools, joint assessments). Reaching convergence or harmonisation through soft governance means, pre-supposes however that the collaboration *process* fulfilled criteria which permitted this to happen (e.g. agreement on common standards and approaches upon which the common tools and methodologies are based). *Outcome* would refer in this regard to the effects of the process and outputs on the broader environment (e.g. HTA arena, EU health policy, stakeholders' policies).

The second sub-research question refers to the uptake of the common tools and practices in national decision-making processes. Exploring whether and how this has been done would require examining it from respectively the *output* and *process* point of view. Indeed, on the one hand, one can identify the number of national decisions having been made on the basis of common tools, methodologies and joint work developed in a European network constellation (*outputs*). On the other hand, using commonly developed tools in a national HTA report or using joint assessments as input for national/local decision-making on pricing and reimbursement will result of *processes* in which elements of trust, learning, adaptation etc. may play an important role. However, besides *process* and *output*, this question also

entails an *outcome* element of effectiveness as these new tools, methodologies and practices may impact national decision-making processes.

Similarly, the effectiveness of HTA cooperation in creating synergies between HTA and European regulatory process on market authorisation of pharmaceuticals can be examined in terms *process*, *output* and *outcome*. *Process* refers here to the development of common cognitive frameworks and understandings regarding the desirability and possibility of synergies between both arenas. *Output* refers in this regard to the establishment of common procedures between HTA and European market authorisation processes accessible to pharmaceutical companies (e.g. single-entry point for requests, jointly developed evaluation procedures and forms). *Outcome* points to the consequences of these outputs on the broader evaluation processes of health technologies and their impact on market authorisation, pricing and reimbursement.

In the next section we outline the research framework which will be based on several factors related to soft governance and playing a role in the typology and in effectiveness of governance networks. This research framework will be used in Part C for a systematic analysis of HTA cooperation in Europe which has taken place essentially through networking.

3.4. THE RESEARCH FRAMEWORK

To answer the thesis research question aiming to understand to what extent soft governance has structured HTA cooperation in Europe, a research framework will be developed in this section which will be based on the central concepts outlined in the previous sections: governance networks, metagovernance and network governance. This framework will allow us to examine the role of soft governance in European HTA cooperation processes through the prism of network analysis. As outlined in chapter one and two, HTA cooperation has been developed by having recourse to networks. Networks are considered here as a medium through which various soft governance instruments can be implemented. Networking also connects with the so-called New Modes of Governance, implemented by the EU in sensitive areas such as health care where competences are shared or held exclusively by the Member States.

Applying the central concepts of 'governance networks' and 'metagovernance' and 'network governance' to HTA cooperation, requires to examine the various networks developed since the early cooperation initiatives and to determine 1) whether these could be considered as governance networks; 2) whether metagovernance has taken place in the case of European

HTA cooperation and 3) whether the recourse to soft governance instruments in their network governance approach has contributed in reaching the goals set.

In the sections above we have outlined how, based on the examination of the literature, general network characteristics have been identified permitting to examine whether a network could be qualified as a governance network. Moreover, besides general governance network characteristics, each network can also be examined by focusing on – what we have called - its 'typology', referring to a network's specific characteristics (e.g. reasons for establishment, membership, governance modes). The network typology is not fixed and chances occurring in its typology can result from a network's governance approach. In this sense, a governance network typology is interrelated with its network governance practices. Section 3.4.1. will examine factors identified in the literature, related to soft governance, and having a potential impact on the typology of a governance network. It will then explore whether these could be integrated in the research framework.

Network governance refers to steering attempts and strategies of network actors to influence processes and/or network characteristics (Klijn and Koppenjan 2016:11). As such, it is related to the strategic objectives of the network and the operational processes to reach those objectives. Network governance can be affected by the manner in which members interact, the instruments used to implement decisions as well as factors laying outside the network's governance scope. Section 3.4.2. will examine factors identified in the literature, related to soft governance, and having a potential impact on the effectiveness of a governance network. It will then explore whether these could be integrated in the research framework.

Based on this examination, a research framework can be designed comprising the central concepts as well as factors potentially impacting them. The various components of the research framework allow for a detailed examination of European HTA cooperation networks from the perspective of 'governance networks', and 'network governance' which both can directly or indirectly related to 'metagovernance'. This framework should structure the examination of the effectiveness of soft governance in European HTA cooperation processes through the prism of network analysis.

3.4.1. Factors affecting the typology of governance networks

We have established in section 3.1.1., a list resuming the general characteristics of so-called governance networks. However, each governance network itself corresponds to a specific set of features that further characterises it. No comprehensive account exists in the literature encompassing all elements that could characterise governance networks. Depending on the academic perspective, different elements will be brought to the fore. In the following section, we will examine features that determine specific attributes of a governance network. We will

base our examination on different strands of the literature on governance networks rooted in either political science, organisational studies or public policy studies. We have structured this analysis according to the following aspects: network formation, network composition (membership), network resources and network governance. The aim is to determine whether these aspects could be integrated in our research framework as elements permitting to examine HTA cooperation networks in the light of governance networks operating via soft governance means.

3.4.1.1. Governance network formation

One of the factors having a potential impact on the typology of a network can be found in the manner and reasons of its establishment. In the sections above on governance networks in national and European policy-making processes, we have outlined several explanatory accounts regarding governance network formation. Many of those were rooted in a functional or historical perspective. They referred to state and public-sector reforms and changes in the society leading to increasingly complex policy issues and policy processes. These accounts related to the emergence of governance networks in general and how these were connected to policy-making processes. In this section we will explore in more depth the factors that explain the creation of specific governance networks which requires to analyse this issue from a different angle.

Hertting (2007:44) for example, examines governance networks from the point of view of 'goal attainment' and 'meaning'. He underscores how networks can result from an *endogenous development* process within a group of actors without the intervention of 'meta-governors'. In these cases, the actors' motivation to participate in the establishment and development of a network can be explained by the conviction that "such institutional arrangements will help them accomplish some kind of goal or meaning". Based on this viewpoint, governance networks can, according to Hertting, be examined by focusing on *contextual incentives* for network formation, *strategic calculations and choices* of single interdependent policy actors and the interactions and games that could be expected to *support or constrain* the formation and institutionalisation of governance networks. This classification can indeed be a useful tool to get a better insight in factors favouring governance network formation and institutionalisation.

Contextual incentives can be diverse and whilst Hertting (2007: 47) develops mainly interdependencies in terms of resources and strategic externalities, other researchers point in this regard to issues such as the difficulty to deal with 'wicked problems' or the need to address highly complex policy issues in interdependent policy fields with multi-level actor interactions (e.g. Klijn and Koppenjan 2016:12). Incentives to establish or participate in governance networks can also be related to factors such as access to information, knowledge

and professional expertise (Rhodes and Bevir 2007). Finally, facilitating service delivery or policy implementation can also be cited as incentives for governance networks to evolve (Klijn and Koppenjan 2016:23).

Strategic calculations and choices of autonomous actors depend on their perceptions of problems, strategies and solutions which can vary among the actors of a network. Network formation can be considered as an institutional design (Tsebelis 1990 in Hertting 2007:50) and permit actors to secure action capabilities and compensate for limited rationality and potential opportunistic behaviour. So, establishing governance networks may be a strategy for efficient negotiations. However, the informal character of networks where cooperation is mostly based on trust also offers a 'cheap exit strategy' (Hertting 2007:50). Hence, high interdependencies between actors in a same policy area can also cause strategic complexity in predicting the course of (inter)actions of actors (Klijn and Koppenjan 2016: 11).

As underscored by Hertting (2007:51), "a governance network is never formed, established or institutionalised once and for all". Participation and 'use' of the network needs to be continuous for the network to survive. Indeed, the latter will testify of the actors' recognition and identification with it. However, participation can take the form of strategic *games* such as the free rider problem[26], the assurance problem[27] and the generosity problem[28] (Hertting 2007). Applied to governance networks, these problems often relate to a matter of trust or insecurity (lack of assurance) of what the other actors will do. A network may be formed by interdependent actors who, although independent cannot always function autonomously. Exchange may be necessary to achieve their goals (Hertting 2007: 50). Support or constrain to a network will thus depend on how actors value the informal relations and coordination based on trust. Balancing between the need for more cooperation and the desire to maintain sovereignty will be central (Hertting 2007:55; see also Rhodes and Bevir 2007:7). Network formation is easier when actors share a mutual understanding and the perception of the policy problem (Hertting 2007: 49; Zafonte and Sabatier 1998).

Governance networks often represent several individual organisations investing in the network formation. The organisations' representatives will not only have to take into account

---

26   The free ride problem refers to a situation where all actors would gain from the cooperation, but a single actor would gain more if everybody, but he/she, would cooperate (Hertting 2007:52).

27   The assurance problem refers to a situation where mutual cooperation is the equilibrium. If one actor decides not to cooperate, it is rational for the others not to either (Hertting 2007:54)

28   The generosity problem refers to a situation where two parties have a common interest in coordinating so that they will reach an outcome that is superior to the one if they do not cooperate. In order to reach a stable cooperation, Actor A has to allow actor B to reach B's most preferred outcome while A accepts a less preferred one" (Hertting 2007:55). Hence generosity is needed.

the horizontal relationships with other network actors but also vertical connections within the organisation they are representing in the network. This can lead to two-fold loyalties: within its 'own' organisation and within the network. On the one hand, commitment towards the network agreements needs to be demonstrated. On the other hand, the agreements made in the network also need to be accepted or approved within their own organisation, which interests need to be respected in the network. Strong ties within network actors may lead to suspicion on the vertical level and negatively affect the role and trustworthiness of the actors on the horizontal level (Hertting 2007: 57). Support or constrain to a governance network can also be influenced by these aspects.

As network formation can have an impact on the typology of a governance network we will integrate this factor in our research framework by relating to this factor the following features to be examined in a network formation: incentives, strategic calculations, support and constrain.

3.4.1.2. Membership of governance networks

Another factor we have identified in the literature having a potential impact on the typology of a network is its composition. Governance networks are composed of different type of social actors that pursue certain goals and take up certain roles in the network. Network actors can represent the public, private or non-profit sector. Their social background will impact on their goal and role in the governance network. Often actors are attuned toward a certain level of geographical scale: local, regional national or international. (Koliba 2011: 67). As such, actors can be organisations or institutions, committees, departments or individuals. Depending on the networks, particular institutions can dominate, whereas in others, the role of institutions will not impact the collaboration efforts.

Moreover, as already touched upon above, examining the relationship between the individual and the institution or organisation it represents, is important to understand governance network dynamics. Network actors may or may not represent the interest of the organisation or actors it represents. An individual may thus participate in a governance network without necessarily represent the views or interest of the group to which it belongs (Koliba 2011:82). Hence when analysing governance networks, it is important to determine whether one looks at the whole network as unit analysis (e.g. O'Toole 1990; Rhodes 1997; Agranoff 2007) or if one takes also into account individual membership together with the whole network (e.g. Agranoff and Mc Guire 2003, Koppenjan and Klijn 2004).

Governance networks can be open or closed in both a social and cognitive[29] understanding (Schaap 2007:118). Social closure refers to the degree of acceptance of (new) members either within separate units of the network or towards the external environment. In a socially open network, membership can relatively easily be extended to new members or the replacement of old members. Social closeness will be more often observed in self-steered networks (Schaap 2007: 131). March and Rhodes (1992) argue that self-interest of actors may cause closure of a network. In a socially closed network, members do often share the same set of basic values. Closeness does not however imply that changes cannot takes place as these can be incremental and based on learning processes or result from external stimuli (Schaap 2007).

Another distinction in composition can be made based on the concept of 'homogeneity' or 'heterogeneity' of a network structure. A homogeneous structure refers to a membership composition sharing similarities in terms of (e.g. social, professional) actors' profiles and backgrounds. Conversely to a homogeneous actor composition, a heterogeneous actor structure refers to a set of interdependent actors presenting a variety of social and professional backgrounds. Often, in case of a heterogeneous network, the actors will represent various stakeholders concerned by the network's activities and goals (Sandström and Carlsson 2008).

The degree of openness or closure of a network can be related to its degree of homogeneity or heterogeneity. Indeed, a network can extend membership to different (new) stakeholders or experts. Some researchers posit that a degree of heterogeneity in the network membership is not only inevitable as a network overtime needs to replace members, but also a necessity for it to develop, reach its goals and innovate (Peters 2007:72; Sandström and Carlsson 2008:517). Both the openness/closure of a network as well as a network's homogeneity/heterogeneity degree bear the potential to affect the interaction between the network partners and the internal negotiation processes (Rhodes and March 1992; Schaap 2007; Sandström and Carlsson 2008; Huppé, Cheech and Knoblauch 2012).

The second factor identified as potentially impacting the typology of a governance is membership and will as such be integrated in our research framework, associating to this factors the following features: public, private or non-profit membership, relation home-organisation/network, degree of openness/closure, degree of homogeneity/heterogeneity.

---

29   Cognitive closure can be interpreted in two ways. It can been interpreted as an inability to perceive (actors have no access to an 'outside reality' and continue to operate within their own frame of references) or un unwillingness to perceive (conscious strategy not to take into account certain approaches). Social and cognitive closure interfere with one another (Schaap 2007:119).

3.4.1.3. Resources of governance networks

Another factor which can impact the typology of governance network is the type and amount of resources available to the network. Resources vary in their forms available and often also create interdependencies between network actors who can either provide re-sources or seek for resources in a network. Koliba (2011:87) identified different types of resource interdependency: financial, natural (e.g.land), physical (e.g. office space, property), human (knowledge and skills, expertise) or social (e.g. social ties, common norms). Moreover, resource distribution can also be unequal in a network (Börzel and Panke 2007:155).

Financial resources can take various forms such as public-private partnerships, subsidies or grants allocated to the network. These financial resources can be provided by private or public sources. Resources can however also take other forms such as in-kind contributions by organisations offering administrative services, office space or detaching part of the working time of employees to the network.

The participation of experts offering a certain level of knowledge, skills and expertise also can be considered as valuable resources for a governance network. Similarly, the establishment of new partnerships and the creating of new social ties are considered as network resources (Koliba 2011). But resources can also be of a different nature: political, cultural. As such, political support and the development of shared social norms could also be counted in as important resources for a governance network.

Resources will thus be included in our research framework as third factor potentially impact-ing the typology of a governance network. It will be considered in relation to the following attributes: financial resources, natural/physical resources, social/political resources and hu-man resources.

3.4.1.4. Governance modes of governance networks

Various forms of governance structures exist across governance networks and as such affect the typology of networks. Although different, these governance approaches all share some common features. The first is that all governance modes of these networks are based on non-hierarchical coordination (Börzel and Panke 2007:155). Whereas hierarchies are based on relationships of domination (public actors) and subordination (private actors), relationship between actors in governance networks are based on the fact that they share an equal status. This, however, does not mean that all actors are equal in terms of authority and relationship (Scharpf 1994, Sorenson and Torfing 2007).

Hierarchical coordination is characterised by authorative decision-making where decisions can be imposed upon actors (e.g. through administrative orders or judiciary rulings). Non-

hierarchical coordination - which characterises governance networks - can take place either through positive/negative incentives or negotiated compromises. Another mean of coordination is via learning processes and persuasion. These permit actors to gradually adapt their position and integrate new norms and rules which will have an impact on their preferences ((Börzel and Panke 2007:156).

Steering mechanism in governance networks are quite diverse and differ in the degree of autonomy and power distribution. Provan and Kenis (2007) distinguish three main types of governance networks. The first type refers to networks with no formal administrative entity where all actors participate in the decision-making process. Governance here is characterised by decentralised collective self-governance. It can be formal through regular meetings of designated organisational representatives or informal through uncoordinated efforts. Network members interact on a more or less equal basis regarding governance. These networks depend exclusively on the participation and commitment of all. Hence, network participants are responsible for the internal management as well as the implementation of activities and the development of external relationships. Provan and Kenis (2007:234) refer to this model as a *Participant-Governed Network*. This type of governance can however be associated to inefficiencies. Networks can therefore opt for a more centralised approach of governance.

Governance networks adopting governance modes based on centralisation often function on the basis of asymmetric power distribution. In these cases, it is common that one organisation takes the lead. This is often an organisation having sufficient resources and legitimacy to play this role. It also provides for administrative support and facilitates the implementation of the activities (Provan and Kenis 2008: 235). Hence, this so-called 'Lead-Organisation' plays a role of project coordinator. Funding is often also regulated by the coordinator through, for example, collecting the financial contributions from network members or by applying for grants and subsidies. Cost of network administration can be entirely bore by this entity as well. Members may design a project coordinator, or the Lead-Organisation may be mandated by an external actor (e.g. funding source) (Provan and Kenis 2008: 236). This type of governance is also called *Lead-Organisation Governance* (Provan and Kenis 2008:235)

Finally, a governance network may be governed by a separate administrative entity specifically setup for this purpose. Governance in this case is also centralised and the new entity plays a major role in coordinating and sustaining the network. An important distinction with the previous model is that the administrative entity is not a member of the network but acts as a network broker and its exclusive reason of existence is the coordination of the network. The entity may be established by the network members themselves or it has been mandated by an external actor. It can be a governmental entity or a non-profit organisation. The scale of the entity can vary from a single person network facilitator to a full-fledged

organisation comprising for example an executive director, staff, and a governance board. In these cases, strategic questions are being dealt with by the board, leaving the operational issues to another level. Provan and Kenis (2007: 236) refer to this model as the *Network Administrative Organisation*.

The models above vary thus in the degree of self-steering or active steering (see also Schout and Jordan 2003). We have seen above that decision-making processes can be organised in different ways according to the governance model adopted. However, these decisions are always taken collectively. Whether they are binding is being decided in each network separately. No uniform governance approach exists in this regard. Hence, governance modes will be integrated in our research framework as the fourth and last factor having a potential impact on a network's typology.

In the next section we will examine network governance from the perspective of effectiveness. Based on the examination of the literature, we will seek to identify factors, related to soft governance, that potentially can have an impact on a network's effectiveness in terms of goal attainment as outlined in section 3.3.2.

3.4.2.   Factors affecting effectiveness of network governance

3.4.2.1. Social interaction

Network governance involves, as we have seen above, coordination between interdependent but autonomous actors who are gathered in a self-regulated network to achieve a certain goal of public interest. As underscored in the definition of Sorenson and Torfing (2007:9) outlined above, interaction among these actors takes place though negotiations within a regulative, normative, cognitive and imaginary framework. This framework in which deliberation takes place, facilitates learning and common understandings (Sorenson and Torfing 2007:10) which are necessary to establish common values and norms upon which a common approach and policy instruments can be developed.

Many scholars underscore the importance of a certain number of concepts which need to be present in the interaction and deliberation processes taking place in networks to favour their effectiveness. As such we can mention trust, (social) learning processes, mutual understanding, shared values and beliefs and (goal) consensus (e.g. Dedeurwaerdere 2005; Provan and Kenis 2008; Klijn, Steijn and Edelenbos 2010). Hence, the social, cultural and professional background of the network actors may impact the development of certain network processes. These analyses show some similarities with notions present in the literature about epistemic communities and the advocacy coalition framework (see further on epistemic communities e.g. Haas 1990 and on advocacy coalition framework e.g. Sabatier and Weible 2007).

To develop our research framework, we will draw on the work of Huppé Cneech and Knoblauch (2012:4) who suggest that effectiveness of a network can be analysed through social capital, network heterogeneity and collaborative visioning processes. Their research encompasses many of the concepts discussed above and which have been identified in the literature as playing a role in the effectiveness of networks. Social capital refers here to the presence of trust, shared values and understanding, permitting actors to work towards common goals. Network heterogeneity and collaborative visioning are important aspects in the collaboration between network members and impact social capital.

In examining social capital, Huppé, Cneech and Knoblauch (2012) point to an 'efficacy paradox' (Voss et al. 2006) which evolves from the necessity to open up a network so as to address complex problems with distributed capacity and knowledge. Enhancing capacity to solve a problem by including more actors from different backgrounds in the network, may actually render the problem-solving more complex as the actors will have different interests and views making it more difficult to reach common agreements (Huppé Cneech and Knoblauch 2012:6). However, learning processes may help to overcome diversities in views, motivations and interests and move towards what the researchers call 'collaborative visioning' where network actors align their individual strategies to the shared visions and network goals.

Hence, collaborative visioning can be achieved through second-order (or double loop) learning processes. The latter refer to an evolutionary process where problem solving concepts are empirically tested. The experience will again feed into the theoretical framework. The aim is here to create shared visions which will also add to the members' sense of commitment to the network goals. Collaborative visioning will positively impact social capital. Social capital will affect the effectiveness of a network. The higher the social capital in a network, the more a network will be able to reach its governance goals (goal attainment) (Huppé, Cneech and Knoblauch 2012).

In our analysis to assess the effectiveness of a governance network in terms of goal attainment, some key aspects of the work on social capital of Huppé, Cneech and Knoblauch (2012) will integrated as described below. However, as the term 'social capital' refers to a wider academic agenda including aspects which will not be integrated in our research framework, we will refer in our research to term of '*social interaction*' rather than *social capital*. The degree of social interaction depends on the presence of specific elements that can be sorted in two types of categories. The first refers to cognitive/behaviour aspects and the second to governance/management aspects. Both categories are interrelated but for analytical purposes we will examine them separately by focusing in this section on the first category. The second category will be addressed in the next sections.

Hence, social interaction within a governance network will be partly affected by cognitive and 'behaviour' aspects of interaction processes between actors (either within the network or between network actors and other public or private actors). Four main elements playing a role in developing social interaction can be identified: trust, shared values and understanding, learning processes and goal consensus.

Trust is explained by Provan and Kenis (2008:238) as "an aspect of relationship that reflects 'the willingness to accept vulnerability based on positive expectations about each other's' intentions or behaviours' (Mc Elvily, Perrone and Zaheer 2003:92)". Understanding the importance of trust in network-based interactions requires according to Provan and Kenis (2008:238) to focus on the distribution of trust and on the level of reciprocity. A high density of trust can be observed in networks were trust is widely spread among network members. Conversely, low density of trust reflects that trust is predominantly present within individual network dyads or cliques.

Based on this understanding, trust will be more important in the first type of networks (Participant-Governed Networks) discussed in *section 3.4.1.4.* and characterised by shared governance, since it will constitute an important basis for cooperation. Collective goals can still be accomplished even in case of low trust density. However, in these situations, the network governance will most likely take the form of a Lead organisation governance (type 2) or Network Administrative Organisation (Type 3) (see section 3.4.1.4.). Research of Klijn, Edelenbos, Stejin (2010) confirms the importance of trust in achieving better (perceived) outcomes of governance network (both process and content outcomes). Moreover, their work indicates that trust is manageable and can be developed and sustained through network specific management strategies. Similarly, Nielsen and Pedersen (1988) point to the role of trust in generating compliance with collectively negotiated decisions.

Shared values and understanding are important to develop common languages and allow for a better framing (e.g. Peters 2007). The notion of framing is used to describe a process for developing common conception of policy issues among a set of actors. Reframing refers to changing cognitive maps in a policy which can help resolving policy problems (Schön and Rein 1995 in Peters 2007:67; Bevir and Rhodes 2007). Hence the understanding of a policy problem in this perspective is not fixed but can evolve. One of the means to develop common languages and understandings and (re)frame issues are learning processes.

Learning processes (social and organisational) permit actors to reconsider their context and normative beliefs by considering those of others. As we have seen above, learning in an organisation can take place as a 'trial and error process' leading to incremental organisational changes (Haas 1990). Actors process quantitative or qualitative information, interpret it and

seek to offer a response. This type of learning is also referred to as single-loop learning (Argyris and Schön 1978, 1996). Double-loop learning adds an additional dimension as it questions the governing practices themselves and integrates the observations in the organisational structure allowing even for radical changes in strategy, structure, objectives etc.

Linking these conceptions to learning in governance networks constituted of expert groups, brings us to role of 'social learning' which is more concerned with the development of (shared) normative beliefs and values. Dedeurwaerdere (2005), underscores the importance of social learning in governance networks which respond to many of the characteristics of "epistemic communities" as described by Haas and Haas (2002). According to Dedeurwaerdere (2005:8), single loop learning will mostly occur in self-regulated networks concerned to maintain the stability of the organisation. Basing his observations on the work of Ernst Haas (1990), he furthermore underscores how double-loop learning permits a network to build-in monitoring and evaluation processes aimed at changing the basic beliefs and fundamental principles of the organisation and can redefine its organisational mission if confronted with unexpected or ineffective outcomes of its activities.

Goal consensus will partly depend on the development of mutual understandings and shared values. Reaching consensus in a network will furthermore also be in function of mutual dependence of the network members as well as of the connection of the network with other institutions and networks (Peters 2007:67-68). Establishing and developing external relationships to facilitate the achievement of goals could actually reduce the effectiveness of the network to set and/or achieve its goals as it may reduce internal cohesion (Peters 2007 68). Hence the tendency to be broadly connected to other networks or institutions so as to be more effective into achieving the political goal can negatively affect internal consensus.

In this section we have seen how social interaction can affect the effectiveness of governance networks. Social interaction will therefore constitute the first factor in our research framework addressing the effectiveness of governance networks in terms of goal attainment and will be related to the following features: learning processes, shared values and understanding, trust, goal consensus.

3.4.2.2. Governance instruments

As aforementioned, social interaction is closely associated to governance and management aspects of a network. Several scholars have pointed how they mutually influence one another. Huppé Cneech and Knoblauch (2012) underscore how the degree of social capital can be influenced by governance modes (centralisation), the nature of the actors composing the network (density), the strengths of the relationships among actors and leadership. The more these aspects will be developed in a network, the higher the social interaction and

thus the more effective a network will be. Others point to the impact of social interaction on the governance and management of governance networks. As such, it may support the development of collaborative governance processes in terms of strengthening governance capacity (Adger 2003) improving innovative capacity (Moran 2005), establishing constructive processes of communication, social integration and coordination (Evans and Carson 2005), or even information processing (Tompkins and Ager 2004, in Huppé, Cneech and Knoblauch 2012:18).

However, governance and management aspects of a network do not only bear the potential of impacting the effectiveness of a governance network through its relationship with social interaction. Besides their connection with the latter, the governance and management of a network can be examined on a stand-alone basis with regard to their impact on network effectiveness. In this section we will focus on governance instruments and how these relates to effectiveness in terms of goal attainment in a governance network. In the literature, we have identified four aspects linked to governance instruments and governance network effectiveness: policy instruments, legislative and regulatory instruments, political instruments and financial instruments.

Instrument choice is an important element in the process of policy implementation and can as such be considered as being part of the governance approach to implement specific policies. The choice of *policy instrument*s is not a neutral exercise and often also depends on the knowledge and resources available. The policy-mix that will be elaborated on the basis of policy-instruments aims at reaching the goals set or at resolving particular problems (Bressers 1998 and Bressers and Klok 1988). Taxonomy of policy instruments is most commonly based on instruments used in public policy or state intervention. As such, they can be used to support the production of specific goods and services or at processes regulating interaction between state and society. They can however also be used within a policy network (Howlett 2018: 82; Goldsmith and Eggers 2004; Klijn and Koppenjan 2000; 2006).

Howlett (2000) makes a distinction between 'substantive' policy instruments and 'procedural' policy instruments. Substantive policy instruments "are aimed at the delivery of certain goods and services to society" (Howlett 2018:80). Procedural policy instruments can affect implementation processes of a policy seeking to produce outputs. Howlett (2018:80) describes the latter as tools that "govern state-society relations and affect the support for and participation of actors in government initiatives". Relationship between governments and networks can fall under procedural policy instruments. However, processes taking place within a network can also be examined from this perspective as policy-making is affected by the interaction of multiple actors (state, non-state and international), which can influence policy deliberations and outcomes (Klijn and Teisman 1998 in Howlett 2018:80; see also Flanagan et al.

2011). The choice of policy instruments can affect behaviour, interactions and activities of policy actors "in developing and choosing policy solutions" (Thatcher and Rein, 2004 in Howlett 2018). As underscored by Howlett (2018: 82), "the impact of the deployment of such [procedural] tools to affect actor participation in policy networks can range from minor alteration of network actor behaviour to more deep-seated and overarching restructuring of entire policy subsystems".

When examining the impact of network governance on the effectiveness in terms of goal attainment, other important factors come to the fore related to governance instruments and which are of a legal, political or financial nature. Indeed, the *legal framework* in which the network operates has important consequences for network effectiveness, in particular regarding matters of output. In some countries (e.g. Sweden, Denmark), specific framework laws have supported public services activities of local authorities or private actors. These laws have permitted, in some cases, the establishment of governance networks in combination with economic incentives and evaluations to steer the implementation of the work (Triantafil-lou 2007: 191). The interdependencies created between state authorities and private actors seem to favour effectiveness of these networks. Case studies have shown that the networks created by public intervention did change the way a particular problem was addressed as different actors took part in the process leading to the production of new outputs (see further Triantafillou 2007).

However, similar conclusions can be drawn from governance networks that have developed as a result of other processes. Hence, the analysis of effectiveness of governance networks should not be reduced to a zero-sum power distribution but should focus on different methods and techniques of governing within a wide set of *legally binding and non-legally binding instruments* (Triantafillou 2007). This brings us to an important point regarding effectiveness of a governance network in terms of goal attainment. Legally binding decision-making can be considered 'more effective' in terms of goal attainment but this mode may not always be an option in national or EU policy-making for reasons outlined in chapter 2 (e.g. EU competence area, sensitive issues, absence of political or civic support).

New governing techniques based on self-steering governance modes "may actually enhance the capacity to pursue and implement social and political goals" (Triantafillou 2007:197). However, effectiveness of soft governance modes (especially in an EU setting) may actually be explained by the presence of a 'shadow of hierarchy' (Héritier and Lehmkuhl 2011:62). In these cases, the application of soft governance modes is usually combined "with some form of governmental prompting or pressure". Hence, effectiveness of soft governance mode may be related to the presence of public authorities and the 'threat' of hierarchical decision-making modes if no consensus is found or results achieved via soft governance modes.

Political instruments available to the network can create interdependencies (networks/networks and state/network) affecting the way how policy issues are being handled. We have seen that governance networks are created against the background of a specific policy issue. With governments relying increasingly on governance networks to respond to specific policy questions, the importance of political instruments available will impact on the effectiveness of goal attainment. Of particular interest in this regard is 'agenda alignment' between the network and the government's priorities which can impact network outcomes as government can use different instruments (persuasion, support, constrain etc.) to structure the actions of a networks (O'Toole 2007:227).

However, many other instruments of this nature exist and can affect all stages of the policy cycle (e.g. policy formulation, implementation, evaluation). Hence, political instruments can be used as a form of support or constrain to the activities of a governance network (political support/constrain for new legislation, financial or administrative support/constrain). Taking into account the variety of instruments available it is important in our research to examine whether political instruments have been used to steer HTA cooperation efforts and how they have affected the governance of the networks and the effectiveness in reaching the goals set by those networks.

Similarly, *financial instruments* will also play a role in the governance of networks. Allocation of resources by public authorities can bring about interdependencies between the public authorities and governance networks, but also between partners within a governance network. Presence of public funding for a particular public issue can support network formation and contribute to the production of specific outputs and outcomes. However, commitment to the network and network relationships may be fragile and disappear at completion of the project and termination of its financing (Triantafillou 2007: 192). Moreover, actors' motivation to create a network may be explained by pecuniary concern rather than the pursuit of a (normative) goal (Sherlock et al. 2004, in Triantafillou 2007). Financial resources and financial sustainability of a network can also potentially affect effectiveness of a governance network in the sense of goal attainment. This research will thus seek to identify whether financial instruments have been used to steer HTA cooperation in Europe and if so, how this has had an impact on the effectiveness of the networks in terms of goal attainment.

In our research framework we will integrate governance instruments as second factor potentially affecting effectiveness of a governance network. This will be related to the following features: policy instruments, legislative and regulatory instruments, political instruments and financial instruments.

3.4.2.3. Management

Reaching common goals in terms of concrete measurable outputs in networks with interdependent but autonomous actors remains a certain challenge as in most cases soft governance means have to be used. As participation is based on voluntarism and decision-making is often non-binding, no coercive management methods can be implemented. As such, goal attainment will also depend on the management practices which can be more or less successful in reaching network goals. As underscored by Rhodes and Bevir (2007:85), no specific toolkit for managing networks exists. Scholars commonly point to the fact that network management distinguishes itself by the fact that it is based on trust whereas bureaucracy is based on command and market regulation on price competition (Frances 1991:15, Powell 1991). Although many studies have pointed to the relationship between management practices and network effectiveness, no consensus exists on which practices are most appropriate in reaching network goals. Consensus in the literature exists only on the fact that if the methods are effective, they will most likely be maintained. Conversely, if they do not lead to the desired results, they will be abandoned even if they have been accepted internally (Peters 2007:69, see also Covaleski and Dinsmith 1988).

Several scholars have studied management skills and techniques in the perspective of network output, outcomes and effectiveness. Although these studies have demonstrated a relationship between management skills and network effectiveness, many of these studies were context specific and their findings cannot necessarily be generalized over other policy fields (e.g. Klijn, Steijn and Edelenbos 2010). Moreover, discussing management techniques and practices can quickly lead to a normative discussion on the issue, which is not our aim here. As we believe that disregarding the effect of management of governance networks would be a flaw in our research, we have made the decision to integrate management as a third factor potentially affecting the effectiveness of governance networks in terms of goal attainment. Based on the literature, we have identified two aspects related to management and which are of importance regarding European HTA cooperation: management competences and management styles.

Management competences (especially regarding network managers) is aspect which is commonly highlighted when examining outcomes of governance networks (e.g. Sorensen 2007, Agranoff and McGuire 2007 Edelenbos, Klijn and Steijn 2011). Those competences are compared to those of a mediator or facilitator as a manager has to initiate, facilitate and guide interaction processes among actors in the network (Friend, Power, and Yewlett 1974; Gage and Mandell 1990, in Edelenbos, Klijn and Steijn 2011). Coordination skills are another aspect brought to the fore as managers will be responsible for the coordination of network arrangements and ensure that new ideas and content can be developed (Rogers and Whetten 1982; Scharpf 1978; Koppenjan and Klijn 2004, in Edelenbos, Klijn and Steijn

2011). Moreover, ensuring good relationships between network actors is another key aspect of effective management since negotiation processes underpin the cooperation processes in governance networks. In this regard the notion of 'embeddedness', referring to "the way actors are connected to the whole network" (Klijn, Steijn and Edelenbos 2010: 1069) has been correlated in several studies to network outcomes (Meier and O'Tools 2001, Huang and Provan 2007; Kenis and Oerlemans 2008; Klijn, Steijn and Edelenbos 2010). Hence, in the examination of management competences we will focus in our research on facilitating and coordinating interaction processes whilst connecting actors in these.

In network management two main types of *managements styles* can be distinguished: *project management and process management* (Edelenbos and Klijn 2009). No consensus exists in the literature to determine which one would be most appropriate for public-private network management (e.g. governance networks). Each can favour effectiveness of a network in terms of goal attainment in a certain way. As such, *project management* seems to have advantages in dealing with complexity (Meredith and Mantel 2000, in Edelenbos and Klijn 2009). By breaking up the project into consecutive phases a better internal control of the project development may be offered. However, in this style of management, less attention is given to the environment (stakeholders) of the project. Decision-making will be more centralised and will not comprise stakeholder consultation. Stakeholders will be informed once a decision has been made (Beierle and Cayford 2002; Quah and Tan 2002, in Edelenbos and Klijn 2009). Communication will be based on a so-called DAD strategy: Decide, Announce and Defend (Edelenbos and Klijn 2009: 314).

Process management distinguishes itself from project management among others by the role which is given to stakeholders. The latter are involved from the beginning and consultation with them is continuous. Through open dialogue, managers will seek to identify potential solutions which take into account (competing) interests of stakeholders. The communication will be based on a so-called DDD-strategy: Dialogue, Decide, Deliver (De Bruijn et al. 1998 in Edelenbos and Klijn 2009:315). Decision-making is based on collaborative processes which take place before the project implementation. Hence, conversely to project management, the project is considered to be dynamic and is subject to changes and adjustments throughout the process (De Bruijn et al. 2004; Mandel 2001; Agranoff and McGuire 2003 in Edelenbos and Klijn 2009:315).

Management will be the third factor of the research framework having a potential impact on governance networks' effectiveness. It will be related to the following features: management competences and management styles.

3.4.2.4. External events

Effectiveness of a governance network can also be affected by external events (Milward and Provan 1998). As the network operates in a specific environment, changes within this environment may require the network to adapt. Similarly, networks operating with other networks can be influenced by social changes taking place in these (Peters 2007:70). Changes in governmental practices or priorities may also alter the receptivity of the public authorities to the policy issue of the network. It may even require the network to adapt as the network influence on decision-making may be affected. Hence, change in the networks' environment can affect their functioning and effectiveness. These changes can be of economic, ideological, knowledge/technical and institutional in nature (Rhodes and March 1992:259). They could even lead to the deinstitutionalisation of a network (Peters 2007:70). Examining Governance networks requires thus also to consider the broader environment (Hjern and Porter 1981; Peters 2007).

External events will constitute the fourth and last factor in our research framework regarding the potential impact on effectiveness of governance networks. It will be related to the following attributes: events of a ideological, legal, political or economic nature.

In this paragraph we have outlined various factors, related to soft governance, which can affect the effectiveness of a governance network in terms of goal attainment. We have structured this analysis according to four main aspects: social interaction, governance instruments and management of a governance network and external events. Each of these aspects can be analysed according to a specific set of features. In our research framework, social capital will be examined through trust, shared values, learning processes and goal consensus. The impact of governance on effectiveness will be examined by focusing on policy instruments, legislative and regulatory instruments, political instruments and financial instruments. Management will be explored by focusing on management competences and styles. Finally, external events should be included in the analysis as changes of different origins (economic, ideological, technical or institutional) can affect the effectiveness of a network in reaching its goals.

METAGOVERNANCE			
GOVERNANCE NETWORKS *Typology*		*NETWORK GOVERNANCE* *Effectiveness* (Goal attainment)	
Network formation	*Incentives* *Strategic calculations* *Support/constrain*	**Social interaction**	*Learning processes* *Shared values and understanding* *Trust* *Goal consensus*
Membership	*Public, private, non-profit* *Relation home organisation-network* *Open/closed* *Homogeneous/heterogeneous*	**Governance instruments**	*Policy instruments* *Legislative and regulatory instruments* *Political instruments* *Financial instruments*
Resources	*Financial* *Natural/physical* *Social/political* *Human*	**Management**	*Competences* *Styles (project/process management)*
Governance modes	*Horizontal power distribution* *Asymmetric power distribution* *Centralised power distribution*	**External events**	*Ideological* *Legal* *Political* *Economic*

Table 3.2. Research Framework

3.5.   RESEARCH DESIGN

The research design is developed to address the question regarding the effectiveness of soft governance in structuring European HTA cooperation. As the junction point between HTA cooperation and EU health policy is situated in networks, we will examine this question through the prism of network analysis. Networks are considered here as a medium through which soft governance instruments can be implemented. The research framework serves as a mean to proceed to a systematic analysis of: 1) the HTA networks typology and whether these correspond to so-called governance networks operating via soft governance modes ; 2) the extent in which these networks undergo significant influence on behalf of the European Commission by soft governance means; 3) the effectiveness of soft governance in reaching the networks' goals set. The detailed analysis of soft governance-related factors potentially affecting the typology of governance networks, the effectiveness of network governance or metagovernance, will bring to the fore the (in)effectiveness of soft governance in structuring HTA cooperation within an EU framework.

Through network analysis, necessary information will be gathered, organised and examined to address the general research question regarding the extent to which soft governance has structured HTA cooperation within the framework of the EU. In the introduction of this thesis we have outlined three areas in which this will be explored, so as to delimitate the scope of the research: convergence and harmonisation of HTA tools, methodologies and practices; uptake of joint work in national settings and synergies between the HTA arena and EU regulatory processes of pharmaceuticals.

The research framework will be applied on the specific European HTA cooperation networks. These networks have been selected based on their role and relevance in the cooperation initiatives that have been launched in the field of European HTA cooperation. As such, focus will be on EUR-ASSESS, HTA-Europe, ECHTA/ECHAI, EUnetHTA and the EU HTA Network. Other initiatives taking place through networking and having an impact on the cooperation initiatives (e.g. High Level Group on Health Services and Medical care, Pharmaceutical Forum, Beneluxa) will be included in the research only in relation to specific topics treated (e.g. Relative Effectiveness Assessment, Horizon Scanning).

The data gathered is based on academic literature, grey literature (formal documents of national and European institutions, legislative documents, official communications, documentation HTA networks, meeting reports, informal correspondence of network members, network publications, positioning papers) as well as semi-structured in-depth personal interviews, written contributions and personal observations through attendance at international conferences and stakeholder forums, organised by the European Commission and HTA Networks.

The interviews have been held either face-to-face, by telephone or by Zoom (video communication). The interview sample consists of 30 interviews and 2 written contributions, representing 40 interviewees for a total of 43 interview hours (annex 2). The inclusion criteria were based on active participation in an HTA network, type of professional organisation/institution, and country of professional activity. The types of professional organisation/institution were: HTA Network (executive level), HTA Agency, European Commission, Ministry Member State, Stakeholder group. Stakeholder representatives were selected on the basis of their membership in one of the following stakeholder groups: patients, payers, industry, health care providers. Regarding the country of origin, selection has been made based on the size of the EU Member States (EU MS) in terms of population: > 30 Mio ('Big EU MS'), 7-30 Mio ('Middle EU MS'), < 7 Mio ('Small EU MS').

Ministries of health were hardly represented in HTA Networks till 2016 (3 on average, from small EU MS and no corresponding MS HTA bodies in the networks). Despite the general rise in network membership after 2016, the number of ministries represented in the networks remained relatively low (8 from predominantly small EU MS). Although the final interview sample reflects this representation, we did aim initially for a larger participation of this group in our sample. Due to the ongoing adoption procedure of the Commission proposal for a Regulation on HTA cooperation, recruitment for interviews became however challenging, explaining the final number of MS ministries present in the interview sample.

The final interview sample has been constituted as follows:

Represented organisation/institution	Number of interviewees
HTA Networks	**7**
European Commission	**9**
HTA agencies	**13**
- Big MS (pop. > 30 Mio)	6
- Middle MS (pop. 7-30 Mio)	4
- Small MS (pop. < 7 Mio)	3
Stakeholders	**8**
- Patients	2
- Payers	1
- Industry	3
- Health care providers	2
Member States (Ministries of Health)	**3**
Total	**40**

Table 3.3. Interview sample

Three interview rounds have been held. The first took place from January to July 2016. The second from January to July 2017, the third from March to August 2018. The interviews have been recorded (except two), transcribed, and organised (categories, sub-categories, codes) allowing for a horizontal and vertical (conventional) content analysis method. The choice to work according to this method was motivated by the fact that it allows to examine information retrieved directly from the participants without imposing preconceived categories or perspectives.

The empirical data gathered will be presented and structured by means of the five stages of the policy cycle as developed by Howlett, Ramesh and Perl (2009). Using the policy-cycle allows to break down a complex policy process into several stages such as: agenda-setting, policy formulation, decision-making policy implementation and policy evaluation. As such, the role of multiple actors acting on multiple policy-levels during different timespans can be examined. Explanations about each stage of the policy-cycle will be given in part B. The empirical data will be analysed in Part C by proceeding to a systematic investigation of all factors and their corresponding features constituting the research framework. The outcome of the analysis will be applied to the three main areas outlined above and corresponding to the sub-research questions. Final conclusions will be drawn in the last chapter of the thesis which will address the overarching research question.

3.6.   CONCLUSION

This chapter represents the third and final chapter of Part A of the thesis aiming to establish the theoretical framework and research design. Chapter 1 has outlined the development of HTA, how it relates to national and European regulatory process and the underlying reasons for the development of European cooperation in this field. By reviewing the literature in this field, we have identified a research gap regarding the governance processes steering European HTA cooperation, which has developed by means of networking. Chapter 2 has situated HTA cooperation in the wider EU health policy framework and outlined how the division of competences between the EU and its Member States impacts on the governance modes available in a certain policy field. It has highlighted how in sensitive fields or fields of exclusive Member States' competences, New Modes of Governance are often the only EU governance modes available to support cooperation initiatives. Governance by having recourse to networking falls into this scope and has been used by the EU to strengthen HTA cooperation initiatives.

Chapter 3 has highlighted the relationship between soft governance and networks in the EU governance architecture. It has underscored how networks, though not restricted to the implementation of soft governance means, can be considered as an adequate forum for the implementation of soft governance instruments, herewith allowing the EU to pursue specific aims in sensitive policy areas. The research framework developed in this chapter seeks to support the examination of the effectiveness of soft governance in structuring HTA cooperation in Europe through the prism of network analysis. It is structured upon the central concepts of governance networks, metagovernance and network governance as well as soft governance-related factors potentially impacting the typology of the networks and their effectiveness in terms of goal attainment. In the next part of this thesis, we will set out the empirical data gathered during the research. This data will be examined in part C. The outcome of the examination will allow to give a structured answer to the thesis research question regarding to which extent soft governance has structured HTA cooperation within the framework of the European Union.

PART B

DATA COLLECTION

4 | Governance practices steering initial European HTA cooperation processes

"When you take people from different backgrounds,
put them in front of the same problem, and ask them to solve it,
they're no longer the same people.
They're no longer there to defend their separate interests,
and so they automatically take a common view".
Jean Monnet, Memoirs

4.0.   INTRODUCTION

Part B of this thesis presents the data of the empirical research of HTA cooperation in Europe. It is divided in three chapters each focusing on a particular development stage of the cooperation process. The present chapter explores what has triggered the dynamics to foster HTA cooperation in Europe and how it has been initially structured in the early cooperation initiatives running from 1992 to 2001. This chapter will be followed by chapter 5 outlining developments in the EU health policy sector from 2001 to 2006 and which have laid the basis for the further developments of HTA cooperation in Europe after 2006 and outlined in chapter 6. These chapters will demonstrate how the development of HTA cooperation has been taken place essentially through networking and cannot be dissociated from the development of a European health policy as both processes have mutually reinforced one another.

In chapter 1 we have outlined how health technology assessment – as well as the associated policy domains of pricing and reimbursement - refers to a policy domain falling under the exclusive competences of the Member States. As such, the role of the European institutions is limited, and the subsidiarity principle needs to be respected. To get a more profound insight on how this cooperation process has taken place within the given national and European institutional structures and legal requirements, we will analyse the development of HTA cooperation from a governance perspective. The governance practices applied will be assessed on the basis of the five stages of the policy cycle as defined by Howlett, Ramesh and Perl (2009). These stages offer the possibility to scrutinise in a systematic manner all important elements of governance: agenda setting, policy formulation, decision-making, policy implementation and policy evaluation. Moreover, this approach allows for the inclusion of governance aspects related to transparency, accountability, participation, power delegation as well as legal, administrative, financial and budgetary aspects of project and network governance.

The structure of the present chapter is based on the comparative analysis of the developments taking place in the HTA arena and the developments linked to HTA taking place during the same periods of time in the European health policy field. The chapter will therefore be divided in five sections each focusing on a specific stage of the policy cycle regarding both HTA cooperation developments and EU health policy developments. Each section starts with a brief outline of key aspects of the stage of the policy cycle under examination. These aspects will then be confronted with the developments in HTA cooperation and in EU health policy. A conclusion at the end of each section will analyse how the developments of both levels relate to one another.

The data presented in the present chapter will be confronted in chapter 7 with the elements set out in the research framework. As such, the typology of the networks will be determined as well as their effectiveness in reaching the goals set. The later will permit us to answer the research questions of this thesis and get a profound insight in the governance of HTA cooperation structures and how they are situated within the broader European integration process in the field of health care.

4.1. THE GENESIS OF EUROPEAN HTA COOPERATION

4.1.1. Setting international cooperation on the HTA agencies' agenda

Agenda-setting, or "the politics of attention" (Baumgartner and Jones 2005) is the first and maybe the most critical stage of a policy-cycle as it determines whether and how the issue will be addressed by policy-makers (Howlett et al. 2009: 92). It is most often concerned with the questions of how, when and why an issue has made it on the agenda of a political system, who participated in the process and why that issue received the attention of policy-makers rather than another issue.

The agenda setting process of public policy issues can be examined in many different ways[30]. Baumgartner and Jones (2005: ix) consider it as a "process by which a political system processes diverse incoming information streams" which need to be attended to, interpreted, and prioritized". As Princen (2011:107-108) underscores, the "agenda determines not just which issues will be subjected to decision making" but also regards "the terms by which an issue will be discussed". The latter will have an influence on the options that will be considered and by whom. Hence, agenda-setting is also a matter of "politics of problem definition" (Rochefort and Cobb: 1994), also referred to in the literature as "frames" which comprise concepts and assumptions used to structure reality (Benford and Snow 2000; Schön and Rhein 1995; Princen 2011).

However, besides frames, one should also look at *venues* when analysing the agenda-setting process. Baumgartner and Jones (1993) have defined 'venues' as institutional forums where policy decisions are being taken. Drawing upon that perspective, Princen (2011: 119-120) underscores how the EU can be considered as a *venue* compared to national governments or international organisations. He underscores however that within the EU different venues can also be distinguished (e.g. European Parliament Commission, various Directorate Generals). Receptiveness for issues – prerequisite for issues to make it on the agenda - may be

---

30   See further e.g. Kingdon 1995; Cobb, Ross and Ross 1976; Baumgartner and Jones 1993, 2005; Princen 2009.

influenced by the internal organisation and institutional structure of each venue. This follows earlier findings on the concept of "organisation is the mobilisation of bias" (Schattschneider's 1960:71) referring to political systems creating their own bias by the way they are organised and which explains why some issues will find themselves on the organisation's agenda and why others don't.

Setting European cooperation on the agenda of HTA agencies as well as on the agenda of the European Commission has followed a particular path. Initially, the search for cooperation between HTA agencies in Europe was not motivated out of the need to address a specific public policy problem recognised as such by policy-makers. Since the 1970s and the uptake of new technologies in health care, policy-makers and health professionals did show an increased interest in assessing the safety, effectiveness, and cost-effectiveness of new technologies as well as their impact on social, ethical and legal issues in a given country (Goodman 1988: 10). Rising expenditures due to changes in (an aging) population, disease patterns or new demands from the public certainly also played a role for the consideration given to HTA (Banta et al. 1997: 134). In the US, the Office for Technology Assessment had been established in 1972 for this purpose. This office was the first to reflect upon what content could be given to, what was then called, 'medical technology assessment' seeking to inform the US Congress. The latter could request assessments on a particular innovative technology and the information given aimed at informing policy-making processes. OTA could thus be considered as an advisory college and laid the basis of what would become HTA (personal interview 10). Its example was soon followed by other countries such as Canada, Australia and New Zealand which created specific agencies for health technology assessment.

In Europe, HTA was being practiced since the late1970s essentially through workshops and discussions among experts within different types of institutions to inform pricing and coverage decisions (Sorenson 2009; Thatcher 2010). The first formal European HTA agencies have however only been created in 1987 in Sweden (Swedish Council for Health technology Assessment (SBU) and in Spain (Catalan Agency for Health Technology Assessment).

Others followed[31] but the situation was characterised by the heterogeneity and diversity of these agencies both in their institutional nature as in the methodologies used (Banta et al. 1997:134). These different approaches are partly explained by underlying cultural differences driving national health policies and health economics. The different understandings of the role of government in establishing and implementing policies also has contributed to these different approaches and has had an impact on how HTA has developed in the various countries setting up HTA agencies (personal interview 10).

Some (e.g. Sweden, France) conducting HTA based essentially on existing knowledge (reviews of the literature), others (e.g. UK and the Netherlands) conducting also prospective studies whereas the CAHTA in Catalonia, for example, chose for an integrated approach based on synthesis and prospective studies. Moreover, some agencies functioned by having close ties with governmental structures (e.g. France), whereas others adopted a more independent and decentralised approach (e.g. The Netherlands) (Banta et al. 1997:134). This all led to a more fundamental question on whether a single HTA model was needed or desirable (personal interview 10).

The need for HTA cooperation in Europe was expressed almost simultaneously with the establishment of HTA agencies in Europe. HTA cooperation on an international level already existed since 1984 with the International Society of Technology Assessment in Health Care (ISTAHC, since 2003 HTAi[32]), which had been established upon the initiative of two persons who have played a key role in the development of HTA in Europe: Egon Jonsson and David Banta. The latter recalls how the idea of cooperation came out of a simple observation: *"We were just standing at some place - I remember – and [Egon Jonsson] said "all these people are working on the same subject and they never meet each other, except at international conferences or something, but never for this purpose. It's stupid, we should be sharing*

---

31   In France the Agence Nationale de l'Evaluation Medicale (ANDEM) was founded 1989 (later re-named in Agence Nationale d'Accreditation et d'Evaluation en Sante (ANAES)). Since 2005, HTA is being performed by the Haute Autorité de Santé (HAS). In the UK the first official HTA programme has been established in 1993 as part of the National Institute for Health Research. Since 1999 HTA is being performed by the National Institute for Health and Clinical Excellence (NICE) In Germany, the Institute for Quality and Efficiency in Health Care (iQWIG) has been created in 2004. In Italy, HTA has started in the 1980s at the National Institute of Health and in a few University Hospitals (Favareti et al. 2009). In Austria it took some 15 years from the first research activities on HTA to the foundation in 2007 of a formal Austrian HTA-institute (Federal Institute for Quality in Health Care (BIQG)) (Wild 2009).

32   ISTAHC had to cease its activities in 2003 due to an overstretched budget. It was however recon-stituted into Health Technology Assessment international (HTAi) created the same year (Banta et al.: 2009: 21).

information, we should be learning from each other, we should be putting our strengths and weaknesses together; (…) Why are different countries doing their own report on the same subject? It's a waste of money, we can't' afford to waste money. (…) We have to work together. That's all. That was it. That was all, really" (personal interview 2).

This reasoning also motivated the same actors a few years later to go a step further and develop a project aiming to foster cooperation among *European* actors active in HTA. Informal discussions with other representatives of newly created agencies in Europe led to the understanding that there was a real need to cooperate on a European level (Banta et al 1997: 134). Besides the search to avoid duplication and allow a better allocation of resources, the first cooperation initiatives were driven by the dual objective to enhance the quality of HTA as well as the quantity of HTA agencies and subsequently reports issued by them. The second being intrinsically linked to the first (personal interview 2). To counter criticism targeted at possible bias that could occur as a result of public funding and political pressure, the idea was to ensure HTA would be rooted in a solid scientific principles independent of all political considerations (Liberati et al. 1997: 193). Hence, highly qualitative assessments would increase the chance of uptake in policy decision-making, offering policy-makers the possibility to embed health technology related decisions into evidence-based medicine. As a result of this process, official recognition for HTA could develop, leading potentially to the establishment of new HTA agencies (personal interview 2).

In 1991, the first project proposal aiming to establish cooperation among *European* HTA agencies has been drafted under the denomination of EUR-ASSESS. It was submitted to the BIOMED program of the European Commission for the first time in 1992 but initially turned down. As no initial contacts had been taken with representatives of the European Commission, the project "came in rather cold" (personal interview 2). However, the subject did attract the attention of some administrators who approached the authors of the project proposal and encouraged them to submit it again (Banta et al. 1997: 134). After having introduced some changes upon indications of the EC representative, the project was re-submitted and approved in 1993 (personal interview 2).

The interest of the HTA community for the project was motivated out of considerations strictly linked to the development and recognition of health technology assessment as such. It also coincided with the establishment of the International network of HTA agencies (INAHTA) created as a consequence of informal meetings of European HTA representatives within ISTAHC to promote cooperation between newly created agencies across the world (Hailey 2009; Personal interviews 6 and10). The EUR-ASSESS project proposal followed thus a specific agenda setting process pursuing objectives of the HTA community. This process matched however another agenda-setting process, freshly initiated at the European level.

4.1.2. Setting HTA on the European agenda

As outlined in chapter 2, EU health policy has known a particular development process. It is only in 1992, that a first article about public health has been integrated in the Maastricht Treaty. Several adjustments have since been made throughout the various treaty revisions, leading to a gradual extension of EU's competences in this field. However, the dominant feature of European public health policy remains the fact that Member States remain responsible for the organisation and management and the delivery of health services and medical care as well as for the allocation of necessary resources to this end. EU competences are limited to the promotion and coordination of policies and programmes on the basis of soft governance instruments (see further section 2.2.2).

HTA cooperation in Europe has been directly concerned by the development process of EU public health policy. As outlined above, the first project aiming at establishing HTA cooperation in Europe has been submitted and rejected in 1991 and then re-submitted and accepted in 1992, at a time where significant changes took place in the EU health policy field. Indeed, till 1992, support for health-related issues was given through specific small-scale programs, in the field of Cancer, AIDS/HIV or through research-orientated programs such as the Biomed program (which also financed the first EUR-ASSESS project). However, these programs were not policy-orientated and did not aim nor permit to develop any specific health policy at the EU level.

The Maastricht Treaty, signed in 1992, represented an important change in this regard since it offered possibilities for the European Commission to extend its involvement in the health policy field on a legal basis. The treaty provisions remained rather vague in this regard leaving sufficient room to the Commission to interpret these widely. This interpretation started with the heading of Article 152 "Public health" which lacked a commonly accepted definition. From the Commission's point of view, *public health* concerned "health of the public" and the objectives laid down in the Treaty conferred to the European Union the role to look after the well-being of the European citizens (personal interview 3). So even though the scope of the Treaty objectives could be considered rather narrow by some, in view of the Commission they could be – and were - interpreted in a broader sense: improving the health of European citizens (personal interview 3).

In this regard, the Commission identified national health systems as one of the domains where the EU could bring added value while seeking to improve the health of the public. Indeed, the functioning of national health systems which were increasingly under (financial) strain in the Member States were governed in many different ways across the Member States. Gathering information on how the different health systems were run and providing information and support to Member States permitting them to organise their health systems in the most

efficient and cost-effective ways became since the early nineties a constant thread in what would develop later as EU health policy. This approach represented a fundamental rupture from the way health issues had been tackled by the Commission till then by either addressing public health threats (e. g. BSE crisis[33]) and public health concerns (e.g. cancer, HIV/AIDS) or through decisions often taken in another policy field (e.g. professional mobility)[34]. Hence, the work on the first health strategy departed from the previous policies by taking health and health systems as a starting point. This subtle but fundamental difference has laid the basis for European health policy-making and underpinned all health programs that have been developed since the early 2000s.

The interest in health technology assessment on behalf of the Commission has to be understood in this context. Commission representatives in charge of developing the EU health strategy were introduced to HTA through the EUR-ASSESS project and its initiators (personal interview 3). Indeed, HTA was still a very young discipline in the early nineties in Europe, and unknown to most Commission officials. However, after a personal briefing on the subject, some key Commission representatives rapidly understood the potential impact HTA could have on health systems and consequently on the place it could occupy in the health strategy of the Commission (personal interview 3). Moreover, a report commissioned by the Directorate General V (DG V)[35] in 1995 on securing further health improvement and greater efficiency in the use of health resources on the European level, also highlighted the importance of HTA. The report even recommends that "the Commission should coordinate technology assessment throughout the Union to establish the effectiveness of both new and existing technology in improving outcome; the appropriate uses of these technologies" (Abel-Smith et al. 1995: 130)[36].

The increased insight regarding the potential contribution of HTA for improving health in Europe on behalf of the (ex) public health policy unit within DG V also impacted the funding basis for projects seeking to develop HTA in Europe. If EUR-ASSESS had been financed through a research-based funding program of DGXII, its successor, the 'HTA-Europe project' received financial support from DG V in the course of 1996-1998 (Banta and Oortwijn 2000:300).

---

33   Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease.

34   See further on the development of EU health policy e.g. Randall 2000, Greer 2009; Mossialos et al. 2010.

35   Directorate General V was responsible for Employment, Industrial Relations and Social Affairs and hosted the public health unit.

36   This publication addresses a full chapter on technology assessment based on work of Franco Sassi, Research Fellow in Health Economics, London School of Hygiene and Tropical Medicine (Abel-Smith et al. 1995:VI).

This trend only further developed with the establishment of DG SANCO, a dedicated DG for health, established in 1999 and which funded the ECHTA/ECAHI Project from 2000-2001[37].

At a very early stage of the development of the EU health strategy, HTA had thus been identified as being of strategic importance. It presented an intrinsic link with the national health systems and represented an area where Community efforts to coordinate cooperation could bring added value. In this sense HTA was considered as offering an opening wedge to influence the development of sustainable national health systems and improving the health of the European citizens. As a result, HTA has been associated to the very first health programs developed by the Commission, which represent the basis of any action in the field of EU health policy[38].

4.1.3. Conclusion agenda-setting in early European HTA cooperation initiatives

Analysing European HTA cooperation in a policy setting requires an examination of the issue at three different levels: the HTA agency level, the national institutional level and the European institutional level. We have been able to identify an agenda setting process of HTA cooperation in Europe in its very early stages only on the HTA agency level and the European institutional level. Although the national institutional level has been involved in the first projects by designating agencies for participation in the cooperation process, European HTA cooperation was not identified than as a domestic governmental agenda point. This can be explained by the fact that the European HTA cooperation process has followed what Princen (2009) qualifies as a typical EU agenda-setting process. Agenda-setting on this level is rather distinct than the one which can take place in national settings.

Princen (2009) identifies different types of agenda-setting in the EU policy-making process depending on the policy area concerned. Were policy-making takes place in a rather routine manner (e.g. Internal Market, environment), the agenda setting follows the same pattern as in a 'functioning political system'. Conversely, when policy-making at the EU-level occurs

---

37   Grant Agreement No. SI2.122594 (99CVF3-508), Health & Consumer Protection Directorate General Grant

38   HTA was however not mentioned in the first "Framework for Action in the Field of Public Health" developed in the aftermath of the Maastricht Treaty (1993). This initial strategy document aimed at developing work on public health and comprised a series of eight action programs which were partly a continuation of work already engaged in by the Commission before the Maastricht Treaty: health promotion, cancer, drug dependence, AIDS and other communicable diseases, health monitoring, rare diseases, accidents and injuries, and pollution-related diseases (http://ec.europa.eu/health/programme/policy/eight_programmes/index_en.htm).
.

in areas where the Union is still 'in the process of establishing a presence and carving out a role for itself', the European policy-making system should be considered as an 'evolving integration scheme' (Princen 2009: 9). Policy-making in the field of health care matters, such as HTA, follows the second type of agenda-setting processes since the issues appear for the first time on the EU agenda.

Princen describes three stages in this agenda-setting process which we can also identify in the HTA agenda-setting process. The first refers to the stage in which an issue is debated in transnational policy networks[39]. An issue will rise within these networks, provided that the network is strong enough for members to exchange ideas and that a certain degree of convergence is met in the policy debates (Princen 2009: 15). This will allow these networks to adopt common perspectives on a particular issue. In the case of HTA, ISTAHC (and later also INAHTA) can be considered as transnational policy network where informal discussions among members have resulted to the adoption of a common objective to establish a strong European cooperation network in HTA.

An issue can shift from the transnational policy network agenda to the EU agenda provided it finds receptiveness at the EU-level. This will depend both on the characteristics of the EU institutions that will be confronted with the issue and on the way the issue will be defined (frame) in the transnational network (Princen 2009:15-16). If the frame 'fits' the concerns and interests of a particular European institution (venue)[40], the debate may continue at an EU level[41]. We have seen that although HTA was already known in a certain EU venue (DG research), a real debate regarding the development of HTA on the EU-level started when it was introduced to the 'right' EU venue for this, i.e. the public health unit of DGV. It is here that the HTA agencies' agenda matched the EU agenda.

39　These networks consist of policy experts of national governments and international organisations but can comprise also academics, journalists etc. (Princen 2009).

40　Princen (2009: 10) explains agenda-setting dynamics by looking at the combination of 'venues' (institutional decision-making arenas) and 'frames' (also called 'issue definitions'). Participation of actors in decision-making processes will be determined by those. Different venues will have different responsibilities for specific policy areas. Hence, their receptiveness for a particular issue will not be same. Moreover, venues differ in the authority they have over certain issues as well as in their composition (Schattschneider 1960: 71 in Versluis et al. 2011: 119). According to Baumgartner and Jones (Howlett et al. 2009: 106; Versluis et al. 2011:119) the EU institutions can be considered as 'venues' in the sense described above.

41　Princen (2009:16) underscores that an issue can become part of the EU agenda as a result of a proactive approach of EU institutions that either have picked up the issues in the debates or have initiated a debate about a particular topic themselves and subsequently made policy proposals about it.

Based on an approach developed by Kingdon (1984; see also 1995), Princen (2009: 16) distinguishes two sorts of EU agendas. The first -the 'EU's governmental agenda' – regards the political agenda-setting process during which 'ideas are floated and perspectives developed'. This agenda should be distinguished from the EU 'decision agenda' on which issues appear when they are ripe for active decision-making. In 2000, we can consider HTA just entering on the 'EU's governmental agenda'. Ideas about the potential role and place of HTA in the overall health strategy of the Commission were indeed 'floating' and perspectives of how HTA could contribute to reaching broader objectives of what would become the EU health policy were still being developed.

HTA making it to the EU's governmental agenda can, for an important part, be attributed to the efforts made by so-called 'policy entrepreneurs' in both the HTA as in the European Commission arena. Policy entrepreneurs are characterised by "bringing new policy ideas into good 'currency'" (Mintrom and Vergari 1996: 422). In order words, policy entrepreneurs seek to sell their ideas in order to achieve (radical) policy change. They do so by identifying the problem, shaping terms of policy debates, networking and building coalitions. The latter permits them to understand the position of various parties towards an issue and how to frame that issue to attract support for it and make best use of available organisational resources. Policy entrepreneurs furthermore draw upon their personal resources which include "intellectual ability, knowledge of policy matters, leadership and team-building skills, reputation and contacts, strategic ability, and tenacity" (Mintrom and Vergari 1996: 423). All this combined permits policy entrepreneurs to attract the attention of decision-makers for a particular policy problem by presenting potential policy responses (see further on policy entrepreneurs: Mintrom and Vergari 1996; Kingdon, 1995; Majone, 1988; Smith 1991). Persons such as David Banta and Egon Jonsson could be regarded as policy entrepreneurs from within the HTA arena. But also within the European Commission some representatives such as Bernard Merkel could be cited as examples of policy entrepreneurs with regard to European HTA Cooperation. Their personal and professional investment has permitted HTA to be framed in such a way that receptiveness on a European level was found within the right venue. This has led to renewed commitment to European HTA cooperation on both levels. On the HTA agency level this has been shown by the development of new projects (EUR-ASSESS has been followed-up by HTA-Europe and by the ECHTA/ECAHI). The Commission's commitment to HTA cooperation can be identified through the integration of HTA in the health program opening new (policy orientated) funding opportunities.

In the agenda setting phase of the policy cycle we can observe a few elements related to what will later be affiliated to New Modes of Governance. The initial idea to start cooperation was motivated out of the need to exchange information and experience besides increasing value for money. The way policy entrepreneurs have operated by creating formal

and informal expert networks and framing the debate in such a way to attract support for European HTA cooperation bears also traits which resemble soft policy mechanism in which discourse and learning processes are of high importance. One may wonder whether these working methods were a continuation of New Public Management working processes used in public entities such as the Office for Technology Assessment in the USA.

For a subject to go from the EU's governmental agenda to the decision agenda, Princen (2009) underscores how it will have to overcome two types of blockages. Due to differences in perspectives, some policy-makers on the EU level, may want to prevent an issue to appear on the decision-making agenda. This will lead to what Princen calls the 'horizontal blockage'. A 'vertical blockage' can occur when Member States are reluctant to see the European Union trying to play a role in a particular policy (Princen 2009: 16). In the next chapter we will analyse into more depth the development of HTA on the EU agendas after 2000 and how it has been confronted to the two types of blockages. Before that, we will however first examine the development of European HTA cooperation in its early phase through the other stages of the policy cycle.

4.2. POLICY FORMULATION IN INITIAL EUROPEAN HTA COOPERATION PROCESSES

4.2.1. Policy-formulation in early European HTA cooperation initiatives

An essential stage of the policy cycle regards the formulation of the policy itself. In a 'typical' public policy process, policy-formulation consists of identifying, assessing and selecting potential options to address a particular policy problem. Part of this process can already take place during the agenda-setting stage of the policy cycle (Kingdon 2003: 205; Howlett, Ramesh and Perl 2009:110). A large set of actors can participate in the policy formulation stage, representing the interests of different stakeholders concerned by the issue. This explains why the process itself never produces neutral outcomes and can appear as highly diffuse and disjointed. (Howlett, Ramesh and Perl 2009: 111). Four stages can be identified in the policy-formulation process: *appraisal*, *dialogue*, *formulation* and *consolidation* (Thomas 2001, in Howlett, Ramesh and Perl 2009). Appraisal is mostly concerned with data and evidence collection. Dialogue regards the facilitation of (formal or informal) communication between policy actors having different perspectives on the issue. The two first phases result in the actual formulation of the policy in the form of draft regulations or legislations (in governmental policy processes). The consolidation phase seeks to create consensus and increase support for the policy proposal by providing (formal or informal) feedback and address potential objections (Thomas 2001). An intrinsic part of this process is the identification of the instruments that need to be used to achieve the objectives defined. Many different policy

instruments exist and are often tailored to the particular policy objectives[42]. In the case of European HTA cooperation we will see that a mix of governing instruments will be used due to the hybrid character of the first cooperation initiatives which respond to an institutional as well as a project based policy-formulation approach.

The policy-formulation in EUR-ASSESS (1994-1997), has been highly influenced by the organisational set-up of HTA cooperation. The overall objective of the project had been defined during the agenda-setting phase and sought to develop the quality and quantity of HTA and its up-take in decision-making processes in Europe. The *appraisal* phase in this first European HTA cooperation project did not comprise many actors. The collection of data and evidence has mainly been done by the initiators of the project who based themselves on their professional experiences and past HTA projects[43]. On the basis of the information collected, the EUR-ASSESS project proposal had been drafted, which can be considered as a sort of 'business plan' of the cooperation initiative. This proposal was structured in a particular way where a set of 'sub-objectives' have been defined serving as means to attain the strategic goal of the initiative.

This approach responded to management techniques that could be identified as being de-rived from the so-called "Management By Objectives" (MBO) introduced by Drucker (1954), developed by Odiorne (1965) and later incorporated in New Public Management (Aucoin 1990, Politt 2001, Osborne and Gaebler 1992). MBO seeks to set individual objectives in each section of the organisation which are directed towards the common organisational goal. Hence, the organisation's strategic objective is being broken up into smaller (unit) objectives which are jointly identified with all actors concerned. Accountability for achieving the objectives is thus also spread out over multiple levels (Drucker 1954; Odiorne 1965)[44].

The organisational setup of EUR-ASSESS that will derive from this approach, will have con-sequences not just for the policy-formulation process but also for the overall governance of HTA cooperation as it doesn't identify with a hierarchical management structure and instead opts for a multi-level, inclusive participatory management style. This structure will remain

---

42   See further for a taxonomy on policy instruments: Salomon and Lund 1989; Lowi 1985; Bemel-mans et al. 1998; Hood 1986.

43   David Banta, who has drafted the EUR-ASSESS project proposal had worked from 1974 to 1983 at the OTA. Thereafter he has moved to Europe (The Netherlands) where he has been actively involved in developing HTA in European countries.

44   We have seen in chapter 3 how these management techniques initially developed in the private sector have also been introduced in New Public Management practices reforming public adminis-tration were the accent in management has been put on "steering rather than rowing" (Osborne and Gaebler 1993).

in place throughout the subsequent projects. In this regard the governance of EUR-ASSESS and its successors bears traits that could be associated to New Public Management practices where the accent laid, as we have seen in chapter two, on "steering rather than rowing" (Osborne and Gaebler 1993). Indeed, the EUR-ASSESS project is headed by a *Steering committee* which comprises all project members and which made all policy decisions including defining/approving the strategic goal of the project. Even if the main strategic objective of EUR-ASSESS had, to a certain extent, already been set by the project initiators, it had to be discussed and approved by all participating members in the Steering committee, as was the case of the sub-objectives that have been defined to attain the strategic goal. Implementation of these sub-objectives fell under the responsibility of separate expert units - called 'Subgroups' who were accountable for the outcome of the common work (Banta et al. 1997).

The definition and content of the project's (sub)objectives heavily drew upon HTA policy implementation developed in the American Office of Technology Assessment (OTA)[45] which had done some pioneer work on the definition of HTA as well as the development of methodological guidelines. The (sub)objectives of the EUR-ASSESS project focused on: effectiveness and cost-effectiveness of health care in Europe; methods of priority setting and assessing technology in HTA programs; the international applicability of findings and dissemination of results; stimulating use of HTA in coverage decisions (Banta 1997: 135). Most of these topics have been selected on the basis of OTA reports published in the 1970s and 1980s on the identification of technology assessment opportunities, efficacy and safety and cost-effectiveness of health technologies considered by HTA 'doers' as driving the US health policy (OTA 1976; 1978; 1980a; 1980b: personal interview 2)[46].

---

45   The OTA was established as an office of the US Senate in 1972, it actively started to work after funding was secured in 1973 and closed in 1995. Its objective was to provide the congress with "new and effective means for securing competent, unbiased information concerning the physical, biological, economic, social, and political effects of technological applications" and "to serve as an aid in the legislative assessment of matters pending before the Congress" (US Congress 1972: OTA 1974). Work on HTA within OTA has started in 1974.

46   The establishment of the OTA was closely linked with the implementation of the first US health program developed under the impetus of Senator Edward Moore 'Ted' Kennedy. HTA in the US has always been closely linked to health policy and considered as a mean to deal with the rising costs in health care. The OTA operated as an advisory college working for the US congress who could ask the OTA to carry out assessments of particular technologies. In this sense it distinguishes itself of the European HTA agencies that have been set up after 1990 (Personal interview 2 and 10).

The inclusion of the other topics resulted mostly from informal *dialogues* between representatives of the first HTA agencies in Europe (Banta et al. 1997:134)[47]. The objectives set out in the EUR-ASSESS project have heavily influenced the basic frame-work for the following projects 'HTA-Europe' (1997-1998), which aimed at reaching the same objectives[48]. If the overall aim to create a sustainable network of HTA cooperation has increased in importance in each project, one notable difference between EUR-ASSESS and the subsequent projects was that the topic regarding coverage and HTA has disappeared as formal objective, only to re-appear a decade later as a (in)formal discussion point in many HTA gatherings. Indeed, at the end of the project some participants stressed how dissemination is not sufficient to give HTA power. To create a 'powerful' HTA having impact on policy-making, it is important to establish links between HTA and other (powerful) policy domains such as reimbursement (personal interview 10).

The operational structure of the ECHTA/ECAHI project (1999-2001) remains very similar to the two previous projects by pursuing a strategic goal to be attainted through the implementation of sub-objectives by specific working groups. Whilst the main objective remains the establishment of a (formal) European network for HTA collaboration, the formulation of the sub-objectives distinguishes itself from EUR-ASSESS and HTA-Europe. Indeed, the latter are impregnated by European 'jargon' of the time and seem to be inspired by developments such as the Lisbon agenda (2000) and other Commission initiatives[49].

In particular, the first objective of the ECHTA/ECAHI project is interesting in this regard as it has even been inserted following an explicit request of the European Commission (personal interview 2). This objective underscores that one of the aims of the project is to "assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators"

---

47   Among those were Egon Jonsson, (Sweden), David Banta (the Netherlands), Michael Peckham and Chris Henshall (UK), Yves Matillon (France), Alicia Granados (Catalonia), and Richard Cranovsky (Switzerland) (Banta 1997: 134)

48   The objectives of the HTA-Europe project were: 1. Contribute to the effectiveness and cost-effectiveness of health care in Europe through improved HTA, 2. Contribute to the development of institutions for health care technology assessment in Europe, 3. Strengthen co-ordination of health care technology assessment in Europe, 4. Contribute to the development of methods of information transfer among European countries and 5. Furnish guidance to the European Commission concerning how to strengthen and aid co-ordination of HTA activities in Europe (Banta and Oortwijn 2000b).

49   The European Council gathered in 2000 in Lisbon defined the so-called Lisbon strategy for the EU aiming "to become the most dynamic and competitive knowledge-based economy in the world by 2010 capable of sustainable economic growth with more and better jobs and greater social cohesion and respect for the environment" (European Parliament 2010:11)

(ECHTA/ECAHI 2001:15). HTA supporting health promotion and disease prevention activities complementing EU health indicators had indeed so far never been an objective formulated within the HTA community. The Commission's request to add this first objective in the project proposal could be explained by the fact that the European Commission sought to link HTA to a newly established programme on 'European Community Health Indicators'[50] funded from 1998 to 2008 under the EU health programmes. The aim of this program was to create a knowledge and information system to monitor health at the EU level (http://ec.europa.eu/health/indicators/echi/list/). This initiative is another example of the Commission's interest in HTA and demonstrates how it took an active part in the policy formulation process of HTA cooperation. It also allows to understand how HTA was related to the wider EU health policy developed by the EU institutions.

The formulation of the second objective in the ECHTA/ECAHI project - to exchange information on emerging technologies, priority setting and ongoing assessments and their evaluations - closely follows the objectives as already set out in EUR-ASSESS (ECHTA/ECAHI 2001:8). The third objective - to identify possible joint assessments and to co-ordinate findings and existing resources within the community to support joint assessments - however distinguishes itself from the previous projects (ECHTA/ECAHI 2001:8). It has an explicit focus on "joint assessments" and the coordination of findings and resources within the "community" (another European term not identified in the HTA jargon so far). The fourth objective, although focusing on methodology as in EUR-ASSESS, is of particular interest since it aims at developing and disseminating best practice in undertaking and reporting assessments. The development of "best practices" seems to refer here to a new policy instrument promoted on a broader level in the EU and in 2001 even formalized as a new mode of governance in the Commission's White Paper on governance (2001). The ECHTA/ECAHI report published the same year as the White Paper on Governance underscores that this notion underpins the development of HTA cooperation in Europe since it is stated that "the Commission of the European Union is supportive of health technology assessment as a means of establishing best health practice in the Member States" (ECHTA/ECAHI 2001:7).

The fifth objective points to the development and co-ordination of education and support networks for individuals and organisations undertaking or using assessment of health interventions. It also seeks to identify needs in the field and assist in the establishment of new provisions (ECHTA:ECAHI 2001:8). This objective shows similarities with the previous projects as it focusses on the development of an HTA network to develop the quality of HTA and give support to agencies who need it. The sixth objective - to identify and share

---

50   In 2013 the European Community Health Indicators was renamed into European Core Health Indicators (http://ec.europa.eu/health/indicators/echi/list/)

successful approaches to link findings of assessments, their contribution to health indicators and health care decision-making - stands out compared to the two previous projects (ECHTA/ ECAHI 2001:9). Reference to HTA as contributing to "health indicators" and "health care decision-making" points to a link with the new public health program which was being developed at the time by the European Commission as we will see in the next section. This element underscores how HTA is situated within the broader integration process in health policy which has been taken forward by means of the European public health programs.

4.2.2. Policy-formulation in EU public health

As we have seen in the section above, the HTA policy formulation process has been under influence of developments in the EU health policy domain. Since EUR-ASSESS (1994-1997), objectives have been redefined upon recommendations of Commission's officials. One could consider this as interference on behalf of the European Commission or simply resulting of lobbying activities on behalf of HTA representatives seeking to secure financial support. However, the uptake of the Commission's suggestions in the HTA programs for European cooperation could also be interpreted as the starting point of a cooperation process between two policy arenas that would mutually reinforce each other.

The main objective of the European cooperation process pursued by the HTA arena was to reinforce the quality of HTA on a local/national level and multiply the number of agencies to enhance the uptake of HTA in national decision-making processes. The main objective pursued by the European Commission in developing public health was to improve health of the European citizens. The EU strategy chosen to reach that aim was based on the belief that one should act within the scope of the health systems of the Member States. The health strategies and programs developed by the Commission were structured along that line of thought. HTA has been recognised already in the early nineties as bearing the potential to impact the health systems (personal interview 3). Hence, the EU health policy-formulation process and the European HTA cooperation policy formulation process develop in a parallel manner and are intrinsically linked. In this section we will focus on the developments at the EU health policy-formulation level so as to better understand its impact on the European HTA cooperation process.

As in agenda-setting, the policy formulation stage on an EU level follows a rather different path than what can occur on a national level. Moreover, European policy processes differ among themselves depending on the policy field responding to different dynamics, including different actors and implementing different instruments and venues (Versluis, van Keulen and Stephenson 2011:77). Policy-formulation in the EU is an open process with the Commission playing a pivotal role in it, as it has the so-called right of initiative (Kassim 1994:23). Through this right allowing it to submit draft (legislative) proposals, the Commission has a

significant influence on the formulation of EU policies even though its decision-making pow-
ers are limited (Hix 2005: 74). Policy-making in the EU is characterised by 'comitology' which
refers to different expert committees working on a future Commission's (legislative) proposal.
Indeed, if the Commission plays a crucial role in this process, it does not work in isolation as
it needs to take into account the multiple levels of decision-making and implementation that
will be concerned by its policy (Versluis, van Keulen and Stephenson 2011).

Hence, the policy-formulation stage concerns besides the Commission, Member States rep-
resentatives who need to prepare the final document on which the Council of Ministers will
have to pronounce itself. Here too, a draft policy proposal is often being debated in different
expert committees. The members of expert committees at this level often also offer advice to
the Commission when it is still in phase of drafting the proposal. At this level, government
representatives - who can propose amendments to the draft proposal of the Commission
- seek to reach a consensus on the text before it reaches the official Council of Ministers
who will have to adopt (or not) the proposal. In case of disagreements, the Committee of
Permanent Representatives (COREPER), needs to reach an agreement (Versluis, van Keulen
and Stephenson 2011: 139).

Finally, another institutional player in the policy-formulation process is the European Par-
liament especially in those areas falling under the 'ordinary legislative procedure'[51]. In this
institution too, the policy-formulation process mainly takes place in separate sectorial com-
mittees, dealing with specific policy areas. Each committee is composed of members of the

---

51   The ordinary legislative procedure can take up to 3 stages. In the first stage, the European Parlia-
     ment (EP) examines the published proposal of the Commission and adopts an opinion or makes
     amendments. The text then goes to the Council which examines the proposals as well as the
     position of the Parliament. The proposal is adopted when a qualified Majority Vote (QMV) has
     been found on the text approved by the EP. However, if the Council does not agree with the EP's
     amendments or wishes to add new ones, a new 'common position' will be adopted (by QMV) and
     will be presented for a second reading to the EP. The proposal will be adopted if the EP agrees
     with the Council's common position or if no decision on the latter has been taken. The proposal
     will not be adopted if the EP rejects the Council's common position by a majority vote. If the EP
     proposes amendments to the common position (by an absolute majority vote) the text will return
     to the Commission which can deliver its opinion. In the second stage, the proposal will return for
     a second reading to the Council which can 1) adopt the text by QMV in case the Commission's
     opinion is positive or 2) adopt the text by unanimity is the Commission's vote is negative. If the
     Council decides (by QMV) not to approve the EP's amendments, a conciliation committee will be
     convened (third stage). If no common position can be found, the proposal will not be adopted. If
     the Conciliation committee agrees on a joint text, the proposal can be approved provided it will
     be adopted by both institutions within six weeks (by QMV in the Council and by absolute majority
     vote in the EP). If not, the proposal will not be adopted. (Nugent 2010: 314-319).

European Parliament representing different political parties. In the case of public health, the ENVI committee[52] will be responsible to analyse and propose amendments on draft proposals of the Commission.

Besides debates taking place on the institutional level, the EU policy-formulation phase also includes the interactions of multiple other actors having stake in the proposed draft policy such as interest groups, profit and non-profit organisations, all seeking to influence the policy-formulation stage so that their interests will be safeguarded. This 'lobbying' can also be exercised by professional lobbyists equally seeking to influence the process so as to defend their (industry) interests.

In the early stages of HTA cooperation in Europe, the actors involved in the European policy-formulation process were rather limited and mostly concentrated within the Commission. In particular, the European Parliament was mostly absent in the formulation of European health policy objectives. However gradually, with the revision of the treaties this situation will change. The HTA policy formulation process at the European level has to be analysed in close relationship with the broader health policy developments as discussed above. In this sense, we can identify three crucial factors that have influenced the Commission's interests and involvement in HTA.

The first factor regards the development of the (Public) health programs developed by the Commission to ensure the establishment of a legal basis to act in the field of health policy. Initially, in the aftermath of the Maastricht Treaty (1992) a "Framework for Action in the Field of Public Health" had been adopted. This strategy document aimed at developing work on public health and comprised a series of eight action programs which were partly a continuation of work already engaged in by the Commission before the Maastricht Treaty. HTA was therefore not targeted by this action plan The actions of the Framework were directed towards health promotion, cancer, drug dependence, AIDS and other communicable diseases, health monitoring, rare diseases, accidents and injuries, and pollution-related diseases[53].

In order to give a significant effect to the new Maastricht Treaty provisions, the Commission quickly started a reflection process upon the establishment of a *single* public health program presenting an integrated approach towards protecting and improving health. As outlined before, the entry point of this reflection concerned the health systems which displayed a high diversity among the Member States (and which became even more divergent with the en-

---

52   The ENVI Committee is responsible for issues in the field of Environment, Public health and Food Safety.

53   See further: http://ec.europa.eu/health/programme/policy/eight_programmes/index_en.htm

largement process underway). This approach addressed 'health' from an economic perspective as it sought to help structuring the health systems in a cost-effective and cost-efficient way. Ideas such as "health is wealth" and "value for money in health care" slowly became part of the EU discourse on public health policy and were adopted by other institutions such as the WHO (Personal interview 3; Banta et al. 1997: 133; European Communities 1999; Seychell and Hackbart 2013). HTA fitted perfectly well in this new perception of what EU health policy ought to be. This certainly facilitated the uptake of HTA in the first public health program, aiming at the development of legal and policy instruments, pre-requisite to make an impact with the new competences attributed to the Commission in the field of health.

The health strategy of the Commission, as presented in 1998, and which established the basis of the future *public health program* (2003-2008), was built on three policy strands: a) *health information*, b) *establishing a rapid response mechanism to health threats* and c) *tackling health determinants through health promotion and disease prevention*. HTA was concerned by the first strand putting the emphasis on the exchange of best practices "as regards the safety, efficacy, effectiveness and cost-effectiveness of different approaches to health promotion, prevention, diagnosis and treatment" such as cost-effectiveness of screening programs and new pharmaceutical products (European Commission 1998: 48).

The aim was to promote, pool and coordinate work done in Member States in related fields such as evidence-based medicine, quality assurance and HTA. Gathering and exchanging information and improve the dissemination of findings was considered the key to develop the health systems of the Member States. Indeed, the Commission did not seek to develop an action plan to be implemented 'from above' but rather sought to draw upon the experiences of Member States so that mutual learning processes could be driving the process. The underlying perspective of the Commission was that by exchanging experiences and expertise and through the establishment of networks, better results could be achieved which would permit to every Member State to enhance the quality and efficiency of their health systems. (European Commission 1998; personal interview 3).

HTA has been since then inserted in the health programs of the European Commission. This has played a major role in the development of HTA cooperation in Europe as it became an integral part of a new strategy for the development of a specific EU health policy. Hence, because *health policy* was being considered through the scope of 'health' by a dedicated 'health unit' of the Commission - rather than through the scope of employment, social security or professional mobility – HTA could find its place in the orientations and policies of the European institutions. Even more so, HTA could even be considered as one of the drivers of the EU health strategy.

The second factor having influenced the interest and involvement of the Commission in HTA regards developments on the EU systemic level with the preparation of a new EU Treaty to be signed in Amsterdam at the end of the nineties. Hence, while developing the content of the health strategy and first public health program, discussions were underway regarding the amendment of the public health article in the future Treaty of Amsterdam adopted in 1997. At the time of the Maastricht Treaty (1992), a sort of 'pro-European' atmosphere mostly dominated European politics and was often reflected in the public opinion of European citizens. Many policy areas were touched by integration policies and public health was considered as a field in which still much could be done (personal interview 3).

However, at the end of the 1990s, the enthusiasm for the European Union was gradually replaced by a more critical approach of Member States seeking to secure their powers in sensitive areas such as health. The amendments of the public health article in the Amsterdam Treaty (1997) reflect this trend. Indeed, the revised article underscores that the Commission's action in the field "shall complement national policies (…) and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care" (Article 152). The article furthermore reiterates the condition that the achievements of the objectives "exclude any harmonisation of the laws and regulations of the Member States". This shift in attitude towards integration policies certainly affected the possibilities of the Commission regarding the extension of EU competences in the field of public health. The dominating rational regarding EU integration was the completion of the single market.

The establishment of the European Medicines Agency (EMA) in 1995 should be understood in the same perspective as it sought to facilitate the market authorisation of medicines in the European Union through a single application process. However, market authorisation of medicines fell under the responsibility of DG III (Industry) and not DG V which was responsible for public health. Moreover, these policies did not concern pricing and reimbursement policies as this remained an area of Member States' competences. In this context, Commission officials working on the public health program considered HTA to be a manner to "get into areas we hadn't managed to get into" (personal interview 3). As the *public health* unit wasn't allowed to get into *health care* specifically, nor into *treatment*, it sought to work in areas presenting a clear health objective. HTA responded to this criterion. Moreover, the public health program permitted the Commission to circumvent the limitations set in the Amsterdam treaty by developing collaborative policies in areas concerned with improving Member States capabilities. Here again, HTA responded to the objectives. (personal interview 3).

The third factor impacting the Commission's interest for HTA is related to the need for promoting a social Europe expressed in the late nineties by many different actors. Indeed, developments that took place in the field of social affairs had repercussions on the public health program *in spé.* - and thus indirectly for HTA[54]. Since the Amsterdam Treaty (1997), social policy fell under the so-called 'shared competences' of the European Union. As a result, actions taken on behalf of DG Social Affairs received increased legitimacy (Hervey and Vanbrecke 2010: 106). Strengthened by the extension of its powers and seeking to push the social policy further on the European agenda, the European Commission initiated in 1999 a 'concerted strategy for modernising social protection'. One of the key objectives[55] of this strategy comprised the aim 'to ensure high quality and sustainable health care' (European Commission 1999b: 12-14). The argumentation in this document is consistent to the one underpinning the health programs and underscores again the rising costs in health care as a result of an aging population and innovation in medical technology. The Commission therefore stresses the need to "contribute to improve the efficiency and effectiveness of health systems so that they achieve their objectives within available resources. To this end, ensure that medical knowledge and technology is used in the most effective way possible and strengthen co-operation between Member States on evaluation of policies and techniques" (European Commission 1999b:15).

The governance mode proposed to launch the new strategy responds to a call of the European Parliament in March 1999 "to set in motion a process of voluntary alignment of objectives and policies in the area of social protection, modelled on the European employment strategy[56]" (EES). Indeed, the EES had introduced a new working method called "The Open Method of Coordination" (OMC). The aim than was to address the subsidiarity principle by creating a system where the responsibilities between the Member States and the European institutions where shared through the establishment of common targets to be defined and

---

54   The bridges that can be found between health policy and social policy will remain important for the development HTA as for many other health policy fields such as cross-border health care. See also chapter 5 and 6.

55   The other objectives listed in the Commission's communication are 1) to make work pay and to provide secure income, 2) to make pensions safe and pension systems sustainable, 3) to promote social inclusion (European Commission 1999: 12-14).

56   Resolution on the Commission report to the Council, the European Parliament, the Economic and Social Committee· and the Committee of the Regions on "Social Protection in Europe 1997 (A4- 0099/99).

implemented by Member States and monitored by the European Commission[57] (see also Borras and Jacobsson 2004).

Following the example of the EES, the Commission concludes that, the time was ripe 'to deepen the existing co-operation on the European level in order to assist Member States in successfully addressing the modernisation of social protection and to formulate a common political vision of Social Protection in the European Union'. With this 'concerted strategy' which would be 're-framed' a few years later in the 'Open Method of Coordination process on social policy' (European Commission 2005), the Commission took a proactive stand in launching the debate regarding the coordination of social systems in the EU. Moreover, by introducing the Open Method of Coordination (OMC) in the field of social policy, it prepared the ground for the development of coordination in the field of health care. The latter will be of high importance for HTA cooperation in Europe as it will find its legal basis in the Cross-Border Health Care Directive (2011/24/EU) which emanated from this debate and more specifically from the coordination of health insurance systems as we will see in the next chapter.

4.2.3. Conclusion policy-formulation in early European HTA cooperation initiatives

Throughout the three project-based approaches of HTA cooperation, policy formulation has become increasingly formalized. In the first project, this phase was largely being influenced by informal dialogues, based on previous experiences and materialized in the form of a grant proposal and grant agreement. However, the two subsequent projects responded to a more formal process since governance bodies did exist as they had been established in the EUR-ASSESS project. Hence, *consolidation* of the formulation of project objectives in the HTA-Europe and in the ECHTA/ECAHI projects has taken place in the various working groups were different perspectives were being discussed before they had been adopted in the decision-making bodies. However, one should not underestimate the importance of informal discussions among partners as well as the informal intervention on behalf of the European Commission with regard to the formulation of the project objectives which do also have influenced this process (Personal interviews 2 and 6).

Indeed, as outlined above, the policy-formulation regarding the broader EU health policy fol-lowed a particular path and has had some impacts already on the HTA cooperation projects. The health strategy and - in particular the first public health program - of the Commission

---

57   The EES becomes a key component of the Lisbon strategy launched in 2000 which aimed at mak-ing Europe "the most competitive and most dynamic knowledge-based economy in the world" (European Parliament 2010).

has been influenced by governance practices that were introduced at other levels of the Commission. By taking the health systems as entry point for the development of the health strategy, HTA could find its place in the subsequent program that sought to implement this strategy. The methods proposed were based on soft governance modes such as exchange of best practices and of information and actually did fit the practices already in place in the HTA cooperation projects and which were inspired by NPM. However, to permit the HTA projects to benefit from EU funding, it was important that the objectives were consistent with the broader EU health strategy. This explains some interventions on behalf of the Commission regarding the content and sub-objectives developed in particular since the ECHTA/ECAHI project as we have seen above.

It is interesting to notice how a sort of "rapprochement" is being sought by the HTA arena as the emphasis put on the EU's role to support HTA cooperation in Europe increases in each project. The HTA-Europe report already recommended that the European Commission *assists* in the establishment of a coordinating mechanism. The ECHTA/ECAHI report goes a step further by leaving the initiative up to the Commission as it states that "the European Commission *should establish* a sustainable and properly funded co-ordinating body for an EU-wide network of Health Technology Assessment (ECHTA)" (ECHTA/ECAHI 2001: 39, emphasis added). Hence, the quest at this stage is to move from an informal network to a formal network structure, shifting the role of protagonist of the initiative to the European Commission.

Interest for HTA on behalf of the Commission has been reinforced by the fact that HTA offers the possibilities to enter in health policy areas so far not visited by the European Commission. Moreover, as an integral part of the health system, it permitted the coordination of policies seeking to improve Member States capabilities. Soft governance practices are the only real instruments available to the Commission especially after the amendments in the Amsterdam Treaty reiterating the fact that Commission policies in the field of public health care come as a complement to national policies and excluding any harmonisation of laws and regulations in this regard. Finally, the developments in the field of social policies – introducing the open method of coordination in this policy area will have an impact not only on the governance instruments used but also on the uptake of HTA into European legislative acts as will be outlined in the next chapter.

4.3. DECISION-MAKING IN INITIAL EUROPEAN HTA COOPERATION PROCESSES

4.3.1. Decision-making in early European HTA cooperation initiatives

The decision-making phase of the policy cycle refers to the stage in which one or more (or non) of the policy alternatives envisaged in the previous stages is adopted as the official course of action (Howlett Ramesh and Perl 2009: 139). This stage is an inherently political process involving key-actors influencing the way final choices will be made. This process which can generate 'winners' and 'losers' is firmly rooted in the two previous stages of the policy-cycle. The outcome of this stage is the object of the next stage: *policy implementation*. Decisions can be 'positive' in the sense that they seek to alter a given situation or 'negative' if preserving a 'status quo' is the preferred option. Beliefs and values of actors, the nature of the relevant subsystem and existing constraints, all can affect the decision-making process (Howlett, Ramesh and Perl 2009).

Different theoretical models have been developed seeking to conceptualise public policy decision-making processes. Earlier models (e.g. the rational model) emphasized for example the role of rationality in the process underscoring the search for maximizing solution to complex problems where relevant information is used to assess policy options in a scientific manner. Others (e.g. the incremental model) underscored the political aspects in decision-making where bargaining and negotiations are playing a key-role (Howlett 2009: 143-149). Some models have sought to combine both (e.g. Mixed scanned model of Etzioni 1967; 'poliheuristic model' of Mintz and Geva 1997) or completely refuted both ('Garbage can model' of Cohen, March and Olsen 1972) underscoring irrational, unpredictable and ambiguous elements present in the decision-making process. Weiss (1980: 399-401), has underscored how decisions do not always result in a 'clear-cut' way nor take place in a single institution or are taken at a single point of time. Decisions, according to this point of view, result rather over a lengthy period of time, are taken at multiple levels and by multiple actors. Often it is not even clear to individuals when a decision has actually been taken. Multiple venues, actors and rules occur in the decision-making process each influencing it in a different way (see further e.g. Klijn 2001, Timmermans 2001). Moreover, different decision-making processes can occur simultaneously and can mutually influence each other as well as actors' positions on an issue (see further e.g. Klijn and Koppenjan 2000, Howlett 2007, Howlett et al. 2009).

As the first European HTA cooperation initiatives were run as projects within a limited time-frame, one cannot analyse the decision-making process as if it concerned a full-fledged public policy. However, we will see, in the next sections, that the topic of HTA cooperation in Europe slowly but surely becomes a (European) public policy and that the above outlined process can be applied at the European, domestic as well as HTA network level. The first

cooperation projects should thus be analysed as part of the evolution process that led to the establishment a decade later of a network of a more permanent nature and which had repercussions on HTA policy-making.

The decision-making process in the very first project, EUR-ASSESS (1994-1997), distinguishes itself from the others as the project has established the governance structures on which the subsequent projects and the HTA network have been based. If the first decision to establish cooperation among HTA agencies in Europe has been taken in a rather informal way (see above), the project which has been set up to achieve this strategic objective did operate according to a clearly defined governance matrix comprising a Steering Committee, an Executive Committee and Subgroups. This structure has been maintained throughout the three project-based cooperation initiatives. Moreover, one should also include the grant approval by the European Commission as part of the decision-making process, as without this, the project would probably not have taken place the same way.

The Steering Committee in EUR-ASSESS has been established right from the start and was comprised of all partners in the project. At time of the project proposal submission, it comprised twelve individuals from ten countries[58] all participating with the approval of their respective ministerial authorities[59]. At the end of the project almost all EU countries were represented in the Steering Committee. The Steering Committee met five times during the three-year long project. Due to the large number of Steering Committee members, making it difficult (and expensive) to discuss in depth project policy, an Executive Committee had been set up. The latter served to oversee the project implementation between the Steering Committee meetings. It was composed of the chairs and co-chairs of the so-called 'subgroups'. The subgroups were the actual working units pursuing a specific project objective as defined by the Steering Committee: priority setting, methodology, dissemination and evaluation of impact and coverage. All subgroups were co-chaired by a partner from the north and one from the south. Moreover, the founding partners[60] were represented in all subgroups "to ensure full input and ready acceptance of the results" (Banta et al. 1997:138). The other members were defined on the basis of their expertise and specific interest for a topic. The

---

58   Denmark, Germany, Spain, Italy, Greece, Switzerland, Sweden, Spain (Catalonia), France, UK (Banta 1997).

59   Except for Germany where ministerial representatives which had been contacted, initially did not show any interest in the project. At a later stage, the Ministry of health has designated other German participants. (personal interview 2)

60   The founding partners were: the Swedish Council of Health Care Technology Assessment (SBU), the U.K. Research and Development Programme, The French Agency for Development of Medical Evaluation (ANDEM) and the Catalan Agency for Health Technology Assessment (CAHTA) (Banta et al.1997: 139).

subgroups had to submit a final report to the Steering Committee who would review - and if necessary, amend - it, before final adoption and submission to the European Commission. Besides these structures, a project coordinator had been appointed who besides liaison work between the subgroups[61] also endorsed the responsibility of budgetary control (Banta 1997).

In HTA Europe (1997-1998), the governance structure was identical to the one of EUR-ASSESS. The ECHTA/ECAHI project (1999-2001) also comprised a Steering Committee and Executive Committee which functioned in a similar way as the two previous projects. The Subgroups were renamed into 'Working Groups' but still dealt each with one sub-objective serving the overall strategic aim to establish a formal network on HTA cooperation. New in this project was the establishment of a 'Secretariat' by the project leader who carried the formal legal and financial responsibility over the project. The Secretariat dealt with managerial tasks and administrated the financial resources. As such, it reported progress of the Working Groups and offered administrative and organisational support to the Steering Committee and Working Groups ECHTA/ECAHI 2001: 16).

Although the governance structure in the three projects created clear venues where decisions were adopted, it seems that *in practice* the decision-making process took place in different venues and did not take place at a single point of time. For example, when the Steering Committee of the ECHTA/ECAHI project met for the first time in 1999, the project proposal had already been drafted and submitted. This however did not mean that members of the Steering Committee did not have a say in the decisions regarding the outline of the project. The different members did meet at different venues such as international meetings organised by other organisations or societies. Informal individual discussions and meetings also took place with the project coordinators and partners as it had already been the case with the setup of the EUR-ASSESS project. Moreover, decisions regarding future collaboration and orientation of the collaboration were taken in the Steering and Executive committees from the previous projects. In both committees, decisions were taken by consensus.

In the previous section, we have seen that the European Commission was taking part in the policy-formulation process, its role is less clear in the decision-making stage of the policy-cycle. By granting financial support, the Commission did of course play an important role as a decision-maker since without that decision the project could not have been implemented in the way it has been. However, in the first project-based cooperation initiatives, the Commission did not interfere in daily management issues of the informal networks. As reports had to be submitted to the Commission in the course of the project, the European institution did

---

61   The project coordinator acted as secretary on all subgroups and in the Steering and Executive committee (Banta 1997).

have some sort of decision-making power as it could potentially decide to end the coopera-tion process if it would not have been compliant with the grant proposal. Hence, no real direct intervention of the EU is to be observed in the decision-making processes of early HTA cooperation initiatives. The involvement of the EU on a decision-making level will however change in the future. To understand how this became possible it is important to situate HTA in the wider EU decision-making processes in the field of health policy and the repartition of competences as we have outlined in chapter two.

4.3.2. HTA cooperation decision-making processes from the EU health policy perspective

At first sight, in the period of 1991 - 2001, European decision-making processes in the field of health care had no impact on HTA cooperation in Europe. We have seen in the section above how the EU was absent in the daily management of the cooperation projects. How-ever, a closer look at developments on the super-systemic and sub-systemic levels[62] sheds another light on the situation. Indeed, Treaty changes regarding EU public health policy as well as developments on different levels in the Commission have clearly paved the way for a closer cooperation in the field of HTA as well as a deeper involvement on behalf of the Commission in this regard.

As outlined in the section on policy-formulation, at the time that the Commission was devel-oping the first public health programme, negotiations were underway regarding what would become the Amsterdam Treaty (1997). Treaty amendments are important as they define the scope and areas in which the EU institutions can undertake regulatory initiatives. According to the principle of 'conferred powers' defined in Article 3b of the Maastricht Treaty (Article 5 TEU) the institutions can act only in those areas where the Treaties give them power to act. The article furthermore stipulates that in areas not falling under the exclusive competences

---

62   Peterson (1995) identifies three different levels of analysis in EU decision-making processes. A 'super-systemic' level looking at 'history-making' decisions (taken in e.g. in the Council or in Inter-governmental Conferences), a 'systemic' level that concerns policy-setting types of decisions and a 'sub-systemic' level permitting to grasp decision-making in policy-shaping processes. (see further also Bache and George 2006: 31-32). Peterson's categorisation underscores how, depending of the policy type, different actors are involved and different processes are being set in motion. Wallace, Pollack and Young (2010: 55-61) furthermore stress how EU decision-making processes will also differ among the EU policy areas as a result of different institutional decision-making structures applicable to them.

of the Community, the subsidiarity principle[63] should be applied'[64]. Moreover, the Maastricht Treaty defined as new objective to make "a contribution to the attainment of a high level of health protection" (Article 3(o)).

The public health articles in the subsequent treaties should be read in light of the above. Although the public health article in the Maastricht Treaty was relatively modest in scope, the revision of this article in the subsequent treaties has gradually permitted the Commission to develop its initiatives in this policy field. As such, Article 152 of the Amsterdam Treaty introduces a new sentence in the very first paragraph stipulating that "*a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities*". Although this paragraph could be understood as giving the EU potentially broad powers regarding health policy, this comprehension will be tempered by analysing the second part of this paragraph which seems to be a result of bargaining between the Commission and the Member States. Indeed, the second part of the first paragraph clearly delimitates the scope of EU action which shall come as a 'complement' to national policies. This action should be aimed at '*improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education*' (Art. 152 (1)).

Indeed, compared to the Article 129 of the Maastricht Treaty, the addition of the following line '*which shall complement national policies, shall be directed towards improving public health*" testifies of what seems to be a compromise between the Commission and the Member States (the first part responding to the interests' of the Member States and the second part to those of the Commission). Finally, in the second paragraph, the article now adds the following provision: "*The Community shall encourage cooperation between the*

---

63   The 'subsidiarity principle' refers to the fact that 'in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level' (see chapter 2).

64   These articles will be complemented in the Lisbon Treaty (2007) by 2 articles which will direct have consequence in the field of health care. Article 4 TFEU states that with regard to public health matters, powers shall be shared between the EU and the Member States which means that Member States are allowed to legislate to the extent that the Union has not legislated (Chalmers, Davies and Monti 2010: 208). Article 6 TFEU states that with regard to the protection and improvement of human health 'the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States.

Member States in the areas referred to in this Article and, if necessary, lend support to their action". Although the article reemphasizes the restrictions to Community actions in the field of health, it also offers a new legal basis for cooperation initiatives which offers the Commission new room for manoeuvre[65].

Article 129 of the Maastricht Treaty already referred to the co-decision-procedure (Article 189b) as the decision-making basis of the objectives listed in the public health article. This remains the case for the amended Article 152 in the Amsterdam Treaty. However, to avoid that Member States lose too much 'grip' on this policy field, a new fifth paragraph has been added specifically stipulating that "*Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care"*.

As the Treaty amendments already display, the late 1990s were characterised by an increasing concern of Member States to see too many powers shifted to the supranational level. The same was perceptible in the health policy area which resulted in treaty amendments seeking to insert specific exclusions in the public health article so as to limit EU competences in this field. The new public health program was being developed against this background where the subsidiarity principle was often being referred to by the Member States as a mean to slow down the process, leading to Commission initiatives trying "*to find ways around it"* (personal interview 3). One of the ways to do so was by exploiting the little instruments the Commission had at its disposal: coordinating and supportive policies.

Even if the Amsterdam Treaty has played a role in decision-making processes strengthening the coordinating role of the Commission in cooperation initiatives, the most important developments in the last decade of the millennium remained the establishment of a single public health program which proposal was officially communicated in 1998. This document can be considered as a milestone in the field of EU health policy as it marks the beginning of a new era in this policy field. By focusing on the three strands of action on information, rapid reaction to health threats and health promotion and disease prevention, the Commission can reach out to many domains so far not tackled by community policies.

The health program would become the basis for offering financial support to external projects such as the HTA cooperation projects. Although the new public health program will only

---

65   One should notice however, that although, in general, powers of the EU remained weak in the field of public health, the Amsterdam Treaty did offer the possibility to make binding EU legislation in the field of blood and organs donations and in some veterinary and phytosanitary areas (Article 152 (4)). Harmonisation of laws and regulations remained however excluded.

be adopted in 2002, the draft program, officially communicated in 1998 to launch a public discussion on the issue, already influenced Commission's decision-making with regard to grants attributed to projects. In this regard, we have seen above how the Commission had explicitly asked to insert as first objective in the ECHTA/ECAHI project (submitted in 1998) the aim to "assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators" (ECHTA/ECAHI 2001:15). This insertion becomes comprehensive when examining it in the light of the Commission's public health program *in spé*.

Health promotion and disease prevention are indeed the third strand of action of the proposal. Conversely to all other objectives in the ECHTA/ECAHI project, this one had never been discussed nor considered before in the previous HTA cooperation projects. HTA is indeed indirectly strongly connected to health promotion and disease prevention. However, compared to the initial objectives and motivations of the HTA cooperation, the ultimate goal of cooperation is herewith lifted to another level. Indeed, the new objective of the ECHTA/ECAHI project stipulates that the assessment of health promotion and disease prevention activities should aim at complementing *community* health indicators. The latter reveals how Commission's objectives are being diffused into the HTA cooperation program. The prime motivation of the initiators of HTA cooperation mostly targeted the upgrade of quality and quantity of HTA to insure uptake in *national* health care decision-making processes. By the insertion of this new (community) objective, HTA cooperation is not only directed towards national health policy but will also serve European health-policy-making.

The Commission's proposal for a *single* public health program furthermore underscores how the actions strand on 'health promotion and disease prevention' is closely related to the one on 'information', by which HTA is concerned. Indeed, under the paragraph regarding action strand 1 "improving information for the development of public health" the Commission's proposal of 1998 underscores the importance of cooperation and coordination of activities in areas such as Evidence-Based Medicine and Health Technology Assessment. The proposal stipulates that "co-ordination of work in these fields would be supported and set on a formal footing in order to pool the expertise of the centres in the Member States, to gather and exchange information, stimulate international studies, and improve the dissemination of findings" (European Commission 1998a:13).

It is also noteworthy to stress how the Commission puts a "major emphasis" on "best practice in health care" regarding "safety, efficacy, effectiveness and cost-effectiveness of different approaches to health promotion, prevention, diagnosis and treatment" (e.g. cost-effectiveness of screening programmes, health education programmes, emergency services and new pharmaceutical products). It even stresses that to be "fully effective such a

Community system and its components should ultimately be based on appropriate networks to which Member States would be committed to contribute in respect of the collection, processing and transmission of data, and in relation to taking into account the results of the analysis and evaluations" (European Commission 1998a: 13);

The 1998 communication of the Commission on its proposal for a new single public health program is interesting for our research in two ways. First, it demonstrates how the interest of the Commission for HTA - which has started in the early 1990s - has been translated into real action points of a future EU health strategy. Second, the document also points to the policy instruments that would be used to implement the strategy. Indeed, based on the powers conferred to it by the Treaty (mostly restricted to coordinating and supportive measures), the Commission will have recourse to soft policy instruments such as the exchange of information, best practices and the establishment of networks. The latter also points how developments in the field of health policy have been influenced by developments taking place in other EU policy areas and in particular social policy which already started to implement governance practices which would be later qualified as the 'Open Method of Coordination' as we have seen above.

4.3.3. Conclusion decision-making in early European HTA cooperation initiatives

The decision-making process in the early stages of European HTA cooperation is characterised by formal decision-making bodies but which often act on issues having been agreed upon in informal fora. Dialogue, exchange of experience and establishment of best practices seem to underpin the decision-making process as such. Previous experiences in the earlier projects have influenced content and governance aspects and have thus also played a role in the decision-making process.

Decision-making power was mostly an internal network process in which key-actors, such as project initiators and founding partners seem to have had a preponderant role in the definition of strategic objectives and aims to be pursuit. This also resulted of the fact that partners joining the cooperation initiatives at a later stage often also had less experience in HTA in general and were naturally inclined to follow proposals made by more experienced HTA agency representatives.

However, the cooperation process did respond to requirements of transparency since discussions took place in an overt manner and the diverse governance structures offered sufficient possibilities for discussion and opposition. Decisions were mostly taken by consensus and no issues of discontent partners have been raised in our research. No indication of exclusion of (potential) partners has been found. Work within the subgroups/working groups responded

however to a more flexible approach as to the manner the objectives were to be reached. At this point of time, stakeholders are not involved and national governments do not seem to follow closely the cooperation progress made at a European level.

The framework offered by the EC grant agreement has permitted the structuring of participation as it functioned as a sort of authority since strict respect to the agreement provisions had to be presented. In this sense, decisions as to reaching the objectives had a binding character and (access to) resources did influence the decision-making process as the Commission could - and did – request to amend the project according to its specific wishes. Indeed, by requiring the insertion of a new (community) objective, the overall objective of HTA cooperation in Europe was lifted to higher level. Instead of pursuing objectives which essentially targeted the quality and uptake of HTA at a national-level, the cooperation initiatives served objectives linked to the European health strategy. The policy instruments at the disposal of the Commission to carry out this strategy were based on soft policy governance practices as the treaties conferred only coordination and supportive powers to it in this policy field. Elements of the Open Method of Communication introduced in the field of social and employment policies have also been identified as part of the Commission's approach towards HTA cooperation.

4.4.   POLICY IMPLEMENTATION IN INITIAL EUROPEAN HTA COOPERATION PROCESSES

4.4.1. Policy implementation in early European HTA cooperation initiatives

Once decisions on the course of an action has been taken, the question regarding the implementation will rise. How policy decisions will be translated into concrete actions will depend on the knowledge and resources available as well as the instruments chosen. Commonly, the implementation phase will comprise more actors than in the previous stages of the policy cycle. The responsibility of implementing a public policy typically is conferred to civil servants or administrators but, depending on the countries, non-governmental organisations or other societal actors can also be involved in the process (Howlett, Ramesh and Perl 2009: 160).

Analysing policy implementation in the case of European cooperation in the field of HTA requires a departure from the typical public (governmental) policy implementation and

implementation models and theories[66]. To well understand this stage and its impact on the cooperation process, one needs to take account of the multiple levels involved in this cooperation process. As we have seen, HTA cooperation in its early phase resulted from an initiative stemming from within the HTA community. However, involvement of HTA agencies in the cooperation project has been done with the backing of their respecting (health) ministries. Moreover, Commission interest in the issue has increased over the years, as it considered HTA an important element to pursue the development and implementation of an EU health policy.

Another factor to take into account when analysing the policy implementation phase of HTA cooperation is the fact that the strategic objective of all projects till 2001 implicitly regarded the creation of a *permanent* network of HTA cooperation in Europe. Hence, although the actions to be implemented (sub-objectives) had to take place within a limited project-based time-frame, the overall strategic objective regarded a long-term objective, having potential implications on the domestic and European level. The actual policy to be implemented concerned thus the establishment of a sustainable network for HTA cooperation in Europe. However, at the early stage of the cooperation initiatives, stakeholders' visions (i.e. Member States, HTA agencies and the European Commission) on the subject differed regarding the organisational structure the network should adopt.

An important aspect of the policy implementation process regards the choice of policy design and of policy instruments. This is not a neutral exercise. The selection of various tools or instruments will form a policy mix aiming to resolve the policy problem (Bressers 1998: Bressers and Klok 1988). Howlett (2000) analyses policy instruments by distinguishing them according to their nature: 'substantive' or 'procedural'. The former can potentially influence the substance of policy outputs, the latter can affect the "policy processes associated with the delivery of those outputs" (Howlett et al. 2009: 169). According to Howlett, Ramesh and Perl (2006), this distinction can be applied to a taxonomy of policy instruments such as the 'NATO – model' of Hood (1986) whereby policy instruments are classified in categories of Nodality, Authority, Treasure, Organisation.

Although developed to analyse formal public governance institutions, Hood's 'NATO model' can assist us in getting a better insight in the policy instruments that have been used in the first project-based HTA cooperation initiatives. Hood's model (1986) outlines how govern-

---

66   See further on public policy implementation models and theories: Hargrove 1975; Pressman and Wildavsky 1984 (program implementation) Barrett 2004; Sabatier 1993; Hjern and Porter 1993; Lipsky 1980; Matland 1995; ('*top-down*' versus '*bottom-up*' debate); Scholz 1984, 1991 (game theory); Ellig and Lavoie 1995; Francis 1993; Bozeman 1993 (Principal-agent theory).

ments confront public policy problems through the use of available information ('Nodality'), their legal powers ('Authority'), financial resources ('Treasure') or the formal organisation available to them ('Organisation') (Hood 1986; Howlett, Ramesh and Perl 2009: 115). In the case of HTA cooperation, the available information was based on the experience of the project initiators which has served as a sort of benchmark. No real legal authority in terms of command and control is to be identified in these first initiatives which were mostly run through self-regulation. However, the rules defined by the financial authority (EC) in the grant agreement have framed the initiative and permitted the project coordinator to exercise a certain control over the other partners. Conversely, these subsidies also conferred a certain authority to the European Commission. Indeed, subsidies can be used as policy instrument by an institutional authority and are often considered as a flexible way of governing without high financial investments and permitting to stimulate innovation (Howlett et al.: 123). Prerequisite is however that they match the institutional program. In the case of HTA cooperation, the grants conferred to the HTA cooperation project did offer the European Commission the right to oversee the project and amend it, if it did not comply with the broader health policy program that was being developed at that stage (personal interview 2 and 3).

Applying Howlett's distinction of substantive and procedural policy instruments to Hood's categorisation permits to identify the building blocks on which a policy mix has been designed (Howlett, Ramesh and Perl 2009: 169). Research has shown that a variety of factors intervene in the choice of policy instruments. Some consider it as primarily a technical exercise, others integrate it in their analysis political factors[67]. According to Howlett, Ramesh and Perl (2009: 172) influencing factors involve "the nature of the sub-system involved and especially its propensity to allow new actors and new ideas to penetrate into policy deliberations". Whether an instrument will be able to address a particular issue will depend on the options an authority has at its disposal as well as on the implementation context and the manner on which choices respond to policy goals and means already implemented. In other words, to be effective, policy instruments should be chosen on the basis of their *coherence* with the policy objective and their *consistency* with former instruments. Policy implementation is thus about finding an optimal match between policy *goals* and policy *means* permitting to attain those goals (Howlett, Ramesh and Perl 2009: 172-173).

Since the first European HTA cooperation initiative, policy implementation has primarily been organised on a project-basis. The policy *goal* was to foster HTA cooperation in Europe and to establish a (sustainable) network of HTA cooperation so as to upgrade the quality of HTA

---

67   See further on the selection of policy instruments: Howse et al. 1990, Breyer 1979; Mitnick 1980; Peters 2002; Doern 1981; Howlett, Ramesh and Perl 2009.

and its uptake in domestic decision-making processes. The means set in motion to achieve the strategic objective was by adopting short term (project) objectives to be implemented by smaller expert units having recourse to different type of instruments throughout the three projects. As discussed above, this approach shows many similarities with the so-called governance technique of 'management by objectives' stemming from new public management (see also chapter 2).

In EUR-ASSESS (1994-1997) the operational structure is rather simple and straightforward. As outlined above, the topics to be developed in the subgroups had been selected on the basis of past experience of HTA agencies' representatives and particular needs identified in some Member States (i.e. coverage in Switzerland). As such, four subgroups had been established. The first subgroup concentrated its work on *priority setting*, the second on *methodology*, the third on *dissemination and impact of HTA* and the fourth focused on *coverage*. The working methods were quite similar across the four subgroups and have been based on the collection of information through reviews of the literature, and surveys. The findings were analysed, synthetised and discussed during subgroup meetings. Draft principles, conclusions and recommendations have been drafted and published in a final report (Banta et al. 1997; Henshall et a. 1997; Cranovski et al. 1997, Liberati et al. 1997).

The HTA-Europe project (1997-1998) functioned somewhat differently as its main contribution consisted in the publication of separate EU country-specific papers (plus Switzerland) focusing on the existing health policy and health care system structure and its real or potential relation to HTA (European Communities 1999: 30). The aim was here to better understand the functioning of HTA in different countries as little information about the latter was available (personal interview 10). Country experts drafted the papers which have been reviewed, revised and finalized by the Steering Committee. Each paper has been published separately. Alongside the country reports, four HTA-related seminars have been organised on the following topics: (1) Future changes in health care in Europe and their relation to HTA; (2) The use of health outcomes information in health care systems; (3) Opportunities for international assessments; (4) Identifying future health technology (European communities 1999: 31). These topics are closely related of work that would be carried out in the follow-up project ECHTA/ECAHI (European Communities 1999).

The ECHTA/ECAHI project (1999-2001), proceeded again by Working Groups each focusing on one specific subject to be developed and which was considered necessary to achieve the strategic objective of establishing long-lasting cooperation. The topic of the first Working Group, *Health Promotion and Disease Prevention,* had been explicitly requested by the European Commission and responded to the strategic objectives of the EU health policy (see above). The second Working Group focused on a *Clearing House Function and Emerg-*

ing Technologies. This topic could be related to the one of 'priority-setting' in EUR-ASSESS and the workshops in HTA-Europe. The third Working Group started to actively develop the concept of *European Joint Assessments*. This idea was already present in the report of the EUR-ASSESS project but had never been tackled in this explicit way. 'Joint assessments' require similar working methods and are, as such, closely related to issues of methodology which were being dealt with in the fourth and fifth working group on *Best Practice in Undertaking and Reporting HTA* and *Education and Training*, the latter focusing more on countries where HTA was still emerging. Finally, the sixth Working Group on *HTA in Policy and Practice,* dealt with the dissemination of HTA and its uptake in health-related policy decision-making processes (e.g. market access, coverage and pricing). This topic was in line with EUR-ASSESS's Subgroup on dissemination and impact of HTA (ECHTA/ECAHI 2001).

The outputs of the subgroups and working groups can be analysed from different perspectives. First, the work has permitted to collect for the first-time information on HTA practices and their impact in the Member States and report this in a number of published articles. But more importantly, the project-based stage has played a fundamental role in the development of HTA cooperation as the different projects have permitted to lay down the foundations for work that has taken place after 2001. In particular, the EUR-ASSESS Subgroup on *Methodology* has played a key-role in establishing a cooperation basis by creating a common reporting structure using common elements and a common methodology (Liberati et al. 1997). As we have seen above the aim of the cooperation efforts was two -fold: enhance the quality of the work to ensure its uptake in policy decision-making processes; create the possibility to re-use each other's findings. The latter with the objective that: "agreement on basic standards will then facilitate a process of harmonisation of elements of HTA across groups and countries with better comparability and possibly some international division of labor across Europe" (Liberati et al. 1997: 191).

Although we will go into more depth on the subject of harmonisation of practices in the following chapters, it is important to underscore how the outputs of the very first expert group dealing with methodological issues, have framed the assessment structure that was developed a decade later[68]. Moreover, at this point of time, the experts already referred to

---

68   The report refers to 13 stages in the assessment process: 1. Definition of the policy question 2. Definition of the research question 3. Current state of development and use of the health technology 4 Technical characteristics of a device 5. Efficacy, safety, and effectiveness of the health technology 6. Qualitative synthesis 7. Surrogate endpoint 8. Role and weight of expert opinion 9. Social and psychological effects (clear guidelines are necessary here) 10. Economic evaluation 11. Use of mathematic modeling 12. Effects on the organisation of health services 13. Ethical aspects (Liberati et al. 1997). Many of these stages will be present in the Core HTA model develop by EUnetHTA (see chapter 6).

the importance of what will be called later "relative effectiveness assessment" and which will become a key feature in HTA cooperation after 2006. In the ECHTA/ECAHI project, the Working Group 4 went a step further in developing common methodologies basing themselves on best practices and introducing a "Scientific Summary Report" permitting to "critically appraise HTA reports to evaluate their reliability" (ECHTA/ECAHI 2001: 22).

The project implementation phase in the early cooperation initiatives reveals that a common understanding regarding the ultimate aim of the collaboration was still lacking. Part of the tasks of the different expert group was to examine to which extent convergence of practices was feasible and desirable. In this sense, the EUR-ASSESS subgroup on *Priority setting* came to the conclusion that no harmonised priority setting process should be established as the national/regional needs and contexts still considerably varied. The experts do however develop a common approach regarding the set-up of a priority system (Henshall et al. 1997: 166-167). The ECHTA/ECAHI report (2001:20) confirms these findings and furthermore stresses the importance of using existing structures (e.g. Euroscan) in any European clearinghouse function.

Despite the difficulties of establishing a harmonised approach in HTA practices, call for *joint work* is underscored in one of the subgroup recommendations, as early as in the EUR-ASSESS project: "Those responsible for HTA programs should share information on priorities and discuss opportunities for joint working on expensive assessments of joint interest, and the division between programs of assessments or components of assessments whose results can be shared" (Henshall et al. 1997: 167). The item of joint work is also present in ECHTA/ECAHI Working Group 3 who looked for Joint assessment opportunities. The group on priority setting also already recognised the importance to include various *stakeholders* as of the stage of priority-setting so as "to achieve commitment to the process and the outcomes" (Henshall 1997: 164). We will see that this idea will grow in importance over the years and that gradually perspectives will change regarding both the (early) involvement of stakeholders[69] and the feasibility of establishing joint work, implying (a certain degree of) convergence of practices[70].

Even though *Coverage* received little attention in the early cooperation initiatives, the experts working on this subject in the EUR-ASSESS project already stressed the dilemma faced by many governments seeking to contain pharmaceutical costs on the one hand and supporting at the same time the development of pharmaceutical industry (important for the national

---

69   See further about the involvement of stakeholders: chapter 6.

70   Since 2006, joint assessments will become one of the core outputs of the EUnetHTA collaboration and EUnetHTA network. See further on joint assessments chapter 6.

economy in terms of innovation, jobs, growth). Proposing a new model for coverage policy integrating HTA[71], the experts of the subgroup on coverage appealed for the development of a policy which would be more "explicit, rational, and transparent" (Cranovski et al. 1997: 295). Although disappearing of the network's agenda for some years, salience for this topic will re-appear at a later stage (see chapter 6).

Finally, work of the EUR-ASSESS subgroup on *Dissemination* concerned an objective directly linked to the overall strategic aim: the uptake of HTA in decision-making processes. Here again the implementation has resulted mostly in an overview of practices in the different Member States. The experts highlighted in this regard the disjunction between HTA 'do-ers' ('HTA agencies) and HTA users (governmental authorities responsible for the Market authorisation, pricing and reimbursement decisions). According to the experts, coordination between both groups should be increased and more resources should be allocated for shar-ing and disseminating results of HTA (Granados et al. 1997: 228-230). The ECHTA/ECAHI working group on health promotion and disease prevention confirmed that HTA concerned a significant proportion of prevention activities but uptake in domestic policy decisions varied in the different Member States (higher in countries with well-established HTA programmes) (ECHTA/ECAHI 2000: 18). The ECHTA/ECAHI Working Group 6 continued to gather informa-tion through surveys and workshops on the manner in which HTA was being disseminated and used in domestic policy-making processes. Exchange of best practices was here again a recommended instrument to pursue the objective of an increased HTA-uptake in decision-making processes (ECHTA/EAHI 2001: 23).

4.4.2. Policy-implementation in HTA cooperation from the EU health policy perspective

HTA cooperation in the early stages is not directly concerned by what is commonly understood by policy-implementation processes taking place on a European level. The latter refer mostly to the processes where EU policy decisions are 'translated' into national policies. During the early phase of HTA cooperation in Europe, an EU public health policy was just emerg-ing and health policy remained a national competence. Moreover, soft policy instruments were not yet an official EU governance mode. As a consequence, HTA cooperation was only concerned by the EU through the grant agreements it had signed with the Commission and EU policy implementation policies in the area of HTA mostly regarded the respect of the agreements signed. We will see in the next chapter that his situation will change as HTA will play an important role in the implementation of the EU health programs that will be adopted at the turn of the millennium. In 2011, HTA cooperation will even be part of the Cross-

---

71   This model is comprised of four stages :1) identification of the technology, 2) Literature review, 3) Synthesis of available information, 4) a coverage proposal (see further Cranovsky et al. 1997).

Border Health Care Directive which will have a direct impact on the role of the European Commission in HTA cooperation in Europe by giving it a legal basis to take part and steer the implementation of different policies regarding HTA in Europe (see further chapter 6).

Hence, from 1991 to 2001 EU decision-making processes regarding HTA cooperation still only concerned projects co-financed by the European Commission. The implementation of the projects was only overseen by the Commission to ensure the consistency with the project proposal being accepted for Community financing. Our interviews with the participants in the projects all confirm little or no interference of the European Commission regarding the project implementation which was completely managed by the project partners. Although we have seen above the use of soft policy instruments (e.g. peer education, exchange of best practices) to implement the different program items, these resulted from external influences rather than from an EU influence in this regard.

The European Commission has however played a (non-negligible) role in the implementation phase of the different projects by having the potential authority to withdraw the financial contribution in case of non-respect of the project obligations. In a sense, the project-based approach corresponds to a (embryonic) form of self-regulation by sectoral experts (Héritier and Lehmkuhl 2011:49) which will be one of the innovative forms of governance that will be implemented by the European Commission in the following decade[72]. Recognising the importance and complexity of health technology assessment for the national health systems, the European Commission did not interfere in the actual project implementation which was run by HTA experts. However, its sole presence as financial contributor and supra-national actor having an interest in HTA for its own health program has situated the projects to be implemented to a certain extent under the authority of the European Commission. According to the project coordinators of EUR-ASSESS, HTA-Europe and ECHTA-ECAHI, the presence of the Commission has facilitated the implementation of the projects as the deliverables had to be turned in in time (Personal interviews 2, 4 and 6).

---

72 Self-regulation by expert communities has been a governance instrument falling under the so-called New Modes of Governance and has at first been implemented to deal with complex issues of market regulation. In areas of particular high technical complexity, recourse to self- or co-regulation permit to gather expertise and resources from within the private sector. This furthermore allows to shift specific regulatory activities from the governmental arena to a Community agency (see further Héritier and Lehmkuhl 2011).

4.4.3. Conclusion policy-implementation in early European HTA cooperation initiatives

In the early European HTA cooperation projects the "policy" *goal* was to foster HTA cooperation in Europe and to establish a sustainable network of HTA cooperation (Banta et al. 1997:13: ECHTA/ECAHI 2001: 11). The implementation approach chosen was project-based and organised by means of sub-objectives to be accomplished by smaller expert units. Besides the formal working methods of information collection, literature reviews, surveys and reporting methods, the units operated on the basis of soft governance principles.

Although formal governance structures have been established since the very first cooperation project, many objectives have been pursued and decisions taken as a result of informal discussions as well as through learning processes. 'Peer education' seem to have been present since EUR-ASSESS where the experience of some has influenced future practices of others as underscored by Banta et al. (1997:141): "During these discussions, considerable informal advice has been given, especially to those whose activities are not so mature". Especially in the ECHTA/ECAHI project, the exchange of best practices has become an official implementation instrument in several Working Groups to reach some of the sub-objectives defined by the Steering Committee (ECHTA/ECAHI 2001).

Similarly, the role of *discourse* should not be underestimated in the formulation, acceptance, adherence *and* implementation of policy objectives. Before EUR-ASSESS, structured cooperation initiatives in HTA did not exist in Europe. Although the need to share experience was identified in many of the existing HTA agencies, defining the goal of the cooperation as well as the 'roadmap' to reach that goal, required the development of a basis of common beliefs, values, ideas and expectations as to the role of HTA in domestic and European policy-making contexts. The role of policy-entrepreneurs both on the HTA level as within the European Commission has been of high importance herein. To some extent, one can even consider that the prime role of the sub- and working groups has been to establish this common basis of beliefs, values and expectation on which a future sustainable network could be created.

Moreover, it seems that progressively the project partners started to form a distinct expert community that could be identified as an "epistemic community" defined by Haas (1990:349) as "transnational networks of knowledge based communities that are both empowered through their claims to exercise authoritative knowledge and motivated by shared causal and principled beliefs". Indeed, the more the partners cooperated and shared information and experience the more common beliefs and practices were established regarding HTA. As such an iterative mutual learning process has been set in motion since the early days of the EUR-ASSESS project which has matured in the HTA Europe and ECHTA/ECAHI projects.

At this stage of the cooperation initiatives, much of the policy implementation regards the collection of information and the proposals of theoretical models that could be of use for future *joint work* on HTA. The latter is a notion that is still 'handled with care' and the specific domestic policy-making settings are often being recalled. The idea of harmonising practices is implicitly present in all projects but explicit references to the fact that no standardisation or harmonisation should be pursued can also be found (Liberati et al. 1997: 191; Henshall et al. 1997; Cranovski et al. 1997). Positioning towards standardisation and convergence of practices will slowly but surely shift in the following decade. Joint assessment will even be considered, in 2016, as the 'golden standard' to achieve[73].

Two other factors have played an important role in the implementation phase: *voluntarism* and *inclusiveness*. These stem from the organisational structure that had been set in place since the EUR-ASSESS project. This structure was characterised, as we have seen above, by a multi-level, inclusive participatory governance style. Indeed, all early cooperation initiatives were shared the fact that they sought to include a maximum of actors involved in HTA, creating herewith a sense of adherence to the project objectives amongst them. As in the other phases of the policy cycle, members were free to join, or not, the cooperation initiatives which were governed by means of *self-regulation*. It is however especially in the implementation phase that the impact of a non-binding voluntary approach to cooperation can have a decisive impact on the outcome of the project. Clearly, although all partners had a specific task, key work has been done by a core-group of participants (Personal interviews 2, 6). Adherence to the project objectives was however not the only factor that would explain the commitment of the partners to the project. Having to account for the subsidies received from the European Commission has clearly also operated as a stimulus to deliver results.

It may be interesting at this point to apply the policy mix model of Howlett and Hood as discussed above and laid down in figure 1 (Hood 1986; Howlett, Ramesh and Perl 2009: 115). As we have seen, the substantive information (Nodality) instruments used in the early cooperation initiatives were based on existing published knowledge (literature reviews), collection of information regarding domestic HTA settings, peer education/personal experiences, exchange of best practices. The substantive authoritative instruments were based on self-regulation (steering committee) and voluntarism (Working groups). The allocation of budgets (stemming from the EC grant) for each Sub/Working groups could be considered as substantive financial instruments of the cooperation initiatives, having an impact (especially in the ECHTA/ECAHI project) on the content and duration of the projects. Organisational

---

73   Pilot projects on *joint assessments* will be launched in 2006 but their importance will gradually increase to become one of the core activities in EUnetHTA Joint Action 3 (Work Package 2 joint production) (http://www.eunethta.eu/search/apachesolr_search/Joint%20action%203).

wise, the initiatives could be categorized as project-based 'informal networks' operating on the basis of small expert units.

The official reporting structure of the European Commission could be considered as a procedural information policy instrument since these reports will serve as a basis for the extension of institutional support for HTA cooperation on a European level. Some of these reports become even the basis of policy documents for use of and commissioned by the European Commission (e.g. European Commission 1999[74]). Two levels of procedural authority instruments can be identified. The first regards the grant agreement framework which sets the terms which need to be respected and which give the European Commission the right to terminate the project in case of non-respect of the grant agreement. The second level regards the internal governance structure in the form of a Steering Committee and an Executive Committee. The EC (health) programmes through which the specific project subsidies have been granted could be considered as the procedural financial agreement. Finally, no procedural organisation instrument can be identified in these first cooperation initiatives.

	Nodality/Information	Authority	Treasure	Organisation
Substantive Policy instruments	Existing information Exchange of experience	Self-regulation Voluntarism	Sub-Working Group budgets	Informal project-based network Expert units
Procedural Policy instruments	Project Reporting Institutional policy documents	Steering committee Executive Committee WG chairs EC Grant agreement	EC (health) program	-

Table 4.1. Hood's NATO-model (1986) applied to early European HTA cooperation initiatives

When analysing the policy instruments used according to this mixed model one can notice immediately that the procedural organisational level is lacking. If the *substantive* policy instruments can potentially influence the *substance* of policy outputs the *procedural* policy instruments can affect the *policy processes* associated with producing these outputs (Howlet et al. 2009: 169). In the case of the early HTA cooperation initiatives, no clear organisational structure existed which could serve as procedural policy-instrument. The project-based structure functioned as an informal network structure, limited within the timeframe of the projects. Throughout the projects, ambiguity existed however regarding the fact whether the project-based network structure should be or become the sustainable European HTA network, which became the strategic goal of the different projects (in particular those after EUR-ASSESS). This ambiguity will remain throughout the subsequent initiatives which have

---

74   The report *Health technology assessment in Europe: The challenge of coordination* written by Banta and Oortwijn (1999) has been commissioned by the European Commission and served as a policy reflection document in the field of HTA.

been developed after 2006. The lack of the existence of a clear (legal) organisational entity coordinating HTA cooperation will indeed impact the policy processes associated with HTA cooperation in Europe as we will see in the next chapters.

Awareness of the importance of having such a (legal) entity has been expressed as of the very first program (Banta et al. 1997: 142) and has been more clearly reasserted in HTA Europe (European Commission 1999: 5; Banta and Oortwijn 2000b:634). A concrete HTA cooperation model has been proposed in ECHTA/ECAHI (2001: 25-30). No consensus however existed as to the legal form (and associated competences) this entity should adopt. The question was associated with national health policy processes which remained under national competences. Early reports (e.g. HTA Europe) underscore in this regard the importance of the subsidiarity principle and the fact that no new European agency should be established (Banta and Oortwijn 2000b: 635).

It is Interesting to notice at this point how the Steering committees of all early cooperation projects appeal the European Commission to assist them in the establishment of a formal sustainable HTA network. In the first project, assistance refers primarily to financial aid (Banta et al. 1997: 143). However, in the HTA-Europe project, this task comprises, besides the coordination of a system design and integration, more than a dozen other actions which were so far carried out by expert units in the projects (Banta and Oortwijn 2000b:634). The conclusions of the ECHTA/ECAHI project go a step further and explicitly recommend that "The European Commission should establish a sustainable and properly funded co-ordinating body for an EU-wide network of Health Technology Assessment" and thus implicitly externalize the initiative of establishing a European HTA network to the Commission (ECHTA/ECAHI 2001: 39). Although the Cross-border Health Care Directive adopted in 2011 will permit the establishment of a formal HTA network, the procedural organisational question has, until today, not been resolved. As we will see in the next chapter on the developments after 2000, this question will have an impact on the HTA policy processes that will be developed after the turn of the century.

4.5. POLICY EVALUATION IN INITIAL EUROPEAN HTA COOPERATION PROCESSES

4.5.1. Evaluation in early European HTA cooperation initiatives

Once a policy has been implemented and even during the implementation phase, it is of interest to assess how the policy works in practice. Policy evaluation, the last stage of the policy cycle, concerns not just the outcome of the implementation process, it also assesses which instruments have been used and whether the objectives have been reached. In other

words, policy evaluation is about "effectiveness of a public policy in terms of its perceived intentions and results" (Gerston 1997: 120). As a result of the evaluation process, a policy problem can be re-conceptualised (leading to a new policy cycle), the policy can also be adjusted or discontinued (Howlett Ramesh and Perl 2009: 179). As in the other stages of the policy cycle, evaluation is not a neutral process, but contains, together with technical elements, also a political dimension (since assessments may influence decision regarding the policy (dis)continuation).

Different types of assessments exist. Administrative evaluation will for example assess the process, the performance, the effectiveness (value for money) or efficiency of the policy (Howlett et al. 2009: 185-188). However, evaluation techniques can also comprise the use of performance indicators or benchmarking exercises. Finally, evaluation can also be considered in terms of "policy learning", referring to the fact that evaluation can imply learning processes which in turn can trigger policy change. Some consider these processes to be endogenous whereby the goals or techniques of a policy can be adjusted in the light of past experiences and new information (Hall 1993[75]). Others (e.g. Heclo 1974) refer to external changes in a policy environment which may motivate a government to adjust its policy. Assessments can be carried out by different sets of actors, governmental or non-governmental depending on the subsystems of the political spectrum involved. Hence, evaluation can be carried out by politicians, as well as by experts, interest groups, the media or other actors concerned by a policy (Howlett, Ramesh and Perl 2009: 183-185).

Different types of evaluation processes can be observed in the early cooperation projects. The first is associated to the organisational structure of the initiatives. As we have seen in the first part of this chapter, the three projects functioned according to management practices correlated to NPM integrating a form of "Management By Objectives" where the common strategic goal was split into operational sub-objectives to be implemented by smaller expert units. Evaluation of the project has been being carried out during periodic meetings of the Executive and Steering Committees which served to evaluate progress made of the sub/ working groups (output – orientated evaluation). Moreover, the Steering Committee was responsible for reviewing all draft reports of the sub/working groups before its final acceptance (Banta et al. 1997). These reports served also as a basis for the annual reports that needed to be sent to the European Commission who carried out an administrative evaluation assessing the project in terms of output, effectiveness and efficiency.

---

75   Although according to Hall big changes or so-called paradigm shifts will rather result from exogenous shocks (Hall 1993).

Hence, evaluation was mostly output based and directed towards the goals of the different subgroups. It is interesting to notice here that the outcome of most working groups regarded the elaboration of an aspect of the state of affairs of HTA in different European countries. In EUR-ASSESS (1994-1997) for example, HTA cooperation had been set in motion with the aim to upgrade the quality of HTA as well as its uptake in domestic policy-making. To achieve this aim, sub-objectives have been formulated and the outcome of the project has been measured by looking mainly at the results of the individual subgroups in terms of methodology, priority setting, dissemination and coverage. The deliverables of the subgroups concerned an elaboration of the state of affairs in each of these areas. Additionally, models have been proposed which could serve as a basis for adopting a common approach on these issues (Liberati et al. 1997; Henshall et al. 1997; Granados et al. 1997; Cranovski et al. 1997).

Similarly, HTA Europe (1997-1998) concerns primarily a series of publications of the state of HTA in EU Member States (Banta and Oortwijn 2000b). In ECHTA/ECAHI (1999-2001), the evaluation regards again specifically the outcomes of the individual working groups. These also mainly concerned an outline on HTA related practices in Europe such as practices on health promotion and disease prevention, early identification/priority setting, existing international HTA projects, existing education programs in HTA (ECHTA/ECAHI 2001: 18-23).

Evaluation in these early cooperation initiatives could also be examined through the scope of 'policy learning'. The different EUR-ASSESS reports mention the importance of informal working methods among "about 100 or so technology assessors, academic experts, and others of many nationalities" permitting an "exchange of knowledge and ideas" which "substantially added to the quality of the reports" (Banta et al. 1997:139). The fourth working group of the ECHTA/ECAHI project, continuing the EUR-ASSESS work on developing a common methodology, was even based on the exchange of best practices to identify needs for methodological developments (ECHTA/ECAHI 2001: 402:454). The report here also testifies of endogenous learning processes that took place within each project but also from one project to another and which could lead to some changes as a result of external developments. In this case, it led to modifications in the methodological framework initially developed by EUR-ASSESS and further amended in ECHTA/ECAHI (ECHTA/ECAHI 2001:403).

4.5.2. Evaluation in HTA cooperation from the EU health policy perspective

As in policy evaluation on a governmental level, evaluation processes within an EU setting can take place in administrative, political and judicial manner. Regarding the early European HTA cooperation initiatives, only the first two types of evaluation processes apply. As we have seen in the discussion above on policy implementation, administrative evaluation by the European Commission on the implementation of the project as foreseen in the project

proposal has played a role to ensure the timely production of deliverables and the respect of budget constraints. In this sense the European Commission focused on outputs in terms of value for money, achievement of projects goals and managerial performance. The evaluation and monitoring has been based on interim and final reports produced by each sub/working group and submitted by the project coordinators. Through the evaluation in its role as financial contributor, the European Commission has had a certain authority over the project.

However, besides the administrative evaluation another evaluation process has taken place which could be qualified as 'political evaluation'. We have seen that, within the HTA community, evaluation has permitted learning processes to take place. A similar observation can be made regarding the European level. As we have seen at the beginning of this chapter, most EU officials and administrators were not familiar with HTA until they had been confronted with it in the EUR-ASSESS project proposal. Recognising the need of HTA in the overall development of EU health policy, the European Commission has given support to the development for HTA cooperation in Europe. As such, the early cooperation projects have also permitted bi-directional learning processes between the HTA and the EU (Commission) communities. The HTA community has slowly turned into an expert community of which the European Commission could take benefit in the development of its political strategy in the field of health.

The outputs of the cooperation processes have been integrated in the future health programs and a decade later even in the Directive on Cross-Border Health Care. Informal discussions among HTA and Commission representatives have permitted an exchange of information and experiences and a common reflection on future developments (Personal interviews 2, 3, 4 and 8). At this stage, different 'endogenous' and 'exogenous learning' processes (Bennet and Howlett 1992) are taking place but all still with a rather 'low intensity'. In other words, the evaluation process of the HTA cooperation initiatives between 1992 and 2001, have contributed to the development of the EU health policy agenda. Hence, from a technical issue (assessments) HTA cooperation will progressively be politicised to become in 2004 a "political priority" for the European Commission (European Commission 2004f) as we will outline in the next chapter.

4.5.3. Conclusion evaluation in early European HTA cooperation initiatives

Although no clear written administrative evaluation procedures have been established in the first projects seeking to foster HTA cooperation in Europe, evaluation processes certainly did take place. As the projects were based on a multi-level, non-hierarchical governance structure, accountability for the project outcome was shared. Evaluation processes also took place on multiple levels, in multiple fora, by multiple actors and in multiple ways. As such,

a more administrative based evaluation focused on outcome, effectiveness and efficiency took place on a European level and influenced a similar evaluation process within the project which was conducted by the Steering committee. This evaluation process was based on the assessment of the outcomes of the separate expert working units. Within the individual working units, evaluation also took place in the form of learning processes through the exchange of experiences and the establishment of best practices.

Evaluation remained in a sense small-scaled but was exercised by different type of actors and stakeholders. The processes have been quite influenced by the governance structure put in place as well as by practices stemming from New Public Management. Similarly, from the EU perspective, administrative evaluation was accompanied by a more political evaluation leading to endogenous and exogenous learning processes. These have permitted a better understanding of the potential role of HTA in the wider EU health strategy. Whilst all these processes are at this stage rather small-scaled, they will put down the basis for more structured administrative and political evaluation processes in the future which will contribute to structure the cooperation process within the EU. Moreover, these evaluation and learning processes match with governance practices that will be developed after 2001 in the European Union and more specifically in the field of health policy as we will see in the next chapter.

4.6.   CONCLUSION

Analysing European collaboration in HTA through the scope of the policy cycle as developed by Howlett, Ramesh and Perl (2009), permits the identification of some key features characterising the cooperation processes and structures that have been set up in the early stages of HTA cooperation in Europe. We have seen in the sections above how the development has been favoured by the subsequent development of two distinct *agenda-setting* processes: one at the level of HTA community and one at the level of the European Union. The fact that the two agendas matched has permitted the uptake of HTA cooperation at the European institutional level even before any real domestic policy regarding European HTA cooperation had been developed in the Member States. The role of policy entrepreneurs at HTA and EU level has played an important role in shaping the terms of the policy debates and building coalitions to bring the issue forward on the different agendas of the European Union. As a result, support for the initiatives has been found, opening the way to secure organisational and financial resources.

Analysing the agenda-setting stage of HTA cooperation has also shown how at a very early stage the European Commission has understood the role HTA could play in the EU

health policy which still had to be created. Hence, both in terms of timing and content, the launch of HTA cooperation in Europe and the launch of the EU health policy matched. The development path of both have thus been intrinsically linked which explains how the European Commission has, from the outset, played a prominent role in the development of HTA cooperation in Europe.

The importance of the EU role can be further observed in the *policy-formulation* process, where some interference of the Commission is present as early as the first EUR-ASSESS project which has been revised according to informal instructions of the Commission so as to have the project approved. In ECHTA/ECAHI this becomes even more apparent since the Commission has explicitly requested the insertion of the very first objective of the cooperation so as to match other EC initiatives in the field of health policy. Developing HTA cooperation on a European level responded to a common interest of both the HTA community and the European Commission. The Commission's 'interference' should therefore not be seen as a top-down hierarchical control of the Commission over the cooperation initiatives. On the contrary, the HTA cooperation projects were characterised by multi-level, inclusive participatory governance methods which seem to have been influenced by so-called new public management policy instruments such as: management by objectives, participatory governance, shared accountability, performance measures for increased efficiency (e.g. best practices, benchmarking). Many of these instruments could also be qualified as soft governance instruments as outlined in chapter 2.

The NPM moto 'steering rather than rowing' could also be applied to the *decision-making* culture characterising the early European HTA cooperation initiatives. Although formal decision-making bodies existed, these acted by consensus, often on issues having already been agreed upon in unformal fora. Dialogue, exchange of experience and establishment of best practices as well as previous HTA experience seem to underpin the decision-making process as such. No direct role of the European Commission can be identified in the decision-making processes. However, through its grant agreement, the European Commission did, to some extent, have an authority over the project ensuring the decisions did respect the objectives as set in the formal contract, which as we have seen, also served the higher goal of establishing a European health policy.

The *implementation processes* in the early stage of HTA cooperation have, on the one hand, permitted to gather information on HTA practices and their impact on domestic policy-making (pre-requisite for further cooperation and eventual convergence of practices). On the other hand, they have laid the foundation of the work that has taken place after 2006, with the creation of an official network on HTA in Europe "EUnetHTA", which will be discussed in the next chapter. Policy implementation in the early cooperation processes has

been characterised by the presence of soft governance means such as 'peer education' and exchange of best practices. Moreover, the role of *discourse* has also played an important role permitting the development of an 'epistemic community' (Haas 1990) sharing common beliefs, values, ideas and expectations as to the role of HTA in domestic and European policy-making contexts. This has certainly contributed to the adherence and implementation of the defined policy-objectives as well as to the development of iterative mutual learning processes that have been identified since the early days of the EUR-ASSESS project and which have matured in the HTA-Europe and ECHTA/ECAHI projects. Finally, not underestimating the 'voluntary commitment' of the partners to deliver project outcomes, one need to stress at this point again the fact that the projects were being implemented with the support of the European Commission, subsidizing the projects and thus holding the project partners accountable for delivering results.

Analysing the European HTA cooperation policy implementation process according to the policy mix model of Howlett and Hood (Hood 1986; Howlett, Ramesh and Perl 2009: 115) brings to the forefront that a 'procedural organisational' instrument is lacking in the early HTA cooperation initiatives. This can be explained by the fact that the collaboration was project-based and, at the same time, functioned as an *informal* HTA network within a limited timeframe. However, we have also seen that ambiguity existed regarding the vocation of the informal network which some considered to be the future sustainable HTA network responding to the strategic goal of the projects. The establishment of an organisational entity requires however to define its legal status. This question is still today a matter of debate and intrinsically linked to notion and understanding of the subsidiarity principle in the European Union. The status of what should become a sustainable European HTA network has still not been resolved and lays at the heart of the latest developments in European HTA cooperation. It is clear that in the first decade of European cooperation, the question had not been resolved by the HTA arena itself. We will see in the next chapter that the positioning of HTA cooperation within a wider EU framework will affect this issue.

Finally, *evaluation* processes in the early collaboration initiatives remain mostly informal. Evaluation, which needs to be understood in its broader sense, has taken place on multiple levels, in multiple fora, by multiple actors and in multiple ways, including administrative output-focused and as endogenous learning processes. Here again, we have seen that the assessment processes have been determined by the governance structure put in place since EUR-ASSESS where the non-hierarchical governance structure led to a shared accountability. The latter remains however relative since, here again, the project partners were operating with the financial support of the European Commission which has assessed the projects according to its own (administrative) instruments focusing on effectiveness and efficiency.

In case of unsatisfactory outcomes, the Commission would have had the potential power to terminate the financial support for the projects.

The next chapter will focus on an interlude period running from 2001-2006 where no HTA cooperation project has taken place. However, important developments taking place in three different EU health policy streams have been of major importance for the developments of HTA cooperation after 2006 as they laid the basis for the institutional framework, governance modes and content of the collaboration efforts.

5 | Policy streams structuring European HTA cooperation

"To advance on several fronts at once did not necessarily mean doing so at the same speed.
What mattered was that movement should be general, for only by deeds would Europe take shape."
Jean Monnet, Memoirs

5.0.   INTRODUCTION

The end of the ECHTA/ECAHI project in 2001, coincided with a number of events taking place in the EU at the turn of the millennium and affecting European polities, policies and politics. Some of these events were related to broader political and institutional develop-ments within the EU, but which did have an impact on European health policy-making and indirectly also on European cooperation in HTA. In the period running from 1999-2008, we can identify three main policy streams that have had a direct or indirect impact on HTA cooperation. Whilst HTA cooperation in Europe has been most influenced by developments within the *EU (public) health policy stream*, it has certainly also undergone important influ-ences from two other policy streams which we will call here: the *EU social policy stream* and the *EU pharmaceutical policy stream*. The former with regard to the governance instruments used in HTA cooperation and the latter with regard to the content developed in the European HTA networks.

Each of these policy streams will develop within a different institutional structure: EU public health in DG Sanco; social policy within DG Social affairs and Employment and Pharmaceuti-cal policy within DG Enterprise and Industry. A common feature of these policy streams is the presence of (high-level) expert groups or networks set up by the European Commission and which have an important influence on the policies being developed in each of these streams. This chapter will highlight how HTA cooperation in Europe is concerned by the three different policy streams cited above and how these policy streams will cross-each other at some points through these networks permitting to structure the future European HTA cooperation.

The first policy stream can be situated at the level of *EU (public) health policy* and runs pri-marily within DG Sanco. It has been triggered however outside this institution as complaints filed by two citizens living in Luxembourg have set in motion a process seeking to clarify and (re-)define the role of the European Union in health policy-making. Ceased on the issue of cross-border health care, the cases[76] which have been dealt with by the Court of Justice of the European Union[77] (CJEU) as of 1998, have brought to the fore the complexity of the EU health policy field, which embodies not just aspects of public health and health care but also relates to social, industrial, economic and financial Member States' and EU policies. Each

---

76   Case C-158/96 Kohll v Caisses de Maladie [1998] ECR I-1931 ; Case C-120/95 Nicolas Decker v Caisse de Maladie des employés privés [1998] ECR-I 1831. See further cases listed under footnote 7.

77   Before 2009 it was often referred to as the European Court of Justice (ECJ) but since the entry into force of the Lisbon Treaty the official denomination is Court of Justice of the European Union (CJEU). In this dissertation we will always use the latter even though some cases to which we refer have been judged before 2009.

of these policy fields respond to a different attribution of decision-making competences between the Member States and the EU. Hence, depending on the qualification of a health issue under debate, different levels of decision-making apply (see chapter 2).

The approach the CJEU will adopt in cases related to cross-border health care - qualifying the provision of health care as a 'service' falling under Internal Market rules - has triggered a reflection process which went beyond the issue of patient-mobility and also included HTA. In the first section of this chapter, we will examine how this process has laid down the basis of the future EU HTA network. We will highlight here the role of expert groups in the definition and development of EU health policy and HTA. We will examine in particular the High Level Process of Reflection on Patient Mobility and healthcare developments and the High Level Group on Health Services and Medical Care. The formal and informal processes having taken place in these expert networks have played an important role to bring several aspects of EU health care further on the European governmental agenda (Princen 2011). Eventually they have contributed to the adoption of a new legislative act in EU health care, comprising an article on HTA cooperation. Finally, it is important to understand that these processes took place alongside the preparation and implementation of the Public health programme, which permitted to secure funding for HTA cooperation in Europe.

The second section of this chapter will focus on the *EU social policy stream* and will examine how developments within EU social and employment policies have had repercussions on governance modes introduced in EU health policy and subsequently in the set up and governance of the future HTA networks. We will highlight in this section how 'ensuring high quality and sustainable health care' was part of the 'concerted strategy for modernizing social protection' launched in 1999. This explains how health policy was concerned by EU social policies and justifies the implication of DG Employment and Social Affairs in this policy area. In this section too, attention will be given to the importance of networks and expert groups to promote new governance instruments (OMC) first at a sectorial level (employment policy and social policy) and later at the general EU-level by means of the Lisbon strategy and White Paper on Governance. These New Modes of Governance also had an important influence on the amendments of the public health article in the Lisbon treaty. Moreover, it is also within expert networks, dedicated to social protection policies, that developments within this *social policy stream* will encounter those of the *EU health policy stream*. HTA cooperation in Europe will benefit from this juncture as it will build upon the political support, governance and financial instruments offered by the different institutional structures representing these two policy streams (i.e. DG Employment and Social affairs (and its successors); DG Sanco (and its successors).

The third section will outline important developments in the *pharmaceutical policy stream* which will play an important role with regard to the content of the HTA network and the synergies that will develop with regulatory (pricing and reimbursement) policies. In the European governance architecture, pharmaceutical policy, although closely related to (public) health policy, is predominantly being dealt with, by DG Enterprise and Industry. Whilst the EU's implication in pharmaceuticals stems from a public health scandal in the sixties, emphasis in this policy stream lays in the competitiveness of the pharmaceutical industry and its impact on growth and jobs in Europe. Pharmaceuticals are considered as products falling under the Internal Market regulations. The respective regulatory frameworks adopted, should be considered in this perspective. An important distinction between EU pharmaceutical policy-making and EU social and (public) health policy-making is related to competences divisions between the Member States and the EU, having an impact on the governance instruments used in the policy fields. Although a clear common regulatory framework exists regarding the market authorisation of pharmaceuticals in Europe, pricing and reimbursement policies still remain under the exclusive competences of the Member States. Consequently, two different agendas have been developed by the EU regarding both aspects of pharmaceutical policy: Market authorisation on the one hand, and Pricing and Reimbursement on the other. In the pharmaceutical policy stream, the role of (high-level) expert groups and networks have also played a preponderate role and eventually permit to create a rapprochement between the two agendas. In this regard, special attention will be given to the G10 Medicines group and the Pharmaceutical Forum. These networks, which encompass representatives of DG Sanco and DG Enterprise and Industry, will structure an important aspect of the content of the future HTA network (e.g. relative effectiveness). HTA will play a pivotal role in creating synergies between both aspects of pharmaceutical policy, reinforcing herewith the role of HTA in EU health policy as well as in EU pharmaceutical policy.

By giving an outline of the three policy streams underpinning and structuring the development of European cooperation in HTA, this chapter aims to demonstrate how the latter should not be considered on a stand-alone basis but has to be related to wider developments regarding politics, policies and polities in the EU. The future networks on European HTA cooperation result from the 'synergies' between the *politics* of experts and stakeholders gathered in expert groups, shaping *policies* in the field of health, social affairs and pharmaceuticals within a given *polity* (DG Sanco, DG Social affairs and employment, DG Enterprise and Industry). The bridges between the different policy streams and their related politics and polities are created by some networks as illustrated below. This figure also includes EU research policy which is of interest as it gives financial support to programmes seeking to develop HTA cooperation in specific areas such as hospital-based HTA or complex areas-HTA. These programs are important as they permit new (EUnetHTA-related) initiatives in HTA cooperation to develop. However, our research has not identified any influence of the EU

research policy stream on the governance practices of HTA cooperation. Therefore, this policy field will be mentioned only in relation to the programs it is financially supporting.
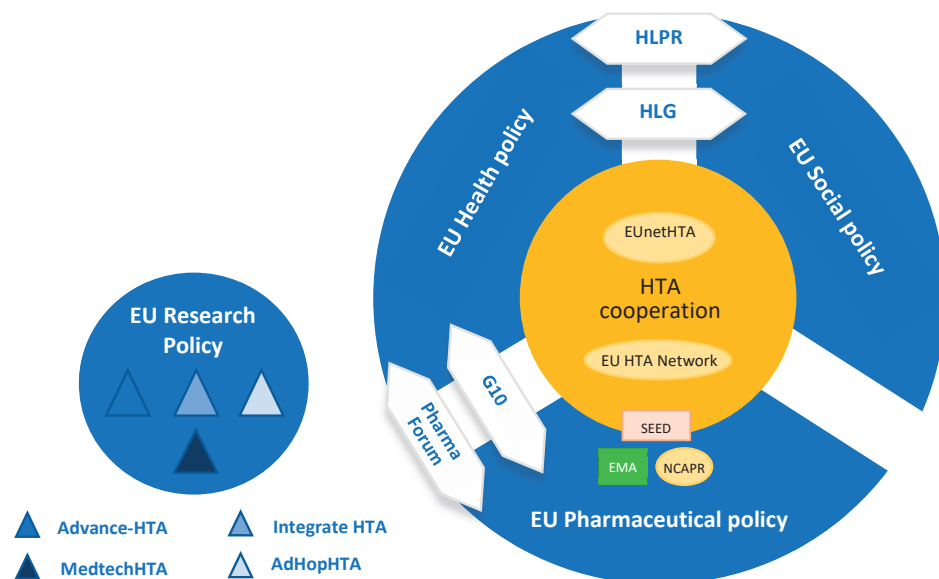
Figure 5.1. Relations between networks and policy streams in EU HTA-related policy-making processes

5.1. THE EU HEALTH POLICY STREAM: PROVIDING THE INSTITUTIONAL FRAMEWORK FOR HTA COOPERATION

5.1.1. Defining the place of HTA cooperation in the EU health strategy

At first sight, the end of the ECHTA/ECAHI project in 2001 seemed to mark a pause in European HTA cooperation initiatives. Indeed, if the previous projects followed each other up without delay, five years passed since ECHTA/ECAHI before a new project has been launched seeking to consolidate HTA cooperation in Europe[78]. On the HTA agency level, the situation was thus rather calm as no financial support was present to pursue substantial network initiatives[79]. On the EU level on the contrary, the turn of the millennium marked the beginning of a new era in health policy with the launch of the health programs which would structure the future activities of the Commission in the field. HTA cooperation in Europe will benefit

---

78   Another project had been introduced on behalf of the DIMDI in Germany in the early 2000s. This project did not receive backing of other HTA agencies and has never been implemented due to a lack of funding and support from other HTA agencies (Personal interview 4, 10 and 22).

79   On the international level however, cooperation efforts within networks such as HTAi, and INAHTA, continued and comprised many partners of the early European HTA cooperation projects.

from these developments since it has been integrated in these programs and was considered by the European Commission, since the early 1990s, as a field bearing the potential to impact health systems in general (see chapter 4).

As such, already in 1998, a Commission communication about the future health program, mentioned health technology assessment as one of the areas which should be covered by the next health program. This communication was being drafted on the basis of input by experts solicited by the Commission to give their ideas and develop concepts in their various fields of expertise. It seems that the report "*Health Technology Assessment in Europe: the Challenge of Coordination (1999)*, written on request of the European Commission, has served this purpose. This report has been drafted by the former coordinators of the HTA-Europe project and reflected in many aspects the key findings of the projects EUR-ASSESS and HTA Europe. Exchange of best practices and coordination of work would be supported by the Commission to pool expertise present in the individual Member States and "gather and exchange information, stimulate international studies and improve the dissemination of findings" (European Commission 1998a:13).

In 2000, the European Commission presents its first proposal of a new public health programme to the European Parliament and the Council which need to approve the program before it can be adopted. This program is structured along three activity strands and includes HTA in the first objective: "To improve information and knowledge for the development of public health and the strengthening and maintenance of effective health interventions and efficient health systems". In this document, the Commission refers to the developments taking place in the sphere of medical technologies which can contribute to improved health status but which will also impact health care budgets. It points to the fact that the "issue of affordability and justification of new techniques and products thus inevitably arises", and so far only few new health technologies have been assessed as to their cost-effectiveness. (European Commission 2000: 7).

Under the heading 'Key Characteristics of the Public Health Framework' the Commission underscores that "Technological developments in the health field will be a focus for action in the new programme. The Commission intends to strengthen health technology assessment structures and mechanisms by supporting collaboration between the agencies involved in order to refine methodologies, promote joint working and help disseminate the results of studies effectively. New technologies will also be used to collect and disseminate validated information" (European Commission 2000: 12). A few paragraphs further, the Commission stresses that it will build upon the informal networks which it had already previously supported but that these "networks will be complemented by new ones in the priority areas identified, such as (…) health technology assessment (…)" (European Commission 2000:

14). Finally, in the first public health program that will be adopted by the Council and the European Parliament in 2002, only one sentence will refer explicitly to HTA[80], but this line will open the way to further actions as we will see below.

As outlined in chapter 4, the development of a public health program was part of an internal Commission process that took place since the insertion of a public health article in the Maastricht Treaty (1992) and which aimed at developing EU's public health competencies as conferred by the Treaties. However, health policy was also being affected by a much bigger process taking place within the European Union: the development of the Internal Market. Within this process, some events will impact the EU health policy – and subsequently HTA cooperation in Europe – in a much more profound way than what could have been achieved solely by the health programs.

In 1998, the *Kohll* and *Decker* cases[81] that took place before the Court of Justice of the European Union (CJEU), marked indeed a turning point in the development of EU health policies. These cases - that according to some result of a so-called 'spill-over process' in European health policy (Greer 2006) - have set in motion a process that has permitted more than a decade later the adoption of the Directive 2011/24/EU on Cross-Border Health Care (OJEU 2011) and which has led to the establishment of a legal basis for HTA cooperation in Europe. Beside a call for legal certainty on reimbursement issues, the *Kohll* and *Decker* cases - which dealt with the purchase of medical assistance in another EU Member State - launched a debate regarding the place of health policy in the wider EU integration process. Indeed, in these and similar subsequent cases[82] the CJEU reasoned from a single market perspective aiming to remove all unjustified restrictions to the free movement of goods, workers, services

---

80   In the section Annex: actions and support measures it is stated under the heading "to improve health information and knowledge for the development of public health by" (…) "review, analyzing and supporting the exchange of experiences on, health technologies including new information technologies." (OJEC of 9.10.2002, L.271 p. 10.)

81   Case C-158/96 Kohll v Caisses de Maladie [1998] ECR I-1931 ; Case C-120/95 Nicolas Decker v Caisse de maladie des employés privés [1998] ECR-I 1831

82   Case C-158/96 Kohll v Caisses de Maladie [1998] ECR I-1931 ; Case C-120/95 Nicolas Decker v Caisse de Maladie des employés privés [1998] ECR-I 1831 ; Case C-368/98 Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC) [2001] ECR I-5363; Case C-157/99 B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen [2001] ECR I-5473; Case C-56/01 Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine [2003] ECR I-12403; Case C-372/04 The Queen on the application of Yvonne Watts v Bedford Primary Care Trust [2006] ECR I-4325; Case C-466/04. Manuel Acereda Herrera v. Servido Cántabro de Salud [2006] ECR I-5341; Case C-512/08 European Commission v French Republic [2010] ECR I-1297.
See for a detailed account: e.g. Sauter 2008; Palm and Glinos 2010.

and capital (Articles 34, 45, 56 and 63 TFEU.). According to the Court, medical treatment received in another Member State is considered as a service in the meaning of Article 57 TFEU[83]. Hence, although health policy fell under the exclusive competences of the Member States, CJEU rulings could indeed affect this policy area, as EU law enjoys 'supremacy' over national law[84].

To many EU health ministries' representatives, health policy should however remain outside the Internal Market process and the question was thus how to organise the health systems within the EU integration process while fully respecting the legal provisions (personal interview 4). To address this issue, a working group had been created in the High Level Committee on Health[85] with the explicit mandate to collect information on the impact of Community provisions on health systems as well as on cross-border health care and service arrangements. Moreover, it had to identify the nature and degree of problems arising and consider options for Community and national actions to resolve them (European Commission 2001a).

Two days after the Laeken Council in December 2001, the Committee on Health published its report on the issue. The report asserts that "[h]ealth systems comprise many components all of which form sub-markets which are subject to Treaty provisions governing the free movement of goods and services" (European Commission 2001a: 6). Hence, the authors of the report follow the reasoning of the CJEU by stating that the "delivery of health care, do not lie outside the jurisdiction of Community law" (European Commission 2001a: 3). However, the report also recalls the particular status of health which is "not a typical market" and is not "easily subject to the competitive model". The development of a "proactive and broader health policy" is considered a priority for the immediate future in order to avoid that Community measures "which will impact on health will continue to be largely influenced and dominated by economic considerations and factors and not by health policy interests" (European Commission 2001a: 22). To stimulate such a proactive approach, the Committee proposes to launch a debate at the domestic and EU level in order to generate discussions, reflections and exchange of views and information.

---

83   This has been asserted for the first time in the Luisi and Carbone case in 1984 and reiterated in Spuc v Grogan in 1991. (Joined Cases C-286/82 and C-26/83 83 *Graziana Luisi and Guiseppe Carbone v Ministera del Tesoro* [1984] ECR 377; Case C-159/90 *Society for the protection of unborn children Ireland Ltd v Stephen Grogan* [1991] ECR 1-4685).

84   This principle, which is not as such enshrined in the Treaties but results from CJEU rulings, means that it takes 'precedence over all forms of national law' (Chalmers, Davies and Monti 2010: 203).

85   The High Level Committee on Health is an advisory body which consists of high level officials from the Member States and provides strategic advice on public health issues (European Commission 2001a).

A few months later, in February 2002, the Spanish presidency organised an informal meeting of health ministers in Malaga where the issue of cross-border health care played a central role in the debate[86]. During this meeting, the findings of the High Level Committee were discussed and permitted the topic of 'patient mobility' to appear as a formal agenda point at the next Council meeting which took place in June 2002 in Luxembourg. The conclusions of the Health Council of 2002 state that the Council "recognises that other developments, such as those relating to the single market, have an impact on health systems". Concerned by the fact that these should interfere with common principles of solidarity, equity and universality, it considered "that there is added value in examining certain health issues from a perspective that goes beyond national borders. In this context it welcomes the debate at the seminar of health ministers held in Malaga in February 2002 which set out a number of priority issues for further cooperation and takes note of the expert discussions on this subject" (Council 2002). Although the priority issues discussed in Malaga did not comprise HTA[87] they will permit to launch a wider debate on EU health policy and which will concern HTA cooperation in Europe (personal interview 3).

The conclusions of this Council mainly seem to reassert the traditional position of the Member States with regard to cross-border health care. However, by the fact that they comprised the Council's mandate to the Commission to pursue a 'High Level Process of Reflection', they did play a crucial role in terms of agenda-setting. By stating that the issue would be re-discussed during the next meeting of the Health Council, patient mobility became more steadily present on the 'EU governmental agenda' opening herewith a pathway to formal HTA cooperation in Europe (Council 2002).

5.1.2. The role of networks in developing the future institutional framework of HTA cooperation

5.1.2.1. HTA taken up in the High Level Process of Reflection on Patient Mobility and Healthcare

Following the mandate given by the Health Council, DG SANCO launched the requested 'High Level Process of Reflection on Patient Mobility and Healthcare Developments in the European Union' (HLPR) which started its work in February 2003. The process was attended

---

86   The importance given to the issue by Spain may be explained by the fact that it felt directly concerned by the issue since many foreign pensioners resided on its coastline.

87   The issues discussed in Malaga were based on the findings of the High Level Committee and concerned cross-border health care, exchange of information and data, implementation of the Open Method of Coordination in health, European centers of reference, Reference framework on quality Standards, e-health (European Commission 2001a: 23-26).

by many stakeholders such as the ministers from all EU Member States, members of the European Parliament as well as representatives of health care associations[88]. Although resulting from judgements of the Court of Justice of the European Union and the need for legal certainty regarding patient's right in cross-border health care, this process will serve as a 'hub' for other health policy related matters. Indeed, the high level process of reflection did not only focus its debates on patient mobility but included in the process other health care related issues such as HTA (European Commission 2003a:3). The experts were asked to conclude their work by the end of 2003, which they did. In the conclusions of the process, the Commission stresses the importance of cooperation "to promote opportunities for access to health care (…) while maintaining the financial sustainability of the healthcare systems" and points to the fact that this will be even more important in the light of the enlargement process (European Commission 2003b: 2). It is precisely under the theme of "European cooperation to enable better use of resources" that the topic of HTA has been dealt with[89]. Underscoring the benefits HTA could offer policy-makers and the "present fragmentation of HTA across the Union", the experts invite the Commission to consider how a sustainable network of HTA could be organised and funded (European Commission 2003b:6).

It seems that the discussion taking place within the HLPR and the other working groups within DG Sanco did have a mutually influence on the developments within those fora. Following the adoption of the new public health program in November 2002, the Commission developed its 2003 Health Work Plan. We have seen above that Health Technology Assessment was only mentioned in one sentence of the public health program, stating the need "to review, analysing and supporting the exchange of experiences on health technologies including new information technologies." (OJEC 2002: 10), However, this offered the European Commission the opportunity to develop further actions pursuing that aim. Hence, under the heading *2.1.5 Promoting best practice and effectiveness*, the Work Plan mentions that strengthening "the capacity to assess and evaluate health strategies and interventions" is the general goal in this field. The paragraph specifies that this should be focused on specific priority areas such as "health technologies, including pharmaceuticals". The key actions listed, resume the findings and conclusions of the early cooperation initiatives and reports written on the subject (e.g. European Commission 1998:60-61[90]), and which were

---

88   International Mutual Association (AIM), the Standing Committee of the Hospitals of the EU (HOPE), the European Health Management Association (EHMA), the European Patients Forum (EPF), the European Social Insurance Partners (ESIP), the Standing Committee of European Doctors (CPME) (European Commission 2003a:3).

89   The other topics falling under this heading were: 'rights and duties of patients', 'sharing capacity and trans-national care'; 'European centres of reference' (European Commission 2003b).

90   Report written by former project coordinators of the HTA-Europe project entitled Health Technology Assessment in Europe: The challenge of coordination (European Commission 1999).

already included in the draft proposals of the public health program as we have seen above. As such, they mention the need for development of tools and methodologies, common approaches and definitions. Action in this field aims, among others, the development of a mechanism permitting closer HTA cooperation between Member States and various stakeholders, strengthening the collection of information as well as its dissemination; the development of methods to evaluate quality and efficiency of health promotion strategies and the development of common approaches and consensus methodologies (OJEU 2003).

In April 2004, the European Commission publishes the conclusions of the High Level Process of Reflection. This communication forms part of a wider strategy including a separate communication on extending the 'open method of coordination' to healthcare and long-term care (which will be discussed in the next section). A specific section of the communication is dedicated to health technology assessment. The document starts by giving a clear definition of what HTA comprises basing itself on the reports of the early HTA cooperation initiatives. The core of the section underscores how cooperation in this field is important and can build on "projects already supported under the public health programmes to harmonise methodology for assessments and to explore the role of health technology assessment in the future systems of health care in the Member States". Moreover, it informs that the "Commission plans to establish a coordinating mechanism to link together the different projects, organisations and agencies which already exist and to pool results and information in a usable and effective way, and will bring forward separate specific proposals, including for a study. According to the Commission these initiatives will help to ensure that health systems can use their limited resources in the most effective and efficient way (European Commission 2004f: 29).

The embedment of HTA within a wider understanding of the aims of EU public health can also be found in a July 2004 Communication of the EU Health Commissioner David Byrne building upon the conclusions of the HLRP. In this document, the importance of developing cooperation in the field of Health Technology Assessment is again underscored (European Commission 2004d: 11). Establishing synergies there where possible to enhance the effectiveness and efficiency of health care systems across Europe is presented as essential to achieve good health in Europe. This aim is furthermore connected with a broader EU objective: achieving economic growth and sustainable development. This document reflects how attention for health matters within the EU institutions is being promoted through the scope of economic competitiveness. It underscores how the so-called disease burden has an impact on long-term health expenditures and other social costs (sick-leave, lower productivity etc.). Hence, promoting good health and "better spending" on health can serve both individual well-being and EU competitiveness (European Commission 2004d:11).

Support for HTA cooperation should be read in this light. Indeed, the Commissioner underscores how scientific and technological progress permits the development of new expensive drugs, which need to be assessed properly. This, however, should not undermine the competitiveness of the pharmaceutical industry which is considered as a major driver of innovation in health care and an important employer in the EU (European Commission 2004d:11). Finally, the communication stresses how "joint health technology assessment" permits to share capacities and save money to national and regional authorities who can learn together and share best practise (European Commission 2004d: 18). To take forward the recommendations of the HLPR, the Commission establishes a High Level Group on health services and medical care which needs to reflect at the practical implementation of European Cooperation on health services including HTA (European Commission 2004b: 3-4).

5.1.2.2. HTA as priority topic in the High Level Group on health services and medical care

The High Level Group on health services and medical care - set up upon the recommendations of the high level reflection process – meets for the first time on July 1st 2004. Health Technology Assessment has been included as one of the six priority topics[91] of the HLG which is expected to deliver a first report to the EPSCO Council[92] at the end of the year. It was agreed during the first meeting that working methods of the HLG would be informal and collegial and would meet at least three times a year. The working groups should also involve relevant stakeholders and organisations in the field of consultation and expert advice. In June 2004, INAHTA[93] had offered it services in this sense, underscoring the contribution of the (European) members of the network to three previous projects supported by EU funding (EUR-ASSESS, HTA Europe, ECHTA/ECAHI) aiming the setup of an HTA network (correspondence INATHA, June 2004). Almost simultaneously, the former Executive Committee of the ECHTA/ECAHI project also draws the attention to the Commission that "an active an efficient network already exists", acknowledging however a low level of activities due to a lack of finances. They offer an active collaboration between the network and the Commission in establishing a reconstituted network that will meet the goals of the commission and Member States (correspondence ECHTA/ECAHI, June 2004). In July 2004, the Commission confirms to INAHTA that HTA has been chosen as a priority topic in the High Level Group and that it

---

91 The six priority areas of the High Level Group were: Cross-border healthcare purchasing and provision (including rights and duties of patients); Health professionals, Centres of reference, Health Technology Assessment, Information and e-health (including data protection), Health impact assessment and health systems (European Commission 2004c).

92 EPSCO Council stands for: Council of Employment, Social Policy, Health and Consumer Protection.

93 INAHTA: International Network of Agencies for Health Technology Assessment (INAHTA)

will make use of the expertise of INAHTA members (European Commission 2004g; European Commission 2004e)[94].

The working group on Health Technology Assessment will meet only twice. Sixteen Member States participated in the working group which was mostly composed of so-called small EU Member States, most of them having, at that time, little or no experience in HTA. However, the group also counted some 'heavy-weights' in HTA having played an important role in the early European cooperation initiatives (EUR-ASSESS, HTA Europe and ECHTA/ECHAI) such as Sweden, Denmark, the Netherlands, the United Kingdom and Germany[95]. Moreover, the strong ties that existed between some representatives and international organisations, such as INAHTA, have played a role in the drafting process of the report of the working group as well as the subsequent developments based on that report[96] (Personal interview 7).

During the September 2004 meeting of the HTA working group, the discussion was held on the basis of a working paper which had been circulated by the Finish chair of the working group. The paper itself had been drafted by a few experts in the field of HTA which had been active in the early HTA cooperation initiatives and in INAHTA (Personal Interview 7 and 22). This document elaborated on ideas for establishing a network on health technology assessment at the European level. The Health Program of the European Commission was considered as an option to finance the collaboration. The advantages of cooperation are underscored and the meeting closes with the agreement that the Chair would circulate a summary proposal for comments before the next HLG meeting held a month later.

The October meeting of the HLG-working group on HTA in 2004 concluded with a pilot project proposal on European HTA networking. The aim was to make progress within the following six areas: developing methods for common core information packages; transferability of health technology assessments; reporting structures on common core information on HTA; quality management procedures for producing HTA; developing tools for identifying needs and priority-setting in HTA; developing tool for tailoring common core information to

---

94   These INAHTA members had also been involved personally or institutionally in the early European cooperation projects and were eager to carry on follow-up initiatives (Personal interviews 4, 7, 10). The un-coordinated exchange of letters of ECHTA/ECHAI representatives on the one side and of INATHTA representatives on the other, seems to point to the positioning of different persons seeking to take the lead in the future HTA cooperation projects.

95   The Member States participating in the Working group on HTA were: Belgium, Denmark, Germany, Estonia, Ireland, Cyprus, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Slovenia, Slovakia, Sweden, United kingdom.

96   The Danish representative in the HLG-Working Group on HTA was at the time of the discussions also the Chairman of INAHTA at that time (https://www.ispor.org/Home/GetPersonBio/5307).

inform health policy within Member States (European Commission 2004e: 3-4). These topics show strong similarities with the areas identified in EUR-ASSESS and ECHTA/ECHAI. Indeed, one of the authors of the paper confirmed that the reflection was predominantly theoretical about which items of the previous experiences should be maintained and what should be "made de novo" (personal interview 4).

The working group of the HLG underscores how European networking on HTA did not intent to "displace national bodies for health technology assessment" but sought to "maximise synergies and avoid duplication between them as well as providing a base of expertise which could be used by Member States to develop their own internal capacities and policies" (European Commission 2004h:4). Within the working group, a large consensus was found on the proposed pilot project which should only be slightly adapted to be integrated in the HLG report at the next Health Council so as to underscore the added-value of European cooperation on health technology assessment (European Commission 2004e: 4).

The report from the High Level Group to the EPSCO Council in December 2004 can be considered as a political milestone in the development of European cooperation in the field of HTA. It outlines the current state of HTA in Europe in a context of costly innovations in health technologies needing to ensure a high level of patient safety, protect public health and develop an optimal use of resources. The HLG underscores how "against this background HTA has become a *political priority* and there is an *urgent need* for establishing a sustainable European network on HTA" (European Commission 2004f:12, emphasis added). Creating a sustainable HTA network was thus already then regarded as necessary. However, considering the Member States' competences and control over the health systems, some also acknowledged the challenge it encompassed: "*I remember that my counterpart who was around in this process (…) said, wow, it is going to be very difficult to see any kind of legal basis for any kind of something that could become a permanent sustainable mechanism*" (personal interview 4).

The HLG report outlines the key tasks of this European HTA network which should address "methods for developing common core packages; methods to support transferability of assessments, methods for helping Member States to identify and prioritise topics and commissioning reports, quality management procedures for the management of common core information or joint assessments, tailoring common core information to national health policy processes; tools for establishing new agencies, tools for sharing methodologies, expertise and practical issues". Moreover, it refers to the public health program who could support the network initially (European Commission 2004f: 2). The HLG stresses the importance of collaboration with international organisations such as INAHTA, HTAi, Euroscan, WHO, OECD, the Council of Europe and other organisations involved in HTA. It also underscores

the value of including patient organisations in this process and carefully consider the role of the industry.

In this document, the set-up of the network is conceived in two phases. The first 3-year phase would concern the launch of the network with funding from the Public Health Program. During the second phase "a financially sustainable solution for running the network should be considered by the Commission and the Member States" (European Commission 2004f: 13). The report concludes on this topic by launching a formal appeal to the European Commission "to support a pilot project to set up a European HTA Network under an appropriate financing mechanism such as EU Public Health Program" (European Commission 2004f: 13).

Although the other working groups of the HLG on health services and medical care continue to meet on a regular basis till 2006, no meetings have taken place after November 2004 by the group working on health technology assessment within the formal framework of the HLG. However, in the meantime substantial progress has been made outside the framework of the HLG as Professor Finn B. Kristensen, a Danish representative in the HLG and at that time chairman of INAHTA, gathered in February 2005 a taskforce in Copenhagen to work on a project proposal to be submitted to the new EC health program. Having to meet the deadline in April of the same year, things moved quickly. Members of the previous European HTA cooperation projects and INAHTA members have been contacted to work on a project proposal aiming to set up an HTA network (personal interview 7; correspondence Danish health institute). Finn Kristensen also sought and received support from the Health Evidence Network of the World Health Organisation (WHO) then directed by Alicia Granados one of the founding members of EUR-ASSESS (Personal interviews 6, 7)[97].

The dynamics in Copenhagen were positive and received backing of the Danish Health Institute. For Finn Kristensen, developing the project by focusing on the health policy processes was key: "HTA is only relevant if it has the decision-maker in its head" (personal interview 7). He was also the person behind the acronym for the new network: *EUnetHTA* which received the support of the taskforce allowing to submit the project to the health program. In the minutes of the HLG meeting of June 2006, an update is given on the progress of the work on HTA. The minutes mention that Prof. Kristensen has taken the lead of the European network for Health Technology Assessment (EUnetHTA project). It furthermore specifies that this project has been "set up on the basis of recommendations of the High Level Group from

---

97   Some European health policy experts refer to a sort of unspoken competition in the early 2000s between the WHO and the European Commission seeking to position itself in health care (Interview 5, 6,7). This could partly explain the request for moral support to the WHO for the European HTA Network.

2004". Member States are invited to join the project through an advisory group structure (European Commission 2006). Chapter 6 will outline the developments of the EUnetHTA network. In the next sections we will examine how other developments in the field of EU Health policy have played a role in shaping the content and governance modes of HTA cooperation in Europe.

5.1.3. The Cross-Border Health Care Directive: setting a legislative basis for sustainable HTA cooperation in Europe

The 'EUnetHTA project' launched in 2006 and which emanated from the HLG on health services and medical care, will be the first of a second generation of HTA cooperation projects which will lay down the basis for a formal EU HTA Network established in 2013. Indeed, as we will develop in more detail in the next chapter, the first project has been followed up by the EUnetHTA collaboration in 2009 and three subsequent EUnetHTA 'Joint Actions' implemented between 2010-2020. Important progress has been made throughout the different Joint Actions which each built further on the work established in the previous projects. As such, in the course of the years, despite important disparities that existed in the national HTA procedural frameworks and methodologies, substantial progress has been made in the development of common methodological guidelines, HTA Core Models, Joint HTAs, adaptation toolkits, capacity-building, information management and evidence generation (see chapter 6). A formal governance structure has also been set up in which stakeholder participation gradually increased in importance.

The biggest challenge faced in these programs was to move from the experimental phase of developing and testing new tools and processes to the "routinisation" of those where joint work[98] and re-use of work in national HTAs would become a norm and an integral part of regular HTA production processes (EUnetHTA 2015: 2). Indeed, the different methodologies, tools and pilot projects developed during the first decade of EUnetHTA's activities, did not permit to really reduce the duplication of work since many agencies continued to follow their own agenda in parallel to the one defined and agreed upon in EUnetHTA-network (European Commission 2016a). Finally, EUnetHTA has differentiated itself from the early HTA cooperation projects by integrating relative effectiveness assessments in its activities (see section below) as well as by developing new projects seeking to establish synergies between regulatory processes and HTA (e.g. SEED). The latter have gradually gained weight in the overall process (see chapter 6).

---

98 *Joint work* refers besides the development of common methodologies, tools and joint health technology assessments also to literature reviews, structured information for rapid or full HTAs, Early Dialogues or scientific advice on R&D planning and study design (European Commission 2016a: 4).

Hence, since 2006 and the decision of the HLG on health services and medical care to establish the first EUnetHTA project, the collaboration efforts have focused on the development of a framework for joint HTA production, ensure the uptake of the joint work in national activities, seeking synergies with European and national regulators and finding a way to guarantee the sustainability of the cooperation. These 'second-generation' collaboration projects were all co-financed by contributions from the Commission and Member States and still project-based. This temporarily financial and administrative governance structure emphasized the need to find a manner permitting to establish a more sustainable cooperation framework from both an organisational and financial point of view. So, more than two decades after the first EUR-ASSES project, it seemed that the cooperation efforts had hit a 'glass roof' since the biggest challenge remained the same: establishing a *sustainable structure* for EU HTA cooperation permitting the uptake of joint assessments and reduce the duplication of HTAs on a national level.

The establishment of a sustainable form of European HTA cooperation addresses inevitably the question of competences in this area. HTA is a domain which falls under Member States competences and based on the Treaties, any EU involvement related to HTA shall fully respect the national responsibilities in the organisation and delivering of health services and medical care (subsidiarity principle). The Article 168 (TFEU) does however confer to the Commission the right to lend support to cooperation initiatives. This support should not aim at harmonising national laws or regulations of the Member States in this area. Hence, the Commission's competences remain rather limited and restricted to soft-governance support and coordination means. It is however exactly on this basis that the Commission has been able to move forward in the field of cross-border health care and in particular in the field of patient mobility, which has become a hub for the development of EU HTA cooperation as will be outlined in the next sections.

5.1.3.1. A call for a legal framework on patient-mobility

In 1998, two 'patient mobility cases' dealt with by the Court of Justice of the European Union (CJEU), had triggered an EU-wide discussion on health care and medical services in various high-level expert groups gathering national governmental representatives and chaired by the European Commission. In the previous sections, we have examined how HTA had become one of the priority areas in these expert groups allowing the topic to move up on the European governmental agenda (Princen 2011). However, to fully understand how HTA cooperation has been developed, it is important at this stage to relate the discussions regarding HTA in the high-level expert groups, within the wider context of patient mobility and health care developments in the EU since the turn of the Millennium.

Indeed, during the timespan of meetings held by the HLPR and the HLG, many other patient-mobility related cases had been dealt with by the Court of Justice of the European Union (CJEU)[99]. The dominant issue in these cases was related to the reimbursement of cross-border health care costs. The latter was for decades regulated by EU social security regulations (e.g. Regulations 1408/71, Regulation 883/2004). However, the CJEU legislation – adopting an Internal Market approach - had created since 1998 a parallel route to reimbursement. Hence, the need to have legal certainty about cross-border health care costs became urgent and had been the trigger to put the issue on the EU governmental agenda.

The first legislative attempt to create 'legal certainty' on cross-border health care issues (e.g. reimbursement) was ceased surprisingly not by a Commission's directorate responsible for social security or health issues, but by DG MARKT (responsible for Internal Market policies). The latter published in 2004 -one month *before* the publication of the conclusions of the HLG on Health services and medical care - its first proposal for a 'Services in the Internal Market Directive' (2006/123/EC) also called 'the Bolkenstein Directive'. This Directive proposal, aiming to develop an Internal Market of Services, included in its Article 23 on the 'assumption of health costs' a provision on patent mobility (European Commission 2004j). The first proposal became a highly-contested document for reasons that lay well outside the scope of our research. Nevertheless, the fact that a health care related issue was included in a *Services* Directive, contributed to the fierce opposition that was set in motion subsequently to its publication (Sauter 2008:33). Moreover, it was also feared that the proposed article would not permit to create the required legal certainty in patient mobility. The debate triggered by the Services Directive proposal led to the request of the European Council and the European Parliament to revise the proposal (Council 2005:7, European Parliament 2005:5). The latter became a new player in the field of patient-mobility and introduced in 2004 a motion for a European Parliament resolution on patient mobility and health care developments in the European Union (European Parliament 2005).

In this motion, the European Parliament referred to the "special nature of health care" and emphasized that "health care services constitute a service for people in need and cannot, therefore, be compared with goods offered for sale". Hence, a "separate Commission proposal" would be needed and health care services should not be included in the general Services Directive (European Parliament: 2005:5). Moreover, the Parliament urged the Commission "to develop urgently a coherent policy on patient mobility in the light of the judgements of the Court of Justice of the European Communities and the Report of the High Level Reflection Process on Patient Mobility and Healthcare Developments" (European Parliament 2005: 5). Eventually, after extensive debates on the issue in the Council, the

---

99   See footnote 71.

European Parliament and within the different DGs of the European Commission, it has been decided in April 2006 to withdraw the Article 23 from the scope of the Services Directive (European Commission 2006a).

5.3.1.2. Adopting the Cross-Border Health Care Directive

Building upon the momentum created by the debates around patient mobility in the framework of the Services Directive, and following the call of the European Parliament, the Commission launches in September 2006, a "public consultation on how to ensure legal certainty regarding cross-border health services under Community law, and to support cooperation between the health systems of the Member States" (European Commission 2006b). Although the main objective of this process regards the application of Treaty provisions on free movement to health services, the process also focuses on "a range of specific areas where the economies of scale of coordinated action between all Member States could bring added value to national health systems". These areas had been identified in the HLPR and the HLG on health services and medical care and comprised HTA (European Commission 2006b). Public consultations are a common measure in the working methods of the Commission. They are strongly inspired by the White Paper on governance as they aim at giving the Commission an insight in stakeholders' position regarding areas where it could bring an added value[100]. They usually prepare the ground for the drafting of future (legislative) proposals. These public consultations are often accompanied by specific assessments, measuring possible impacts for the measures foreseen (interview 9). It also permits other EU institutions (e.g. European Parliament) to publicly communicate on the issue as has been the case here[101].

Based on the outcomes of the public consultation and of the conclusions of the HLG on health services and medical care, the Commission submitted in 2008 a proposal for a Directive on Cross-border health care (European Commission 2008a)[102]. The main objective of the

---

100 The final report summarising the outcome of the public consultation refers to the participation of a "wide range of stakeholders". Indeed 280 responses were given on behalf of participants representing Member States, regional authorities, national and international (health care) organisations, commercial organisations and companies, academia and 'ordinary' citizens (European Commission 2008c).

101 During the consultation period, the Commission received increasing support from the European Parliament which adopted several Resolutions with regard to cross-border health care. (European Parliament 2007a, 2007b).

102 This proposal was part of the renewed social agenda for the 21st century presented by the Commission and which included a wider range of actions targeting a variety of issues such as Roma exclusion or discrimination matters (European Commission 2008b). It was accompanied by the publication of the results of an Impact Assessment which had been made on the topic and in which almost all DGs had participated (European Commission 2008c).

Directive was to create legal certainty in the field of reimbursement of cross-border health care. For DG Sanco, the proposal on cross-border health care presented however a 'golden opportunity' to submit, upon the request of the Member States and the European Parliament, a legislative act in relation to health care which would also touch upon the improvement of health systems. The latter was, as we have seen in the previous chapter, the focus point of the Commission since the insertion of the public health article in the Maastricht Treaty (1992) (personal interview 3). Hence, whilst the main objective of the Directive concerned patient-mobility issues, the opportunity was ceased to insert other items which would improve health systems. HTA cooperation was one of those (Personal interview 3).

Although in the final version of the Directive 2011/24/EU on *the application of patients' rights in cross-border healthcare*, most of the initial Commission's proposals had been "watered down", the new legislative text adopted in 2011 did cover in its chapter IV so-called 'flanking measures' regarding areas laying outside reimbursement issues of patient mobility and which were of particular importance to DG Sanco: mutual assistance and cooperation, recognition of prescriptions issued in another Member State (Article 11), establishment of European Reference Networks (Article 12), rare diseases (Article 13), e-health (Article 14) and HTA cooperation (Article 15). Indeed, in each of these fields, progress was made continuously but still on a project-based (network) level, co-financed by the European Commission. In the area of HTA, one can mention in this regard the establishment of the 'EUnetHTA network' which was making substantial progress (see chapter 6) but which was still struggling to create a sustainable framework to ensure the continuity of the actions implemented.

From the Commission's (DG Sanco) point of view, a legislative basis was necessary to develop on a lasting basis the work initiated in the areas covered by the flanking measures and which permitted the Commission to be active on the level of the health systems. Till then, cooperation in these fields could take place only on a temporarily basis by means of programs (e.g. public health programs, research programs). However, as underscored by a DG Sanco official, sustainable EU cooperation requires a proper governance structure which cannot be established without a legal basis. Having these areas included in the Directive would offer the possibility to establish sustainable cooperation structures and, in a sense, institutionalise the work initiated and carried out so far on a program-basis (Personal interview 3). Establishing a sustainable framework for HTA-cooperation was thus one of the objectives pursued by these flanking measures in the Directive 2011/24/EU.

As the 'ordinary legislative procedure' applied in this case, the Council and European Parliament had to approve the proposal and could propose amendments to the texts. At the core of the discussions laid the sensitive issue of reimbursement of cross-border medical care and the proposed text triggered some important disagreements between the Council, the

Commission and the European Parliament. After almost three years of debates and after having gone through the whole procedure (including two readings in each institution and the necessity to organise a conciliation measure in the form of a 'trilogue'), an agreement has been found and the final text has been adopted in February 2011[103].

Due to the attention given to the core-content of the proposal (reimbursement matters), institutional debates on the 'flanking measures' hardly took place. Indeed, a careful analysis of the reports of the ENVI committee of the European Parliament and the formal debates in the Parliament and the Council, indicates that little attention has been given to these measures and in particular to HTA cooperation[104] (e.g. European Parliament 2009; 2011). Indeed, during the negotiations on the Cross-border Health Care Directive, the representatives of the Member States wanted to ensure that the legislative act would not become a financial burden on their health systems. Issues related to safety and quality of care (related also to the recent EU enlargement) were also frequently debated but mostly as mean to be able to counter the application of the provisions foreseen in the proposal (see further on this issue e.g. Palm and Glinos 2010; Palm and Baeten 2011; Wismar et al. 2011).

The financial impact of the Directive on the MS's health systems laid thus at the core of the debates and this is even more interesting as several studies and Impact Assessment had actually demonstrated that the impact of cross-border health care on the financial systems of the Member States was very limited (less than 1% of public health care expenditure (European Commission 2008c; Wismar et al. 2007; 2011)[105] and even considered by some as a 'non-issue'. This position was also shared by representatives of DG Sanco who valued the debate around patient-mobility mostly because it served the (higher) aim to improve the

---

103 Although the Directive 2011/24/EU is based on the CJEU decisions regarding patient-mobility, it is being debated whether it has brought any legal certainty as the existing Regulations on the matter continue to be applicable and include substantial differences with regard to patient's rights on reimbursement of cross-border health care (see further e.g.; Jelfs and Baeten 2012; Baeten 2012: EHMA 2011).

104 In its first reading of the proposal, the European Parliament does indicate that regarding the cooperation on management of health technologies "the European Commission (rather than Member States) shall, in consultation with the European Parliament, facilitate the establishment of a network connecting the national authorities or bodies responsible for health technology assessment" (European Parliament 2009: 2008/0142(COD)).

105 Other studies have pointed to around 0.1%-0.2% of total health care expenditure during the late 1980s and 1990s, (Hermesse et al. 1997; Palm et al. 2000). It is argued however that these figures may be underestimated as they do not include so-called waiver agreements, or out of pocket patient expenditures (Bertinato et al. 2005). Nevertheless, a 2003 survey by European Commission did not find higher numbers (Bertinato et al.:2005) (see further European Commission 2014:38-41).

health systems in the EU. Indeed, the Directive would offer the possibility to create a legal basis permitting the Commission to act in the areas where it sought it could make a difference. Hence, by the fact that the Member States focused their attention on reimbursement issues and considered the 'flanking measures' as (complex) "niche areas" (of lesser importance?), the latter did not become the subject of controversial debates. However according to some observers, with time, "since the patient mobility issue is not really a particularly large problem, it may turn out that the flanking measures will be more important in the long run" (personal interview 3).

5.1.3.3. Paving the way for the establishment of the EU Health Technology Assessment Network

The insertion of an article on HTA cooperation in the Cross-Border Health Care Directive should be examined by keeping in mind the progress made on HTA cooperation in the different EUnetHTA projects and the Joint Action that have been implemented during the negotiation and adoption phase of the legal act (see chapter 6).These have indeed played an essential role in establishing the content of the Article 15 of the Directive 2011/24/EU which offers the legal powers to the Commission to setup and manage a "voluntary Network of national authorities or bodies responsible for HTA", permitting it herewith to institutionalise HTA cooperation in Europe.

Indeed, the Article 15, outlines in the first paragraph that "the Union shall support and facilitate cooperation and the exchange of scientific information among Member States". The network shall be based on "the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations". The second section outlines the objectives of the network which are in line with the previous projects and Joint Actions: "(a) support cooperation between national authorities or bodies; (b) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies; (c) support the analysis of the nature and type of information that can be exchanged; (d) avoid duplication of assessments. The third paragraph specifies that EU aid may be granted to fulfil the objectives, the fifth and sixth section specifies how aid may be granted.

The fourth paragraph is of particular interest, since it specifies that the Commission can "adopt the necessary measures for the establishment, management and transparent functioning of this network". This however has to be done in full respect of the Member States' competences "in deciding on the implementation of health technology assessment conclusions and shall not harmonise any laws or regulations of the Member States and shall fully

respect the responsibilities of the Member States for the organisation and delivery of health services and medical care" (Article 15 (7)).

The developments on the HTA arena level and those on the EU health policy level thus mutually reinforced each other: the establishment and activities of the EUnetHTA network has permitted the European Commission to propose the adoption of a legislative framework to secure this cooperation. Conversely, the article on HTA cooperation inserted in the new Directive on cross-border health care has certainly contributed to secure the future cooperation within the form of Joint Actions. In chapter 6 we will examine how this has taken place and how the Cross-Border Health Care Directive has served as a basis for the establishment of a new policy-orientated EU HTA network and paved the way for a new proposal for an Regulation on European HTA cooperation.

We have seen in this section, how HTA cooperation has been impacted by 'external' developments in the *EU health policy stream*. The Member States' request for more legal certainty on the question of patient mobility has been ceased by the European Commission as an opportunity to push forward other important areas of EU health policy among which HTA. First by inserting these areas as priority areas of the different expert groups on health (HLPR and HLG). The conclusions of these expert groups have been integrated in the 'flanking measures of the Cross-Border Health Care Directive which in the end has offered a legal basis to the Commission to pursue its work in areas which can have a direct impact on the health systems. HTA cooperation has been one of these. Before outlining in more detail these developments in the chapter 6, we will examine two other policy streams which have impacted HTA cooperation in Europe.

5.2.   THE SOCIAL POLICY STREAM: PROVIDING SOFT GOVERNANCE INSTRUMENTS FOR HTA COOPERATION

The Prodi Commission, which took office in 1999, sought to reinvigorate the European integration process with the launch of the Lisbon agenda seeking to make Europe "the most competitive and dynamic knowledge-based economy in the world" (www.europarl. europa.eu/summits/lis1_en.htm#a). To support this aim, new governance practices have formally been introduced based on soft governance instruments such as the Open Method of Coordination, discussed in chapter 2. These so-called New Modes of Governance (NMG) were based on experiences made in the European Employment Strategy carried out by DG Employment and Social affairs. To understand how soft governance instruments have helped structuring HTA cooperation in Europe it is important to highlight in this section, the relations

between social policy and health policy on the one hand and social policy and employment policy on the other.

5.2.1. OMC entering the EU social policy agenda

Social affairs and Employment have been governed within a single DG since 1986. They have however become more strongly related policy fields since the Delors' *White Paper on Growth, Competitiveness and Employment* published in 1993 (European Commission 1993). Indeed, in the early nineties, Europe was facing a recession and the Commission was of the opinion that a combination of macro-economic and structural policies was needed to pull the European Community out of this situation. The underlying idea was also that reducing unemployment would reinforce many social objectives defined by the European Commission (European Commission 1994:17; Régent 2002:2-3).

With the Amsterdam Treaty (1997), social policy becomes more firmly enshrined in the Treaties and falls under the so-called *shared competences* between the EU and the Member States. As such, social affairs became to play a different role within EU policymaking. Moreover, the Amsterdam Treaty offered also a legislative basis permitting to develop a European Employment Strategy (EES) based on newly established 'coordination strategies'. This EES will be officially launched together with the Open Method of Coordination (Luxembourg process) during the Santer Commission at the extraordinary Job Summit, taking place on 22-23 November 1997 in Luxembourg[106]. This strategy will be continued by the Prodi Commission which takes office in September 1999. In 2000, full employment becomes even one of the overarching objectives of the Lisbon strategy and the OMC will be presented as an appropriate tool to implement these. The *White Paper on governance* (European Commission 2001), published a year later, will further outline how these soft governance means fit in the overall governance architecture of the EU (see chapter 2).

Since the insertion of the public health article in the Maastricht treaty (1992) till 1999, EU public health policy was governed by the 'public health unit' hosted in the DG V responsible for Employment and Social Affairs and having launched the EES. Although separate policy fields, the fact that both health and social policy were run till 1999 in the same Directorate General did create some ties between both policy areas. With the establishment of the new DG Sanco under the Prodi Commission in September 1999, health policy could be governed separately from social policies to which it was often associated. However, just before the creation of a separate DG for public health policy, important developments took place in the field of social protection and which will have an impact on health care policy.

---

106   The EES has been reviewed in 2002 and relaunched in 2005 when economic guidelines have been integrated in the Broad Economic Policy Guidelines (European Parliament 2017).

In the period between the resignation of the Santer Commission (15 march 1999) and the entering into office of the Prodi Commission followed by the creation of DG Sanco (1 September 1999), the Commission (read here DG Employment and Social Affairs) launches its 'concerted strategy for modernising social protection'. This strategy comprised the aim "to ensure high quality and sustainable health care", (European Commission 1999b: 3). The strategy "aims at deepening the co-operation between the Member States and the European Union, based on exchange of experience, policy discussion and monitoring of ongoing political developments in order to identify best practice" (European Commission 1999b: 12). This new approach also answered a call of the European Parliament in March 1999, for a "process of voluntary alignment of objectives and policies in the area of social protection, modelled on the European employment strategy" (European Commission 1999b: 12).

The concerted strategy should be considered within the wider process of the integrated socio-economic strategy of the Lisbon agenda which comprised the streamlining of economic and employment coordination strategies. Economic policy coordination was carried out through the so-called Broad Economic Policy Guidelines (BEPGs), multilateral surveillance and the Stability and Growth Pact. Employment policy coordination was organised in the framework of the European Employment Strategy (EES) implemented through National Action Plans. The overall aim of the coordination strategies was to provide full employment, quality at work, the promotion of social cohesion and inclusion (European Commission 2003).

EU protection policy aiming to contribute to the promotion of social cohesion and inclusion was built on three pillars: social inclusion, pensions and health and long-term care. In line with the Lisbon agenda, promoting these policies was closely connected to the Lisbon strategy, the BEPG and the EES. The social protection policy (including health and long-term health) fell under the responsibility of the same DG responsible for the EES. Moreover, to bring forward work in the field of social inclusion and pensions, the OMC had been identified by the Lisbon European Council as an appropriated mechanism. Health and long-term care were considered by the Commission as key-issues for the development of Europe's social model as they related to social and economic policies in particular and represented almost a third of all social expenditure in the EU (European Commission 2005:30). This explains why health and long-term health care were included in the Commission's social policies and remain so even after the establishment of a dedicated Public Health Directorate. It furthermore clarifies how New Modes of Governance, such as the OMC, were taken into consideration for the implementation of health-related policy objectives within the wider social protection policy implemented by DG Employment and Social Affairs. It is thus through social policies - which themselves are linked to employment policies - that soft governance mechanisms have been considered for health-related policies. The ties that existed between the two policy areas

before 1999 will still resonate in the early days of DG Sanco and have an indirect impact on the governance instruments used in HTA cooperation.

5.2.2. OMC in health care and long-term care policies

Although envisaged in the early 2000s, the OMC has first been introduced in social protection policies outside health care and long-term care. Based on an invitation of the Brussels European Council (2003) to create a coherent framework on social protection within the OMC, the Commission did however commit itself to streamline the disparate actions linked to social inclusion and pension and "in time cooperation in relation to healthcare and "making work pay" into a single Open Method of Coordination" (European Commission 2003). Recognising the benefits of the OMC for health and long-term care policies in the EU, the Commission (DG Employment and Social affairs) refrains at first however from bringing this method into practice in this policy field, as it awaits the conclusions of discussions taking place in other processes such as the high level process on patient mobility and health care developments and the Intergovernmental Conference (IGC) preparing the Constitutional Treaty[107]. These discussions partly sought to clarify the place and nature of health care policy within the wider political, institutional and legislative frameworks of the EU as outlined in the previous section.

The excerpt below, taken from the 2003 Commission communication on streamlining the OMC in the field of social protection, clearly highlights the different challenges faced by the EU regarding health policy, as this policy field is highly connected to other policy areas such as social protection (social security and long-term health), economic policies (sustainability health systems), public health and patient mobility (safety and quality of health care) and Internal Market (pharmaceutical industry). The Commission therefore distinguishes three areas within health policy: issues related to health and long-term health care, issues relating to public health and the advancement of better treatments and issues related to the application of Internal Market principles. The same distinction will underpin the reflections regarding the application of OMC in health policy.

Questions regarding health and long-term care have not yet been considered in detail within cooperation in social protection. Healthcare issues are relevant for the development of Europe's social model and its social, economic and employment policies in particular.

---

107 The project of the 'Treaty establishing a Constitution for Europe' had been published in 2004 (OJEU 2004/C 310/01. 16 December 2004). The project has been abandoned as such, following the negative outcomes of the Dutch and French Referenda on this subject.

Health systems and health policies across the EU are also becoming more interconnected than in the past, which raise many health policy issues with a clear European dimension. Nevertheless, as recognised in the Joint Report on Health and Long-term Care to the Spring 2003 European Council, there are very specific circumstances and complexities attaching to policy cooperation in this area. A number of joint challenges facing the Member States in the area of health and healthcare are currently being assessed in the high level process on patient mobility and healthcare developments in the EU.

The European Convention is also looking at how to better define the EU's role and responsibility in this area. In particular, it will be necessary to specify which methods are the most appropriate to deal with social protection issues related to health and long-term care (ensuring access for all based on need and regardless of resources and ensuring that health and long-term care needs do not cause poverty to patients and their relatives), issues relating to public health and the advancement of better medical treatments and, finally, issues relating to the application of Internal Market principles in the area of healthcare (patient mobility, free provision of services).

In the light of the conclusions of these processes and depending on the subsequent decisions on health taken by the IGC, the Commission will examine the modalities of enhancing policy coordination in this field in the context of a streamlined social protection process. (European Commission 2003: 8)

In 2004, the Council decides to extend the OMC to areas of health and long-term health and the process described above is put in to practice. Hence, from then on, Member States will submit each year National Preliminary Policy Statements which will be used by the Commission to propose common objectives. A "Joint report on social protection and social inclusion" will be issued addressing the key challenges of the fields in which the OMC is being implemented: poverty and exclusion, healthcare and long-term care and pensions. The reports are based on a quantitative analysis of the economic and demographic contexts and developments in the Member States as well as the social situation in the EU and the role and effectiveness of social policy. Strategies put into place to address each of the three challenges are being outlined and progress made in these fields evaluated. A country profile of each Member States constitutes the final part of the (first) reports.

In April 2004, following the conclusions of the HLPR, the Commission will adopt simultaneously two interconnected communications. These two documents present "the overall strategy for developing a shared vision for the European health care and social protection systems" and propose a global strategy for health care systems (European Commission 2004i: 2; 4). The first communication regards the follow-up of the work of the HLPR and the

second refers to use of OMC to support sustainable health care and long-term care polices (European Commission 2004a; European Commission 2004i).

The Communication focusing on the conclusions of the HLRP resumes the overall objectives to be pursued as a follow up to this process. This document is also of interest as it places HTA into the broader EU objective of achieving economic growth and sustainable development *and* to the competitiveness of the pharmaceutical sector (European Commission 2004a:11). It furthermore outlines how a coordinating mechanism can be established to support a sustainable network on HTA cooperation. OMC is being envisaged as a method to develop this initiative, as stated in the text below:

"The Commission plans to establish a coordinating mechanism to link together the different projects, organisations and agencies which already exist and to pool results and information in a usable and effective way, and will bring forward separate specific proposals, including for a study. *The cost-effectiveness of health technologies may also be the subject of specific objectives within the open method of coordination proposed for health and long-term care*. These initiatives will help to ensure that patients throughout Europe benefit from care reflecting the latest advances in medical technology, and also that health systems can ensure that they are using their limited resources in the most effective and efficient way". (European Commission 2004a:11; italics added).

The second communication on the implementation of the OMC in health care and long-term care highlights the importance of health in the European Social Model. It builds further upon the Resolution of the European Parliament a month before, calling for "greater cooperation on health and long-term health" and calling on the Commission to "present relevant proposals in the spring of 2004, allowing the Council to apply the "open method of coordination" in this field and adopt common objectives (European Commission 2004i: 2). No explicit reference to HTA as such is made in this document but implicitly this policy field is being taken into consideration as the text refers to the importance of "appropriate assessments of practices and treatments" and the evaluation of costs and benefits of drugs and how this should relate to national practices and the development of European cooperation (European Commission 2004i: 9).

This communication emphasizes that the added value of the OMC lays in the identification of challenges common to all Member States and can support reform in the organisation and funding of health care and elderly care. The actions it proposes for the future bear traits of the OMC including the use of indicators and country reports covering challenges of national health systems, medium-term policy objectives and statistical data. These reports would be assessed by the Commission and could be taken into account in the process of streamlin-

ing social security process discussed above. Each year the conclusions of these assessments would be published in a Joint report on social protection and social inclusion.

In 2006, the integrated Open Method of Coordination is introduced and comprises health care and long-term care. It will be even further consolidated in 2008 (European Commission 2008e). Hence, the Joint reports on social protection and inclusion comprise a section on health care and long-term care. However, although the policies evaluated in this regard do in a sense overlap with those treated by DG Sanco, they mostly relate directly to social protection and inclusion policies. As such, the country reports will be focused on issues such as reducing inequality in health care (e.g. reducing risk factors through health promotion, prevention activities, increase population coverage, address cultural barriers to use of health services). Long-term care is being addressed as a result of demographic ageing and socio-economic changes which increase life expectancy and the incidence of invalidity and dependency. This requires considering long-term care as a new social risk to be covered by social protection policies (European Commission 2008d: 116-117).

Hence, the core content regarding health care and long-term care of the joint reports between 2005 and 2010 will be based on a macro-analysis of the health systems in the EU by focusing in particular on the question of inequalities (access to health care, universal coverage, waiting times, lack of general practitioners etc); patient safety (patient-centred care) and sustainability and coordination. The latter however covers over the years mainly issues of staff shortages and the management of chronic diseases. Long-term care is being addressed focusing on the issue of finding the appropriate mix to finance it (private insurance, co-payments etc.) as well as by the shortage of personnel.

Two reports make however a direct reference to HTA. In these reports, one can observe a sort of coordination between key-messages and policies developed by DG Sanco and DG Employment and Social affairs. In its section on health care, the 2007 Joint Report on social protection and social inclusion makes references to the need to maintain a high-quality care across the health systems. It encourages health care professionals "to use centrally evaluated and accessible clinical guidelines based upon the best available evidence". It also underscores that "national health technology assessment agencies have been established and are cooperating at EU level (EUnet-HTA). They help to ensure that new interventions are effective, safe and cost effective" European Commission 2007a:11).

The 2010 report (which will be the last of the kind) gives a general overview of the health care and long-term care in the EU focusing again on the key areas cited above. In its section regarding the sustainability of health systems, the report underscores how "Technological development can increase expenditure by creating new treatment opportunities" and how

HTA (including a cost-effective and cost-utility analysis) is being considered as a mean "to decide if a certain care intervention or drug should be included in the publicly funded or reimbursed basket of care and to what extent, notably in comparison to other interventions or drugs" (European Commission 2010: 111). It finally mentions that "building on a number of previous actions and projects, the Commission and Member States are currently working on a joint initiative aimed at increasing cooperation, sharing information and developing the same core methods in the area of HTA" (European Commission 2010:111).

These two passages will be the only ones making a direct reference to HTA. One should notice however that this is mentioned in the overview on health policies in the reports and does not seem to be really integrated in country reports on health policies which lay at the basis of each report. From the above, we can conclude that the OMC has been applied to a certain extend to health policy issues within the framework of social protection and inclusion. This has permitted to establish an overview and comparison of Member States' policies in this field allowing for the development of some general objectives to be pursued by the EU as a whole. If, at times, reference is being made to the importance of HTA regarding the sustainability of the health systems, no 'explicit' OMC has been implemented in this area. A close analysis of the passages in the reports seem to rather indicate that this issue is moving upwards on the wider EU health policy agenda and that the importance of HTA is being more widely recognised within the European Commission.

5.2.3. OMC and the EU public health strategy: the role of networks

5.2.3.1. High-level expert networks disseminating the soft governance approach

From the above, we can observe that even before the publication of the White Paper on Governance (2001), soft governance instruments, of the type of OMC, were envisaged to promote EU health-policy objectives. This resulted from the connection between social policy and the employment policy on the one hand and the inclusion of health care objectives in social protection policies. Moreover, the fact that this has been developed at a time were public health policy was hosted by DG Employment and Social affairs, further explains the proximity and interrelationship that existed between the different policy fields. However, with the creation of a separate DG for Health, the implementation of OMC in health-related issues by DG employment and Social Affairs has gradually been limited to social protection and inclusion policies.

In this sense, it thus doesn't come as a surprise that the health care related objectives comprised in the 'concerted strategy for modernising social protection' published by DG Employment and Social Affairs showed many similarities with those of the (public) health

strategy, outlined in the first section of this chapter. The health strategy was, as we have seen, initially developed by the public health unit (hosted within the same DG Employment) and later pursued by DG Sanco. One of the 'common' objectives between the 'concerted strategy for modernizing social protection' and the public health strategy was HTA cooperation in Europe. Indeed, the 'concerted strategy' comprised, amongst others[108], the objective "to improve the efficiency and effectiveness of health systems", make an effective use of medical knowledge and technology; strengthening the co-operation between Member States on evaluation of policies and techniques; ensure access to high quality health services and reduce health inequalities as well as support long-term care of elderly people (European Commission 1999b: 14-15).

Hence, as an integral part of social policy, some health-related policies will continue to be promoted by the DG Employment and Social affairs even after the establishment of DG Health and Consumers (DG SANCO). The dual involvement in health care policy on behalf of the Commission is also reflected in its representation in the different high-level expert networks. Indeed, representatives of both DGs participated in the High Level Process of Reflection on Patient Mobility and Healthcare Developments in the EU, launched in 2002 and including HTA as a priority topic. We have seen in the sections above how this reflection process emanated initially in 1999 from patient-mobility cases at the CJEU which triggered discussions on the issue in the High Level Committee of Health. The latter created in April 1999 the working group on the Internal Market and Health with a mandate to explore information on the impact of Community policies on health care and cross-border health care and service arrangement. Hence, the work was initiated still under DG Employment and Social Affairs (before the establishment of DG Sanco) but the final report has been published in 2001 by DG Sanco (European Commission 2001a:4).

Both DGs will remain involved in the follow-up of this process which can thus be explained from a polity, policy and politics point of view. Indeed, during the time-span of the meetings of the working group on Internal Market and Health, a new institutional structure responsible for EU health policy has been created (i.e. DG Sanco). However, policy-wise, long-term health care and issues related to patient mobility and health care (e.g. social security systems, long-term care and elderly) still fell under the responsibility of the institutional structure responsible for social protection (i.e. DG Employment and Social Affairs). As explained by a senior representative of DG Sanco, in the early days of this new directorate, a sort of com-

---

108 The other objectives listed in the communication are related to the promotion of employability and the provision of a secure income; making pensions safe and pension systems sustainable and promoting social integration (European Commission 1999).

petition for health competences did exists between both institutional structures (personal interview 3).

Hence, the High Level Process of Reflection on Patient Mobility and healthcare developments has been launched upon the initiative of both Commissioners Byrne (DG Sanco) and Diamantopoulou (DG Employment and Social Affairs). This dual Commission representation in these expert networks also offered a dual contribution on behalf of the Commission. The participation of DG Employment and Social affairs in the working group on Internal Market and healthcare and in the HLPR had, amongst others, an impact on the governance methods proposed. As such, the conclusions of the report of the working group do, for example, recommend to "implement the method of "open co-ordination" for health (..) by defining targets and objectives on the European level, defining, quantifying and qualifying indicators and benchmarks, and monitoring, analysing and evaluating the achievements in the Member States" (European Commission 2001a: 25-26).

This recommendation will be further worked out in the HLPR. In the February 2003 meeting of the HLPR, Commissionner Diamantopoulou refers for example to the fact that, in social policy, no new European competences are needed but that the existing means (including the OMC) needed to be strengthened. After developing work to implement OMC in social exclusion and pensions, the Commissioner stated "that there was now an ongoing exercise concerning health and long-term care for the elderly" (European Commission 2003a: 2). Hence, the idea of extending OMC to health care will be carried on in the expert working groups and integrated in the conclusions of these. Several distinct Commission communications will be based on these HLPR conclusions which will also be further discussed in Council meetings. The two connected 2004 Commission communications setting the global health strategy (discussed above) can be cited as an example.

Through consistent discourse in different networks, reflections upon an OMC in health policy and related soft governance instruments were being brought to the fore mainly by representatives of DG Employment and Social Affairs. Eventually this will lead to the fact that these instruments are also being considered in health policy areas laying outside social protection policy and will, at times, also regard HTA cooperation. In July 2004, for example, the Commissioner David Byrne (DG Sanco) launches a reflection process to define the new EU health Strategy. In his communication on this issue, he relates HTA cooperation to several items linked to New Modes of Governance such as openness, civil participation, good governance as well as Member States "learning together and sharing best practices, sharing capacities and saving money on joint health technology assessment" (European Commission 2004d:11).

Another connection between OMC and HTA can be found in the report of the High Level Group on health services and Medical technologies, prepared in November 2004 for the 'Employment, Social Affairs, Health and Consumer Protection Council' taking place in December 2004. Referring to the recommendations of the HLRP (in the meantime re-named into 'patient mobility reflection process') regarding European cooperation to enable better use of resources and covering issues such as the evaluation of medical technologies, it is stated:

"The task for the High Level Group is to implement these recommendations by developing concrete action bringing benefit to patients and helping to improve the effectiveness and efficiency of the health systems across the Union while respecting national responsibilities for health systems. This should be undertaken in close cooperation with other bodies working on relevant issues at European level and ensuring a coherent approach with regard to other policy areas, *in particular with the open method of coordination* on healthcare and long-term care". (European Commission 2004f: 4, italics added).

Although never implemented as such, reference to the OMC will remain present in the HTA cooperation processes in Europe. In a 2007 communication of the HTA cooperation project "EUnetHTA" regarding the public consultation on the New Health Strategy, OMC is again being considered as an appropriated tool to strengthen HTA cooperation in Europe. Here too, the connection between HTA and OMC is made via social protection policies:

"During the current EUnetHTA project period (2006-8), the open method of coordination for healthcare and long-term care should be the legislative tool for the High Level Group on Health Services and Medical care to continue developing mechanisms for practical cooperation on HTA. (…) Concomitant to using the open method of coordination to develop the network further into a committed collaboration, legal certainty of such collaboration should be provided" (EUnetHTA 2007).

Reference to the implementation of the OMC to HTA cooperation has thus been made at several occasions and in several fora. However, in practice, deploying an OMC in health policy reflected essentially a willingness on behalf of the DG Employment and Social Affairs. The latter included long-term health care and elderly care in its social protection policies. As DG Employment and Social affairs seeks to streamline the application of OMC to its social protection policies, health care is often associated to OMC in a variety of communications emanating from this Directorate General. However, these issues were being dealt with separately from the DG Sanco, which most of the time was not involved in OMC related policy projects (Personal interview 3).

The implementation of an explicit OMC in health policy – and thus in HTA cooperation – has never been an official objective pursued by DG Sanco (for which it did not have a legislative basis conversely to DG Employment and Social Affairs). Nevertheless, if establishing the OMC as a formal working procedure was not an objective of DG Sanco, this did not mean that the governance instruments used to implement its health strategy - and therefore also HTA cooperation - were not quite similar to those applied in the OMC. Indeed, in the 2003 work plan of the first health programme, the 'Promotion of HTA cooperation' falls even under the heading "Promoting best practices and effectiveness".

5.2.3.2. Soft governance instruments underpinning the health article of the Lisbon treaty

The soft governance approach, initiated in DG Employment and Social affairs and later fully integrated in the Lisbon strategy, will ultimately have a profound impact on the legislative basis of the EU health policy. Indeed, the developments in the High Level Reflection Process and the High Level Group as well as the development of the health strategy, have to be analysed against the background of the Constitutional Treaty that was being prepared for ratification in 2005. Within DG Sanco, during the early 2000s, significant efforts were also made to introduce amendments to the public health article of the Constitutional Treaty. Due to the rejection of this Treaty proposal in 2005 by some Member States, it was only with the adoption of the Lisbon Treaty (2007) that a revised public health article (Article 168 TFEU) has been adopted. A close analysis of this article permits to acknowledge that most amendments actually refer to the introduction of soft governance principles which closely resembles the OMC without formally naming it.

Hence, although only adopted in 2007, these amendments were actually being discussed and developed almost simultaneously with the discussions going on in the different expert networks outlined in the previous section. Indeed, the call for a debate on the future of Europe had been launched at the Laeken European Council in December 2001 (simultane-ously with the publication of the report of the High Level Committee on health which has launched the different high level expert network discussions). This led to the establishment of a European Convention which would ultimately lead to a proposal for a 'European Constitu-tion' submitted in June 2004 and signed in October but rejected by the French and Dutch citizens in referenda held in May 2005. A close comparison of the proposed amendments of the public health article in the 'Treaty Establishing a Constitution for Europe' (OJEC 2004) with the public health article of the Lisbon Treaty adopted in 2007 shows however that both are almost identical.

It is in particular paragraph 2 of art 168 (TFEU) which is most concerned by these soft policy related amendments. Indeed, the paragraph recalls that the EU "shall in particular encourage

cooperation between the Member States to improve the complementarity of their health services in cross-border areas. (…) "in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation". Finally, a sentence has been added here in which the emphasis is put on cross-border cooperation in health services areas.

Paragraph 3 of Article 168 TFEU remains unchanged compared to Article 129 EC and foresees 'cooperation with third countries and the competent international organisations in the sphere of public health'. As with the fourth paragraph of the public health article, the Lisbon Treaty stipulates that the achievement of the article's objectives should be made in accordance with the ordinary legislative procedure in this regard. This procedure (previously called 'co-decision procedure') gives besides the Council, an important role to the European Parliament (EP) in the decision-making procedure. Indeed, as a co-legislator, the EP has a crucial role in the adoption of new legislative proposals in this area. As a result, the parliamentary committee responsible for Environment, Public health and Food safety affairs (ENVI[109]) will see its workload increase. We will see that this will play a role in the development of HTA cooperation in the future.

Article 168 TFEU furthermore stipulates that the Economic and Social Committee as well as the Committee of the Regions need to be consulted before any new legislation in this field. Adoption of new legislation should also meet common safety concerns regarding quality and safety standards of 'organs and substances of human origin, blood and blood derivatives', medicinal products and devices for medical use as well as measures in 'veterinary and phytosanitary fields which have as their direct objective the protection of public health'. These provisions were already present in the Maastricht Treaty.

Another innovation regarding health policy in the Lisbon Treaty is the fact that the European Parliament and the Council 'may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol'. However, it is explicitly stated that these

---

109 The ENVI committee is responsible for dealing with environment, food safety and public health issues at the European Parliament (http://www.europarl.europa.eu/committees/en).

measures exclude 'any harmonisation of the laws and regulations of the Member States' (Article 168 (5) TFEU)[110].

Finally, the provision in Article 11 TEU introduces new measures regarding the consultation of the civil society. It stipulates that '[t]he institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society'. Indeed, the article can also have a potential impact on future relationships between representative organisations active in the health policy areas. It is also in line with good governance principles outline in the White Paper on Governance (2001).

Although the powers of the EU in the field of health care are limited - making it even to be considered by some as a 'supranational *non-topic*' (Lamping 2005: 20) - the Treaties give space for manoeuvre to the EU institutions. According to a senior representative of DG Sanco, the reason why these soft policy measures had been included (without officially referring to OMC) was to enable the Commission to act on the basis of official legislation. Although the Lisbon Treaty still conferred only coordinative and support-lending powers to the Commission, it did offer a legal basis to extend the Commission's actions to new domains within health policy, by means of soft policy governance instruments. In a way, the Lisbon Treaty formalised the manner by which the Commission already worked for almost twenty years (Personal interview 3).

Although the amendments seem rather limited in conferring extra powers to the Commission it did permit the adoption of the Cross-Border Health Care Directive (2011/24/EU) which offered, as outlined in the previous section, for the first time a legal basis to act in HTA cooperation. It is indeed, on the basis of this Directive that the 'EU Health Technology Assessment Network' (EU HTA Network has been established in 2013, herewith institutionalising

---

110 Two other points of differentiation with the previous Treaties should be highlighted. The first is related to the Charter of Fundamental rights which becomes legally binding under the Lisbon Treaty. Different provisions in the Charter are indirectly related to health matters such as the right to human dignity (Article 1), the right to life (Article 2), the right to integration of persons with disabilities (Article 26), the right to the protection of personal data (Article 8). The latter can be of importance with regard to information that is collected by the medical professionals. The right to the freedom of conscious (article 10) can affect professionals in the medical field (EHMA 2009). The Charter also refers in its Article 34 to social security benefits and social services providing protection in case of illness. Finally, Article 35 can have a direct impact on health related matters since it refers to the right of 'access to preventive health care and the right to benefit from medical treatment under the conditions established by national law and practices'. Furthermore, it stipulates (once again) that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities' (OJEC 2000).

HTA cooperation in Europe. For a better understanding of the content that will be developed in the newly created HTA networks, the third part of this chapter will outline some developments in the pharmaceutical policy stream and which have impacted the course of action of those networks.

5.3. THE PHARMACEUTICAL POLICY STREAM: PROVIDING KEY CONTENT FOR HTA COOPERATION

Pharmaceuticals and HTA are often considered rather distinct policy areas which are also being dealt with separately in the EU institutions (HTA falls within the policy areas of DG Santé and pharmaceuticals within DG GROW). This distinction is indeed in many respects justified. However, as we shall outline in this section, developments in EU pharmaceutical policies are of prime importance for the HTA cooperation efforts, both in terms of content and of sustainability. To get a more profound insight on how this policy stream has at times crossed the one of HTA cooperation and had a profound impact on it, it is important to briefly recall some important milestones in the history of EU pharmaceutical policy.

5.3.1. Setting European standards in a common market of pharmaceuticals

The EU has been first confronted with the need to develop a specific policy regarding pharmaceuticals after the Thalidomide scandal in the early 1960s. This sedative drug developed in 1953 was considered to be safe (mostly because it made it very difficult to commit suicide with it) and became widely prescribed to treat a variety of medical conditions among which morning sickness of pregnant women. In 1962-63 however Thalidomide was found to be responsible of causing important malformations in unborn children (Dally 1998). This public health scandal resulted first in the establishment of national authorities to evaluate the safety of drugs (Jeffrey and Jones 1995). Soon these developments led to the adoption of the Directive 65/65/EEC on the "approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products". Hence, developed from a public health perspective, this Directive sought to lay down some definitions on medicinal products and establish guidelines regarding market approval and post-marketing monitoring of drugs based on safety, efficacy and therapeutic benefit criteria. Market access was still to be granted by competent national authorities (Permanand and Mossialos 2005).

Ten years later, two new Directives (75/318/EEC and 75/319/EEC) will address market access of pharmaceuticals through the principle of mutual recognition of national marketing authorisations procedures and with the creation of a central coordinating body: the Committee for Proprietary Medicinal Products (CPMP) (Jeffery and Jones 1995). These and the

following legislative documents were however not rooted in a public health perspective but rather responded to Internal Market concerns. Indeed, the main objective pursued here was to ensure a smooth access of pharmaceuticals on the EU market ruled by free movement principles. Introducing the concept of "Mutual recognition", the Directive 75/318/EEC created the possibility for a product having received a market authorisation in one Member State to seek marketing authorisation simultaneously in five or more Member States (till then a separate procedure had to be followed in each country separately). In practice, the implementation of these principles faced resistance from Member States who almost systematically objected and sought arbitration from the CPMP whose decisions were non-binding. The usual arguments brought forward by the Member States, regarded the fear for potential negative health effects. Hence, instead of speeding up the procedure, these two legislative instruments caused, in practice, substantial delays (Permanand and Mossialos 2005:51).

In 1983, the Directive 83/570/EEC sought to facilitate implementation of the mutual recognition concept with the introduction of the 'Multi State Procedure', reducing the threshold of recipient states from five to two. Although more applications were introduced, it didn't really alter the situation since the Member States still systematically objected market authorisations requests by this procedure[111]. Moreover, as the procedure was based on voluntary recognition, and as the CPMP could only issue non-binding opinions, the vast majority of products were submitted in one of the national routes for product licensing (Jeffrey and Jones: 1995:473; Permanand and Mossialos 2005:51).

The arrival of Jacques Delors at the head of the European Commission and his White Paper on the completion of the single market published in 1985, gave another impetus to develop a single medicines market on pharmaceuticals. Pharmaceuticals were given attention here in the light of the fight against illicit trade of drugs (European Commission 1985: 11). Following the adoption of the 1986 Single European Act aiming to complete the single market based on the principles of free movement of goods services and capital by 1992, a new Directive (87/22/EEC) had been adopted in 1987. This time, the so-called 'concertation procedure' was introduced for biotechnological and other high technology products. The procedure required that drug manufacturers submitted market authorisation applications simultaneously to the CPMP and a Member State (acting as rapporteur). After having taken into consideration possible objections of Members States, the CPMP could recommend an EU-license. Although

---

111 By the end of 1993, only one out of more than 300 products submitted in the Multi State Procedure had been authorised without reasoned objections. The CPMP had to give an opinion in more than two-thirds of cases of which about 86 % were in favour of licensing by 1992. There are however hardly any cases where identical product datasheets have been agreed across the Community (Jeffrey and Jones 1995: 474).

the procedure was mandatory for products of biotechnological origin, the CPMP arbitration was still not binding for other products and, in most cases, thus disregarded by the Member States (Jeffreys and Jones 1995: 473).

In the meantime, another issue invited itself on the Commission's agenda regarding the regulation of the pharmaceutical market. The pricing policies of pharmaceutical companies (closely linked to their market access strategies) raised concern in many countries. After a company had obtained the approval to market their drug, price and reimbursement negotiations would start with each Member State separately. As reimbursement policies can differ among the EU Member States, pricing policies are often adjusted accordingly and negotiated separately. The price differences that can result from these procedures have given rise among others, to so-called parallel trade where wholesalers purchase the product in another Member State at a lower price than the one negotiated in their home country. This situation led to the adoption of the Price Transparency Directive (89/105/EEC) which set out a number of criteria to create transparency in price settings and their inclusion in national health insurance systems[112]. This Directive, which is until today the sole EU legislative document regarding pricing of pharmaceuticals, did not aim any harmonisation of pricing or reimbursement of pharmaceuticals. Hence, price differences within the EU remains a fact (Chambers and Belcher: 1994; Permanand and Mossialos 2005). The Transparency Directive mostly serves to ensure that the national pricing and reimbursement procedures are fair, transparent and efficient. It is also an instrument permitting the Commission to verify whether Treaty obligations in terms of free movement and competition are being respected (Hancher 1992: 405).

The situation above resumes the challenges faced by the Commission more than 25 years ago and still present today in EU pharmaceutical policy: addressing the four-fold objective of ensuring safety, efficiency, equity and financial sustainability of both the health systems and the industry. Hence, developing a specific EU policy on pharmaceuticals requires to address health policy needs (safety and efficacy) as well as industrial needs (competitive advantage) and economic needs (employment, growth). Moreover, this policy field concerns multiple stakeholders ranging from those that produce the pharmaceuticals to those that prescribe, deliver, research, assess, reimburse and consume them.

---

112   The main criteria set out in the Transparency Directive and regarding individual pricing and reimbursement decisions concern the following: decisions must be taken within a given timeframe (90 or 180 days); the applicant receives the communication which includes a statement indicating the reasons based on objective and verifiable criteria; applicants can appeal the decision on a national level. Moreover, the Directive also concerns other issues such as labelling, packaging, patent protection, advertisement and sales promotion as well as wholesale distribution (Transparency Directive (89/105/EEC) - OJEC 1988)

As in all policies, trade-offs sooner or later have to be made. The difficulty in this particular policy area is that these choices confront public health/health care issues with (conflicting) economic/industrial interests and thus concern often ministries of health, finance and trade (Mossialos et al. 2010; Permanand and Mossialos 2005b). Hence, a government can seek to develop a health care policy based on costs containment and improved efficiency in health care services whilst pursuing both the regulation on safe and efficacious medicines. It moreover will also be responsible for the promotion of research and development and ensuring the competitiveness of the pharmaceutical industry (see further Permanand 2006).

This dichotomy and the difficulty to unite the different interests is also reflected in the internal organisation of the Commission where public health is being dealt with by one Directorate General (DG SANTE) and Industry and economic growth by another (DG GROW). Moreover, the allocation of HTA to DG SANTE (and its predecessors) and pharmaceuticals to DG GROW (and its predecessors) shows which element is dominating the EU perspective in the respective policy fields. The allocation to different Directorates has however an important impact on the policy development. Indeed, pharmaceutical policy considered from an industry perspective, falls into the scope of Internal Market polices which respond to the so-called shared competences between the Member States and the EU (Article 4 TFEU). The latter refers to the fact that Member States can legislate "to the extent that the Union has not legislated" (Chalmers Davies and Monti 2010: 208). Hence, the governance instruments available to the EU in the pharmaceutical policy differ from those in the health policy where it can mainly resort to soft governance instruments and can act only in the light of the subsidiarity principle.

Medicines are thus on the one hand considered as industrial good and their *market authorisation*, refers to policies responding to Internal Market principles. On the other hand, in *pricing and reimbursement procedures*, medicines are being considered in the light of the safety and efficacy and refer exclusively to national health care policies. This explains why Member States are very attached to setting their own pricing and reimbursement rates and are not inclined to pursue any harmonisation policies at the EU-level (Hancher 2010:637). In the next section, we will outline how the European Commission has developed a separate agenda for both aspects of pharmaceutical policy and how eventually some synergies have started to appear through HTA cooperation, reinforcing herewith the role of HTA in EU health policy and EU pharmaceutical policy. Moreover, this dual approach of considering medicines in the light of the Internal Market and in the light of national health care policies lays at the basis of a Regulation proposal on HTA cooperation made by the European Commission in 2018 (chapter 6).

5.3.2. Creating a European Agency for Pharmaceuticals

In 1992, in the light of the establishment of the single market, a legislative framework consisting of three Directives and one Regulation set-out the so-called "future system" on pharmaceutical policy (Directive 92/25/EEC: wholesale distribution; Directive 92/27/EEC: classification of pharmaceuticals; Directive 92/26/EEC on labelling and packaging; Directive 92/28/EEC on advertising; Regulation 1786/92 on patent protection[113]). A year later, two new pieces of EU legislation completing this framework, will have a profound impact on the pharmaceutical policy of the EU. The Directive 93/39/EEC and the Regulation 2309/93 announce the establishment of the European Medicines Evaluation Agency, which became the entry door to apply for a Market Authorisation of a product license.

The Article 53 of Regulation 2309/93, setting out the objectives of EMEA, resumes the dual policy objectives of protecting human health and promoting the completion of the Internal Market pursued by the European Commission. Indeed the article stipulates that: "In order to promote the protection of human and animal health and of consumers of medicinal products throughout the Community, and in order to promote the completion of the Internal Market through the adoption of uniform regulatory decisions based on scientific criteria concerning the placing on the market and use of medicinal products, the objectives of the Agency shall be to provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, the safety, and the efficacy of medicinal products for human or veterinary use, which is referred to it in accordance with the provisions of Community legislation relating to medicinal products".

The EMEA introduced two new procedures. The 'Centralised Authorisation Procedure,' applicable to biotechnology products and certain other innovative medicines. In this procedure, the EMEA appointed a rapporteur (usually a Member State) to assess the product and produced a report to be submitted to the new CPMP committee[114] having to provide an opinion on the product. A positive opinion was then communicated to Members States and if no objections would be raised it will be adopted by qualified majority in a Standing Committee (Jefferys and Jones: 1995). The 'Decentralised Procedure', was still based on mutual recognition of licenses, as a license granted in one Member State could be expanded to others on the basis of the same initial dossier submitted. These other Member State would have 90 days to recognise the first license. Objection could be raised only in cases of serious public health concerns, in which case a discussion would take place with the rapporteur and the countries concerned. In case of persistent disagreement, the case would be submitted to

---

113   OJEC 1992; 1992a; 1992b; 1992c; 1992d

114   The CPMP has been renamed in 2001 into Committee for Medicinal Products for Human Use (CHMP).

the CPMP which would issue a *binding opinion* which could be adopted by qualified majority in the Standing Committee.

Binding arbitration by the CMPM distinguishes this new procedure from the previous ones and will have a major impact on the role the EMEA will to play in the future. Moreover, after a transition period of three years, the procedure became compulsory. A manufacturer had to choose between the two routes: the centralised procedure or the national authorisation procedure (either via the mutual-recognition procedure or the decentralised procedure[115]). Finally, a new coordination system of pharmacovigilance was also implemented through the EMEA. Today, the above outlined authorisation processes are still in place and amendments have regarded mostly the extension of the centralised procedure to new medicines[116].

Although the authorisation through the national route via the mutual recognition procedure and the decentralised procedure still exist for medicines outside the scope of the centralised procedure, the vast majority of new innovative medicines receive market license through the centralised procedure (EMA 2016:5). Moreover, the name of the Agency has been changed in 2009 into European Agency for Medicines (EMA). Similarly, the CMPM had been renamed in 2004 into the CHMP[117], responsible for preparing the Agency's opinions on questions concerning human medicines and appoints, together with the Pharmacovigilance Risk Assessment Committee (PRAC), (co-)rapporteurs to conduct the scientific assessment. The PRAC and the Committee on Advance Therapies (CAT) provide input on aspects related respectively to risk management and to advanced therapy medicines. After the evaluation, the CHMP issues a scientific opinion on whether the medicine may be authorised or not. The legal decision to grant or not market authorisation lays within the hands of the European Commission which publishes its decisions in the Community Register of medicinal products

---

115 The Mutual Recognition Procedure applies where the medicinal product has already received a Market Authorisation in a Member State at the time of application. The Decentralised Procedure applies where the medicinal product has not received a Market Authorisation in a Member State at the time of application.

116 The centralised procedure is compulsory for human medicines containing a new active substance to treat: human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS); cancer; diabetes; neurodegenerative diseases; auto-immune and other immune dysfunctions; viral diseases; medicines derived from biotechnology processes, such as genetic engineering; advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; orphan medicines (medicines for rare diseases); veterinary medicines for use as growth or yield enhancers. It is optional for other medicines such as those containing new active substances for indications other than those stated above; that are a significant therapeutic, scientific or technical innovation; whose authorisation would be in the interest of public or animal health at EU level (EMA 2016:5).

117 CHMP stands for 'Committee for Medicinal Products for Human Use'

for human use. A European public assessment report (EPAR) is published by the EMA both in cases of approval or refusal of market authorisation (EMA 2016; www.europa.ema.eu).

As outlined before, the pharmaceutical policy of the European Commission was rooted in a single market perspective and predominantly influenced by concerns for the competitiveness of its pharmaceutical industry. Partly, this approach has resulted from the fact that pricing and reimbursement remain a national competence. Hence, full harmonisation of the 'medicines market' cannot be pursued and policies seeking the convergence of national practices need to circumvent the EU lack of competences in this area while respecting the subsidiarity principle. Regarding pharmaceuticals, the EU will follow the path of price deregulation through competition policies. However, this approach has also triggered fear of convergence at higher prices on behalf of patient and consumer groups. In some cases, economic concerns form a barrier at Member States' level, as some national governments fear that more competition will negatively affect some local pharmaceutical companies. Pricing and reimbursement policies can indeed be used as a mean to offer support to those companies (Permanand and Altenstetter 2004: 46).

Hence, although the European Commission has tried to develop its policies to support the industry in terms of productivity, competitivity and employment, it is often restricted in its 'maneuver space' in this regard. The Resolution 96/C 136/04 of the Council, adopted in 1996, is an example of how the Member States and the industry have carefully watched over the fact that pricing and reimbursement policies firmly remain a national competence as all references to price harmonisation, which were present in earlier drafts, do not appear anymore in the final draft (Permanand and Altenstetter 2004: 46). The final draft of the Resolution further stresses the need to work towards a European industrial policy for pharmaceuticals. It underscores once more the presence of intense international competition in this field and the new challenges to address, such as the "growing costs of pharmaceutical research and development" and "the emergence of new technologies". Therefore, it considers that "sufficient profitability is necessary if the European pharmaceutical industry is to cover the investment required to guarantee its capacity for innovation and thus ensure its competitiveness at international level ".

At this stage, we encounter another obstacle for the EU to pursue its policy in the field of pharmaceuticals. At the beginning of this section, we have outlined the Commission's dilemma to conciliate public health policy objectives (safety, efficacy and quality) with economic policy objectives (competitiveness, growth, employment). Having very limited competences in the public health field, it has concentrated its efforts in pharmaceutical policy on the accomplishment of a 'Internal Market of medicines'. Price deregulation and competition have traditionally constituted an integral part of the establishment of the EU's Internal Market.

However, in this particular policy area, pricing policies remain a national competence and are often considered as a tool to strengthen the local pharmaceutical industry. Moreover, pricing policies are intrinsically linked to reimbursement policies, which in turn are often directly or indirectly related to fiscal policies (depending on the social health insurance systems in the Member States[118]).

Besides the historical heritage having influenced the organisation and functioning of social health insurance systems, differences in national regulatory regimes are also due to different responses to factors such as health care budget constraints, drug consumption, life-style patterns and industry strategies (Permanand and Altenstetter 2004: 47). The latter further increase the differences between regulatory systems and make it thus even more difficult to establish convergence between policies. Hence, even by addressing pharmaceutical policy through the scope of the Internal Market, the European Commission is confronted to the application and interpretation of the subsidiarity principle, substantially restricting its margin of maneuver. Any efforts of convergence of policies faces Member States' and industry resistance, unwilling to give in regulatory control over pharmaceuticals. We will examine in chapter 6 how European cooperation in the field of HTA will trigger some regional initiatives to extend the cooperation into price negotiations.

5.3.3. The role of networks in content development of HTA cooperation

5.3.3.1. The G10 process on medicines
In 2000, the DG Enterprise requests a report on the competitive position of the European pharmaceutical companies and industries in particular with regard to the US. The report *Global Competitiveness in Pharmaceuticals: A European Perspective*, published in 2001 and commonly known as the 'Pammolli report', concludes that the European pharmaceutical industry is losing competitiveness as compared to the USA and that "Europe is lagging behind in its ability to generate, organise, and sustain innovation processes that are increasingly expensive and organisationally complex" (European Commission 2001c:4-5). Moreover, it stipulates that the "growth of the industry in Europe is likely to depend to a good extent on factors other than R&D, capital or labour" and points to the regulatory environment in this regard (such as licenses from international companies, pricing policies, or peculiarities of the public regulatory and health care systems or demand in individual European countries). Hence, according to the report "the competitiveness of the European pharmaceutical industry is negatively affected by the perstistence (*sic*) of insufficient degrees of competition and institutional integration, still centred on domestic and fragmented markets and research systems" (European commission 2001c: 8).

---

118   See further on Social Health Insurance Systems e.g. Saltman, Busse and Figueras: 2004.

The Pammolli report was published in 2001, simultaneously with the "Review of the Community Regime for market authorisation for pharmaceutical products" based on an audit on the functioning of the EMEA as foreseen by Article 71 of Regulation 2309/93. This process, which reviewed the pharmaceutical legislation, focused on four main objectives: guarantee a high level of public health protection for Europeans, further complete the Internal Market in pharmaceuticals and establish a regulatory framework favourable to the competitiveness of European pharmaceutical industry, meet the challenges of EU enlargement and rationalize and simplify the system to improve its global coherence, its visibility and the transparency of the procedures (European, Commission 2001c). The review process eventually led to the adoption of new legislative documents and the amendments of existing ones. We can mention here in particular the adoption of Directive 2001/83/EC (amended in 2004 by the Directive 2004/27/EC) on human medicines replacing and consolidating the legislative framework on pharmaceuticals, comprising all the aspects of wholesaling, classification, labelling packaging and advertising[119].

Although the Review process would have important consequences for the functioning and influence of the EMEA, the Pammolli report will indirectly also impact HTA cooperation in Europe. Indeed, as a response to the conclusions of the report on the competitiveness of the European pharmaceutical industry, a High Level Group on innovation and provision of medicines in the European Union has been established. The latter is also known as the 'G10 group on medicines'. The group was constituted of ten members (but with a double representation of the European Commission) representing the highest level from different administrations and (industrial) organisations[120]. The presence of Commissioner Liikanen of DG Enterprise and Information Society and Commissioner Byrne of DG Health and Consumer Protection, both heading the G10, testifies of the willingness to consider competitiveness issues in the light of public health and social objectives. Moreover, as stated in the preface, "the enclosed report bring (*sic*) to fruition a process which represents a real departure for industry and public health in the European Community". The G10 Medicines Group was convened as a practical measure, in line with the « Lisbon Method » of Open Co-ordination to bring together, under European Commission chairmanship, a variety of people who were asked

---

119 Directive 65/65/EEC, Directives 75/319/EEC and 75/318/EEC and their respective amendments; Directives on wholesaling (92/25/EEC), classification (92/26/EEC), labelling and packaging (92/27/EEC) and advertising (92/28/EEC).

120 The membership consisted of Health and Industry Ministers from five Member States (France, Germany, Portugal, Sweden, United Kingdom), representation from different sectors of the industry, mutual health funds and a specialist in patient issues. The Group was chaired jointly by the Commissioners for Directorate-General for Enterprise and Directorate-General for Health and Consumer Protection.

to identify possible solutions on which it has proved difficult in the past to gain agreement" (European Commission 2002a:3).

The group met three times between March 2001 and February 2002 and was organised in three working groups each focusing on one of the following agenda areas: Provision of Medicines to patients; Single Market, Competition and Regulation; Innovation. Applying the approach of the 'Lisbon method', the G10 group launched a public consultation in which it confronted the issues raised and conclusions reached in the working groups with broader stakeholder groups. To increase the transparency of the process, a dedicated website was created as well as a programme of workshops (European Communities 2002:9). Moreover, the general approach in the working groups was based on examining areas of interest were cooperation was possible and to propose "ways forward that might not necessarily require legislation". Benchmarking, the establishment of performance indicators (on competitiveness; the treatment of diseases and emerging health threats), the exchange of best practices and exchange of information underpin the general approach adopted in the G10 (European Commission 2002a).

Pricing and reimbursement structures for medicines were one of the issues being debated in the light of improving speed and transparency of national decision-making processes, presenting still big differences in the Member States. Related to this debate was the question on which basis innovation should be rewarded the most and whether a treatment should be judged upon its so-called 'relative effectiveness' (i.e. the effectiveness compared to treatments that are already available or considered as best available treatment). Indeed, the regulatory structure of the EMEA focused on quality, safety and efficacy criteria. However, within Member States, increasingly relative clinical and cost-effectiveness criteria were applied in pricing and reimbursement decision-making procedures.

The G10 group acknowledges that assessment of relative effectiveness falls under the national competences but calls for the facilitation of exchange of information on national practices within the EU. According to the expert group, this should include reviewing, analysing and supporting the exchange of experiences on health technologies, including new information technologies. Based on this reflection, one of the final recommendations (recommendation nr. 7 on relative effectiveness) issued by the G10 regards the development of HTA:

"The Commission should organise a European reflection to explore how Member States can improve ways of sharing information and data requirements to achieve greater certainty and reliability for all stakeholders, even if the decisions they take may differ. The objective is to foster the development of health technology assessment (HTA), including clinical and cost effectiveness, in the Member States and the EU; to improve the value

*of HTA, to share national experiences and data while recognising that relative evaluation
should remain a responsibility of Member States".* (European Commission 2002a: 17)

Hence, seeking to "achieve the twin goals of both encouraging innovation and competitive-
ness and ensuring satisfactory delivery of public health and social imperatives", the European
Commission departs from traditional harmonisation policies and adopts convergence meth-
ods based on soft governance means (European Commission 2002a: 5). In its final report
presented in 2002, the G10 calls for a continuation of the process and the implementation
of the agreed benchmarking exercises through a set of fourteen recommendations.

Based on the report of the G10, the European Commission issued a response in its 2003
Communication *A Stronger European-based Pharmaceutical Industry for the Benefit of the
Patient – A Call for Action* (European Commission: 2003b). The purpose of this communica-
tion was to propose ways to take the G10 recommendations forward and translate them
into concrete action. Regarding the G10 7th recommendation on relative effectiveness, the
Commission proposes several actions to be implemented in the timeframe of 2003-2008.
The first of these proposals regards the establishment of a "forum for Member States to
generate and share information on common relative effectiveness issues in the context of
pricing and reimbursement decisions".

Based on the work already realised in a working group of the Transparency Committee, the
idea is to develop common methodologies for the assessment of relative effectiveness and
make a stock-taking exercise on how these assessments are used in the Member States as
part of pricing and reimbursement decisions. The Commission recalls that relative effective-
ness of a medicine has two components: 1) the added therapeutic value (ATV) referring to
its clinical effectiveness compared to other treatments); 2) its cost-effectiveness (building on
ATV and comparing cost considerations). At that time indeed, cost-effectiveness evaluations
were increasingly used in the pricing and reimbursement decision-making processes in the
light of rising health care costs.

Still related to the G10 recommendation on relative effectiveness, the Commission issues
other implementing actions regarding the wider context of public health issues. One of these
states that:

*"The Commission will take forward work on health technology assessment under the
new Public Health Programme (2003-2008). Proposals are being sought in relation to
developing mechanisms to bring together competent authorities in the EU and applicant
countries, and where applicable, other stakeholders with the aim of enabling them to
co-operate more closely in health technology assessment. This topic is also being pursued*

under the High Level Process of Reflection on Patient Mobility and Health Care Develop-
ment in the EU" (European Commission 2003b: 11)

We recall here that this statement has been issued in 2003, at the time of the launch of the
establishment of the High Level Group on Patient Mobility and Cross-Border health care.
The latter, as we have seen, reflected upon HTA cooperation in a specific working group
which would eventually lead to the establishment of EUnetHTA (see section 5.1.2). Hence,
the uptake of HTA in the G10 which focused on pharmaceutical policies indicates how
HTA cooperation was taken into consideration in different policy streams which developed
independently although in a parallel way. In the next section, we want to highlight the link
between HTA and relative effectiveness established in this particular policy stream, since this
will be of high importance for the future EU HTA cooperation framework and its sustain-
ability.

As indicated in the Commission communication "The G10 Medicines group has served a
useful purpose serving as a catalyst for ideas and building links between stakeholders. As
a time-limited exercise the G10 will continue its work till the 2004 EU-enlargement, after
which work needs to be continued in several ways by all stakeholders concerned" (European
Commission 2003b: 26). One of the spin-offs of this process will be the establishment of
the Pharmaceutical Forum which will focus on some of the key-recommendations brought
forward by the G10[121].

5.3.3.2. The establishment of the Pharma Forum and the development of REA

The Pharmaceutical Forum has been launched by the European Commission in 2005 fol-
lowing discussions in the Health Council of June the same year. The process aimed to take
forward the recommendations issued by the G10 Medicines Group and gathered besides
the representatives of the European Commission, the Member States, the European Parlia-
ment and EFTA, also a wide range of stakeholders[122.] The Forum focused its work around
three key themes: information to patients on diseases and treatment options; pricing and

---

121 The Pharmaceutical Forum will focus its work on the recommendations related to information to
     patients, pricing and relative effectiveness. The other recommendations will be addressed by the
     Commission as part of the review of pharmaceutical legislation or in research programmes and
     support to patient groups (European Commission 2008:7).
122 European Patients Forum (EPF), Standing Committee of European Doctors (CPME), Pharmaceutical
     Group of the European Union (PGEU), Association Internationale de la Mutualité (AIM), European
     Social Insurance Platform (ESIP), European Federation of Pharmaceutical Industries & Associa-
     tions (EFPIA), European Generic medicines Association (EGA), European Self-Medication Industry
     (AESGP), European Association for Bioindustries (EuropaBio), European Association of Full-Line
     Wholesalers (GIRP) (European Commission 2008:8).

reimbursement policy; and relative effectiveness. This high-level political platform met once a year between 2006 and 2008. It was supported by a Steering Committee and three expert working groups which met on a regular basis during the same time frame. The Pharmaceutical Forum initiative was officially concluded in October 2008. As the political driver, the Forum created a political momentum to steer the discussions on competitiveness and related public health issues.

The initiative was backed by two DGs concerned by pharmaceutical policies and whose representatives at the highest level co-chaired the forum: DG Entreprise and Industry (DG ENTR) and DG Health and Consumers[123]: The Steering Committee served as a bridge to provide strategic and operational guidance between the High Level Forum meetings and the expert working groups. The Steering Committee was also chaired jointly by DG ENTR and DG Health and Consumers and comprised members representing Member States, the European Parliament and stakeholder organisations. It is interesting to notice here that the dual representation of DGs was applied only in the working group on Information to patients. The working group on Pricing was chaired and co-chaired by representatives of DG ENTR and the one on Relative Effectiveness was chaired by a representative of DG Health and Consumers and a representative of the Italian Ministry of health. The tasks of the working groups consisted to make concrete progress on the three key topics of the Forum. The working methods were based on the Lisbon strategy and included the exchange of best practices to examine potential efficiency gains as a way to achieve the three-fold objective: ensure patient access to medicines within a sustainable healthcare budget while enhancing the competitiveness of the pharmaceutical industry (European Commission 2008:8-9).

Regarding HTA cooperation, two of the three working groups are of interest. Both deal with an aspect which, at first sight, seems to be only indirectly concerned by HTA: Relative effectiveness and Pricing and Reimbursement. As we have seen above, in the early 2000s, both issues are intrinsically linked for the Commission and cooperation between Member States on relative effectiveness is considered in the context of pricing and reimbursement issues (European Commission 2003b). Relative effectiveness itself contains two aspects according to the Commission: the added therapeutic value and its cost-effectiveness (European

---

123   The Forum was co-chaired by Vice-President Verheugen representing DG Enterprise and Industry and Commissioner Kyprianou, followed by Commissioner Vassiliou representing DG Health and Consumers (European Commission 2008: 8).

Commission 2003b). We will see in the next sections and in chapter 6 how these two themes will increasingly influence the work of the HTA cooperation networks[124].

The work of the Pharmaceutical Forum's Working Group on Relative Effectiveness (RE) was rooted in the G10 recommendation no 7 which called for "the development of health technology assessment (HTA), including clinical and cost effectiveness, in the Member States and the EU; to improve the value of HTA, to share national experiences and data while recognising that relative evaluations should remain a responsibility of Member States" (European Commission 2008:17). The specific aim of the working group on RE was "to assist EU countries in applying relative effectiveness assessment systems that can contain pharmaceutical costs while also offering a fair reward for innovation" (European Commission 2008f). The link between Relative Effectiveness and pricing has also been underscored as the working group highlighted how the outcome of relative effectiveness assessments is an aid to identify the most valuable medicines, "both in terms of clinical efficiency and cost-effectiveness, and will help set a fair price for these medicines" (European Commission 2008f).

As Relative Effectiveness was a rather new concept and did not refer in all countries to the same reality or as the same reality was not always defined by the same terminology, the working group preceded first through formal and informal exchanges to define some key aspects related to this concept. The aim was to to agree upon a common approach towards REA (European Commission 2008h, Personal Interview 13). However, as the process was still in its very early stages and considering the fact that the discussions were held with parties that had different interests at stake (e.g. industry, insurance companies, Member States), it was still challenging to translate different ideas in concrete actions points (Personal interview 13): *"It was a very informal exchange (…) [about] a definition on Relative Effectiveness and Health Technology Assessment and what the difference was between efficacy and effectiveness. We have put that down on paper. But as it was still in its infancy at the European level, it did not lead to much, also because the Pharma Forum was made up of the industry,*

---

124 The manner in which they will do so however highly differs. Even their understanding and role in relation to HTA will evolve in an unexpected manner. Relative effectiveness will be the key component seeking to foster convergence in HTA cooperation and is key in a Regulation proposal submitted by the European Commission in 2018 (Personal interview 15, European Commission 2018). However, REA will be considered then only in its aspect of added therapeutic value regarding its clinical effectiveness as compared to other treatments or technologies. Pricing and reimbursement issues will be connected to HTA cooperation in several future regional cooperation initiatives which have developed independently from (and sometimes in reaction to) European cooperation networks supported by the European Commission (Personal interviews 15, 17, see also chapter 6).

insurance companies and Member States, so that was a bit heavy and we couldn't really do much with it" (Personal interview 13).

Nevertheless, three reference documents resuming the outcomes of the work performed have been issued by the working group on RE. The first one focused on core principles of RE and is of value as it defined common definitions on *Efficacy*, *Relative efficacy*, *Effectiveness* and *Relative Effectiveness*.[125] A set of "good practice principles" has been developed as a first step to support collaboration and the development of common methodologies in this area. The second reference document addressed the issue of data availability to conduct relative effectiveness assessments (REA) regarding the two main phases of a product's life: before and after Market Authorisation. This document also underscores how "new methodologies and scientific principles from other related areas such as health technology assessment could be included in the search for existing tools and methods that can be incorporated into relative effectiveness assessment" (European Commission 2008g:2).

Finally, the third reference document is dedicated to the development of networking and collaboration. A mapping exercise had identified twelve existing networks dealing with RE, among which EUnetHTA[126]. The document concludes that instead of creating a new network, work on RE should be integrated in one of the existing ones. This becomes also one of the official recommendations of the Pharma Forum (Recommendation 6.5, European Commission 2008:16). Initially the Slovenian Presidency Initiative (SI) and the MEDEV were considered suitable networks which could constitute a basis for the establishment of a future network (European Commission 2008f:3). However, both initiatives comprised important pro's *and* con's as the SI offered the advantage to have a clear mandate from the Competent Authorities of the Member States. It did however focus mainly on pricing and reimbursement issues. The MEDEV dealt explicitly with RE of pharmaceuticals but functioned on a purely

---

125 *Efficacy:* is the extent to which an intervention does more good than harm under ideal circumstances. *Relative efficacy:* can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions. *Effectiveness* is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice. *Relative effectiveness* can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice (European Commission 2008f).

126 The twelve networks identified in the mapping exercise comprised : AGREE collaboration, EUnetHTA, Guidelines International Network (G-I-N), Medical Evaluation Committee (MEDEV), Networking of the Competent Authorities for Pricing and Reimbursement of Pharmaceuticals ("Slovenian Presidency Initiative"), Nordic PharmacoEpidemiological Network (NorPEN), European Patients' Forum, Transparency committee, UK, Germany, France Collaboration, Working Group on Relative Effectiveness of the Pharmaceutical Forum (European Commission 2014b:3).

informal basis. Neither one of the networks comprised among its members the industry or other stakeholders. Ultimately, EUnetHTA has been identified as suitable platform to further develop REA and this topic will even become a key element of the network's activities as will be developed in the next chapter. Although the SI has not taken up REA, it has nevertheless played an important role as it has led to the establishment in 2008 of the Network of Competent Authorities on Pricing and Reimbursement. This network will later work to some extent with EUnetHTA to develop the collaboration between regulators, HTA bodies and payers and issues such as adaptive pathways.

The working group on RE comprised among its experts: representatives of the SI, the MEDEV and EUnetHTA. The latter was represented by the newly appointed coordinator of the EUnetHTA project which just started its activities. Hence, although from the start, it had been acknowledged that it was important to exchange information regarding progress in both initiatives, EUnetHTA had not been considered at first the appropriate network to further develop cooperation on RE despite the fact that many similarities had been identified and that it was recognised that work from EUnetHTA could serve as input for the Working Group on Relative Effectiveness (European Commission 2006b). It is only later upon strong recommendations of the European Commission (DG Sanco) that it has been decided that REA would be a priority point within EUnetHTA as of the first Joint Action starting in 2008 (Personal interview 8).

EUnetHTA has actually been a platform permitting to further develop several other items discussed in the Working group on RE. One can mention here the discussions around the need to streamline data production for assessments supporting the Market Authorisation and data for pricing and reimbursement decisions. The European Public Assessment Report (EPAR) of the EMEA is mentioned already in 2006 as a potential tool which could increase access to Market Access data which could be useful for pricing and reimbursement decisions. Investigating how the EPAR and the National Public Assessments Reports (NPAR) can contribute to REA has been integrated in one of the final recommendations of the Pharma Forum (Recommendation 6.4). This item too will be further developed within the framework of EUnetHTA at a later stage (see chapter 6).

Moreover, the need to inform the industry as early as possible about what kind of data is needed for Market Authorisations and Pricing and Reimbursement decisions, has also been highlighted by the experts in the working group on Relative Effectiveness and has been integrated in the final Recommendations of the Pharma Forum (Recommendation 6.3). Collaboration with the pharmaceutical sector in particular on relative effectiveness was considered hardly feasible by some representatives of the European Commission and of Member States, as they feared strong resistance of this sector who was not eager to see

the establishment of joint European relative effectiveness assessments (personal interview 7). However, the next chapter will outline how the pharmaceutical industry, while remaining indeed reluctant to collaborate on joint relative effectiveness assessments, has been very supportive of the European collaboration on Joint Scientific Advice (also called Early Dialogues) related to data to be submitted for market authorisation and pricing and reimbursement decisions. (see chapter 6).

The other working group of the Pharmaceutical Forum which is of interest for the development of HTA cooperation in Europe regards the one on Pricing and Reimbursement. This group followed closely the work of the group on RE as both topics are linked. The group on Pricing and Reimbursement organised the work in six streams. These concerned issues such as the development of a toolbox on pricing and reimbursement assessment, clarifying the value of innovation, how to use assessment of innovative medicines into pricing and reimbursement decisions, access to medicines and in particular ensuring availability of medicines on small markets, assessment of orphan medicines and risk sharing and conditional pricing practices.

During the discussions among the experts of the working group, suggestions were made to consider a broader use of the databases managed by the EMEA and to reflect upon new clinical trial designs. The possibility to consult regulators in the early phase of the product pipeline has been evoked as this would allow for a targeted steering of drug development responding to real needs of the society. In its final recommendations, the Pharma Forum stressed the need for Member States to "set clear and common expectations on what innovation they consider valuable and would reward" as this will allow companies "to give a clear direction on healthcare priorities and indications on the evidence needed by authorities, while bringing authorities clarity on the mid- to long-term budget needs" (European Commission 2008: 19). They also call upon the national systems on pricing and reimbursement to be well aligned with systems that assess the value of medicines (Recommendation 8.3).

Two points are worthwhile highlighting at this stage. The first regards the importance that is given to the need to develop 'Early Dialogues' between the industry and national pricing and reimbursement authorities. The underlying idea is that establishing regular dialogue in the very early stages of drug development could bring an expanded set of data out of the clinical trials that would go beyond the safety, quality and efficacy data, as it could bring evidence in the benefits and value of the future drug. Moreover, Early Dialogues would allow for more transparency and confidence which would benefit both the companies and the future payers. This point has also been highlighted in the working group on RE and will become a key item within EUnetHTA where the SEED-project will be further developed into a full-fledged cooperation between EUnetHTA and European Medicines Agency permitting

pharmaceutical companies to receive at a very early stage information on data required for the different regulatory processes (see chapter 6).

The second point which requires particular attention, is the shaping of the ideas around "equal access to medicine". This topic has been present in the debates of the working group since the first session. Initially the discussion will be framed around orphan medicines and availability of medicines in small and/or low-income countries. Indeed, the non-availability of many medicines to small markets is often of economic nature. Economic operators (manufactures, wholesalers and pharmacists), which ensure the creation and supply of medicines, are driven by economic incentives. If the costs incurred to market the drugs are higher than the expected revenues, medicines may not be available on these markets. The importance of this topic will develop so as to become included in the final recommendations of the Pharma Forum (Recommendation 7). Moreover, in 2007, head of medicines agencies will also seek for solutions from a regulatory point of view. A decade later, the European Parliament will develop this topic further into various motions and resolutions on equal access to medicines in which it calls on the Commission "to propose legislation on a European system for health technology assessment as soon as possible" (European Parliament 2016, see also European Parliament 2017a).

5.4. CONCLUSION

EU HTA cooperation has gradually developed into a full-fledged European policy being debated at the highest level of key-institutions of the European Union. The place which HTA occupies at present in the EU health policy framework has not resulted from a top-down approach but has developed in a bottom-up manner within different EU policy streams. We have identified in this chapter three EU policy areas which have had a profound impact on the content and governance of EU HTA cooperation. Developments within the *EU (public) health policy* have favoured the uptake of HTA in policy expert networks which have determined the course of action of the EU after 2000. This chapter has demonstrated how these networks have picked up the key messages and ideas to structure HTA cooperation developed in the early cooperation projects such as EUR-ASSESS, HTA Europe and ECHTA/ECAHI. Hence, the learning processes which had taken place in these projects initially on a national/agency level continued to be disseminated on an EU institutional level and created wider awareness for the need of HTA cooperation in Europe.

The comparison of the initial objectives of the EUR-ASSESS project with the ones of the first EUnetHTA project, bring to the fore many similarities. However, by having been integrated in the report of the High Level Group on medical care and health services, and as such

presented to the Health Council, they have gained political weight as HTA even became a "political priority". As in the early initiatives, policy entrepreneurs have ensured this up-take of HTA cooperation at a higher European institutional level though their investment in the expert networks and later in the EUnetHTA projects or within specific units of the European Commission.

These expert networks, developed under impulse of the European Commission, have also permitted the establishment of links between the *EU health policy stream* and the *EU social policy stream* affecting HTA cooperation in Europe. Indeed, we have outlined in this chapter how the expert groups functioned on the basis of soft governance measures. The latter had been developed initially by DG Employment and Social Affairs before becoming integrated in the Lisbon Strategy and widely implemented in many other policy areas. Although envisaged, the implementation of a formal OMC in HTA cooperation, has never taken place. Nevertheless, in this area too, through discourse in the expert groups as well as within different units and departments of the European Commission, a soft governance approach has been considered as a feasible manner to favour cooperation and convergence in health policy in general and in HTA cooperation in particular. The most tangible example of this can be found in the amendments of the public health article foreseen for the Constitutional treaty (2004) but eventually adopted in the Lisbon Treaty (2007). Soft governance also underpinned the working methods of the HLPR and the HLG and have been further implemented in the subsequent HTA cooperation projects and EUnetHTA Joint Actions.

Finally, the *EU pharmaceutical policy stream* has also had an important impact on HTA cooperation as regard the content of the cooperation processes. We have seen how the objectives of HTA cooperation in the expert networks (e.g. HLG) were highly similar to those developed in the early HTA cooperation project. However, what will differentiate EUnetHTA from the three previous projects, is the integration of relative effectiveness assessments. In this chapter, we have outlined how this idea has been developed within the G10 group on medicines and the Pharmaceutical Forum. Here too, through these expert groups – working on the basis of soft governance principles - synergies have been created between pharmaceutical policy at the one hand and EU HTA cooperation projects at the other. These synergies will further develop through other aspects initiated in these expert groups. In particular, the concepts of early dialogue, Horizon Scanning and equal access to medicines. The latter will occupy an important place with HTA cooperation and national and European regulatory affairs. (see chapter 6).

Since the early cooperation initiatives, one of the main difficulties to achieve a sustainable cooperation in HTA was the lack of a specific legislative basis to act in this policy field. However, the debate on patient mobility in Europe has created a window of opportunity in

this respect. When developing the future Directive on Cross-Border Health Care and Patients' Rights (2011/24/EU), the European Commission managed to shuffle in policy areas which were bearing the potential to impact the national health systems. As the debates in the adoption process of the Directive focused almost exclusively on reimbursement issues, the flanking measures - including HTA cooperation in Europe – have been adopted without hardly any discussion, permitting the establishment of a legal basis for EU HTA cooperation.

In the next chapter we will examine how the European HTA cooperation has been taken forward since 2006. Although no formal HTA cooperation has been implemented from 2001-2006, this 'interlude period' in which key aspects of HTA cooperation have been developed in expert networks set up under impulse and direction of the European Commission, will have been determinant for the further course and governance of HTA cooperation in Europe.

6 | Establishing a sustainable network for HTA cooperation in Europe

"But time is passing, and Europe is moving only slowly on the course to which she is so deeply committed…
…what matters is to have an objective clear enough always to be kept in sight."
Jean Monnet, Memoirs

6.0.   INTRODUCTION

The end of the ECHTA/ECHAI project in 2001 seemed to mark a halt of HTA cooperation in Europe. However, as outlined in chapter 5, although no new project had been carried out by the HTA arena, HTA cooperation did move forward on the EU agenda through different networks operating in three different EU policy streams. Each of these would lay the basis on which future HTA cooperation would be structured. As such, the EU health policy stream allowed for the development of a new HTA network proposal (EUnetHTA). Moreover, it offered a legal basis to continue support and coordination of HTA cooperation (Lisbon Treaty). The Cross-Border Health Care Directive would even present a legal basis for the establishment of an EU HTA Network. The social policy stream underpinned the development of soft policy means in health care cooperation and the pharmaceutical policy stream designated HTA networks to carry on the topics of Relative Effectiveness Assessments and Early Dialogues.

European HTA cooperation, as of the mid 2000s, would be characterised by the establishment of the EUnetHTA network followed by the EU HTA Network. This chapter will therefore examine the cooperation process by focusing in particular on these networks. For a systematic scrutiny of the events, policy and governance choices, we will follow a similar structure as in chapter 3 on the early European HTA cooperation efforts. Hence, by means of the five stages of the policy cycle[127], we will lay down how the developments in the EUnetHTA network are interlinked with the developments in the wider EU health policy leading to the establishment of an EU HTA Network and a legislative Commission proposal for a Regulation on HTA cooperation. To this end, each paragraph will address a particular stage of the policy cycle by analysing the developments on two levels: the HTA arena (through EUnetHTA) and the EU health policy-making arena (through developments linked to the EU HTA Network). It is important to underscore that this distinction is made only for analytical purposes as both processes become highly intertwined the more they progress.

As outlined in chapter 5, the High-Level Group on health services and medical care (HLG), elaborated a new project to carry on HTA cooperation in Europe by means of the establishment of a new network called *EUnetHTA*. In October 2004, the objectives of this 'EUnetHTA' project had been outlined and it was agreed that finance would be sought in the European health program. This project re-launched HTA cooperation in Europe and built further upon the work established by the previous projects. In the present chapter we will outline how, gradually, it became clear that to create a sustainable network, the project-based governance structure would not be sufficient. A so called "Joint Action" will be proposed by the Euro-

---

127   The five stages of the policy cycle comprise: agenda-setting, policy-formulation, decision-making, policy implementation and evaluation (Howlett 2009).

pean Commission to drive the cooperation efforts further, still project-based though. Until today, three Joint Actions have been implemented in which the European Commission not only co-finances the initiatives but also becomes a full partner in the cooperation process.

These developments have taken place simultaneously with a new process laying in the EU health policy stream and which have led to the adoption of the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU). This legislative act will play an important role in EU health care in general, but also in the governance of HTA cooperation in particular. Indeed, the Directive foresees in its Article 15, the establishment of a European HTA Network which will even more change the role of the Commission in coordinating HTA cooperation in Europe. As we will outline in this chapter, the newly established network - which we will call in our research the 'EU HTA Network' - will take over the role of defining the strategic policy orientation of HTA cooperation in Europe and prepare the basis of a new proposal from the European Commission for an EU Regulation on HTA cooperation in Europe.

Simultaneously to these developments, new regional (intergovernmental) cooperation structures will be established in the EU. These will often build upon the work established by EUnetHTA but will differ in their network structures, governance modes and final objectives. Hence, from a pure voluntary bottom-up approach originated in the HTA arena, HTA cooperation will stand at the end of the 2010 decade before a cross-road where it could take the direction of an EU regulatory framework with mandatory aspects to be applied by all Member States; or choose for an intergovernmental cluster approach in HTA cooperation. The complex processes and interplay between the various policy arenas and stakeholders involved, require a close analysis of each stage of the policy cycle so as to acquire a profound understanding of the role of the governance processes in structuring the cooperation efforts.

In the following sections we will explore this process by outlining the developments and examine them through the lens of the policy cycle. As the changes in governance and policy objectives have taken place through small and what could be considered as insignificant steps, the data has been explored in detail combining sources from grey literature (e.g. official reports, policy positions of (institutional) actors involved), personal interviews and written contributions from HTA actors. This data will be further examined in chapter 7 in the light of the research framework on network governance outlined in chapter 3, allowing us to examine the role of soft governance in structuring HTA cooperation in a European framework.

6.1.   AGENDA-SETTING IN EUROPEAN HTA COOPERATION

In the section discussing the agenda-setting process in chapter 4, we have seen that accord-ing to Baumgartner and Jones (2005), agenda-setting in policy-making is a matter of politics of attention. How an item gets on the political agenda depends on the conditions under which the information about the issue will be supplied and on how it will be interpreted and prioritised. Princen (2009:9-10) underscores how the EU agenda-setting process can take place according to two distinct manners depending on whether it takes place in the so-called 'functional political system' or in a 'evolving integration scheme", such as in EU health policy, where often issues appear for the first time on the EU agenda. Princen explains the EU agenda-setting process by looking at a combination of 'venues' and 'frames', the venues referring to the institutional decision-making arenas and the frames to the 'issues definitions'.

Academic research has also brought to the fore how the agenda-setting process "is influ-enced by key actors in prevailing policy subsystems, the dominant set of ideas about policy problems they espouse, and the kind of institutions within which they operate" (Howlett, Ramesh and Perl 2009:107). Kingdon (1984) underscores how agenda setting results from a complex interrelationship of ideas, actors and structures in which policy-entrepreneurs play a key role by seizing opportunities - or *policy windows* – to put an issue on the governmental agenda. Baumgartner and Jones (1991) have further developed this idea and stress how the construction of a political discourse is developed within a specific subsystem by a set of actors defining the nature of the (new) ideas. What will influence the agenda-setting process in this interpretation, is the ability of some actors to gain control over the interpretation of an issue and the way it is going to be discussed and framed. Hence, the way a policy problem is presented matters since "when they are portrayed as technical problems rather than as social questions, experts can dominate the decision-making process. When the ethical, social or political implications of such policies assume center stage, a much broader range of par-ticipants can suddenly be involved" (Baumgartner and Jones 1991: 1047; see also: Howlett, Ramesh and Perl 2009).

The nature of the actors involved in a policy-process can thus have an influence on the manner in which an issue will be discussed and put on a national or European policy agenda. In this section we will examine how HTA has evolved in the different sub-systems and how, gradually, it has been re-framed from a 'technical issue' into a social and political one. This has allowed HTA cooperation to become an official agenda point in different political settings herewith also enlarging the set of actors involved in the process. This section will therefore examine the developments in the formal and informal (institutional) settings focusing in par-ticular on the actors involved and the ideas brought forward by them. It is the combination

of the choice of venues, frames and actors that has determined the institutional framework in which HTA cooperation would be embedded as well as the importance it would get within the wider EU health policy.

6.1.1. Agenda-setting process in the EUnetHTA network

The agenda-setting process of the EUnetHTA project finds its origins in the High Level Group on health services and medical care (HLG) established in 2003. Indeed, by becoming integrated in the HLG, HTA cooperation moved up in the EU agenda-setting process. Information about the role of HTA in the health systems has been brought under the attention of a high level policy network which had an important influence regarding the weight given to some issues on the EU health policy agenda. This network considered HTA cooperation as sufficiently important to prioritise it and dedicate a specific working group to the subject. As outlined in chapter 5, the initial conclusions of the early European HTA cooperation projects (e.g. EUR-ASSESS, ECHTA/ECAHI) have been further developed in the HLG and have led to the creation of the EUnetHTA project submitted and accepted for funding in 2005 and implemented from 2006 to 2008.

Although again project-based, the EUnetHTA project bore a fundamental difference with the previous HTA cooperation projects. The latter had been submitted by actors of the HTA arena and did not receive any formal backing of national or EU high-level decision-makers. The project initiators in the 1990s still had to convince decision-makers of the importance HTA for the national health systems and how the EU could play a role in this. The EUnetHTA project, on the contrary, stemmed from a high-level policy-making venue, recognising the need for HTA collaboration to improve the governance of national health systems by ensuring quality development and effective use of resources in health care services (Nielsen 2008; see further chapter 5). Herewith, HTA cooperation has been lifted to another policy-making level.

Though the collaborators of the early cooperation projects already considered HTA as a bridge between science and policy "*at an adequate distance from public to have influence, but not too far from academia to be credible*" (Personal interview 6), the focus within the European cooperation projects of the late 1990s remained predominantly on the scientific and technical side of HTA cooperation. This will shift in the HLG on health services and medical care, where a more active stand will be taken to introduce HTA into the policy-making level (Personal interview 4). This move can be attributed at one side to 'policy-entrepreneurs', such as Finn Kristensen, the initiator of the EUnetHTA project, having a scientific background but working in a policy-orientated institution. While understanding the scientific rigor necessary in HTA, he also grasped the importance of working with policy-makers to make HTA cooperation in Europe sustainable. Due to his different previous professional occupations, he had developed a know-how of policy-making mechanisms which, according to him,

facilitated to perceive "*how to do the HTA work inside of policy-making and planning and understanding the need to create something that is actually useful and seen as useful by the decision-makers*" (Personal interview 4).

At the other side, the broader developments taking place in EU health policy (see chapter 5) were also an opportunity for HTA to make this move towards the policy-making level. As it was being decided that health policy should stay outside the single market, discussions were ongoing regarding the exact place health policy should have within the EU policy architecture (Personal interviews 3, 4). Like in the early 1990s, HTA cooperation, in a sense, profited from this reflection while at the same time giving food for thought to the Commission on how to support the national health systems. Hence, instead of being seen almost exclusively as a scientific and technical exercise, HTA was increasingly considered to play a role in addressing social, economic and safety issues of EU health policy. The fact that the Commission sought to enter into new areas of health policy was, according to some, also reflected in the name change of the "*Public health program*" into "EU *health program* " and considered as one of the signs of "*a constant 'sled' or tendency of the Commission to gradually get closer to the health systems and not just public health matters*" (Personal interview 4).

Incorporating HTA cooperation in the new EU *health program (2008-2013),* allowed to se-cure funding for the EUnetHTA project which could then be launched and be put more firmly on the agenda of national and EU health policies: "*as the call was on its way, it was the time to make the move*" (Personal interview 4). Hence, as in the early 1990s, the collaboration between the HTA arena and the European Commission was considered by the actors in the field as a win/win situation (Personal interviews 2, 3, 4 and 8). The difference however with the early cooperation period was that, at this period of time, besides financial support, the HTA arena could also count on political support on behalf of the EU, as more actors became involved in the cooperation process.

Moreover, the place attributed to HTA by EU representatives in health policy initiatives of DG Sanco, allowed it to move upwards on the EU governmental agenda and to benefit from future initiatives of this Directorate, such as the 2008 proposal of the European Commis-sion for a Directive in Cross-Border Health Care (EU/2011/24). As a result, whilst clearly an HTA arena initiative at first, the 'ownership' of the EUnetHTA project gradually shifts, in the perceptions of some, to the European Commission. One can find an example of this in the opening speech of the first EUnetHTA conference, where the Director General of the French Ministry of Health attributes the EUnetHTA initiative to the European Commission. Moreover, he also indicates how HTA cooperation has been inserted in the draft proposal for a Directive on Patient's rights in cross-border health care and becomes thus an official agenda point of the EU:

"In 2004, the European Commission proposed to Member States and other European countries and organisations to build up a network – EUnetHTA - enabling an effective exchange of information with the purpose of developing the methodology of epidemiological studies and clinical trials, finalising practical tools and helping decision making processes in public health policy.

More recently, the European Commission included into its draft Directive on the application of patients' rights in to cross-border healthcare, the intention to establish a permanent network for health technology assessment, in order to encourage cooperation between competent authorities, supply and exchange of reliable data and improve the decision making process by Member States" (www.eunethta.eu).

Hence, establishing a working group on HTA cooperation in the HLG has allowed the topic of HTA cooperation to be discussed within the 'right' venue, allowing it to enter the national and EU agenda-setting processes. As underscored by Schattschneider (1960:71 in Versluis et al. 2011:119), venues differ in the authority they have over certain issues as well as in their composition. In the case of EU health policy, the HLG appeared to be extremely important in drafting the agenda of the wider EU health policy and included herein HTA cooperation. It also played a role in establishing bridges between networks developing in various policy streams (see chapter 5). Moreover, most of the items discussed in the HLG between Member States will be included in the Cross-Border Health Care Directive (EU/2011/24) which will play a prominent role in shaping the post-2008 EU health policy.

According to Princen (2009:11), the institutional framework will define within each *venue* the specific tasks, authority and resources allocated to them as well as the persons who will participate in the decision-making process and the procedure according to which a decision will be made. In the case of HTA cooperation, it has been the 2002 Health Council which has given the impetus to establish the High Level Process of Reflection leading to the establishment of the HLG. The Commission - i.e. DG Sanco and DG Employment and Social Affairs - has coordinated the work of the HLPR and of the HLG, represented by senior-level representatives of the Member States' health ministries. Resulting from work in the HLG, the EUnetHTA Project (2006-2008) has been able to secure funding and authority to carry out the project resulting from the work of both experts' networks.

The above shows how the initial agenda-setting process of EUnetHTA was situated mostly during the period in which the HLG took place, comprising the informal meetings which took place in Denmark to prepare the EUnetHTA project (Personal interview 7, see also chapter 5). The follow-up to the project follows however a distinct agenda-setting process which will lay partly within the EUnetHTA project itself and (again) partly within DG Sanco. Indeed,

towards the end of the EUnetHTA project, it became clear that, although substantial work had been carried out, much would still have to be done to reach the strategic objectives defined by the HLG and inserted in the EUnetHTA project. The network structure that had been set-up still didn't respond to any form of financial, organisational or administrative *sustainability* as it only existed within the project framework, primarily funded through the EU health program. Moreover, even though important tools and methodologies had been developed, many of these had never been tested in real settings. The pilot projects that had been realised, still revealed the necessity for important improvements of the models developed (Personal interview 8).

Although the main objectives of the project had not been reached at the end of the EU-netHTA project, many Member States involved in the program did continue to manifest interests to pursue the cooperation initiative (Personal interview 4). At that stage, it became however clear that "*knowing the idea, the ultimate goal of sustainability, you need to figure out a flexible but robust solution which allows you through the project-based approach to go towards something sustainable. That also relies on the readiness, technical matters of cooperation methodology, people working in the HTA agencies and then also taking advantage of political readiness*" (Personal interview 4). Hence, the challenge was to es-tablish something which was "concrete, operational and implementable" while having the organisational structure enabling researchers, HTA-representatives "*to do their work while bringing the results into the policy processes and being sustainable despite the project solu-tion for making it happen*" (Personal interview 4).

In order to pursue the initial and ultimate objective of sustainable HTA cooperation in Europe, the European Commission proposes to adopt a different approach. In the general EU setting, a new type of projects had been introduced in the form of so-called 'Joint Actions' (JA). In EU health policy, no such a framework had yet been used. Establishing a Joint Action on HTA cooperation seemed however suitable to achieve the objectives which remained on the agenda of both the Commission and HTA bodies. The Joint Action diverged however from the previous project-based approaches by the fact that the Commission's role would funda-mentally change. From a funding institution in the EUnetHTA project - approving the project proposal and implementation but taking no formal part in the governance and management of the project - the Commission's role would evolve into becoming a full-fledged partner in carrying out EU HTA cooperation initiatives.

As underscored by a senior DG SANTE representative*: "The painful moment was when we had to decide what to do next after the EUnetHTA project. This was a moment in my team when we started to reflect again, using the famous phrase: 'moving from fishing to farming'. There was a problem in the health programme. We understood that we do a little bit of*

fishing, so we have ideas and people are meeting that in grant proposals. We are ready to do something more substantial and that goes a little bit like farming. You need to plan, to organise, to know where you like to be next year. And this is how the Joint Action came in as a tool. We got this tool under discussion with Member States, but we didn't know how to use it (…). The system was new." (Personal interview 8).

The Joint Actions were not only new to the Commission representatives, it was also new to the representatives of the Member States and the HTA bodies who did not always understand the Commission's role in these Joint Actions. Recalling the first meeting to prepare the post-EUnetHTA project phase, a DG Sanco representative underscored how some participants were wondering "*Why is the Commission here, telling us what to do?* The Commission representative answered: "*It is called 'Joint Action' and Joint Action means: Member States and Commission". Oh, that is what you mean!"* (Personal interview 8). Although adjustments to this new approach were needed, many Member States did support the new initiative as the first Joint Action comprised 33 associated partners and 26 collaborative partners (EUnetHTA 2013: xii-xiv). As such, European HTA cooperation remained on the agenda of the Commission as well as many HTA agencies.

Most organisations that decided to get involved in the Joint Action had already been engaged in the EUnetHTA project and were favourable to pursue the cooperation efforts. However, the call to participate in the Joint Action came this time through the respective Ministries of health in the different Members States: *"If you think of the Joint Actions, those initiatives – as far as I understand – always came from the Commission to the Ministry. So, then the Ministry of health and social affairs would contact us to invite us to the project"* (Personal interview 18). The choice of HTA agencies and other partners to join the EUnetHTA Joint Action was motivated by contextual incentives as well as sometimes more strategic calculations.

As such, some expressed the need to exchange experiences with colleagues from different countries as HTA was rather new in their Member State. Others were aware that cooperation could allow to avoid duplication and thus be profitable financially or time wise by leveraging upon the work of others, receive additional financial resources and compensate for internal lack of human resources. The need to build capacity in HTA, receive training and experience would also be beneficial to national HTA agencies and would at the same time contribute to the harmonisation of processes and methods and the standardisation of best practices. For some agencies, participating in an international project would enhance their visibility, both nationally and internationally. Some joined simply because of the sense that something was moving and that it was better to be inside rather than outside the network (Personal interviews e.g. 11, 18, 19, 22, 24, 25, 29).

The fact that the European Commission became more and more involved in the HTA coopera-
tion also clearly had an impact on the motivation of partners to play a role in the Joint Action:
"In many discussions it was recognised that it is important to develop collaborative methods
and then I think that the agencies were very happy about the fact that the Commission was
active in this and supporting it. So, in that sense, I think it was a mutual win/win situation
in a way that it was on the political agenda of the Commission and on the other hand, the
agencies felt that this is important to do" (Personal interview 18).

To ensure a smooth transition between the EUnetHTA project (2006-2008) and the EUnetHTA
Joint Action (2010-2012), the EUnetHTA collaboration has been implemented in 2009. This
project ensured continuation of work established in the EUnetHTA project and determined
the governance, management and work plan of the Joint Action. Financial resources to
support this interim period came from Member States and their HTA agencies herewith
showing a real commitment at agency level to drive the initiative further (Personal interview
4, 18, 22). The first EUnetHTA Joint Action has been succeeded by two other Joint Actions.
Joint Action 2 has been implemented from 2012-2015 and Joint Action 3 from 2016-2020.

The agenda-setting process of the Joint Actions (JA) 2 and JA 3 have taken place during the
previous projects and based on internal evaluation processes and external developments.
Building further upon the work started in the JA1, the JA2 would introduce new areas of
collaboration with external European regulatory bodies. The general objectives remained the
same, but collaboration was to be strengthened. Indeed, in the project application of JA2 it is
underscored how "The JA2 aims at bringing collaboration to a higher level resulting in better
understanding for the Commission and Member States (MS) of the ways to establish a sus-
tainable structure for HTA in the EU" (EAHC 2010). Moreover, it elaborates on developments
that have taken place in the wider EU health strategy with the adoption of the Cross-Border
Health Care Directive in 2011: "Specifically, the JA2 will develop a general strategy, principles
and an implementation proposal for a sustainable European HTA collaboration according to
the requirements of Article 15 of the Directive for cross-border healthcare". (EAHC 2010).

Hence, the ultimate goal remained the establishment of a sustainable cooperation struc-
ture which the Joint Action 1 failed to deliver. The progress made in this collaboration did,
however, allow to maintain the item on the agenda of the agencies, ministries and of the
Commission. Even more so, new partners have been invited to join the initiatives and these
comprised at this stage also organisations representing stakeholders other than HTA agen-
cies. As such, European HTA collaboration entered more firmly on the agenda of organisa-
tions representing the pharmaceutical and medical device industry, insurance companies,
patients and health care providers.

The agenda-setting process of Joint Action 3 follows a slightly different path than the one of Joint Action 2 as it has been influenced by external events related to the EU health policy scene. The ultimate target of creating a sustainable European HTA network had not changed - as also the Joint Action 2 still did not deliver this - the means put in motion to achieve sustainability would however differ. First, the Commission decided in 2013 to establish the policy-orientated EU HTA Network[128], created on the basis of Article 15 of the Directive on Cross-Border Health Care (2011/24/EU). This would have an impact on the future of the EUnetHTA network which will be incorporated in a broader vision of future European HTA cooperation. As such, it would become the scientific and technical arm of the EU HTA Network who would be responsible for the strategic policy orientations of European HTA cooperation. The agenda of the Joint Action 3 would be drafted in line with this perspective. Moreover, soon after the establishment of the EU HTA network, the European Commission would launch a consultation procedure preparing the ground for the elaboration of a future legislative proposal on HTA cooperation in Europe, as will be outlined in the next sections.

Another point of distinction between the Joint Actions 2 and 3 and which affect the agenda processes to some extent, regards the membership structure which were still established in close cooperation with the Member States' respective ministries, the European Commission and the EUnetHTA secretariat. In Joint Action 2, membership had already increased to a total of 69 organisations comprising 49 government-appointed organisations as well as regional agencies and not-for-profit organisations producing or contributing to HTA from 31 countries in Europe (including all EU Member States). In the Joint Action 3, the member-ship grew even more, to reach a total of 81 organisations (www.eunethta.eu). Although a stakeholder policy had already been developed during the first Joint Action, it's weight on the EUnetHTA agenda setting process became more important during Joint Action 2. This was also reflected by the number of stakeholder organisations and their involvement in this project. Whereas in Joint Action 1, the cooperation took place almost exclusively between HTA agencies, this changed in Joint Action 2 where stakeholders became more involved (e.g. Personal interviews 12, 13, 23).

Incentives to participate were mainly the same as for those in the Joint Action 1 but at this stage other motivations and strategic calculations came to the fore. Indeed, as the development of HTA cooperation grew in importance in Europe, some organisations decided to join or to take a more active part in the collaboration:

---

128 The Commission refers to this network as the 'HTA Network'. In this thesis we will always refer to this network as the 'EU HTA Network' for a better distinction between the various HTA networks that have been created.

"[Our organisation] has an interest in international development and especially developments in Europe. So, that is why we participate. As this development grew, the importance of HTA in Europe grew, we decided to engage a bit more" (Personal interview 22).

"There was a decision on behalf of the leadership of this department that they want to speed up HTA. They also want to catch up on HTA and they want to try if they can be engaged in a meaningful cooperation" (Personal interview 28).

"For years I was alone, so for me it was really important to work with others. This gave me the opportunity to be part of systematic clinical effectiveness and safety. Because when you are alone, you cannot do systematic reviews" (Personal interview 11).

Hence, different standpoints motivated organisations to become a new member or become more active in the Joint Actions. These motivations varied from the interest to exchange experiences, develop expertise and know-how, harmonise practices so as to benefit from the different tools developed by EUnetHTA, optimise financial and human resources, develop a legal framework as well as build on the personal and institutional relationships that had been developed. Moreover, the introduction of specific topics, such as, Relative Effectiveness Assessments, Early Scientific Advice or Additional Evidence Generation also led some organisations to join the initiative (e.g. Personal interviews 4, 11, 14, 19, 22, 27, 28, 30). Some organisations also had the impression that the HTA cooperation process would lead to some (EU) initiatives which could have an impact on their organisation and work processes and preferred thus to take a leading role to ensure that the direction of these developments would suit them (e.g. Personal interviews 12, 22, 23, 24, 27) :

"I think the reason to take a larger role in Joint Action 3 was because of the knowledge it was going to work towards the permanent HTA cooperation and our desire to influence the permanent mechanism of HTA cooperation. That is why we got involved in Joint Action 3 in a larger role. Our role in Joint Action 1 and Joint Action 2, I think, primarily stems from our interest in working with our European colleagues creating relationships with them, understanding how they work and using our HTA experience in order to create and improve HTA practices around Europe." (Personal interview 27).

Representatives of stakeholder groups too became more aware of the growing importance of HTA, not just on the European scene but also in their national markets. "*We were no fools, but we felt that we could not do anything against the HTA 'steamroller' and the reason why it has been invented. So, we prefer to take part in it so as to limit in any case its side effects that bother us the most*" (Personal interview 12). Hence, they became more involved and started to closely follow the developments from the 'inside' by taking part in the

different structures that had been established for them (e.g. Stakeholder Forum). Through their participation they wanted to ensure the insertion in the EUnetHTA strategy of what they considered to be key issues in HTA (e.g. patient access, ethical issues, timely access, evidence generation) (e.g. Personal interviews 12, 21, 23, 24, 25).

Although the balance between the arguments in favour regarding partnership in the EUnetHTA Joint Actions, bore often more weight than those against, some organisation did question the real benefits of it, especially as a certain amount of investment from the organisations itself was needed. Moreover, if the gain of time and resources was often a motivation to join, some also reported the fact the membership of EUnetHTA actually added to the workload of departments which were already under strain: "*The agency is not really highly involved in reports production for example, because it is a big effort in time and personal efforts. (…) So, the benefits are not clear, not obvious. It will still be the activity for a small group of persons, personally interested in international cooperation rather than a systematic procedure of involvement and using the outcomes of involvement*" (Personal interview 30). Indeed, when agencies or other stakeholder group joined, the work related to EUnetHTA was often allocated to a small group of people and not the priority of the wider organisation they belonged to (e.g. Personal interviews 14; 19; 30).

Hence, progress accomplished in the field of HTA cooperation during the first two Joint Actions did provide sufficient reasons for the European Commission to allow for a third Joint Action as a mean to ensure the continuation of the work and bridge the gap between the newly established EU HTA network and the future proposal for a Regulation in the field of HTA cooperation. The aims of this (supposedly last) Joint Action in the field of EU HTA cooperation should be considered in this perspective. The Joint Action 3 focused on turning pilots into routinely activities in the Member States and develop a sustainable model for the scientific and technical mechanism of a permanent European cooperation on HTA. These events demonstrate that HTA cooperation at this stage cannot be examined anymore without a close analysis of events at the European institutional level which we will develop in the next section following the same time-path as in the current section.

6.1.2. HTA cooperation entering the EU decision-agenda

We have seen in chapter 3, that, based on Princen's classification of EU agenda's (2009:15-16), the early HTA cooperation projects (EUR-ASSESS, HTA-Europe and ECHTA/ECAHI) could be considered as an agenda topic debated first in *transnational policy networks*[129]. Indeed,

---

129 Transnational policy networks consist of policy experts of national governments and international organisations but can comprise also academics, journalists etc. (Princen 2009: 15-16, see further chapter 3).

we have highlighted that a certain convergence of policy debates among participants of the network and the structure permitted the exchange of ideas. A common perspective on HTA cooperation in Europe has emerged in these first cooperation initiatives and have structured the future efforts on this issue as we will outline in this section.

Princen (2009:15-16) also demonstrates how an issue can shift from the *transnational policy network agenda* to the *EU agenda* if there is receptiveness for the issue at the EU-level. The latter will depend on the institutional characteristics of the venues within the EU and on the way the issue will be framed. Princen (2009:16) underscores how issues can shift to the EU agenda if it fits the concerns and interest of a particular institution or by a pro-active approach of an institution. He distinguishes here the '*EU's governmental agenda*' (stage of the EU political agenda-setting process, during which 'ideas are floated and perspectives developed') from the '*EU decision agenda*' (on which issues appear when they are ripe for active decision-making). We have outlined in chapter 3 how the newly created DG Sanco did show interest for HTA cooperation from the early days on. Putting HTA as a priority topic in the HLG and qualifying it as a 'political priority' for the Commission can be considered as a pro-active approach of the Commission permitting the topic to enter on the *EU governmental agenda.*

As outlined in the previous section, the EUnetHTA project (2006-2008) can be considered as the product of the HTA Workgroup of the HLG on medical care and health services. The later was coordinated by DG Sanco and DG Social Affairs and Employment. Whilst the HLG met on a regular basis from 2002 to 2006, DG Sanco continued to deploy its health strategy and implement its work plan as adopted by the Council. A close analysis of the annual work plans of the Commission's public health strategy shows how the work of the HLG was taking into account in the public health program. HTA cooperation can be cited as an example hereof. Hence, the HLG states that*: "In conclusion, the Working Group on Health Technology Assessment proposes that the European Commission support a pilot project to set up a European HTA Network under an appropriate financing mechanism such as EU Public Health Programme"* (European Commission 2004f:13).

To qualify for funding, a project needs to fulfil several criteria and needs to respond to the objectives set out in the annual work plan (European Commission 2005a). This programme is defined by representatives of the Member States and is coordinated by DG Sanco. It is interesting to see how the priorities in the field of HTA, as identified in 2004 in the HLG work group on HTA, figure in the 2005 work plan of the EU public health programme. Indeed, the 2005 work plan states that:

> "*Work will be carried out following up the high-level process of reflection on patient mobility and health care developments in the European Union with the following priori-*

ties: Quality assurance in Europe and health technology assessment: without prejudice to projects supported by the Community Research Programme, take stock of activities related to quality assurance and improvement and accreditation systems across Europe and develop networking and collaboration at EU level covering also patient safety and involvement of patients with their care. Necessary studies on performance assessment of health care institutions to assess and compare quality strategies need to be developed in cooperation with the OECD." (European Commission 2005a:11)

Based on this work plan, a call for proposals had been issued by DG Sanco in January 2005 regarding projects qualifying for funding within the public health program (OJEU 2005). The project proposal of the HLG workgroup on HTA perfectly matched the objectives and criteria set out in the 2005 call for proposals. The latter created thus a favourable ground to take the HTA cooperation initiative further, according to the discussions and conclusions of the HLG.

Inserting HTA cooperation as one of the priority areas in the public health programme can be identified as preparing the transition of HTA cooperation from the EU *governmental agenda* to the EU *decision agenda*. Princen (2009: 16) considers that for an issue to move from the first to the latter, horizontal (EU level) and vertical blockages (MS Level) should be over-come[130]. The fact that HTA cooperation had been discussed in an expert group steered by the two DGs involved in health policy, probably facilitated to find consensus on the issue on EU level. Moreover, the members of the working groups in the HLG all were representatives of Member States. Hence, the HLG has permitted to find consensus on this issue on Member State level and has avoided that eventual horizontal or vertical blockages could develop at this stage.

The initial shift from the *EU governmental agenda* to the *EU decision agenda* can be situated in 2008 when DG Sanco introduces the proposal of a Directive on Patients' rights in Cross-Border Health Care (2011/24/EU). Indeed, as outlined above, this Directive adopted in 2011, has inserted EU HTA cooperation in its Article 15. The debates during the adoption phase (2008-2011) mainly focused on reimbursement issues. The flanking measures (among which HTA cooperation) had not triggered any fierce debates within the different institutions having to adopt the legislative act (see chapter 5). The absence of controversy regarding HTA in the adoption procedure may also have played a role in the absence of horizontal and vertical blockages. The latter has contributed to the fact that HTA has moved smoothly from

---

130 Horizontal blockages appear when, due to differences in perspectives, some EU policy-makers may want to prevent an issue to appear on the decision-making agenda. Vertical blockages can occur when Member States are reluctant to see the European Union trying to play a role in a particular policy (Princen 2009: 16).

the *EU governmental agenda* to the *EU decision agenda*. Hence, the consensus found in the HLG representing both Commission and Member States' officials and in the Council and European Parliament when discussing the Cross-Border Health Care Directive, has permitted HTA cooperation to move further on the EU agenda. Its insertion in the Directive 2011/24/EU represents in this regard a landmark as it will give the EU Commission a legislative basis to act in the HTA policy area.

The adoption and implementation processes of the Directive 2011/24/EU have taken place simultaneously with the preparation and implementation of the EUnetHTA Joint Actions. The aim pursued in the Directive is actually still the same as the one pursued by the various projects since EUR-ASSESS. In chapter 5 (section 5.1.3.3) we have examined the content of Article 15 of the Directive 2011/24/EU which offered the legal powers to the Commission to setup a "voluntary Network of national authorities or bodies responsible for HTA", permitting it herewith to institutionalise HTA cooperation in Europe. Hence, the Commission had a mandate to establish an EU HTA network, which it will execute in June 2013 (OJEU 2013). This newly created EU HTA Network will however closely build on the work so far achieved by the EUnetHTA Joint Actions as the latter will become the scientific and technical arm of the EU HTA Network which will be responsible for setting the political and strategic objectives of network (HTAN 2014). The strategic objectives comprise a broad scope of HTA cooperation; fostering cooperation between Member States and stakeholders, develop synergies between European and national HTA activities as well as synergies between regulatory and HTA issues (HTAN 2014).

From the start, the EU HTA Network will orientate its work to develop a (newly created) sustainable structure for HTA cooperation. As such, the 2016-2020 Multiannual Work Programme stipulates that "The HTA Network is expected to act as key strategic forum to contribute to defining the possible scope, sustainability and governance of the European cooperation on HTA, beyond Joint Action 3. (…) During the coming years, one of the main objectives for the HTA Network should be to take an active role in clarifying and ensuring conditions for a sustainable functioning of the scientific and technical cooperation when the EUnetHTA JA3 ends in 2020" (HTAN 2016:3). By creating this new network, the European Commission seeks to lift the European HTA cooperation to a strategic policy-level setting the agenda for the future cooperation initiatives.

As a policy orientated body, the EU HTA Network membership would be distinct from the EUnetHTA network. As such, the former would comprise among its members Member States' representatives on a policy level, while work in EUnetHTA would be done by scientists and researchers, the so-called ' HTA doers'. In both cases, it would be the ministries responsible

for health who would appoint members in the networks. In practice, however, overlap in membership between both bodies did exist and this could be explained by different reasons.

First, HTA knowledge is often situated in HTA agencies. Hence, HTA expertise can be lacking on a ministerial level in some countries. In those cases, ministries would turn to HTA agencies to represent them in the EU HTA network: "*I know that in the HTA network, fifty percent are really people from the Ministries of Health and the others are HTA people also involved in EUnetHTA*" (personal interview 11). *"It tends to be the bigger countries sending people from the Ministry and the smaller countries send someone from an agency because they don't have someone with enough expertise in the Ministry"* (Personal interview 19).

Second, by proposing membership on a policy-level, the European Commission sought, according to some, to "*move towards a political network*" and "*make the ministries more interested in HTA*" (personal interview 18). The appointment of Member States representatives remained however in the hands of the respective ministries. "*It was very difficult for the Commission to teach the Member States. The Ministries of Health appoint, and I think that was a little unclear. Maybe it could have been built up better from the Commission so that the signals had been clearer, that this is actually about strategic policy and not scientific, not HTA. What could we do? It is all networking. We talked about it. We couldn't give any single instruction to any partner. (…) It was a process that was not possible for us to influence.*" (Personal interview 4).

After the setup of the EU HTA Network, the European Commission has launched several initiatives in close consultation with this network and which would follow the classical path of the development of a new legislative proposal. As such, an impact inception analysis will be organised in 2015, proposing five potential scenarios for future HTA cooperation in Europe (European Commission 2016). These scenarios ranged from a proposing the status quo to an intense level of cooperation on production of joint Full HTA reports and their uptake[131]. In November 2016, the European Commission launches a public consultation on HTA cooperation (European Commission 2016c) to formally evaluate the response of all stakeholders regarding future HTA cooperation. The latter will be further examined in section 6.2.2.3.

---

131 The five scenarios are: 1. The status quo – Joint Action until 2020; 2. Long-term voluntary coopera-
tion (financed by the EU beyond 2020); 3. Cooperation on collection, sharing and use of common
tools and data; 4. Cooperation on production of joint REA reports and their uptake (cooperation
on clinical/medical matters); 5. Cooperation on production of joint Full HTA reports and their
uptake (cooperation on cost-effectiveness) (European Commission 2016).

This consultation is followed by an Impact Assessment in 2017 which will be published simultaneously with the formal proposal of the European Commission for a new Regulation on HTA cooperation in January 2018. This proposal foresees that certain aspects of the HTA cooperation, such as joint relative effectiveness assessments, will become mandatory for the Member States. As a consequence, HTA becomes the subject of (sometimes fierce) debates in the Council and European Parliament meetings who, according to the Ordinary Legislative Procedure, need to pronounce themselves on this proposal. At this point, HTA cooperation has thus been firmly set on the EU decision-making agenda and - as we will develop in the following sections - will trigger vertical (within the Council) and horizontal blockages (between reluctant Member States in the Council and the Parliament, which will increasingly support cooperation in HTA) (e.g. European Council 2014; 2015; 2016; European Parliament 2015; 2017). By setting HTA on the EU decision-making agenda, all actors concerned by the matter will have to clarify their positions regarding the scope and extent HTA cooperation in Europe should reach. These positions will be outlined in further detail in the following sections on policy- formulation and decision-making.

6.1.3. Conclusion agenda-setting processes in European HTA cooperation

As underscored by Howlett, Ramesh and Perl (2009) the agenda-setting process should not be considered in isolation from the other stages of the policy cycle. We have seen in this paragraph how indeed each previous project outlined the agenda of the next. This had already been the case since the EUR-ASSESS project in the early 1990s. The conclusions of the ECHTA/ECAHI project have been taken up in the discussions and project proposals of the HTA Work group in the HLG on Medical services and Health Care. Funding for the first EUnetHTA project has been secured through the health program as on an EU level the HTA objectives had been inserted in the annual health work plan. Similarly, the agenda for the Joint Actions was elaborated during the previous exercise to ensure continuity of the project as the main objectives (e.g. setting up a sustainable network for HTA cooperation in Europe) were still not reached and tools still needed to be further developed.

An important difference between the EUnetHTA activities with the early cooperation efforts lays in the fact that HTA cooperation post-2006 is not driven by the HTA actors only. Indeed, since its uptake in the high-level reflection process, the issue of European HTA cooperation had been officially discussed and supported in high-level policy arenas by both Commission and Member States' officials. Whilst the EUnetHTA project will still be run by the HTA arena, the Joint Actions will adopt a different approach with the Commission becoming a full-fledged partner of the initiative and the EUnetHTA partners being appointed by the Member States. Not only did the number of members increase, the typology of its members also broadened to include stakeholder groups representing the patients, payers, industry and health care professionals. As such, HTA cooperation did not only enter an EU agenda-setting

process but also moved up the domestic health policy agenda and became a point of attention in stakeholder organisations which increasingly felt concerned by the matter.

Being shuffled-in as flanking measure in the Cross-Border Health Care Directive (2011/24/EU), setting up an HTA Network to support the cooperation becomes a formal action point to be implemented by the Commission. With the establishment of the EU HTA Network, the Commission alters the governance of the cooperation efforts by separating the policy-orientation side from the scientific and technical operational side of HTA cooperation. This decision is politically not neutral as the strategic orientation of HTA cooperation now falls under direct influence of the European Commission which will set the agenda for future EU HTA governance initiatives. Moreover, membership of the two networks (i.e. EUnetHTA and EU HTA Network) is also affected by the Commission measures which in turn may have an impact on strategic decision-making and implementation. In the next sections we will further examine to which extent this decision has impacted the course of actions of EUnetHTA and other HTA cooperation initiatives. However, at this point it is important to highlight the importance of the agenda-setting process for the future developments in HTA cooperation. Hence, by means of what could be perceived at times as insignificant steps forward, HTA co-operation has inserted itself into high-level agenda-setting processes and, as such, developed from a technical HTA arena topic into a major EU public health issue.

6.2. POLICY-FORMULATION IN EUROPEAN HTA COOPERATION

The formulation of a policy is an essential stage of the policy cycle. The aim of this stage is to identify, assess and select policy options addressing a specific policy problem. Policy-formulation can already be initiated in the agenda-setting stage of the policy-cycle (Kingdon 2003: 205; Howlett, Ramesh and Perl 2009:110, see also chapter 4). The role stakeholders play in this process is of particular importance. Indeed, at this stage, a large set of actors concerned by the policy can be included and can influence the outcome the process (Howlett, Ramesh and Perl 2009: 111).

Policy-formulation can be analysed by breaking up the process into 4 stages: *appraisal*, *dialogue*, *formulation* and *consolidation* (Thomas 2001). Appraisal regards the data and evidence collection. Dialogue permits the facilitation of (formal or informal) communication between policy actors having different perspectives on the issue. The first two phases result in the actual formulation of the policy in the form of draft policy proposals. Seeking support and creating consensus on this proposal will take place during the consolidation phase (Thomas 2001). The identification and choice of policy instruments permitting to reach the

objectives set will also take place during the policy-formulation stage (see further Howlett, Ramesh and Perl 2009; chapter 4).

In this section, we will examine how policy-formulation has taken place in the EUnetHTA network and on an EU institutional level. We will proceed through the scope of four phases which make up this process *appraisal, dialogue, formulation* and *consolidation*. We will seek to identify how this process has developed throughout the different projects and Joint Actions as well as in the EU HTA Network. Particular attention will be given to the role and interests of the different stakeholders. The examination starts with the EUnetHTA project which took place from 2006 to 2008 as it has laid the basis for the subsequent HTA cooperation project (2009) and the Joint Actions (2010-2020). The latter will be discussed following the same analysis scope. The section closes with an outline of the policy formulation on an EU level with special attention given to the EU HTA Network and the events related to the Commission Proposal for a Regulation on HTA cooperation in Europe.

6.2.1. Policy-formulation in the EUnetHTA network

6.2.1.1. Policy-formulation in the EUnetHTA project

The *appraisal* stage of the first EUnetHTA project can be situated closely to the agenda-setting process. Data and information, underpinning the EUnetHTA project, had for an important part been gathered from the previous projects. This information has been inserted in the different working papers of the HLG which have permitted on the one hand the adoption of the final EUnetHTA project proposal. On the other, it has shaped the HTA discourse on a national and EU policy level during the discussions in the health Council. The project proposal presented in the HLG set out six priority areas which showed strong similarities with those of the previous projects (EUR-ASSSES, HTA-Europe and ECHTA/ECAHI). On 30 November 2004, the project proposal was integrated in the report of the High Level Group to the Employment, Social Affairs, Health and Consumer Protection Council which would take place on 6-7 December 2004.

Besides the six priority areas, defined in the October HLG meeting, the report also mentioned two additional objectives which are related to soft governance practices. The so-called *Key task 7* focused on the development of "tools for information support in the establishment of new agencies through benchmarking and training". *Key task 8* addressed the aim for designing and testing "tools for sharing methodologies, expertise and practical issues" (European Commission 2004f: 13). The inclusion of the two added objectives reflect the importance given to soft governance in the HLG and seem to result from the input of representatives of DG Employment and Social Affairs in the HLG as we have outlined in chapter 5.

ECHTA/ECAHI

Main goal

- Develop and strengthen the network(s) of HTA organisations in the EU by promoting cooperation between the various centres and activities concerned with assessments of health interventions in the member states

Strategic objectives

- Develop of a system for continuous collaboration and exchange of information and experience in the field of assessment of health care interventions in the EU
- Develop a model for formal networking in HTA

HLG Proposal

Main goal

- Set up a European HTA Network to connect public national HTA agencies and health ministries, enabling an effective exchange of information and support to policy decisions by MS.
- The network should help to provide reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies

Strategic objectives

Designing and testing methods for:

- Common core information packages
- Transferability of assessments
- Helping MS to identify and prioritise topics and commissioning reports
- Tailoring common core information to national health policy processes
- Sharing methodologies expertise and practice issues

EUnetHTA Project

Main goal

- Create an effective and sustainable network for HTA across Europe able to develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in Members States.

Strategic objectives

- Reduce overlap and duplication of effort and hence promote more effective use of resources
- Increase HTA input to decision-making in Member States and the EU and hence increase the impact of HTA
- Strengthen the link between HTA and health care policy making in the EU and its Member States
- Support countries with limited experience with HTA.

Table 6.1. Comparison general objectives HTA cooperation projects

Sources: ECHTA/ECAHI: 2001, European Commission: 2004a, b; EUnetHTA: 2009

These priority areas also reveal a sort of conducting thread since the early cooperation projects and which is reflected in the general objectives of the EUnetHTA project. Table 6.1 outlines how the priority areas identified by the working group on HTA cooperation in the HLG are closely related with the ECHTA/ECAHI project and how they have constituted the basis of the EUnetHTA project objectives. The overall goal of developing a sustainable European HTA network has, as outlined in chapter 4, been present since the very first EUR-ASSESS project. The ECHTA/ECAHI project concluded its final report by submitting an explicit request to the European Commission to develop such a network (see chapter 4). Table 6.1 shows how this request has been taken up by the experts of the HTA working group of the HLG who based their work on the early European HTA cooperation projects and adopted almost identical aims. After having been present in the HLG communication to the Health Council of December 2004, these objectives have been inserted in the EUnetHTA project proposal submitted four months later and will remained present in subsequent projects till the Commission regulatory proposal in 2018.

Whilst the *appraisal phase* of the EUnetHTA project can be situated mostly in the HLG and regarded essentially Member States representatives, the second phase of the policy formulation process – *dialogue* – has been developed outside this group and included mostly representatives of the HTA arena. It can be situated during the short preparatory phase before the project submission to the EU public health programme when the Danish Health Council representative reached out to the participants of the previous cooperation projects (see chapter 5). The content of the proposal has been discussed during the several informal encounters which took place between the project coordinator, representatives of HTA agencies (often former members of the early HTA cooperation projects and members from international organisations (e.g. INAHTA) (Personal Interview 7).

The actual 'policy-*formulation*' for the EUnetHTA project has been formally accepted during a preparation meeting in Copenhagen in February 2005 where the project proposal has been discussed and an agreement has been reached on the proposal to be submitted (personal interview 7). The meeting is sometimes being recalled by the absence of the "Big 4", referring to persons that could be identified as the 'policy entrepreneurs' of the early European cooperation initiatives (i.e. David Banta, Egon Jonsson, Alicia Granados and Chris Henshall). Although the reasons for this were multiple and linked to changing professional

occupations[132], it also indicates a shift in policy-making, seeking to position HTA on the political spectrum with the support of national decision-making institutions.

Hence, although the input and support on behalf of HTA agencies remained predominant, securing political endorsement at different institutional levels will become a goal that will be actively pursued by the project coordinator Finn Kristensen. As such, he will multiply encounters with policy-makers and in this sense he could be identified as another 'policy entrepreneur' of HTA cooperation in Europe (Personal interview 7). Indeed, several participants in the early stages of EUnetHTA underscore his sense of policy-making: "*He understood that it was not enough to work within the HTA agencies but that political support was needed*"; "*Finn had sense for policy-making and politics, he played a political game which was not always appreciated by all but often understood as necessary to take HTA cooperation a level up*" (Personal interviews 3, 6).

Seeking support through dialogue is also reflected in the support requested for EUnetHTA to the Health Evidence Network (HEN) (see chapter 5). The HEN had been created by the WHO and first headed by Egon Jonsson followed up by Alicia Granados, two key players in the early European HTA cooperation efforts. It aimed to develop HTA in Europe through an approach focused on evidence collection and dissemination[133]. Since 2001, no new European HTA project had been implemented and to a certain extent, the HEN sought to fill this gap. To avoid any competition between the HEN and the EUnetHTA project, WHO support had been requested (and obtained) by the project coordinator of the EUnetHTA project[134] (Personal interviews 6,7). With the moral support of the WHO adding up to the political support received on behalf of DG Sanco, the Council, the project was ready to be launched.

---

132 Reasons for their absence were multiple: Egon Johnson, had moved to Canada, where he pursued his activities in HTA. David Banta, although he had shown interest to remain active in the projects, did not wish to take any leadership position, Chris Henshall had taken up responsibilities in the HTAi. Alicia Granados was the newly appointed director of the Health Evidence Network (HEN) of the WHO. She will become involved in EUnetHTA at a later stage (Personal interviews 2,10,6).

133 The "HEN produces a variety of publications to meet policy-makers' needs: evidence reports synthesizing the best available evidence in response to policy-makers' questions; joint policy briefs and policy summaries, produced with the European Observatory on Health Systems and Polices, which synthesize the evidence around specific policy options for tackling key health system issues; and HEN summaries of reports, including synopses of the main findings and policy options" (http://www.euro.who.int).

134 Since the establishment of DG Sanco, a sort of non-written competition could be sensed between the WHO and DG Sanco regarding the promotion of health policy issues in Europe (Personal interview 5).

ECHTA/ECAHI Project
Policy formulation Strand 1
Organisation

WG 1 Health promotion and disease prevention
- Assess health promotion and disease prevention activities in terms of benefits/risks and economic, social and ethical implications as a complement to health indicators

HLG Project Proposal
- No information present in proposal

EUnetHTA Project
Policy formulation Strand 1
Organisation and communication

WP 1 Coordination
- Establish the organisational and structural framework for the network with a supporting secretariat

WP 2 Communication
- Disseminate and handle HTA results,
- Share information
- Coordinate HTA activities

WP 3 Evauation
- Evaluate the project (internally)

ECHTA/ECAHI Project
Policy formulation Strand 2
Joint assessments

WG 3 European Joint Assessments
- Identify possible joint assessments
- Co-ordinate findings and existing resources to support joint assessments

WG 4 Best Practices in HTA
- Develop and disseminate best practice in undertaking and reporting HTA
- Identify needs for methodological development

WG 6 HTA in Policy and Practice
- Identify and share successful approaches to link findings of assessments, their contribution to health indicators and health care decision-making

HLG Project Proposal
- Quality management procedures for production of common core information or joint assessments
- Tools for sharing methodologies, expertise and practical issues
- Transferability of HTA information between various European settings using a common framework
- Develop tools for tailoring common core information to inform health policy within Member States

EUnetHTA Project
Policy formulation Strand 2
Joint assessments

WP 4 HTA Core-model
- Produce generic core models for HTA for interventions and treatments
- Produce specific core HTAs on selected topics

WP 5 HTA Adaptation toolkit
- Develop and implement generic tools for adapting assessments in new (national) contents

WP 6 Transferability Health Policy
- Develop and implement tools to transfer HTA results into health policy advice
- Develop systems for identification and prioritisation of HTA topics
- Develop systems for assessment of impact of HTA advice

ECHTA/ECAHI Project
Policy formulation Strand 3
Monitoring, Prioritisation and Capacity building

WG 5 Clearinghouse and emerging technologies
- Develop system for exchange of information on emerging technologies, priorities for future evaluation, conduct and timing of ongoing evaluations

WG 5 Education and training
- Develop and coordinate education and support networks for individuals and organisations undertaking or using assessments or health interventions
- Identify needs and assist in establishment new provisions

HLG Project Proposal
- Develop tools for identifying needs and priority-setting in HTA
- Provide content support for emerging HTA agencies
- Develop tools for information support new agencies through benchmarking and training

EUnetHTA Project
Policy formulation Strand 3
Monitoring, Prioritisation and Capacity building

WP 7 Emerging / new technologies
- Structure prioritisation HTA
- Provide healthcare decision-makers with policy relevant information on new and emerging technologies
- Provide tools to monitor development health technologies and share results

WP 8 Support and capacity building
- Establish a support system for countries without institutionalised HTA activity

Sources: ECHTA/ECAHI: 2001, European Commission: 2004a,b; EUnetHTA : 2009

Table 6.2. Comparison specific objectives HTA cooperation projects

Hence, after intense dialogue in several formal and informal fora, consensus on the project has been found (*consolidation phase*) and its content could be submitted in the form of the EUnetHTA project proposal. A close analysis of the sub-objectives of the EUnetHTA project (Table 6.2) highlights again the continuity that existed between the EUnetHTA project and the early HTA cooperation initiatives. Transmitted through the HLG and, as underscored by some participants in the EUnetHTA project: "*the experience of previous projects was therefore important for informing the development of EUnetHTA*" (EUnetHTA: 2008a: 16).

The sub-objectives of the EUnetHTA project can be divided into three strands. The first regards the organisational, structural and communication aspects aiming the development of a sustainable European network for HTA. This also includes the evaluation of the projects and the functioning of the network. In this first category, a soft governance approach underpins these facets of the cooperation. Although the EUnetHTA project still follows a project-based approach it seeks to lay down an organisational structure on which a sustainable network can be established. The communication strategies are based on exchange of best practices and information sharing. Three specific workgroups in EUnetHTA will address these aspects: WG1 (Coordination), WG 2 (Communication) and WG 3 (Evaluation). The themes of these WG do not find an equivalent in the previous projects. They seem to result from the project submission format which is fixed by the European Commission.

The second strand could be considered to be the core of the cooperation initiatives: developing practical tools enabling the realisation of common assessments that will give input to national decision-making processes. This objective was also the driver of the early cooperation projects and incorporates the biggest challenge in terms of outcome. The ultimate aim is still to better coordinate HTA activities to avoid duplication of assessments, increase the quantity and quality of HTA output and enhance the uptake of joint HTA in national decision-making processes. This requires not only to agree on a solid methodology but also network management and governance skills. The EUnetHTA project has tried to meet the objectives of the second strand through activities organised in three different Work Packages (i.e. WP 4,5 and 6).

WP 4 focused on the setup of an HTA Core Model which should allow for the elaboration of joint assessments. This WP can be considered as a follow-up of what had been developed in WG 3 (European Joint Assessments) and WG4 (Best practices in HTA) of the ECHTA/ECAHI project and even work done in EUR-ASSESS: "*When we started this work trying to find out how we could work together and structure it, it led to the HTA Core Model. (…) How are we going to see this joint work, what is context unspecific or sufficiently context independent to be actually valuable across borders. So, there we were going back to some of the structure of EUR-ASSESS. The model is that way and EUR-ASSESS was very much reflecting the general,*

original definitions of HTA that is policy analysis and has a broad scope, is multi-disciplinary, all the things they got right. And that came out of people that understood policy analysis" (Personal interview 4). Hence, whilst the early HTA cooperation initiatives laid the basis for joint work by means of definitions, identification of best practices and methodological development, the EUnetHTA project sought to develop a concrete common Core Model which should be able to deliver joint HTAs.

Moreover, too ensure the uptake of those common HTAs in Member States, the WP 5 of the EUnetHTA project should develop a so-called 'adaption toolkit' permitting to adapt the outcome of the joint assessments in national contexts and facilitate HTA input in national health decision-making processes. Related to this objective and to ensure uptake of joint assessments in Member States, WP 6 focused on the development of tools to ensure the transferability of the HTA results into health policy-making processes. This work had already been initiated in the ECHTA/ECAHI project WG 6 which sought to identify successful approaches to link findings of assessments to health indicators and health care decision-making (see chapter 4).

The third strand of the sub-objectives of the EUnetHTA project regards prioritisation and capacity-building. These objectives too, were already present in the early cooperation projects (e.g. WG 2 ECHTA/ECAHI on Clearinghouse and emerging technologies). Indeed, to decide which health technologies would be subject to a common assessment, prior monitoring of new and emerging technologies as well as prioritising these, becomes essential. This was the focus of the WP 7 of the EUnetHTA project. Finally, assistance to agencies with limited experience in HTA is another aspect integrated in the EUnetHTA project WP 8 and which was also already present in the EUR-ASSESS project and the ECHTA/ECAHI project (see chapter 4).

Although stakeholder involvement was an important topic debated in the HLG meetings, it did not characterise the first EUnetHTA project. Nevertheless, during the appraisal phase, the importance of collaboration with important international HTA organisations, patient organisations and NGOs had been underscored (e.g. INAHTA, HTAi, Euroscan, Guidelines International Network, Cochrane Collaboration, OECD, WHO, and the Council of Europe). According to the Commission, the role of the industry "should be considered carefully as it is a major player in the field of HTA as well" (European Commission 2004b). Stakeholder involvement is also mentioned in the EUnetHTA proposal as important "to ensure transparency and early involvement of relevant parties in the development process". However, despite these reflections, stakeholders did not play any role in the policy-formulation process of the EUnetHTA project. This will change in the following EUnetHTA projects and Joint Actions as we will outline in the following section.

6.2.1.2. Policy-formulation in the EUnetHTA Joint Actions

As in the EUnetHTA project, the *appraisal, dialogue, policy formulation* and *consolidation* phases of the subsequent projects will mostly take place as a follow-up of the evaluation phase of the previous projects. However, a distinction of this phase of the cooperation efforts lays in the fact that at the end of the EUnetHTA project, insecurity still existed regarding the adoption of the Cross-Border Health Care Directive. The proposal was under examination since 2008. As outlined in the sections above, this proposal included an article on European HTA cooperation foreseeing the establishment of a formal EU network. Hence, whilst preparing the EUnetHTA collaboration and the future EUnetHTA Joint Action, the partners were aware of the necessity to pursue the collaboration efforts till the adoption of the Directive which could potentially affect the manner in which HTA cooperation would be governed as highlighted in the final report of the EUnetHTA project:

*"In July 2008, the European Commission published the proposal for a directive on cross-border health care, which provides for the establishment of an EU network for HTA (Article 17). Its intent is to enable Member States to facilitate development and functioning of an HTA network that connects national and regional HTA agencies. (…) Alongside this high-level European policy work, there is a need to ensure the continuity of EUnetHTA and that the work of the Project is used, piloted and developed. So, building on the effective collaboration that has been created in the EUnetHTA project, the encouragement of the European Commission and the support of the Member States that host EUnetHTA members, the partners have decided to create a sustainable, permanent European HTA collaboration to ensure continuation of communication, collaboration networks and activities" (EUnetHTA 2009:*16-17).

The *appraisal* phase (collection of data and evidence) of the first EUnetHTA Joint Action lays partly as we have seen in the EUnetHTA project and partly in the EUnetHTA Collaboration. The latter had been launched in November 2008 and could be considered as an 'interim-project' necessary to bridge the gap from the EUnetHTA project to the Joint Actions (EUnetHTA 2010:1)[135]. Its main activity regarded the preparations of the formal application for a Joint Action on HTA (EUnetHTA Joint Action) including the organisation of the consortium of partners and the development of the technical, financial and organisational structure of the Joint Action (EUnetHTA 2010: 1).

---

135   Indeed, the project proposal for the first Joint Action (JA1) was sent to the European Agency for Health and Consumers on 20 May 2009 (European Commission 2009). The EUnetHTA Collaboration was therefore prepared in the final stage of the EUnetHTA project.

Dialogue permitting to facilitate the communication between the actors concerned by the EUnetHTA Joint Action has mainly taken place in formal and informal arenas. Indeed, unofficial meetings and discussions had taken place in different fora within Commissions DG and HTA agencies permitting to exchange ideas about the continuation of HTA cooperation (Personal interview 4). The first official meeting between the national HTA appointed bodies and the Commission to setup the Joint Action took place in Brussel on 20 February 2009. Ideas for the future Joint Action were presented by both DG Sanco representatives and the EUnetHTA coordinator.

By being present in the preparatory meetings, DG Sanco was also in the capacity to influence the policy formulation process of the first Joint Action. The introduction of the concept of Relative Effectiveness Assessment (REA) is a good example hereof. According to Commission representatives, in the EUnetHTA project, the main focus had been on setting up the EUnetHTA commodities, framework, methodologies etc. However, insufficient progress had been made on the actual implementation of joint assessments. Hence, to push the idea of joint assessments forward, it introduced the concept of Relative Effectiveness Assessment (REA) in the EUnetHTA network during the preparatory meeting of the first EUnetHTA Joint Action (Personal interview 8).

REA was a topic that had been brought to the fore in the Pharmaceutical Forum (see chapter 5). As we have outlined above, this issue did not appear on the agenda in the early European HTA cooperation initiatives, neither in the EUnetHTA project. The Commission, steering the work from the HLG as well as the activities of the Pharma Forum, did however identify EUnetHTA as a suitable framework for the development of REA. A DG SANTE representative recalls: *"The EUnetHTA project was mainly [about] starting networking, starting some communication tools and so on. After the Pharma Forum came the issue of whether we could do assessments together. That was the trigger."* (Personal interview 8).

The proposal on REA had to be implemented alongside the work of EUnetHTA on the HTA Core Model, which targeted precisely joint assessments. At that point, it was not entirely clear how to articulate the distinction between both approaches on joint assessments: "*There was something called the high-level Pharmaceutical Forum and there were some discussions about relative effectiveness assessments (…). So, that has led to a lot of focus on relative effectiveness assessment and not to the broad assessment approach that is reflected in the HTA Core Model. I think that in terms of things that come out of EUnetHTA and will be influential on the long run, the HTA Core Model is going to be key, and that lays directly on the shoulders of EUR-ASSESS*" (Personal interview 4).

Besides the input of the Commission, other suggestions were brought to the fore during the preparatory meetings of the Joint Action. Most of these ideas were conceived as a follow-up of the EUnetHTA project Work Packages[136]. However, one new item had been presented pointing to the importance of "working with EMEA/national regulatory authorities to assess how available information at different bodies can be mutually used" (European Commission 2009a). Developing synergies between HTA and (European) regulatory authorities will be an issue of increasing importance over the years. However, in 2009, the concept of so-called 'Early Dialogues' was rather new in Europe and few HTA agencies applied it in their regulatory processes (Personal interview 29). This concept refers to need to establish a structured communication between the pharmaceutical industry and regulatory authorities aiming "to improve the quality and adequacy of early evidence generation in order to be useful for the HTA process of reviewing and synthesising evidence to inform coverage decisions" (www.eunethta.eu).

Indeed, as studies proving the safety and efficacy of technologies (especially in the case of pharmaceuticals) are long and costly, it is important to plan at an early stage the content of the study and the type of evidence to be provided. HTA bodies, intervening at a later stage of the assessment process, may however request information for coverage purposes which will differ from the needs of market access regulators (e.g. additional comparison, information on organisational or economic aspects). Moreover, there can be situations where evidence is indeed inadequate or insufficient at time of the assessment which consequently can generate insecurity and thus become an obstacle to timely access to health technologies. Early Dialogues are thus targeted at companies developing health technologies and seeking market authorisation and reimbursement access. They aim at exchanging views on scientific issues during the different stages of technology development and improve the quality and adequacy of initial evidence generation. As such, the HTA process could be facilitated which would potentially accelerate the coverage decision-making processes and thus patient access to new health technologies (EUnetHTA 2015b; see further 6.4.2.2).

Although the idea to develop common Early Dialogues – also called Joint Scientific Advice – had been discussed amongst EUnetHTA partners in 2009, it had not been introduced in the first Joint Action which was then being prepared. *"In 2009, we could not envisage to have a collaborative activity on scientific advice or Early Dialogues as it was just starting at the level*

---

136 The ideas brought forward by the participants included: capacity-building, non-pharmaceutical HTA, core HTA models and their practical application (piloting, including models to cover the full life-cycle of technologies from emerging to potentially obsolete), development of tools for exchange and dissemination of information on HTA (clearing house function), implementing HTA, stakeholder involvement (European Commission 2009a).

of HTA bodies. So, it is normal that it took a certain time and also, a Joint Action, once it has started, you cannot modify its fields of activity" (Personal interview 29). Hence, whilst not integrated in the Joint Action 1, the idea has nevertheless been launched during the Joint Action 2 as a pilot project called SEED: Shaping European Early Dialogues. It will be continued in a work package of the Joint Action 3 and incorporated in the 2018 Commission proposal for an HTA Regulation.

Hence, as the Joint Action 1 was being prepared with representatives of DG Sanco, support of the latter was guaranteed. Partners in the Joint Actions were being appointed through the Ministries of Health, indirectly endorsing thus the initiative as well. This support would continue over the subsequent Joint Actions 2 and 3. The adoption of the Cross-Border Health Care Directive would further impact the role and support of the Council and Commission in the policy formulation process. Indeed, since the adoption of the Directive 2011/24/EU, ensuring the continuation of HTA cooperation in Europe became even more important to the Commission and the Member States. Moreover, based on Article 15, the Commission became responsible for the establishment of a permanent network on HTA cooperation. This objective which had been present in all European HTA collaborative projects since 1994, but remained unattained, would, henceforth, formally fall under the responsibility of the European Commission. As such, it would actually be in line with the one of the formal requests of the ECHTA/ECAHI project (see chapter 4).

The policy-formulation process of the Joint Action 2, submitted in May 2011[137], has, to a large extent, been influenced by the adoption of the Cross-Border Health Care Directive (Directive 2011/24/EU) adopted in March 2011 (CBHC Directive). Indeed, the first prepara-tory meeting of the Joint Action 2 took place on 8 March 2011, one day before the formal adoption of the Directive. Agreement on this new legislative act had already been found in December 2010 between European Parliament, the Council and the Commission during a 'Trilogue' meeting, (EHMA 2011; www.europolitique.info). Hence, since that date, DG Sanco could take into account the fact that it would soon have a mandate to establish an EU HTA Network.

During the January 2011 meeting of the EUnetHTA Executive Committee, the EU representa-tive states indeed that: "*an agreement between the Council and the Parliament on the text has been reached. In the Directive, HTA is clearly defined as one of the areas of cooperation*

---

137 The initial deadline was actually set in April 2011. However, considering the recent adoption of the CBHC Directive an extension of this deadline has been ask and obtained, setting the new submission date on 20 May 2011. The project proposal for the EUnetHTA Joint Action 2 has finally been submitted on 23 May 2011 (EUnetHTA 2011b: 71-72).

between MS which opens a possibility for regular funding of this activity from the Commission. The signing of the Directive is expected for June 2011. It is a bit early to say when different steps on implementation of the Directive will take place, however, with regard to HTA, the complementary Joint Action on HTA is a main step towards the implementation of the Directive regarding HTA cooperation in Europe. The JA2 will serve as a framework for how this cooperation could be functioning. Based on that, an agreement could be reached between the MS and the Commission on setting up a permanent cooperation on HTA in Europe" (EUnetHTA 2011b: 71).

The relation between the Joint Action 2 and the Directive has also been highlighted during the second meeting of the JA2 preparation: "JA2 should provide continuity of HTA tools from JA1 to JA2, appropriate stakeholder involvement, training and education for partners and stakeholders (especially patients and providers of health care), and clear deliverable results to end of 2015 to inform how Article 15 of the CBHC Directive could work" (EUnetHTA 2011b:2*). Moreover, in the discussion about the implementation period of JA2, the role of the Joint Action with regard to the CBHC Directive has been once more underscored: "[JA2] ending on Sept 30 2015 with reporting of results at the end of 2015, will provide comprehensive information important for national implementation of Article 15, Cross Border Health Care (CBHC) Directive although the Directive implementation will begin in October 2013" (EUnetHTA 2011b:3).

Although it is clear that the JA2 should prepare the ground for the permanent EU HTA Network, confusion exists whether the EUnetHTA network will be transformed in the future European HTA Network or whether a different approach will be adopted. In absence of clarification on the latter, the content and objectives of the JA2 will, however, be defined by seeking to be conform to the requirements of the Article 15 of the CBHC Directive (EUnetHTA 2011b 13-18). This has been reiterated during the EUnetHTA Plenary assembly in May 2011: "*The general objective of JA2 is to strengthen the practical application of tools and approaches to cross-border HTA collaboration with the aims at bringing collaboration to a higher level resulting in better understanding by the EC and MS of the ways to establish a sustainable structure for HTA in the EU. Specifically, the JA2 will develop a general strategy, principles and an implementation proposal for a sustainable EU HTA collaboration according to the requirements of Article 15 of CBHC Directive.*" (EUnetHTA 20011b:50). In the JA2 application to the EAHC, the role of the JA2 is defined as "*Thus, the JA2 provides the empirical basis needed by the Commission and the MS to make decisions regarding the design and running of the voluntary HTA network within the framework of Article 15*" (EAHC 2011).

During the preparation of the JA2, the pressure on behalf of the Commission regarding expenses and deliverables becomes more tangible and will impact the policy-formulation

process. The Commission requiring a stronger commitment regarding the production of joint work and in particular joint assessments. The Commission also insists on the production of a solid business model for HTA cooperation: "The JA needs to demonstrate savings/efficiencies as well as increased quality as a result of cross-country collaboration. There needs to be a balance between HTA information production and other production aspects e.g. methods, capacity-building and networking with a focus to avoid any excessive allocation of resources for non-production such as methodology, administration etc. At the end of JA2 the business model should be deliverable and realistic" (EUnetHTA 2011b:8).

The *formulation* and *consolidation* phases of the policy-formulation process of Joint Action 2 can be situated at the time of the adoption of the JA2 project proposal. Its content has been discussed among the EUnetHTA partners in several formal meetings (see EUnetHTA 2011b). Discussions were based on a draft proposal developed by the EUnetHTA Joint Action 1 coordinator. Input to this had also been given by the Executive Committee and Collaborating partners. The proposal regarded mostly the continuation of the work established in Joint Action 1, taking into account the evaluation within the Working Packages and governing structures (EUnetHTA 2011b). The latter is reflected in the strategic and sub-objectives as shown in table 6.3. As the policy-formulation process took place with the participation of all key-actors, consolidation and support for the policy on behalf of the EU and MS institutions was a natural outcome.

Section 6.4 will outline in further detail how these objectives have been implemented. At this stage it is interesting to notice a fundamental difference between the objectives of JA1 and those of JA2 and JA3 and which is directly related to the CBHC Directive. As in all previous projects, the main objective in JA1 is to create a sustainable network of HTA cooperation. In JA2 and JA3, this has shifted into the strengthening of the practical application of tools and approaches to cross-border HTA collaboration. This is comprehensive when analysing the developments on the EU-level which will indeed impact the role of EUnetHTA, as we will outline in the next section. Since these are closely connected to the formulation of the objectives of JA3, we will discuss the latter in the same section.

6.2.2. Policy-formulation in the EU setting

With the proposal on the CBHC Directive, the Commission builds upon the work established in different networks and in particular in the HLG on health care and medical services. Indeed, following the removal of an article on health in the *Services Directive*, which had launched the debate in the Council and European Parliament, a window of opportunity was offered to DG Sanco to introduce a new proposal specifically aimed at Cross-Border Health Care. As outlined in chapter 5, the Commission shuffled in this proposal so-called 'flanking measures', which were in essence topics discussed in the HLG. The adoption of the CBHC

Joint Action 1

Main goal

- Put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level. This includes work on Relative Effectiveness Assessments.

Strategic objectives

- Development of a general strategy and a business model for sustainable European collaboration on HTA
- Development of HTA tools and methods.
- Application and field testing of developed tools and methods.

Joint Action 2

Main goal

- Strengthen the practical application of tools and approaches to cross-border HTA collaboration.
- Bringing collaboration to a higher level for a better Commission and MS understanding of the ways to establish a sustainable structure for HTA in the EU.

Strategic objectives

- Develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration according to the requirements of Article 15 of the Directive for cross-border healthcare.

Joint Action 3

Main goal

- Increase use, quality and efficiency of joint HTA work at European level.
- Support structural voluntary cooperation at scientific and technical level between HTA bodies.

Strategic objectives

- Support evidence-based, sustainable and equitable choices in healthcare
- Ensure re-use in regional and national HTA reports
- Avoid duplication of assessments
- Propose a sustainable model for the scientific and technical mechanism of a permanent European cooperation on HTA (2020 onwards)

Table 6.3. Comparison objectives Joint Actions
Sources: EUnetHTA 2013; 2013a; www.eunethta.eu

Directive in March 2011, will change the role of the European Commission in the field of HTA significantly and will impact the governance of HTA cooperation. Indeed, based upon the provision inserted in the Directive, the Commission could depart from the project-based approach which, till then, had failed to establish a permanent sustainable structure. Whilst the Commission had the mandate to establish a permanent EU HTA Network, the question remained which form this structure should adopt. The latter will be at the core of the Commission's HTA policy formulation process as of 2011. A question that needed to be resolved with the Member States, since the Commission still only had coordinating powers in this field. Hence, any regulatory proposal on its behalf would have to adopted by the Member States, united in the Council, as well as by the European Parliament which, in 2011, would not really be concerned by the matter yet.

6.2.2.1. Policy-formulation in the EU HTA Network

The CBHC Directive specified an implementation period of eighteen months regarding the provisions to be implemented by the European Commission. Even before the adoption of the Directive, DG Sanco had already created a Committee on cross-border health care which started to work as of June 2010 on a draft Implementing act regarding the establishment and functioning of the HTA network (EUnetHTA 2011b:51). After various discussions within the Committee, the Member States and interservice consultations (ISC) on the scope and purpose of the future network, the Commission adopted the implementing decision in June 2013 (OJEU 2013)[138]. This decision also acknowledged that "the HTA Network shall build on the experience gained in previous actions in the field of HTA supported by the Union and ensure relevant synergies with ongoing actions" (OJEU 2013). It specified that the "Members of the HTA Network shall be national authorities or bodies responsible for HTA designated by the participating Member States. Experts may be designated to accompany the Member" (OJEU 2013).

If in 2011, the impression was given that EUnetHTA would constitute the basis of the future HTA network, this becomes less clear in 2013, once the implementing decision had to be carried out and the network formally set up. During the first preparation meeting of the JA2, it was being specified that, as the Joint Actions were time-limited projects, a new permanent cooperation network formally had to be established through Commission decisions. This network had to be set up before the end of the Directive's transpositions period (October 2013). As there would be an overlap between the Joint Actions 1 and 2, these projects would

---

138 The latter provides "the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment" (2013/329/EU).

have to provide input for the Directive's transposition regarding the future network activities (EUnetHTA 2011b :9).

During the meeting of the EUnetHTA Plenary Assembly in May 2011, upon a question regarding the interaction and perspectives of the JA2 and the future HTA Network, the DG Sanco representative stressed that "EUnetHTA will continue to function on its way to a permanent structure (the network can keep the name EUnetHTA, or change it)" (EUnetHTA 2011b:51). However, during the meeting of the EUnetHTA Executive Committee, in October 2011, it was specified that, as this new network had to be established by way of comitology with the Member States, it could not be "taken for granted that this Network will be EUnetHTA. EUnetHTA should be evaluated based on its experience and influence" (EUnetHTA 2011b: 14). The Business Model to be developed in the JA2 should play a role in this evaluation process.

Meanwhile, the committee continued its work alongside the implementation of the Joint Action 1 and 2. In 2013, the EU Network for HTA Cooperation has been officially established (HTAN 2014). The strategic objectives of the EU HTA Network comprised a broad scope of HTA cooperation and in many ways correspond to those of EUnetHTA: fostering cooperation between Member States and stakeholders, develop synergies between European and national HTA activities as well as synergies between regulatory and HTA issues (HTAN 2014). From the start, the EU HTA Network will orientate its work to develop a (newly created) sustainable structure for HTA cooperation.

The first meeting of the EU HTA Network will take place in October 2013. The meeting needed to take a stance on the Multiannual Work programme (MWP) 2014-2016 of the new network. A draft MWP had been prepared based on the results of a consultation process held earlier. This process had gathered background information around key questions regarding the scope of the cooperation at EU level on production of HTA joint work as well as the impact of the EU HTA cooperation on national decision-making process. Moreover, a cost-benefit study on HTA at EU level had been commissioned by DG Sanco[139]. The latter underscored that increased HTA cooperation at EU level was associated with "significant scientific and economic return for HTA Agencies". Moreover, production of "joint HTAs" would lower production costs per report in the Member States up to 19 million euro per annum shared between HTA agencies and industry. Finally, a sustainable cooperation would also permit a more efficient use of national resources and make specialised expertise available in all EU Member States (Tenhave et al. 2013). Work related to HTA in other networks such as

---

139 Ten Have et al. (2013). European Cooperation on Health Technology Assessment. Economic and governance analysis of the establishment of a permanent secretariat. Final report.

the Working Party on Public Health at Senior Level[140] and an expert panel on effective ways of investing in health[141] had also been highlighted by the Commission. Furthermore, the European Semester Agenda[142] and Country specific recommendations were also identified as means where HTA related elements could be integrated since cost-effectiveness and efficient use of health care resources would be part of those.

These different studies accompanying the setup of the EU HTA Network can be considered as part of the *appraisal* phase of the EU policy formulation process and shapes the discourse which will be further developed in the *dialogue* phase. Besides the arguments that pleaded for increased HTA cooperation in Europe, other issues have been discussed, such as the scope of the HTA cooperation process (mostly pharmaceuticals and medical devices or also e.g. complex interventions?) or the question whether the EU action should also address issues related to the performance of health systems. Finally, the debate also addressed the relationship between the EU HTA Network and previous and existing initiatives in HTA cooperation. Similarly, it was being examined whether the EU HTA Network should focus only on clinical dimensions of HTA or also include organisational and economic ones (HTAN 2014).

Besides the main goal of establishing a sustainable network for HTA cooperation in Europe, two sub-objectives stand out in the discussions of the EU HTA Network. The first regards the increase of the production of joint work in the EUnetHTA JA2 which should also lead to a better uptake in reports of national or regional HTA agencies. This should be done however "within the limits of the EU competences, not interfering in the final decisions made at national or regional levels on the uptake, investments and disinvestments in health technolo-

---

140 The Working Party has set up 5 working groups to look at the following topics: 1) health and the European Semester Agenda; 2) Key success factors for investing in health through cohesion policy (where HTA is considered as a relevant tool to prioritise investment; and where structural funds may also be devoted to reinforce national HTA capacities); 3) Rational use of pharmaceuticals; 4) Integrated care and hospital management; 5) Performance assessment of health systems (European Commission 2013a)

141 This panel has been established in 2012 upon the Commission decision 2012/198/6). It aims at providing scientific advice and knowledge on the sustainability of health care systems. (https://ec.europa.eu/health/expert_panel/home_en).

142 "The EU Semester Agenda is a yearly cycle of economic policy coordination lead by the EU Institutions to support Member States in their efforts to meet Europe 2020 targets and implement growth-enhancing policies. As part of this process each year the European Commission undertakes a detailed analysis of EU Member States' programmes of economic and structural reforms and provides them with recommendations for the next 12-18 months. Member States have to respond with National
Reform Programmes. Healthcare is part of the European Semester" (European Commission 2013a:4).

gies" (European Commission 2013a:5). The EU HTA business model - one of the objectives of the EUnetHTA JA2 - was considered as mean to enable a broader joint production which could also facilitate the reuse of the tools and evidence generation produced at the European level into the national decision-making processes.

Second, explore possible synergies of successive phases of technology development, licensing and market access was also underscored. This need should be put in relation with the search for a faster access to new technologies which was debated in wider health policy circles. According to the Commission, processes enabling patients to access new technologies - from research to regulatory approval and CE marking – did not interact optimally. Hence, access to technologies could be delayed by different requirements made from different regulatory authorities (at the EU or national level). Synergy and defragmentation in the process would offer a timely patient access to innovative technologies, increase business predictability and reduce administrative hurdles for regulators and developers, while maintaining EU safety and efficacy criteria (European Commission 2013a:5).

During the first EU HTA Network meeting, the role of the Network and the distinction with the work carried out so-far has been explained: "Up to now HTA cooperation has relied on capable scientists to do the work but now we also need committed leadership to provide the strategic direction and long-term vision, avoid duplication and facilitate national follow up and re-use of EU joint work. (…) We are at a turning point: either we accelerate and build on results achieved so far or we may need to reconsider the entire initiative" (European Commission 2013a). This line will be at the heart of the Commission policy formulation process on HTA and will drive most interventions of the European Commission in the HTA cooperation process post 2014. In short, the message delivered is: either HTA should deliver more tangible results measurable in national HTA and regulatory processes or the Commission could withdraw all of its support.

The *policy-formulation* and *consolidation* phases can be identified in respectively the drafting of the First Multiannual Work Plan (MWP) and the adoption of the latter in October 2013. To ensure a smooth implementation of the MWP, a working group was established which would be responsible for drafting the strategy of the network. Hence a strategic vision of the network (including its long-term sustainability) had to be developed and priority areas identified, which could be potentially co-funded by the EU. Moreover, the working group highlighted the importance of facilitating links with EU policy developments. Reference in this sense was made to the EU Semester agenda, the Network of competent authorities for pricing and reimbursement as well as the reflection process on sustainable health systems (European Commission 2013a). Finally, a possible third Joint Action on HTA was not ruled out. (European Commission 2014c:4).

Since the implementing decision regarding the establishment of the EU HTA Network, the policy-formulation process of both networks (i.e. EU HTA Network and EUnetHTA) become intrinsically linked. In the following section we will therefore examine this process in both networks simultaneously as, in particular since the Joint Action 3, EUnetHTA's course of action will be determined by policy strategies defined in the EU HTA Network.

6.2.2.2. Synergies between policy-formulation of EU HTA Network and EUnetHTA Joint Action 3

Comparing the objectives of EUnetHTA and the EU HTA Network brings to the fore many areas where they overlap. This can be explained by the fact that, at time of the setup of the EU HTA Network, both needed to be complementary. Indeed, from the beginning, it is officially clarified that the key role of the EU HTA Network would be to "reach agreement on a common vision of HTA Cooperation at EU level, and to trigger reflections at national level on how EU cooperation can support national activities" (European Commission 2014a). However, the network also needed "to reflect on the longer term scenario (post 2020) to find a sustainable way to secure scientific cooperation when funding from the Health Programme ends" (European Commission 2014a). The scientific cooperation till then would be organised with EUnetHTA by means of a third Joint Action. The proximity between both networks and their activities is also revealed through the designation of the rapporteur of the Strategy paper of the EU HTA Network, who would be the future coordinator of the Joint Action 3.

Hence, the objectives of the JA3 will be mostly defined within the EU HTA Network. In this sense, the third EUnetHTA Joint Action follows a different path than the previous ones. As EUnetHTA's status has evolved to becoming the scientific and technical arm of the EU HTA Network, it's objectives and activities will be entirely defined by the strategic objectives and MWP of the latter (European Commission 2014b: 3-4). The strategy of the EU HTA Network will be published in 2014 along the MWP 2014-2015. This paper also reflected on how the newly established network would henceforth take over the 'ownership' of constructing the future of EU HTA cooperation: "The goal of European cooperation is to increase use, quality and efficiency of HTA production in Europe and to promote HTA in decision-making, in accordance with national practices and legislative frameworks" (European Commission 2014c). Moreover, the Strategy paper outlined that "the Network aims at designing and implementing a model of collaboration which could enable HTA bodies willing to do so: to rely more extensively on each other's work to perform national HTA reports; to engage in joint work, for further national consideration and adaptation; to cooperate more efficiently in defining evidence requirements through the life cycle of technologies from scientific advice (during development and scientific evaluation - pre licencing) to surveillance after introduction to healthcare practice" (European Commission 2014c: 6).

The Strategy paper furthermore underscored how consensus on a range of HTA issues had been found. Indeed, the EU HTA Network would adopt a broad scope of HTA cooperation including the full-life-cycle of health technologies (from Horizon Scanning to post-marketing assessment) and the whole range of technologies (besides pharmaceuticals and medical devices it included also companion diagnostics, surgical procedures, preventive and health promotion programmes, Information and Communication Technology (ICT) tools and integrated care processes). Moreover, all different domains of HTA would be considered and the network should provide support and input to a wide-range of decision-makers in health care. Hence, according to this document, the cooperation should facilitate joint HTA activities and enhance the exchange of experience and good practices. It should in this respect address the needs of different target groups: policy-makers providers, payers, regulators, developers of innovative health technologies and patients. (European Commission 2014c: 7-8).

This broad scope and life-cycle approach also explains the importance of elaborating cooperation efforts with other networks and bodies, regulations or projects concerned by HTA. The EMA, represented in all meetings of the EU HTA Network is an example hereof and important work will be done with this agency with regard to the development of synergies between HTA and regulatory bodies and in particular with Early Dialogues. Besides the collaboration with the EMA, the EU HTA Network expressed the importance to seek cooperation with the reflection process on safe and timely access to medicinal products (STAMP), the MAST assessment model for telemedicine and eHealth, the Network of Competent Authorities responsible for Pricing and Reimbursement (NCAPR), the Pharmaceutical Committee, the Council reflection process under the Working Party at Senior level on Public Health, as well as with ongoing regulatory work taking place on a European level (e.g. Clinical Trials Directive, implementing Decision on the Post Authorisation Efficacy Studies (European Commission 2013a; 2014a; 2014b; 2015a).

It is in this context that the Joint Action 3 will be developed as again submission for funding had to respect the timelines of the Work programme of the EU Health Programme. The *appraisal* and *dialogue* phase take place for an important part in formal and informal meetings within the JA2 structure. The experiences and lessons learned from the JA2, form an important input in the policy-formulation of Joint Action 3. Another input is, as outlined above, being provided directly by the EU HTA Network which will discuss all proposals for the JA3 and contribute to the elaboration of its objectives and policy instruments. These objectives will be fully in line with those fixed by the EU HTA Network. The EUnetHTA network itself, as scientific and technical arm of future EU cooperation, becomes a policy instrument for the implementation of the strategic objectives of the EU HTA Network (European Commission 2014a, 2014b; 2015a; 2015b). As such, the adoption of the Strategy paper almost coincides with the timelines of preparation and submission of a potential new Joint Action.

The *policy-formulation* and *consolidation* phases can be situated in the drafting and adop-tion of the Joint Action 3 project proposal which highlights two strategic objectives. First, it would seek to increase the use, quality and efficiency of joint HTA work at European level. Second, it would seek to support structural voluntary cooperation at scientific and technical level between HTA bodies. The first aim would be pursued by supporting evidence-based, sustainable and equitable choices in health care; ensuring re-use in regional and national HTA reports, avoiding duplication of assessments. The second strategic objective should be at-tained by the development of a sustainable model for the scientific and technical mechanism of a permanent European cooperation on HTA after 2020 onwards.

Again, the importance of producing joint work and its uptake in national policy and decision-making process had been brought to the fore. The need to have a structure permitting to maintain and develop the tools needed in this regard was once more underscored. The long-term objectives of ECTA/ECAHI had thus become short term project-based objectives which should be attained by 2020. This would be the first time in the EUnetHTA history that the establishment of a permanent sustainable structure had been linked to a deadline. With the establishment of the EU HTA Network, the EUnetHTA governance structure and means would however change, impacting the approach chosen by which these objectives would have to be reached (see section 6.3). The Commission proposal for a Regulation on HTA cooperation is the most tangible outcome of a changing EU policy towards sustainable HTA cooperation in Europe. In the following section we will examine the process which has led to the publication of the Regulation proposal in January 2018.

6.2.2.3. Policy-formulation at the EU Regulatory level

6.2.2.3.1. Preparing a new legislative proposal on HTA cooperation
With the work of the EU HTA Network and the Joint Action 3 being set in motion, a new policy-formulation process is underway and taking place, this time not on a network-level but on the EU institutional level. As of 2016, the Commission will develop several actions preparing the road for its Proposal of a Regulation on HTA cooperation which it will officially submit to the Council and the European Parliament in January 2018 (European Commission 2018).

Indeed, before proposing a new legislative initiative, the European Commission needs to assess potential social, economic and environmental consequences its initiative may have in the Member States. As such an *impact assessment* takes place, analysing the pros and cons of various policy options (https://europa.eu/european-union/eu-law/decision-making/procedures_en). In the case of HTA cooperation, the Commission proceeded by starting with an *Inception Impact Assessment* (IIA). The IIA has been implemented in 2016, outlining the

state of play of HTA Cooperation in Europe and recalling the work done in the different cooperation initiatives. The voluntary aspect of the cooperation had been highlighted since it had an impact on the uptake of the joint work which remained at the full discretion of the Member States. Indeed, the report underscored that: "While HTA bodies cooperate on developing common guidelines and even produce joint assessments, they can – and in practice do – still carry out parallel national processes. They can also decide whether to use or not the joint work (so called re-use or uptake). In the same way, also industry can decide whether and, if so, which health technologies they submit for joint assessments, thus possibly giving priority to products with a high profit margin over products with a high potential benefit for patients" (European Commission 2016:5).

Two main weaknesses of the cooperation efforts had been identified and which, according to the IIA, would justify action on behalf of the Commission. The first one was related to the limited impact of the cooperation efforts in national HTA processes. Explanatory reasons brought to fore legal, organisational and linguistic barriers. The second weakness was related to the lack of long-term sustainability of the cooperation model based on Joint Actions (European Commission 2016: 8). The Commission underscored how HTA cooperation depended largely on EU funding and how it would not be "rational to invest public funds into HTA cooperation at European level, if the uptake of the work is not improved and the duplication of efforts is not avoided" (European Commission 2016: 9). It underscored how Member States still highly differed in their procedural frameworks and administrative capacity which had an impact on the duration of the procedure, the product scope and the amount of assessments carried out per year. Hence, the potential of HTA cooperation would not fully be exploited and a new approach should be envisaged. Implicitly, this approach conveyed the message that, in case of a status quo, EU funding would be withdrawn (European Commission 2016).

To address these challenges, the Commission believed it should adopt an innovative approach, more firmly imbedded in an EU legislative framework. As such, it proposed to base any new initiative on article 114(1) TFEU which allows for the adoption of measures aiming to improve the functioning of the Internal Market, whilst ensuring a high level of public health. Article 168 (4) (c) TFEU would complement the first legal basis mentioned. Any proposal should however take into account what is stipulated in Article 168 (7) TFEU referring to the respect of the responsibilities of the Member States for the definition of their health policies and for the organisation and delivery of their health services and medical care. Hence, any policy regarding pricing and reimbursement should remain outside a new legislative proposal of the Commission.

Choosing Article 114 TFEU to foster HTA cooperation had however consequences for the overall approach to the cooperation process as this represented a shift from a public health

approach towards an EU market integration one. The rationale outlined in the Impact Assessments also clearly indicates the latter. The disparities amongst HTA processes in different countries would here be presented as an obstacle to the free movement of health technologies, reducing business predictability and create unequal access of health technologies to patients:

> *"Most health technologies are products which benefit from the free movement of goods within the internal market. Despite this, a number of obstacles to their free movement have been outlined in section 2 of this report. The procedural and methodological differences, along with the considerable duplication of HTA across the EU Member States, have a significant negative impact on when and where health technologies reach the market, thus reducing business predictability for companies, particularly SMEs. This, in turn, contributes to differences in patient access to innovative health technologies. These divergences and duplication also result in considerable additional costs for HTA bodies and industry alike.*
>
> ***The aims of this initiative cannot be achieved sufficiently without strengthened cooperation at EU level****. As described in section 2, the diversity and multitude of approaches to HTA across the Member States means that, due to their scale and effect, only action at Union level can eliminate the obstacles described. **Without action at EU level it is unlikely that national rules on how HTAs are carried out would be harmonised and thus the current fragmentation of the single market would persist.***
>
> *(…) Without an EU initiative, it is unlikely long-term cooperation on HTA between Member States would be significantly strengthened through bilateral or regional cross-border initiatives"* (European Commission 2018a:41, bold added).

Although the legal basis, placing HTA cooperation into an EU Internal Market logic, had been clearly expressed in the Impact Assessment, this had not been discussed, as such, during the *dialogue* phase preceding the publication of the Impact Assessment accompanying the official publication of the Commission proposal for a Regulation on HTA Cooperation. Hence, the fact that the new proposal would base itself on EU market law came as a surprise to most observers: "*nobody of us knew that they had the idea to put the proposal on the basis of the market. (…) And I do understand why they wanted to do that because it is easier. (…) This came as a surprise*" (Personal interview 22). Indeed, as we have seen in chapter 2, in the field of health care, the EU has only supporting powers to foster integration but no mandatory regulatory ones as in the field of the Internal Market. Hence, a Regulation in the field of HTA cooperation can only be legally justified with an Internal Market approach.

However, as outlined in chapter 2, any legislative proposal in the field of EU health policy needs to respect the subsidiarity principle[143]. To address this issue, the Commission concluded already in the IIA of 2016 that: "The on-going cooperation – namely the Joint Actions and the HTA Network – demonstrated the benefits of the EU cooperation (both in economic terms and on the quality and quantity of reports and other tools), while this cooperation model did not remove the fragmentation of the national systems and the duplication of efforts. *It is thus concluded – on the basis of the current experience – that the objectives cannot be sufficiently achieved at national level. An initiative strengthening cooperation and increasing synergies and reducing duplication of efforts would therefore be best pursued at EU level"* (European Commission 2016:12, italics added). This rationale will remain the same during the consultation process and will be integrated in the Proposal for a Regulation on HTA Cooperation (European Commission 2018:4).

Hence, the general objective of a new legislative initiative sought to "Enable Member States to strengthen their cooperation on HTA in a sustainable manner". This goal is fully in line with all the previous cooperation efforts. However, the two other main objectives that had been added, differed from the previous cooperation initiatives as they responded to EU common market objectives: "Ensure a better functioning of the Internal Market of health technologies" and "Contribute to a high level of human health protection, as stated in Article 168 TFEU and Article 35 of the Charter of Fundamental Rights". The 'traditional' objectives of HTA cooperation showing a continuation since the EUR-ASSESS project, would now figure as sub-objectives for a new legislative proposal as mentioned in the IIA. Indeed, these resumed again the objectives of the Joint Actions and concerned the reduction of duplication of efforts; the promotion of convergence in HTA procedures and methodologies; the increase in uptake of joint work in Member States and the long-term sustainability of EU HTA cooperation (European Commission 2016: 13).

Finally, the IIA presented also five possible scenarios for a future sustainable HTA cooperation in Europe. These scenarios would be submitted to a public consultation before a full Impact Assessment of them would be made. The first proposed the status quo – Joint Action until 2020. The second envisaged a long-term voluntary cooperation which would be financed by the EU beyond 2020; the third foresaw a mandatory cooperation on collection, sharing and use of common tools and data; The fourth, mandatory cooperation on production of

---

143 The subsidiarity principle refers to the fact that "in areas which do not fall within its exclusive competences, the Union shall act only if and so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at a central level or at a regional and local level, but can rather, by reason of scale or effects of the proposed action, be better achieved at Union level" (Art. 5 (3) Treaty of the European Union) (see also chapter 2).

joint REA reports and their uptake (cooperation on clinical/medical matters); and the fifth scenario targeted mandatory cooperation on production of joint Full HTA reports and their uptake (comprising economic, ethical, legal and organisational domains). (European Commission 2016: 13-15). Hence, the level of engagement was different in each option, ranging from very low to very high. Only Options 1 and 2 could be implemented by non-regulatory means. The other three options required to proceed via a specific regulatory route (Directive or Regulation).

The Inception Impact Assessment can be considered as representing the *appraisal* phase of the (EU institutional) policy-formulation process on European HTA cooperation. The second phase – *dialogue* - will mostly take place during the public consultation process that ran from 21 October 2016 to 13 January 2017. Besides the online questionnaire, bi-lateral meetings between various stakeholders and the Commission have been organised. An impact analysis of the policy options[144], a mapping exercise of HTA methodologies in the EU and Norway[145] and a mapping of HTA national organisations, programmes and processes in the EU and Norway[146] have been carried out to assess the options as well as a separate, industry-commissioned study[147]. The conclusions of those studies have been taken into consideration in the Impact Assessment (IA) which has been published in January 2018 alongside the Commission proposal for a Regulation on HTA Cooperation and which can be considered as the actual *policy-formulation* phase. In the following section we will examine in more detail the content of the Commission proposal and the various responses to that by the actors in the field.

6.2.2.3.2. Proposing a new EU legislative framework on HTA cooperation
The "*Commission Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU on HTA cooperation*"

---

144 European Commission (2017a). *Study on impact analysis of Policy Options for strengthened EU cooperation on Health Technology Assessment (HTA) Final. Available at:* Report https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_ia_policyoptions_en.pdf. Last accessed on 9 July 2019.

145 European Commission (2017b). *Mapping of HTA methodologies in EU and Norway.* Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_mapping_methodologies_en.pdf. Last accessed on 9 July 2019.

146 European Commission (2017c). Mapping of HTA national organisations, programmes and processes in EU and Norway. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_mapping_npc_en.pdf. Last accessed on 9 July 2019.

147 Charles River Associates (2017). Report: *Assessing the wider benefits of the EU's proposal on strengthening cooperation on HTA.* Prepared for EFPIA. Available a*t:* https://www.efpia.eu/media/219813/cra-efpia-european-cooperation-on-hta-impact-assessment-final-report-july-2017-stc.pdf. Last accessed on 9 July 2019.

submitted on 31 January 2018, proposed to establish a new framework where HTA coop-eration at the EU level would be organised according to four main pillars: 1) Joint Clinical Assessments; 2) Joint Scientific Advice; 3) the identification of emerging health technologies and 4) voluntary cooperation in non-clinical aspects of HTA (e.g. economic, social, ethical) (European Commission 2018: 11). As the proposal was made in the form of a Regulation, the text would become binding once adopted by the Council and the European Parliament (see chapter 2). Hence, whilst voluntary cooperation could still take place for assessments regarding non-clinical domains, use of cooperation outputs for clinical assessments would become mandatory to all EU Member States.

As underlying reason for the choice of this legislative instrument, the Commission argued that "the diversity and multitude of approaches to clinical assessments across the Member States means that, due to their scale and effect, only action at Union level can eliminate the obstacles described. Without action at EU-level it is unlikely that national rules on how HTAs are carried out would be further aligned and thus the current fragmentation of the Internal Market would persist" (European Commission 2018: 4). As such, the Commission had recourse to the subsidiarity principle arguing that although the cooperation efforts in the Joint Actions and the EU HTA Network have "illustrated benefits of EU cooperation, in terms of establishing the professional network, the tools and methodologies for cooperation and piloting joint assessments, this cooperation model has not contributed to the removal of the fragmentation of national systems and the duplication of efforts" (European Commission 2018:4).

Moreover, the proposal underscored that "while Member States have carried out some joint assessments within the framework of the EU co-funded Joint Actions, the production of output has been inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the Joint Actions, including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed" (European Commission 2018: 17).

Besides respecting the subsidiarity principle, a new legislative proposal also needs to respond to the principle of proportionality as enshrined in Article 5 of the Treaty of the European Union stipulating that; "the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties". This principle underpins the rationale of the Commission to only make the Joint Clinical Assessments mandatory and not a full core-HTA. When defining 'Joint Clinical Assessments' (JCA) the Commission proposal referred to the HTA domains as defined by EUnetHTA. The Joint Clinical Assessments would correspond

with the domains used in the Relative Effectiveness Assessments: 1) the identification of a health problem and current technology, 2) the examination of the technical characteristics of the technology under assessment, 3) its relative safety, and 4) its relative clinical effectiveness (European Commission 2018: 16).

As such, the proposal would, according to the Commission, respect the principle of proportionality as the proposal stipulated that it "does not oblige Member States to carry out an HTA on health technologies which are the subject of joint clinical assessments. However, where Member States do carry out HTAs on such health technologies, there is a requirement for mandatory use of the joint clinical assessment report and no repetition of the clinical assessment in Member States' overall HTA processes" (European Commission 2018:13). Therefore, the proposal would constitute a "proportionate and necessary response" to problems such as duplication at national level of joint clinical assessments and, as such, reduce the administrative burden of health technology developers having the same technology being assessed in multiple Member States (European Commission 2018:4).

Proportionality was also reflected, still according to the Commission, in the fact that the scope of joint work in the proposal would be limited to certain types of medicinal products and medical devices allowing flexibility when it comes to timing of JCA for medical devices[148] (European Commission 2018: 5). Moreover, no new requirements had been introduced for health technology developers compared to what already existed in national legislation. However, the proposal aimed at ensuring that "when HTA is performed, the methodologies and procedures applied are more predictable across the EU and when subject to joint clinical assessment such assessments are not repeated, avoiding duplication and discrepancies" (European Commission 2018: 5). A phase-in approach had been foreseen, allowing Member States and industry to adapt to the new system (European Commission 2018: 5).

---

148 The Commission proposal for a Regulation on HTA cooperation differentiated the HTA approach between medicinal products and medical devices. Regarding medicinal products JCA would regard "all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council, which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication (European Commission 2018: 11). For medical devices, JCA should be carried out only for "devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views and which have been selected by the Coordination Group set up under this Regulation based on the following criteria: unmet medical need; potential impact on patients, public health, or healthcare systems (e.g. burden of disease, budget impact, transformative technology); significant cross-border dimension; Union-wide added value (e.g. relevance to a large number of Member States); the resources available to it" (European Commission 2018:11).

The second pillar of the proposal regarding Joint Scientific Advice (JSA) - corresponding to the 'Early Dialogues' implemented by EUnetHTA - would adopt a similar approach as the JCA. The main difference would reside in the fact that the reports regarding JSA would not be published nor bind the health technology developer or the Member States at time of (joint) clinical assessment. Transparency would be assured by including information about the JSA in the annual reports of the Coordination group (European Commission 2019: 13). Horizon Scanning, as known in EUnetHTA, constituted the third pillar of the proposal where an annual study would be carried out to identify new emerging technologies "expected to have a major impact on patients, public health or healthcare systems" (European Commission 2018: 13).

The non-clinical domains, for which voluntary cooperation has been foreseen, correspond to the last five domains of the HTA Core Model: cost and economic evaluation, ethical analysis, organisational aspects, social aspects, and legal aspects. It would also apply to all health technologies other than medicinal products and medical devices, or devices not selected for JCA (European Commission 2018:13-14; www.eunethta.eu). Use of previous HTA research outputs on Real World Data or evaluation of innovative technologies (e.g. e-health, personalised medicines) as well as the assessment of non-clinical domains, should not be excluded from the cooperation efforts, according to the Commission proposal (European Commission 2018: 14).

The choice to propose a Regulation on HTA cooperation with a mandatory uptake of Relative Effectiveness Assessments for some pharmaceuticals and medical devices, came as a surprise for most observers. Indeed, scenarios presented in the public consultation[149] and in the IA online survey, did offer a more flexible option where uptake would be mandatory only for those who had decided to opt-in in the joint work (European Commission 2016c; 2017d). The latter seemed to present the preferences of most HTA stakeholders in both studies. One should notice that in the public consultation, the term 'joint work' was very broadly defined and comprised activities ranging from literature reviews to Early Dialogues REA and Full

149 The scenarios in the Public Consultation were: 1) *voluntary cooperation with voluntary uptake of joint work*, 2) *voluntary cooperation with mandatory uptake of joint work for the participants* or 3) *mandatory cooperation with mandatory uptake of joint work*.(European Commission 2016c).

HTAs[150]. Hence, assessing real preferences regarding HTA domains which should fall under binding legislation was hard to assess.

In the IA online survey[151], options had been clearly specified and were more in line with those of the IIA: besides project-based voluntary cooperation (option 2), some options did foresee binding legislation regarding cooperation on common tools and Early Dialogues (option 3), or the possibility to Opt-in for joint REAs plus option 3 and making uptake mandatory only for those who would choose to participate (option 4.1). Option 4.2 would be similar as Option 4.1 without the choice for participants to opt-in or not. Hence, in this case, joint REA combined with the previous options would be mandatory for all. Only the joint full HTA would remain voluntary. The last scenario (option 5), was considered in most studies the least feasible as it proposed a mandatory approach on all types of joint work including the Full HTA[152] (European Commission 2017).

It is unclear which arguments have convinced the Commission of choosing the approach adopted in their Regulation proposal and to what extent the conclusions of the different studies have weighted in their policy-formulation process. Some of these studies and their design had indeed been contested. The IA had to assess, amongst others, the costs of joint collaboration and their economic and social/health impacts regarding the several options presented. However, this seemed to be a very challenging exercise. As activities amongst HTA agencies highly differ, the allocation of resources regarding the specific items investigated in the studies was for some agencies sometimes hard (or impossible) to measure. Moreover, the questionnaires comprised cooperation options in fixed combinations. They were presented as possible combinations of the options mentioned in the IIA. However, although the idea was to fine-tune options which were provisional, the study did not offer the possibility to as-

---

150 Joint work was specified in the questionnaire as: "*'Joint Work' refers to activities in which countries and/or organisations work together in order to prepare shared products or agreed outcomes. These may include, for example, literature reviews, structured information for rapid or full HTAs, Early Dialogues or scientific advice on R&D planning and study design. Joint work aims at supporting Member States in providing objective, reliable, timely, transparent, comparable and transferable information and enable an effective exchange of this information (according to HTA Network's "Strategy for EU Cooperation on Health Technology Assessment" adopted in October 2014)"* (European Commission 2016c).

151 The online survey was part of the "Study on impact analysis of Policy Options for strengthened EU cooperation on Health Technology Assessment (HTA)" (European Commission 2017).

152 The policy options in the online survey were Policy Option 1: Baseline scenario - No EU action after 2020; Policy Option 2: Voluntary cooperation supported by the Public Health Programme; Policy Option 3: Legislation covering Common Tools and Early Dialogues; Policy Option 4.1: Opt-in for Joint REA plus option 3; Policy Option 4.2: Mandatory Joint REA plus option 3; Policy Option 5: Option 4.2 and Opt-in for Full HTA (European Commission 2017).

sess opinions regarding specific characteristics of the presented options. As such, no further elaboration of the policy-options was possible and respondents had to remain within the given grids, even though this would only partially reflect their preferences (European Commission 2017e; Personal interview 20).

Similarly, the accuracy of the assessment regarding the costs of cooperation of each option had been questioned as, due to the survey format, no fine-tuning was possible. Respondents were for example asked to answer questions such as: *"To what extent do you expect each policy option to impact on the total costs of a REA submission (if applicable)? (Total costs including costs for staff, (re)submission costs, administrative cost, costs for including stakeholder, etc.)"* (European Commission 2017e). Analysing the impact of a new activity requires to put it in relation with the degree of implementation before and after, as well as many other aspects such as the repartition of (external) funding sources, the division of labour in the future collaboration model, etc. Due to the rather rigid format of the questionnaire and the lack of information regarding some items (which could therefore not be taken into account), some respondents casted doubts on the accuracy of the outcome of the study (Personal interview 20). The European Commission acknowledged the limitations of the study and confirmed that "the results do not allow precise quantification but should be taken as general indications on the overall trends" (European Commission 2017e: 81).

Option 4.2 has been indicated by the authors of the report as the most preferred option to fulfil the general and specific objectives set out in the IA concerning HTA cooperation and which regarded Effectiveness, Efficiency, Coherence, Subsidiarity and Proportionality (see above). According to these criteria, it scored better as the Option 4.1 as, indubitably, convergence would be higher in case of a mandatory approach applicable to all Member States compared to an opt-in approach where some Member States would not adopt the measures. The same goes for all other criteria. Although, the mapping study did conclude that the transition would be possible for all European countries, taking into account the legal, administrative and timelines applicable in certain countries, it did not further assess the *willingness* of national administrations and HTA agencies to go for a full mandatory approach.

Whilst stakeholder participation had been an integral part of the consultation process, the actual participation of the various stakeholder groups in the consultation process and the IA study showed quite some representation disparities. Indeed, few contributions came from the patients, payers and health care providers. A majority of the contributions came from the

industry which clearly outnumbered representatives of HTA agencies[153]. However, the Commission has organised a separate consultation round in which it has held some 25 meetings with different stakeholder groups so as to better understand their position (https://ec.europa.eu/health/technology_assessment/events_en#anchor2).

The interests at stake in HTA cooperation clearly varied among the different stakeholder groups, each pursuing their own agenda. As such, the pharmaceutical industry highlighted how the diversity of HTA procedures (e.g. starting period, length, scope, data accepted) across the EU represented a hurdle for developers. The medical device industry underscored how HTA processes often played a limited role in market access processes. The latter would be country specific and no established HTA processes would often be in place. Hence, HTA cooperation would thus be of lesser importance to this stakeholder group. Medical device representatives also expressed their concern to have HTA processes being developed for medical devices based on a pharmaceutical product approach not addressing the specificities of their sector. Moreover, due to variable timelines of market access and assessments of products, a compulsory HTA process could, according to some, even become a "market barrier with major implications on the development of new products" (European Commission 2017d:13). Patients and health care providers would be favourable towards strengthened HTA cooperation. They, however, argued for more transparency in the assessment processes as well as a better involvement of these stakeholder groups in the HTA processes.

All stakeholder groups agreed with a large majority that EU HTA cooperation was "useful" or "to some extent useful" and that cooperation should be pursued (European Commission 2017d:16-19). The most preferred policy option for future cooperation was the "voluntary participation with mandatory uptake". The option "mandatory participation and mandatory uptake" gathered only a third of favourable positions and showed also the highest opposition with 66% indicating this as their least preferred option (European Commission

---

153 The Public Consultation Process gathered in total some 249 replies (63 from individual/citizens and 186 from administrations, economic stakeholders, associations and organisations). The participation of the various stakeholder groups did not follow an equal representation: the industry (Pharmaceutical and medical technologies) represented more than half of the responses (53%) followed by the public administrations (14%), patients and consumers (13%), healthcare providers (9%) and payers (3%) (European Commission 2017d). The online survey, aiming to assess the costs of HTA processes and effects of different policy options, also included an important share of the industry compared to the other stakeholder groups. Out of the 177 responses collected, 120 came from the medical device industry, 20 from the pharmaceutical industry and 32 from Public administration, 2 from payer organisations and 1 from patient organisations and 2 from academia. Moreover, few representatives from ministries have participated in this consultation (6 replies) as the group on public administration comprised mostly HTA agencies (European Commission 2017).

2017d: 23). In favour of the latter were in particular patient organisation indicating that this option would offer more commitment from Member States. Pharmaceutical companies supported harmonisation of relative effectiveness assessments at time of launch and pleaded for synergies between regulators, HTA bodies and payers regarding evidence requirements. Their preferred option actually laid outside the three options proposed (other) followed than by the "voluntary participation with a mandatory uptake" until the process had proven itself. Medical device companies emphasized their need for a differentiated approach adapted to their needs. Health care providers were divided as regards their preferred option. Some opting for a voluntary/voluntary approach, others preferring a voluntary participation with a mandatory uptake. Payers preferred the voluntary participation with voluntary uptake (European Commission 2017d: 23-24).

The public consultation and the online survey do refer to responses of public administrations. The reports states that the contributions from this group were provided mostly by HTA bodies. It remains unclear to what extent opinions have been collected from representatives of Ministries of health of the Member States. Indeed, their contributions in the public consultation was very limited and even though it is mentioned that some discussions had been held between the Commission and representatives of Ministries of health, the latter did not seem to feel quite concerned by this topic at the time of the Consultation process (European Commission 2017d). It is only after the Commission proposal publication that (fierce) reactions from some Member States have been expressed. Several countries (e.g. Germany, Czech Republic, France and Poland) calling upon the subsidiarity principle to challenge the proposal in front of the legal European authorities (Council 2018; 2019). Hence, with the publication of the Commission proposal for a Regulation on HTA cooperation, the policy-formulation process enters a different policy arena, as first the Parliament needs to pronounce itself on the proposal after which it will be debated in the Council. Although the Commission hoped for a smooth adoption process before the next Parliamentary elections in May 2019, the Proposal encountered opposition on behalf of several Member States. At time of writing, a new European Parliament term had started. The European Parliament had voted on amendments in its first reading (European Parliament 2018) and proposal would still be under examination of the Council (first reading) as many unresolved issues would lay on the table.

6.2.3. Conclusion policy-formulation in European HTA cooperation

The formulation of a policy is an essential stage of the policy cycle and aims to identify, assess and select policy options addressing a specific policy problem. In the present case, the policy-formulation process sought to address the challenge of creating a sustainable European HTA cooperation structure allowing for the development and uptake of joint work. In the above sections we have analysed the HTA cooperation policy-formulation process since the EUnetHTA project and we have seen how each stage did built upon the work of the

latter. However, we have also seen how, gradually, the European Commission has become increasingly involved in this process to even take over the ownership of the cooperation initiative and propose a Regulation on HTA cooperation.

Herewith, not only the actors involved in the policy-formulation process would change, but also the policy objectives would gradually be adjusted. As such, whilst the first EUnetHTA project had been designed within the high-level group on medical services and health care, it demonstrated a continuity with the objectives of EUR-ASSESS an ECHTA/ECHAI. The EUnetHTA Joint Actions will mark an important difference in the policy-formulation process, as the European Commission became a full-fledged partner in the process and had to approve the objectives of the initiatives. Moreover, it will introduce important changes in the networks activities by incorporating the development of, for example, joint REAs in the network's objectives.

The adoption of the Cross-Border Health Care Directive will be another landmark in the policy-orientation and formulation process of HTA cooperation in Europe. Indeed, based on this new legislative instrument the EU HTA Network will be established and take over the strategic orientation of HTA cooperation in Europe. Although initially often considered as being the future sustainable network, EUnetHTA becomes the scientific and technical arm of the EU HTA Network and its work will be fully determined by the EU HTA Network. The latter will remain focused on elaborating a sustainable model for HTA cooperation and will serve as a hub for the Commission to develop a new legislative proposal for a Regulation on HTA. However, new objectives will enter the policy-formulation process, allowing to find a legal basis for a proposal in the EU legislative framework.

This proposal departs from the previous cooperation initiatives by introducing new (market-orientated) objectives. Indeed, from a health policy approach, HTA cooperation will be regarded in the scope of market integration policies, as this is the only basis allowing the Commission to make a regulatory proposal in the field of public health policy. The general objectives of HTA cooperation are thus altered and turned towards an optimisation of Internal Market policies besides the (pre-existing) objectives turned towards improving human health protection. Whilst the approach adopted in the early cooperation initiatives and the EUnetHTA project and Joint Actions was predominantly turned towards the sustainability of health systems and increased patient access to new health technologies, the new Commission approach is turned towards Internal Market objectives herewith seeking to conciliate the industry interests with public health interests. Consequently, what used to be the main objectives of the previous cooperation projects in EUnetHTA and its predecessors become so-called 'Operational objectives' in the Regulation proposal (e.g. convergence in HTA tools, procedures and methodologies; reduce duplication of efforts for HTA bodies and industry; uptake and long-term sustainability of EU HTA cooperation (European Commission 2018:2).

Hence, as for the agenda-setting process, at the surface, it seems that over the years the overall project objectives remain the same. However, a detailed scrutinisation of the policy-formulation process brings to the fore how slowly but surely the European Commission takes over the strategic direction of HTA cooperation in Europe and re-orientates the overall policy-formulations which will lay the basis for the decision-making process regarding HTA cooperation. There were the sustainability of health systems and patient access had been driving the (early) cooperation efforts, industry interests find their place in the debates, potentially altering the overall objectives of the (future) cooperation initiatives. From a voluntary soft governance approach, the HTA cooperation process is proposed to enter a mandatory legal EU framework, despite the opinions expressed in the public consultations indicating that this option would trigger the most opposition.

In principle, the Commission has followed the traditional Community approach before proposing a new legislative act. Indeed, an Inception Impact Assessment had been made followed by a public consultation and an Impact Assessment. However, again, a close examination of these studies brings to the fore how this process has maybe not been utilised to its full potential. Stakeholder groups have not been equally represented in this process; some groups (e.g. industry) being over-represented and others (ministries of health) being under-represented. The general opinion in terms of preferences has not been taken into account. Moreover, the cost-effectiveness analysis did not permit to make a reliable assessment of the potential impact of the proposal due to the survey format which did not seem fit for purpose.

The analysis of the policy-formulation process shows how the insertion of HTA cooperation into EU legislative texts allowed for a shift in ownership of the cooperation process on the one hand as well as a shift of competences on the other. Indeed, shuffling HTA cooperation in the flanking measures of the Cross-Border Health Care Directive, offered the Commission the opportunity to create the EU HTA Network and thereby steering the strategic orientation of the cooperation. By means of this network, preparatory studies have been paving the way for a new Regulatory proposal of the Commission based on Internal Market principles and thereby potentially changing the nature of the cooperation initiatives.

In the next section we will examine how these policy-formulation processes have impacted the next stage of the policy-cycle: decision-making. We will first analyse the governance and decision-making processes in EUnetHTA before we turn to the EU (institutional) level. Specific attention will be given to the role of stakeholders and how they have been able to influence the overall process of European HTA cooperation.

6.3. DECISION-MAKING IN EUROPEAN HTA COOPERATION

6.3.1. Decision-making in the EUnetHTA network

In chapter 4 we have outlined how the decision-making phase of the policy cycle refers to the stage in which one or more (or non) of the policy alternatives envisaged in the previous stages are adopted as the official course of action (Howlett, Ramesh and Perl 2009: 139). As an inherently political process, it involves key-actors which will have an impact on the final choices. The outcome of this stage is the object of the next stage: *policy implementation*. Beliefs and values of actors, the nature of the relevant subsystem and existing constraints, can all affect the decision-making process. Different theoretical models exist to conceptualise decision-making processes underscoring either the role of rationality (e.g. rational model), bargaining and negotiation (e.g. the incremental model), or conversely irrationality and unpredictability (e.g. 'garbage can' model) (see further Howlett, Ramesh and Perl 2009). Decisions do not take place in a single institution nor at a single point of time (Weiss 1980: 399-401) and can be taken over a period of time at multiple levels and by multiple factors (see further e.g. Klijn 2001; Timmermans 2001). Finally, several decision-making processes can occur simultaneously and can mutually influence each other as well as actors' positions on an issue (see further e.g. Klijn and Kloppenjan 2000, Howlett 2007, Howlett et al. 2009).

6.3.1.1. Decision-making in the EUnetHTA project

The governance structure of the EUnetHTA project (2008-2010) closely followed the recommendations made by the ECHTA-ECAHI project. This is being confirmed by the final technical report of the EUnetHTA project which states that:

"*The European Commission has funded three major projects over 1994 – 2002 that sought to support collaboration on HTA methods and working: EUR-ASSESS, HTA-Europe and ECHTA/ECAHI. The later projects stressed the need for a permanent structure to support HTA coordination in Europe to avoid duplication, maximise scarce resources, strengthen HTA in Member States and ultimately contribute to the better health of all European citizens. It was proposed that the structure to support HTA coordination should include all Members States via a Steering Committee, with an administrative group to support the activities of the network, mechanisms to involve relevant European expertise and funding support*" (EUnetHTA 2009:2).

The governance structure of the EUnetHTA network in the 2008-2010 project still underwent influence from its project-based funding basis. The contract signed within the framework of the EU public health program required that a main partner would be responsible for the project. The National Board of Health of Denmark (the Danish representative in the HLG) 'naturally' took this position. It was joint by 33 Associated Partners who all co-funded the

Project (and received funding for their activities) and 24 Collaborating Partners representing regional and national HTA agencies, research institutions and relevant international organisations (at the end of the project 6 other organisations joint the initiative). Ministries of Health in Member States, not involved in the Project, were however kept informed of progress. In total, the EUnetHTA project involved from 64 organisations in 33 countries, including some countries outside Europe[154] (EUnetHTA 2009: 20-21; see also Annex 1).

In May 2006, a Standard Operating Procedure had been adopted and regulated the governance and management of the project. Comparing the governance structure proposed in this SOP to the one proposed in the ECHTA/ECAHI project brings to the fore many similarities:
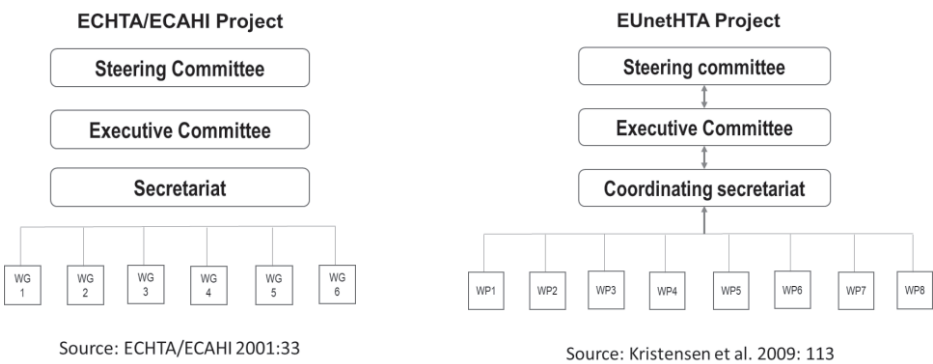
Table 6.4. Comparison governance structures ECHTA/ECHAI project and EUnetHTA project

As in the early European HTA cooperation projects, the structure included a Steering Committee and an Executive Committee. The Steering Committee included one representative from each Associated Partner organisation and was chaired by the Director of the Main Partner (Project Leader). It was responsible for the strategic orientation of the project. The Steering Committee met only at the start and closure of project. The last meeting served also to prepare the post-2008 EUnetHTA activities (EUnetHTA 2009). The Executive Committee included the Main partner and Work Package Lead Partners. Its role focused on the delivery of the project. It was responsible for reporting the project activities to DG SANCO by issuing yearly technical reports. The Secretariat was hosted by the main partner and ensured daily work and coordination the activities between the different working groups.

As in the previous projects, the project structure was divided in Working Groups, each responsible for achieving one of the sub-objectives defined (see next section). The Working Groups were headed by so-called 'Lead Partners' (LP), some Working Groups having 2 Lead

---

154   i.e. Canada, Australia, USA and Israel (EUnetHTA 2009: 21).

Partners as the work in these WP was divided in two streams (WP2 and WP7). Lead partners were responsible to direct and oversee the work of each Working Group. The EUnetHTA governance approach was based on a soft governance principles as participation remained voluntary and regarded mostly interaction between HTA agencies, hence peers. The structure established since the EUnetHTA project sought to enable the researchers – the HTA doers – to do their work "*whilst bringing the results into the policy-processes and being sustainable despite the project solution to make it happen. That has been quite a challenge!*" (Personal interview 4).

The European Commission, playing only a role as a funding organism, did not have any formal role in the governance and management of the project. However, based on the contract, regular updates regarding the progress of the project were given to DG SANCO as well as to the HLG on Health Services and Medical Care (EUnetHTA 2009: 5). Similarly, no formal role was given to key stakeholders showing interest for the project (e.g. policy makers, patients health care professionals, and health technology manufacturers). However, the project started to establish contacts with these organisations and reflections about their role in the network did take place and further developed in the establishment of dedicated structures.

As such, in 2008, a Stakeholder Forum has been established and the outcome of the first discussions regarding their role in the cooperation initiatives did have an influence on post-2008 EUnetHTA activities[155] where stakeholder involvement will become more significant. Although still rather closed in terms of membership, the EUnetHTA project responded however to some form of transparency in the sense that non-partners could have access to information published on the EUnetHTA public website (the organisation had also setup an intranet, only accessible for partner organisations) and subscribe to regular updates (EUnetHTA 2009: 5). Some validation or commenting processes regarding project deliverables would also be open to stakeholders.

It is important to keep in mind that the project pursued two main strategic objectives: establishing a sustainable network of HTA cooperation in Europe and developing tools and information systems permitting to deliver common core HTAs as input for national decision-making processes. Although related, both objectives require a distinct governance approach. Besides the repartition of the topics addressed in the Working Groups (network development: WP1,2,3 and Tools and information systems: WP4,5,6,7), it is not clear how

---

155   The opinions of the stakeholder forum will be included in a 'topic catalogue' for post 2008 project and which was being discussed during the last meeting of the Steering Committee of the EUnetHTA project. (EUnetHTA 2009).

this has been organised within the other governance bodies. The monthly meetings of the Executive Committee had to ensure the timely delivery of the project outputs and the coherence between the work implemented in the different subgroups as sometimes coordination problems between subgroups could occur (EUnetHTA 2009). It seems that attention was primarily focused on the development and implementation of tools and methodologies.

The EUnetHTA project has been governed based on self-management with reporting obligations towards the European Commission. Strong ties also still existed with the HLG on health services and medical care. It is interesting to notice that in a contribution to a public consultation process launched by DG SANCO, the coordinator of the EUnetHTA project underscores that "the 'open method of coordination' for healthcare and long-term care should be the non-legislative tool for the High Level Group on health services and medical care to continue developing the mechanisms for practical cooperation on HTA. (…) Concomitant to using the open method of coordination to develop the Network further into a committed collaboration, legal certainty of such collaboration should be provided" (EUnetHTA 2007). This statement indicates that although soft governance mechanisms, such as the OMC, seem to be an instrument of choice for setting up HTA collaboration in Europe, it does not deliver legal certainty this cooperation structure would require. We will see that this remains a point of concern in all subsequent collaboration projects. In the next section we will examine to what extent governance structures have developed in the EUnetHTA Joint Actions and in which manner this has affected decision-making processes. Special attention will be given to the role of stakeholders in this process.

6.3.1.2. Decision-making in the EUnetHTA Joint Actions

6.3.1.2.1. The principle EUnetHTA governance bodies
The EUnetHTA Collaboration was established in November 2008 by 25 founding partners from 13 EU MS, Norway, and Switzerland. The aim of this project was to take forward the Joint Action process between the Member States and the Commission. For this purpose, governance guiding principles have been adopted for the period covering the EUnetHTA Collaboration and the future JA1. These guiding principles have been endorsed by the EUnetHTA Plenary Assembly in December 2009 (EUnetHTA 2009a). The principles outlined different categories of participants: EUnetHTA Collaboration Partners[156], EUnetHTA Collaboration

---

156 Founding partners (having signed intent to establish the collaboration) and other publicly funded HTA organisations nominated by the respective Ministries of health (EUnetHTA 2009a).

Associates[157,] Lead Partners[158]. The Coordinator of the EUnetHTA Collaboration and the first Joint Action was, as in the EUnetHTA project, the National Board of Health of Denmark.

A new Consortium Agreement will be integrated in the grant application for the Joint Action 2. The purpose of this agreement was to facilitate the implementation of the JA 2 as defined in the grant agreement and to coordinate the interactions between the Partners appointed by the Ministries of Health. This document allowed to lay down the legal responsibilities of the partners and define the terms of their engagement and the consequences in case of a breach to these engagements. In other terms, it regarded the responsibility of the partners towards EUnetHTA (Personal interview 4; EUnetHTA 2012).

No major changes were introduced in this document compared to the governing principles defined for the JA1. Amendments mainly regarded the rights of partners and the organigramme which had been simplified. Finally, some changes regarded the potential membership of founding EUnetHTA collaboration partners in the Plenary Assembly which replaced the Steering committee of the EUnetHTA project but also fulfilled the role of main governance and policy-setting body of the JA (EUnetHTA 2012: 12; EUnetHTA 2013: 6). Indeed, according to the project coordinators "*you need to have a body that has the primary responsibility for strategy and policy and the direction you want to go as the consortium*" (Personal interview 4).

Although this agreement was important for the governance structure of the Joint Action, it was the Grant Agreement with the Commission which was governing the relations between the Consortium (EUnetHTA as a whole) and the Commission (Personal Interview 4; personal correspondence, July 2016). The EUnetHTA Coordinator being the single point of contact between the Commission and the Consortium (EUnetHTA 2012: 13).

As only candidate, Denmark was being elected as coordinator for the second Joint Action on HTA. The Governance bodies remained the same as in JA1. During the preparatory phase of the JA2, the Commission had indicated its wish to have a formal position in the Executive Committee. It also expressed it desire to establish a more formal cooperation with the EMA and other EU institutions and networks of relevance (EUnetHTA 2011b). The adopted

---

157 Nonprofit organisations producing or contributing to HTA and willing to be actively involved. Status is granted by executive committee and confirmed yearly on the basis of continuous active input (EUnetHTA 2009a).

158 Those leading the WPs, functions. In exceptional cases Co-Lead partners (must be approved by Plenary assembly). The number of functions/WPs are subject to change according to the needs (EUnetHTA 2009a).

Consortium agreement specified that the European Commission could participate in the meetings of the Plenary Assembly and Executive Committee however without voting rights (EUnetHTA 2012). The responsibility of the JA2 implementation laid by the coordinator and the Executive Committee. The Lead Partners were responsible for coordinating the work in the Work Packages. The Stakeholder Forum provided a consultative function in the Joint Action 2. A specific Stakeholder Involvement policy would be developed accompanied by Standard Operating Procedures which would guide the interaction with the stakeholders during the Joint Action 2 (EUnetHTA 2012: 14)
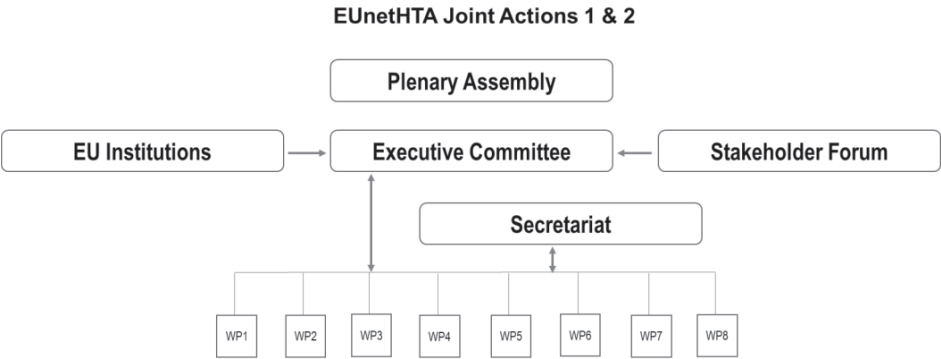
Source: EUnetHTA 2010a: 7

Table 6.5. Governance structure Joint Actions

The governance structure of the Joint Actions followed a similar structure as in the EUnetHTA project with a Plenary Assembly, as principle policy setting body, replacing herewith the Steering Committee in the EUnetHTA project; an Executive committee as strategic leadership/main executive body and a secretariat having the operational leadership. The Plenary Assembly (PA) was composed of the Head of each partner organisations (or its representative). Its Chair was elected by the members of the PA by absolute majority for 2 years and maximum 2 terms. Lead Partners and Co-Lead Partners were not eligible for this position. As outlined above, the European Commission could participate in the meetings but had no voting rights. Decisions were taken by a majority vote of PA members, in case of ties, the decision of the chair would prevail. The Assembly met once a year. Extraordinary meetings could be convened on the basis of recommendations of the Executive Committee (EC) or on request of a minimum of one-third of the PA members.

The Chair was responsible for ensuring the liaison between the PA and Executive Committee. He was also as a non-voting member of the EC. The election of the Chair would take place by secret ballot with an absolute majority rule. The same would apply for the election of the

deputy chair (EUnetHTA 2009a). Whilst in the Joint Action 1 and 2, decisions would still be taken by the Plenary Assembly as the "principle governing body" (EUnetHTA 2012: 12), the role of the latter has changed in the Joint Action 3 where meetings became "*mainly informative*" (Personal Interview 30). This seems to be a direct consequence of the changing role of EUnetHTA since the setup of the EU HTA Network who would steer the policy orientation of HTA cooperation in Europe.

Another body having impact on the EUnetHTA course of actions was the Executive Committee (EC) composed of Lead Partners. Whilst the Plenary Assembly was conceived as the policy-making body, defining the implementation strategy would fall under the responsibilities of the EC. This body was responsible for coordinating the activities, implementing the policy decisions and managing the affairs of the project. It was composed of representatives of the Lead Partners (LP), representatives of the Secretariat, three representatives of partner organisations (not being LP) and the chair of the Plenary Assembly (having no voting rights). Moreover, there could not be more than two partners from the same country. Members would be elected for one year and maximum two terms. This would, however, not apply for Lead Partners which could serve three years. The EC would be also responsible for supervising the Secretariat. The chair would be appointed by the members of the EC. They would meet every month, either face-to-face or by means of web-based conferences. All reports of the EC were made available to the partners. The EC would have the final decision-making power in case of difficulties encountered in a Work Package and if no solution would have been found by the Secretariat. If the EC could not resolve the problem, the Plenary Assembly would have to be involved (EUnetHTA 2009a).

Whilst the Plenary Assembly comprised all members, including members which did not demonstrate a high involvement in EUnetHTA, the members sitting on the Executive Committee would manifest a bigger involvement and also have a better access to information (Personal interview 30).The weight and role of these partners in the decisions of the EC could however vary according to their size and weight in national decision-making structures and their personal investment in EUnetHTA activities. This influence would however not necessarily translate the weight of EUnetHTA's work in national agencies or national decision-making processes. Often, the opposite could be observed. As such, big national organisations could send middle-staff representatives to EUnetHTA. Although, their personal investment and competence could be of the highest level, and despite attempts to inform their 'home-organisations' about EUnetHTA's activities, many acknowledged that few of their national colleagues would be aware of the European cooperation efforts (Personal interviews 1,14,18, 19, 20, 24, 25 27).

Conversely, small HTA agencies would often send their top-ranking representatives to EU-netHTA who would be more likely to translate EUnetHTA activities in the agency's national activities and thus increasing the potential to have an impact on the national decision-making processes. Hence, although EUnetHTA represented an important activity for its members who would invest a significant amount of time and energy in it, the EUnetHTA activities would not always receive sufficient attention in the respective 'home-organisations' to impact national decision-making processes. (e.g. Personal interviews 1,14,18,19, 20, 24, 25 ,27).

The Secretariat in the EUnetHTA Joint Actions 1 and 2 was composed of a Secretariat Director, a Secretariat Manager and staff members. It could not represent more than two partners from the same country. The secretariat would be bounded by the legal requirements of the Joint Actions. Its work would be led by the Director who would work under supervision of the European Commission. The Director would be co-responsible with the European Commission of implementing the policy decisions. He would act as facilitator of close coordination with the Work Packages with an emphasis on content matters. He would also be responsible for the external promotion of the project and could act on behalf of EUnetHTA, with however the obligation to report to the European Commission on major issues. The Secretariat Manager would be responsible for the coordination of the work of the Secretariat and the day-today management (EUnetHTA 2009a).

Compared to the early European cooperation initiatives, the governance of the EUnetHTA network was in particular marked by the role of the secretariat who became in practice the "*other executive body*" and had a preponderant role in the running of the network. As underscored by an EUnetHTA representative, the secretariat was the "*operational heart, brain hands, legs and everything needed to make sure that is operationally, it's impeccable because of many reasons. It is a big network, it is a complex matter. It is not only technical scientific, it is related to other policy processes, so this body needs to have the capability and competence that would have both understanding of the technical matter and HTA as such, the understanding of the policy processes, the understanding of management and organisational structures and the tools and solutions that would be most effective to support the activities and keeping it not only functioning but progressing and making sure that we are meeting our own milestones, deliverables and keeping people on the project management road*" (Personal interview 4). The secretariat was located in the Danish Health Authority from the EUnetHTA project till the Joint Action 3 when it has been relocated to the Zorginstituut Nederland, located in the Netherlands.

According to some members the relocation of the EUnetHTA secretariat also represented a governance shift: "*The Danish secretariat was soft coordination rather than leadership. Now in the Netherlands, the secretariat has called themselves 'Directorate'. It is maybe only*

a name, but at the other hand, it may be understood as taking leadership". Indeed, when taking over the network coordination, the Zorginstituut (ZIN) had decided to establish a Directorate composed of two entities: a Director's office responsible for the daily work of the EUnetHTA's Director and a Secretariat which would manage the EUnetHTA activities, the cross Work Package activities as well as the governance and activities of other bodies of the Consortium (EUnetHTA 2018:7). The Director, a ZIN representative, had previously been involved in EUnetHTA. He would be assisted by a project manager which for the first time in the EUnetHTA history would have no previous ties with HTA nor with EUnetHTA (www. eunethta.com, personal interview 15).

Others also perceived a shift from a more horizontal governance approach to top-down leadership: "*Very nicely they tell us, this is how things will be done now*"; "*(…) as of today, this is how it has to be done*" (Personal interviews 12, 30). Moreover, the organisational structure on the renewed EUnetHTA website during the third Joint Action presents the organisational and governance structure by highlighting only the Executive Board and the Secretariat (https://www.eunethta.eu/about-eunethta/organisation/). Hence, the Danish secretariat would be considered by the members as operating through soft governance – co-ordination – means. The Dutch secretariat would be perceived by applying a more top-down, hierarchical approach. This shift of governance methods could partly be explained by the changing nature of EUnetHTA in the Joint Action 3 where it became the technical and scientific arm of the EU HTA Network working with an agenda decided by an "external" network and operating under its supervision. We have seen in this section how the nature and role of some governance bodies has changed in the course of the Joint Actions impacting the governance structure and decision-making processes. The same can be identified regarding the role of stakeholders in EUnetHTA, as we will outline in the next section.

6.3.1.2.2. Stakeholder involvement in EUnetHTA

A new body officially set up since the EUnetHTA Collaboration has been the Stakeholder Forum, established in 2010 and which was part of the governance structure of the JA. Stakeholder involvement marks a clear difference in governance structure of the Joint Actions compared to the early cooperation projects in which this was completely absent (Personal interview 10). The idea to extend the network to stakeholder groups entered the discussions of the EUnetHTA project in 2006. However, it took several years before a formal representative stakeholder body has been integrated in the governance structure of the first Joint Action (Personal interview 4). Indeed, since 2006, stakeholder groups themselves have started lobby activities to participate in the HTA cooperation activities. Often their efforts were backed by the European Commission considering their participation as important and seeking to include stakeholder participation in the governance structures of EUnetHTA (Personal interviews e.g. 4, 8, 12, 13, 15, 18, 20, 24).

With the establishment of the Stakeholder Forum, the aim was to facilitate information exchange with stakeholders who could also participate in the Plenary Assembly meetings (EUnetHTA 2013:6). The Stakeholder Forum would be composed of representatives of European Umbrella organisations (Policymakers (regional/national/hospital level), Patient organisations, Health care professionals, Payers, Industry). The participants of the Stakeholder Forum had to be invited by the Executive committee which also developed and applied the Stakeholder membership criteria. Members could hold their position for 3 years. Final decisions on issues regarding stakeholder involvement could only be taken by the Plenary assembly.

Integrating stakeholders in the work of EUnetHTA was however a challenging exercise as opinions diverged among members on the necessity and the practicalities of a stakeholder policy. *"One of the big issues of the beginning were also the stakeholders. The industry, how would they be represented (…) but also the doctors, health care providers, that was kind of a tricky one"* (Personal interview 8). Often positions regarding the role of stakeholders in HTA, reflected national practices. Some countries having legally organised stakeholder consultation/participation in HTA, others lacking any experiences with the latter. Sometimes stakeholder participation would not necessarily be legally organised but a pragmatic approach towards their inclusion at some stage of the HTA process would nevertheless be adopted. In other countries, the inclusion of stakeholders would be accepted but regarded as a "necessary evil" (Personal interviews e.g. 1, 12, 22, 23).

According to some observers, views on stakeholder participation in HTA processes also depends on the perspective one takes on a medicine/medical device: economic or public health. As such, one could consider a drug or medical device as a stronghold of economic growth, or one could view it as an essential element in public health (Personal interviews 11, 20). From a public health perspective, the role of stakeholders is often considered to be mostly informative. In this regard, industry would be offering the data allowing the scientists to analyse it independently. Similarly, patient representatives could inform assessors about (medical) priorities that, according to them, should be taken into account in the market access, pricing and reimbursement processes of health technologies. Having the industry indicating its priorities (from a profit-making perspective) would, however, fall into the economic perspective of stakeholder participation in the development of a new health technology. Hence, either a health technology is being considered as serving economic development or it is being regarded as serving public health. Whilst both perspectives are fully legitimate, they do reflect very different perspectives. "*But when you start mixing both, you get what we see now. (…). The multinationals increasingly dominate the economic reality and Europe has to, wants to follow that*" (Personal interview 20).

It is not clear which perspective has been adopted in the EUnetHTA Joint Actions as both have been present to a certain extent. Although an official stakeholder policy and Standard Operating Procedures had been developed, informally, there was an ongoing debate among the members to what extent stakeholders should participate in the process. As outlined above, individual positions often reflected national practices and cultural backgrounds. Finding a common ground on the issue remained challenging, some countries insisting on stakeholder participation in the HTA process (e.g. Austria, Great Britain) others being much more reluctant to that (e.g. Germany) (e.g. Personal interview 12, 23). Moreover, besides defining the role of the stakeholders and whether their inclusion should be for informative or collaborative purposes, some also brought to the fore that stakeholder participation would require the need for expertise, both on the side of the stakeholders as on the side of the agencies: "*you need the right people who can engage in an in-depth dialogue. People who do not only have an academic mindset but who can also operate in a general dialogue. Not everybody is capable of doing that*" (Personal interview 23).

To some, stakeholder representation hasn't been equal in the EUnetHTA Joint Actions. The industry is often mentioned as the stakeholder group being the most influential in EUnetHTA decisions or strategic orientations, followed by the patients' representatives. However, the role of industry participation in HTA assessment triggered a variety of reactions. Some would argue that as technology developers, they should be involved in the assessment process or at least keep an open dialogue with them. Moreover, including the industry to some extent in the assessment process would allow for a better acceptance of the assessment outcomes by the industry. Others, on the contrary, considered that being the manufacturer, the industry would have a conflict of interest and should therefore not be involved in the process so as to avoid bias in the assessments (e.g. Personal interviews 15, 23).

Health care providers and payers often underscore the little impact they have had on the EUnetHTA assessment processes (e.g. Personal interviews 12, 13, 20, 21, 24). Payers for example have stressed their desire to become more involved in the HTA processes in particular regarding issues such as the prioritisation of drugs eligible for assessments. They also underscored that their input could be of use to assess data and methodologies used in clinical studies (e.g. Clinical endpoints, surrogate end points, real world evidence collection etc.) as this would be taken into account in cost-effectiveness processes at a later stage. Moreover, inclusion of payers, has sometimes be considered a mean to access large (payers') datasets which could potentially be of use for HTA assessments (Personal interview 13, personal observations debates EUnetHTA Forum 2018).

Although involved, to a certain extent, in assessments in Joint Action 2, the patient stakeholder group representatives also called for an increased and more structured participation

in the EUnetHTA network especially in the Joint Action 3: "*During the Joint Action 2, patient participation was organised in a more intelligent and more interesting manner than today as there was a real willingness on behalf of EUnetHTA to organise things by reflecting upon that on a European level. With the third Joint Action, we have fallen back at the national level and every agency does things the way it is used to on a national level*" (Personal interview 12).

Indeed, whilst in the Joint Action 2, stakeholders benefited from an observer status in the Plenary Assembly of EUnetHTA and played a role in assessment processes, this ceased to be the case in the last Joint Action. As a consequence of the setup of the Stakeholder Pool in the EU HTA Network which led to the dissolution of the EUnetHTA Stakeholder Forum, stakeholder participation has been altered in the EUnetHTA Join Actions 3. According to patient representatives, as no specific governance process had been foreseen, conversely to the former Joint Action, patient participation became often organised at a local level by the agencies in charge of the assessments. However, lacking the experience of the coordi-nated action in the JA2, patient participation (identifying qualified persons, dealing with the logistics of participation, reimbursements etc.) became often burdensome to local agencies which, instead of turning towards the European level (e.g. European umbrella organisations), organised stakeholder participation on a national basis applying the rules, habits and experi-ences of the agency's home-country (Personal interview 12).

Hence, with the launch of the Stakeholder Pool in the EU HTA network, the role of stake-holders in the Joint Action 3 became again an issue of debate. Whilst in Joint Action 2, stakeholders had a say through the Stakeholder Forum and the Stakeholder Advisory Groups (SAG), this has changed in Joint Action 3, where stakeholders were only officially represented in the Stakeholder Pool of the EU HTA Network. Many stakeholders however pointed to the differences regarding the role and functioning of both structures. In the Joint Action 2, the Stakeholder Forum could appoint representatives to the SAGs who could provide advice on technical issues. Specific processes had been developed permitting to install dialogue and cooperation with stakeholders leading in some cases also to stakeholder consultation (Personal interview 1, 18, 23).

Even though this approach could, according to some, be improved, it seemed to have been preferred over the functioning of the Stakeholder Pool established by the European Com-mission in the framework of the EU HTA Network (e.g. Personal interview 12, 18). "*The stakeholder pool stems from the European Commission in the framework of the multiannual HTA Network. EUnetHTA consults the stakeholder pool in an opportunistic manner. It could very well consult other organisations, but it has abolished every structure that would permit it to interact with the interested parties as it has done so in the past: the industry, the [health care] professionals, the payers, the patients. There isn't a structure anymore which allows*

for this interaction, so now it happens in an anecdotal manner" (Personal interview 12). *"Some expert meetings have been established [in Joint Action 2] allowing for dialogue, but unfortunately that has been completely scaled back in Joint Action 3 where there is thus no Stakeholder Forum anymore and where it is up to the work packages themselves to decide whether one want to establish a stakeholder consultation or not"* (Personal interview 23).

Although several representatives of stakeholder groups have indicated to have discussed stakeholder participation with EUnetHTA before the launch of Joint Action 3, at mid-term of this project, many were dissatisfied and had the impression that the governance structure put in place did not allow for much interaction and cooperation with the stakeholders, as it had been in the past. The annual EUnetHTA conferences and the EU HTA Stakeholder Pool did not replace the Stakeholder Forum that existed before and which allowed a more continuous dialogue with the stakeholders (e.g. Personal interviews 12,13, 21, 24, 25). *"The involvement of the members of our organisation to EUnetHTA's work is at present – I assure you - zero. And this becomes a bit frustrating because, I believe they have started some two and a half years ago"* (Personal interview 13). Some have the impression that attention to stakeholders is only given at time of the annual EUnetHTA conference, but that a real strategy towards stakeholder participation is still lacking.

The project-based approach has been brought to the fore as the underlying reason for the latter. As every three year a new Joint Action had to be developed developing new strategies etc., stakeholder participation could not be expected to be the top priority of project leaders (e.g. Personal interview 24). This is indeed also underscored by an EUnetHTA representative explaining how things changed with the Joint Action 3 where, besides the setup of a new project, there was a clear distinction established between strategy at the political level through EU HTA Network and the technical and production side through EUnetHTA. *"The Stakeholder pool of the HTA Network was meant to be a resource, a pool for anything related to policy strategy and inclusion of stakeholders within HTA as such (…) There is a long period in which all partners needed to find their individual new roles. But also, we had to adapt to the very fast pace changing environment where we had to take up suggestions that were left to us from Joint Action 2, we had to look into suggestions we received from stakeholders, industry and patients. We needed to understand how can we include them, are there realistic processes? All these considerations we had to them take up and now we are trying to go one step at a time towards the stakeholders and see how we can find models that are stable on both sides"* (Personal interview 15).

Indeed, the establishment of the stakeholder pool did influence the overall attitude towards stakeholder participation in HTA which was not only debated in the European HTA cooperation process but was also a topic of debate in other HTA networks (e.g. HTAi). Although

the new EU HTA network does foresee an official body for stakeholder representation by means of the Stakeholder pool, in practice the influence of stakeholders on the strategic orientation of the network seems to be limited. In a typical EU HTA Network meeting, two representatives of the different stakeholder groups (payers, patients, industry and healthcare providers) would be invited to join the afternoon session. Each having five to ten minutes presentation time. This contrasts with the EUnetHTA Stakeholder Forum which would last a full day and was open to a bigger amount of stakeholder representatives. Hence stakeholder participation in the EU HTA Network is considered to be limited to informative purposes rather than being open to participatory purposes as had been the case in the EUnetHTA Joint Action 2 (Personal interview 21, 22, 23). "*With time we have seen the process move from establishing a closer dialogue to a more closed doors policy where during the biggest part of the meeting the Member States debate internally with the Commission. At the end of the meeting a few updates will be given to stakeholders informing as such the Stakeholder Pool*" (Personal Interview 23).

Despite some critical remarks on behalf of the stakeholder representatives, from the point of view of some HTA agencies, stakeholders have been well integrated both in the governance structures as in the different HTA assessments. The changes operated in the JA3 were considered to be beneficial for stakeholder involvement in EUnetHTA. Some agencies believed that the changes operated since the Joint Action 3 had actually improved the situation compared to the Joint Action 2: "*This forum was considered not very successful since EUnetHTA received little input from stakeholders. Also, the public consultations proved not valuable. Therefore, in JA3 EUnetHTA aimed for different involvement processes for stakeholders*" (Written contribution 1, see also e.g. personal interview 28). This position contrasts with the one from the stakeholders who often believed more could have been done to include them better: "*I think that we could have hoped for a much more developed stakeholder involvement after ten years of European collaboration*" (Personal interview 24).

Hence, since the introduction of a dedicated stakeholder policy in EUnetHTA, the role of stakeholders has initially developed into a more inclusive approach, though no consensus existed on what should be their exact role and degree of participation in HTA processes. With the establishment of a new Stakeholder Pool by the EU HTA Network, the position of stakeholders in EUnetHTA as well as on the EU level has been restructured still failing to reach consensus on the matter. Indeed, different approaches regarding stakeholder involvement continued to be displayed between HTA bodies and amongst the stakeholder groups themselves. Stakeholder involvement remained a topic of debate which has also played a role in the Commission proposal for a Regulation on HTA cooperation in Europe. The next section will outline how decision-making has been taken place at the EU level and how it has been envisaged in the Regulation proposal.

6.3.2. Decision-making in the EU setting

With the Cross-Border Health Care (CBHC) Directive, the European Commission receives an official mandate to coordinate HTA cooperation in Europe. The governance structure of the newly established EU HTA Network has been laid down in the implementing decision of July 2013 (OJEU 2013). It specifies first that "Members of the HTA Network shall be national authorities or bodies responsible for HTA designated by the participating Member". Member States may also designate an expert to accompany the Member (this will be later extended to more than one). The Network will operate on the basis of the adopted Multiannual Work Programme (MWP) and will be supported in this by a scientific and technical cooperation. Working groups can be setup to examine specific questions and shall be disbanded as soon as their mandated is fulfilled (European Commission 2016b).

The EU HTA Network is chaired by a Commission representative, which will have no voting rights. Other Commission officials having interest in the proceedings may also attend meetings and working groups of the Network. Participation of the European Medicines Agency is possible upon request of the Commission. Other European and international organisations can also be invited to attend the meetings as observers. The Commission provides the secretariat of the HTA Network. The latter is responsible for drafting the agenda of the meetings which should be in line with the MWP adopted by the Network. Proposals can be made in this regard by Network Members, observers and the scientific and technical cooperation mechanism (European Commission 2016b).

From the start - and basing itself on the Article 15 of the CBHC Directive - the Commission insists on the importance of associating stakeholders to the HTA Network. At first, the HTA Network will rely on the Stakeholder Forum of EUnetHTA. However, in 2016, the involvement of stakeholders in the Network would not be based anymore on the technical mechanisms provided by the JA2 but on a Stakeholder Pool composed of representatives of different stakeholder groups who would receive an 'observer' status. The same status is given to European and international organisations whose activities would be relevant to the Network. Similarly, competent HTA Authorities of EEA/EFTA countries and of accession countries could participate in the meetings as observers without voting rights. EUnetHTA, as the scientific and technical cooperation mechanism would also be considered as a 'third party' which would be invited to attend the meetings but without holding voting rights (European Commission 2016b).

The decision-making procedure will run "as far as possible" by consensus (European Commission 2016a). A vote should be taken only if a Network Member requests so. In that case a majority of two-thirds of the Network's Members present at the start of the vote would be needed to adopt a decision. Each Member State would have one vote. In normal

circumstances, decisions of the HTA Network would be made public. In some cases, decisions could be kept confidential or could be subject to explicit public consultation (European Commission 2016b).

The EU HTA Network would develop as an entity working at a senior policy level and which main aim would be to gather policy makers to discuss the course of the European HTA cooperation process. This approach would differ fundamentally from the governance structure in the EUnetHTA projects represented mostly by HTA agencies. The underlying idea behind this approach would be to improve and facilitate uptake of joint work in the Member States. Indeed, by including national representatives of ministries of health, is was hoped that input of European HTA into national decision-making processes could be increased. As underscored by a Commission representative: "*This network was a mean to translate this discussion from a technical to a strategic level*" (Personal interview 8).

The strategic objectives were not anymore only defined by HTA agencies cooperating in EUnetHTA but could be officially endorsed by the Health Ministries. The new EU HTA Network changed thus the governance approach from a bottom-up policy-making approach to a mixed model. If before, EUnetHTA members needed to advocate about their work in their local settings, in the new governance structure of the EU HTA Network they needed to follow the line established by their senior policy makers. Hence, even if the input which laid at the basis of the strategic orientation of the HTA Network would stem from the work established by EUnetHTA and the precedent projects, the HTA Network turned around the policy-making structure by laying the strategic orientation of European HTA collaboration in the hands of national policy-makers.

Another fundamental difference with the governance processes in EUnetHTA is the opportunity created by this new network to establish formal cooperation mechanisms between different networks from the EU. We have seen above how the Commission would refer to work established by networks or bodies such as the EMA, the reflection process on safe and timely access to medicinal products (STAMP), the MAST assessment model for telemedicine and eHealth, the Network of Competent Authorities responsible for Pricing and Reimbursement (NCAPR), the Pharmaceutical Committee and the Council reflection process under the Working Party at Senior level on Public Health (European Commission 2013a; 2014a; 2014b; 2015a). Chairing the meetings of the HTA Network and being in charge of the agenda, the Commission would be in a position where it could steer the activities of the EU HTA Network by ensuring coherence and consistency across the different initiatives related to HTA in Europe.

In terms of governance, it is interesting to see how the Commission proposal for a Regulation submitted in January 2018, considered the EU HTA Network as a transition body to prepare the ground for a more permanent structure coordinating HTA cooperation in Europe. Indeed, if adopted, the Regulation would allow for the establishment of a Member State-led coordination body which would govern the future sustainable European HTA cooperation structure (European Commission 2018). In the various consultation processes and Impact Assessments, different governance structures had been proposed regarding the future HTA collaboration. As such in the public consultation, the following options had been presented as to which structure could govern the collaboration 1) the European Commission 2) an existing EU agency 3) A new EU agency 4) Member States HTA bodies functioning on a rotational basis (5) Other. The first two options were considered the most preferable and corresponded to the outcome of a previously held online survey (European Commission 2017:122).

In its proposal for a Regulation, the Commission has opted for the establishment of the Coordination group which would be hosted in the premises of the European Commission. Moreover, the proposal outlines that the Coordination group would be composed of members designated by Member States and would represent their national authorities and bodies responsible for HTA. Member States would be allowed to designate more than one authority or body responsible for HTA as members of the Coordination group (Art. 3.1). The Coordination group would act by consensus, or where necessary by simple majority (Art. 3.3). It would be co-chaired by the European Commission and a chair elected by the members of the Coordination group. The rules and procedures of the Coordination group should be adopted by the group itself. Moreover, the Coordination group should coordinate and approve the work of the sub-groups which it should establish for: 1) Joint Clinical Assessments; 2) Joint Scientific Assessments; 3) identification of emerging health technologies; 4) voluntary cooperation and 5) the preparation of annual work programs and reports. The Coordination group should also ensure cooperation with Union level bodies to facilitate additional evidence generation necessary for its work and ensure appropriate stakeholder involvement (Art 3).
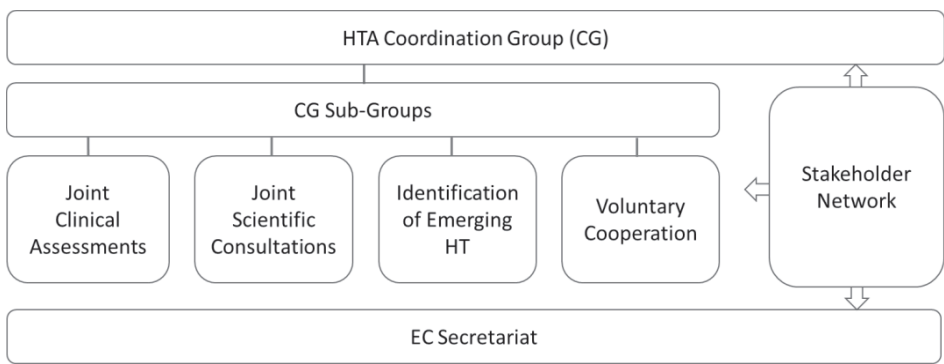
Table 6.6. Governance structure HTA Cooperation in Commission Proposal for a Regulation on HTA cooperation
Source: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20180209_co01_en.pdf

The proposal furthermore states that a report regarding the support framework should be made no more than two years after the end of the transitional period foreseen in the proposal. "The report may in particular consider whether there is a need to move the support framework to a *Union agency* and introduce fee-paying mechanism through which health technology developers would also contribute to the financing of joint work" (European Commission 2018: 21; italics added). Hence, although initially proposing a governance body by means of a coordination group and functioning as a high-level Member State-led expert group, the Commission did foresee the possibility to transform the governing body (i.e. Coordination group and sub-groups) in a Union agency, such as, the EMA.

The proposal also foresees the establishment of a Stakeholder network where "suitable stakeholder organisations" will be selected based on criteria established in a future call for applications". These stakeholders will be invited to add-hoc meetings between the Stakeholder network and the Coordination group in order to "update stakeholders on the work of the group" and provide for an exchange of information. Patient and clinical experts could be invited to attend meetings of the Coordination group as observers. The stakeholder network could also support the coordination group in the identification of patient and clinical expertise for the work of the sub-groups (European Commission 2018: 35-36).

It is not clear whether these provisions will respond to the requests of the stakeholders themselves, as outlined in the section above. However, with the Regulation proposal, many stakeholder groups have become even more interested in taking an active part in HTA cooperation: "*the new Regulation suddenly makes the future system very real*" (Personal interview 15). Since the publication of the Commission proposal, many of them have adopted an official position on the issue and would closely follow the developments of the adoption

procedure. In the section on policy implementation (6.4.3.3.) we will outline the latter in further detail.

6.3.3.   Conclusion decision-making in European HTA cooperation

The initial EUnetHTA governance structure was based on a soft governance approach as participation remained voluntary and regarded mostly interaction between HTA agencies, hence peers. The structure established since the EUnetHTA project sought to enable the researchers to develop their work which should be used as input in national policy processes. Despite the project-based approach, the coordinators aimed at establishing a sustainable structure allowing to continue the cooperation initiatives. The EUnetHTA governance bodies served to enable decision-making and implementation of the project objectives. The Plenary Assembly was conceived to be the principle policy-setting body with the Executive Committee defining the strategy to achieve it. The Secretariat would ensure the coordination and smooth implementation of the work. However, despite the various roles and responsibilities given to the governance bodies of the EUnetHTA network, the EUnetHTA governance structure did not permit to reach the ultimate aim of establishing a sustainable network. It was characterised by a project-based governance and management system running on a time-limited basis and requiring a resubmission of grant applications every 3 to 4 years.

This approach was increasingly considered by EUnetHTA and the European Commission as inadequate to establish a sustainable network allowing sufficient production and uptake of joint HTA work (Personal interview 4, 8, European Commission 2016; 2017a). At first, the EU HTA Network, has been considered as a mean to overcome this challenge. Moreover, by becoming responsible for the overall policy of HTA cooperation, it took over the role of the EUnetHTA Plenary Assembly. The work of the EU HTA Network eventually led to the 2018 Commission proposal for a Regulation on HTA Cooperation which even envisaged the abolishment of this network which should be replaced by a high-level policy governance structure at EU level, not excluding the establishment of a Union agency.

These developments have not occurred overnight but result from a slow but consistent process steered by the Commission allowing it to gain increasingly control over the networks' course of action. Indeed, in the first EUnetHTA project, the Commission had no formal role, except for controlling the funding mechanisms and ensuring the project would fulfil the funding requirements. This will however change with the setup of the Joint Actions where the Commission becomes an official partner in the process. This did not automatically lead to any voting rights for Commission representatives in the various EUnetHTA governance bodies. However, as we have seen, upon request of the Commission, in the JA2, the latter obtained a seat in the Executive Committee of EUnetHTA and could thus supervise the course of action of the network. With the setup of the EU HTA Network, the Commission became

also responsible for setting the agenda of the latter and coordinating the implementation of it through its own secretariat. As outlined above, before the establishment of the EU HTA Network, the EUnetHTA Plenary Assembly was the principle body responsible for setting the HTA cooperation policy. This role has however shifted to the EU HTA Network with EUnetHTA itself becoming the scientific and technical arm this network.

Similarly, the role of stakeholders has gradually developed. Increased participation of stake-holder in the HTA cooperation initiatives had been instilled by the Commission. However, although stakeholder groups formally had no say in the decision-making processes, the man-ner in which stakeholders tried to influence these processes would differ. Some, managing to have more influence than others. In particularly the interests of the (pharmaceutical) industry seems to have been protected in the preparatory process of the Commission proposal for a Regulation in HTA cooperation. Part of the explanation hereof lays in the fact that putting the proposal on an Internal Market basis was the only legal manner for the Commission to propose such a Regulation. However, relationships between the Commission and the pharmaceutical industry predates HTA cooperation and the established lobby activities of the latter certainly also have contributed to the fact that their interests were taken into account in the decision-making processes.

In the next section we will develop how decisions taken in the various fora have been implemented through projects and instruments developed since the EUnetHTA project till the Commission proposal on HTA cooperation in Europe. We will examen how these actions related to one another and to which extent the various frameworks in which they have been implemented have been helpful to reach the envisaged aims. The section will address both *procedural instruments* - related to organisation, communication, capacity-building and evaluation matters - as well as *substantive instruments* - related to joint work, uptake and the life-cycle approach.

6.4.   POLICY – IMPLEMENTATION IN EUROPEAN HTA COOPERATION

In chapter 4, we have outlined how policy implementation concerns the stage in the policy cycle where decisions are translated into concrete action. This stage comprises usually more actors than the previous one and its outcome will depend on the knowledge and resources available as well as on the policy instruments chosen (Howlett and al. 2009: 160). We have also explained how policy-implementation in the early European HTA cooperation projects (i.e. EUR-ASSESS, HTA-Europe, ECHTA/ECAHI) departed somehow from typical national public policy implementation processes as HTA cooperation was mostly project-based and involved multiple levels. The choice of policy design and policy instruments in policy imple-

mentation is not a neutral exercise. The policy-mix that will be developed on the basis of the instruments selected will aim to resolve the policy problem or reach the policy objective (Bressers, 1998; Bressers and Klok 1988).

In the following section, we will examine the policy-implementation process of the EUnetHTA network. Based on Howlett (2000) we will seek to distinguish in the EUnetHTA project and Joint actions 'substantive' policy instruments from 'procedural' instruments. Substance of the policy outputs can be influenced by the former whereas the latter can affect "the processes associated with the delivery of the outputs" (Howlett, Ramesh and Perl 2009: 169). In chapter 3, we have outlined how the choice of policy instruments can affect behaviour, interactions and activities of policy actors "in developing and choosing policy solutions" (Thatcher and Rein, 2004 in Howlett 2018). These tools can thus affect the members participations' in networks which can potentially even lead to more profound changes in a networks organisational structure (2018: 82). The activities and output of the various EUnetHTA projects will examined in the following sections according to the following scheme:

Procedural instruments	Substantive instruments
Organisation • Internal (Project Coordination) • External (Network development)	**Joint work** • Methodologies/tools • Joint assessments
Communication • Internal (information management) • External (dissemination)	**Uptake** • Re-use of joint work • Impact on decision-making processes
Capacity-Building • Internal (training partners) • External (training stakeholders)	**Life-Cycle Approach** • Horizon Scanning • Early Dialogues • Post-Launch Evidence Generation
Evaluation • Internal (project implementation) • External (Evaluation network proposals)	

Table 6.7. Procedural and substantive policy instruments in EUnetHTA
(Based on Howlett 2007; 2018)

6.4.1. Policy implementation in EUnetHTA: Procedural policy instruments

6.4.1.1. Procedural policy instruments: Organisation

The organisational structure and functioning of the network has received significant attention in the course of the different EUnetHTA Projects and Joint Actions since it represented one of the main objectives of the cooperation initiatives. Specific Work Packages dedicated their attention to the internal coordination of the network's activities. The Secretariat and the Executive Committee played an important role in this regard. One could characterise the organisational structure as one of self-management when it comes to the work within the different work packages as each Lead Partner was free to decide about the most appropriate

working methods. The overall network coordination was ensured by the Secretariat who played a pivotal role in this regard (Personal interview 4).

The general structure of the EUnetHTA project and Joint Actions organising the various activities into different Work Packages was mainly determined by a format given by the European Commission. Although at times, an adaptation of this format had been proposed, the Commission-induced structure remained the same across the Joint Actions (Personal interview 22). The challenge was to avoid working in silo's by promoting cross-section communication (Personal interview 4). However, considering the overall structure and the fact that HTA agencies representatives could only be active in one or two Work Packages or activity centres, made meeting this challenge rather difficult (Personal Interview 30).

Managing a network firmly imbedded in scientific research and mainly composed of scientists, offered another challenge which, according to some, has impacted the internal management and course of action of EUnetHTA. Indeed, as explained in the previous chapters, EUnetHTA resulted from the initiative of HTA doers. The members taking the lead in the different Work Packages across the EUnetHTA project and Joint Actions most often came from a scientific background and had occupied management positions as a natural follow-up of their scientific activities. Hence, EUnetHTA could be characterised as a network managed by scientists whose main tasks comprised the coordination of scientists (Personal interview 22).

Establishing common European HTA frameworks and methodologies among scientists from different European countries required to abandon some national or local procedures often developed by the same scientists who had dedicated a significant part of their professional occupation to the strict follow-up of these same procedures which ensure scientific robustness. Although international cooperation remains a challenge in many different fields of activities, some believe this challenge may be even bigger for scientists. As such, strong management and coordination skills would be required to coordinate the activities and permit scientists to remain confident that new framework would still respond to scientific robustness (Personal interview 22). Even though, since the EUnetHTA project, personnel with specific project management skills had been appointed in the Secretariat, the actors active in the work packages of EUnetHTA remained HTA doers and the network could be qualified as a *network of peers* or as a network of *scientists managed by scientists* .

Besides the internal network coordination, an important aspect across all EUnetHTA's projects and Joint Actions was "Network development". Indeed, the overall strategic goal of the EUnetHTA project was to "establish an effective and sustainable European Network for Health

Technology Assessment – EUnetHTA that informs policy decisions"[159]. This did not differ in any sense with HTA cooperation projects developed earlier. In chapter 4 we have observed how the goal to create a network of a permanent character, had to be reached by means of a project which, by definition, was limited time wise. The visions regarding the organisational structure of such a network differed among the stakeholders before the turn of the century. Moreover, we have underscored how, at that time, it was unclear whether the governance structure created for the purposes of the projects should be considered as the governance structure of a future sustainable network. The approach chosen in the EUnetHTA project (2006-2008) was in this sense identical to the early cooperation projects.

As outlined above, the Work Packages 1 and 2 of the EUnetHTA Project aimed at network development. The general objectives of Work Package 1 sought to establish "the organisational and structural framework for an effective and sustainable European network for HTA with a supporting secretariat". A literal interpretation of this objective points towards the establishment of a framework distinct from the EUnetHTA project. In practice however, it seems that the organisation and structure of the EUnetHTA project was considered to be the framework of the – to be established – sustainable European network for HTA. Indeed, in the EUnetHTA project report, the EUnetHTA organisational structure, including a supporting secretariat, is listed as one of the key deliverables of Workgroup 1 (EUnetHTA 2009: 11).

The aim pursued by WP 1 to create a sustainable HTA collaboration was in a sense complicated by the developments that took place on an EU level. As outlined in the previous sections, the European Commission introduced in 2008 the proposal for a "Directive on the application of patients' rights in cross-border health care" (2011/24/EU) which mentioned the establishment of a voluntary network on Health Technology Assessment which would be coordinated by the EU Commission (Article 15, OJEU 2011). Time wise, the proposal was introduced at the end of the EUnetHTA project. The EUnetHTA Collaboration (2009) which sought to ensure the continuity of the work and bridge the gap with the future Joint Action, also aimed the establishment of a permanent HTA cooperation network (EUnetHTA 2009: 23).

This aim is again mentioned in the project proposal of Joint Action 1 which sought "to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level" (http://ec.europa.eu/chafea/projects/database. html?prjno=20092302). It is interesting to underscore here the semantic changes in the wording of the objective: establish a "sustainable *network*" in the EUnetHTA project and a "sustainable *Collaboration*" in the Joint Action. Whilst the EUnetHTA project Work Package

---

159 http://ec.europa.eu/chafea/projects/database.html?prjno=2005110.

(WP) 1 dealt besides 'Coordination' also with the setup of a sustainable network, the JA1 will address this issue in a separate WP 8 on 'Strategy and Business model development' (EUnetHTA 2013). The JA1 - WP 1 on 'Coordination' will conversely essentially deal with the coordination of the project. Hence, in the first Joint Action the objective of establishing a sustainable network framework will be dissociated from the project framework itself. This stems directly from Commission proposal to setup of a sustainable HTA Network as listed in the Cross-Border Health Care Directive Proposal.

The WP 8 of the first Joint Action would elaborate a strategy and future business model, presented in a 2012 report but never implemented (EUnetHTA 2012a). The ideas and suggestions brought forward in this document will however feed into the discussions regarding the setup of a sustainable HTA Network. The 2012 WP8 report describes the potential business model for EUnetHTA after JA2. It specifies that it concerns "a network organisation, and thus, a network business model. The business model development process for EUnetHTA builds upon commercial business model perspectives as well as network/alliance-specific parameters" (EUnetHTA 2013b:3). It considers EUnetHTA to be the future EU sustainable HTA network. It presents value propositions towards clients (i.e. HTA producers) which were fully in line with the output of the EUnetHTA projects and JA1[160] (EUnetHTA:2013b). Moreover, it is proposed that the Work Packages of JA1 and JA2 evolve in so-called activity centres, each coordinating a specific activity. It is also envisaged that within a 10-years' time span some agencies will have specialised in specific HTA fields (EUnetHTA 2013b: 15). The business model furthermore proposed listed a certain number of "Functions of the *permanent EUnetHTA*" [161] (EUnetHTA 2012a, Italics added). Although the wording "permanent EUnetHTA" would disappear in the final draft, it did indicate the state of mind at the time of the JA1.

The proposed business model did also launch the discussion regarding the future legal entity of the network (EUnetHTA 2013b: 14). Here again, it was envisaged that EUnetHTA would be the entity which would evolve into the to be created 'EU HTA Network', underscoring the challenges to ensure the transition: "EUnetHTA is not a corporation, nor an EU agency. At

---

160 Content production and related services around the EUnetHTA tools; Facilitation of transparency of methods and data used for HTA reports; Quality assurance of HTA methodology. It foresaw a potential for integration whilst preserving full national autonomy on national decision-making processes (EUnetHTA 2013b).

161 These functions are: 1. be a contact point for the HTA community in Europe 2. maintain a shared HTA Information and Communication system 3. develop common processes for performing and reporting HTA 4. pilot processes for the collaborative production of HTA information taking into account also European priorities in the healthcare field 5. facilitate adequate evidence generation 6. facilitate the establishment and continuous development of HTA institutions" (EUnetHTA 2012a).

this moment, EUnetHTA is a network of independent government nominated and founding partner organisations and does not have a legal entity. While this will be maintained during JA2, the question is how this can flexibly develop and adapt to future changes after JA2" (EUnetHTA 2013b: 14). Other issues, such as retribution measures to partners have also been brought fore, proposing a fee-based and credit system permitting to reward those that invested in the system (EUnetHTA 2013b: 8-10). As regards the financing of the future sustainable network, a MS/EU co-financing model had been proposed, leaving also the possibility open for other financial opportunities (grands, commercial fees).

Since the Commission Proposal for a Cross-Border Health Care Directive, the future of a sustainable European HTA network became intrinsically linked to the adoption process of the latter. Indeed, once adopted in 2011, this Directive would offer, as we have seen above, a legal basis to establish a European HTA cooperation mechanism. The internal organisation of Joint Action 2 (2012-2015) sought therefore to be aligned with the Directive. Hence, one of the three key objectives of the Joint Action 2 was "to develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration according to the requirements of Article 15 of the Directive for cross-border healthcare" (www.eunethta.eu). The input of Joint Action 2 with regard to the development of a sustainable permanent structure for HTA collaboration will be - content wise – however of lesser importance than the Joint Action 1.

This situation can be explained by the developments in the broader European context with the setup of the policy orientated EU HTA Network. Whilst during the JA1, the status of EUnetHTA with regard to the future sustainable network was still vague, during JA2 this has been clarified to a certain extent. Indeed, based upon the decision taken in the EU HTA Network, the deliverables of the JA2 recalled that, the EUnetHTA JA2 was mandated to be the scientific and technical level of the cooperation process working in synergy with the HTA Network established on the basis of Article 15 of the CBHC Directive (EUnetHTA 2014:5). However, besides strengthening the practical application of tools and methodologies, the JA2 needed to contribute to the development of a strategy for the actual implementation of a sustainable European cooperation on HTA.

Conversely to JA1, no specific Work Package had been dedicated in the JA2 to the reflection on the framework and governance of a future sustainable HTA collaboration structure as this also was being dealt with by the EU HTA Network. This however does not mean that no attention has been given to the latter. Indeed, one of the objectives of Work Package 1 on 'Coordination' regarded the delivery of recommendations on the implementation of a sustainable European network for HTA (www.eunethta.eu). It is interesting to notice how the recommendations developed by the JA2 do not refer to the business model developed

in JA1. Although the model developed in the JA1 had not been implemented as such, some ideas had nevertheless been (partly) accomplished in JA2. One can cite as an example the proposal of establishing activity centres which have not been created officially. However, in practice, the international organisation did function according to this idea with some agencies (often lead partners of Work Packages) coordinating the work in specific activities such as Relative Effectiveness Assessments or Early Dialogues (Personal Interview 30). Moreover, a similar idea lays at the basis of the structure presented in the Commission proposal for a Regulation on HTA cooperation (European Commission 2018).

Another example regards the functions of EUnetHTA and the differentiation in status of membership as described in the official EUnetHTA document outlining the recommendations on the implementation of a sustainable European cooperation on HTA. The latter focused mostly on the scientific and technical aspects of cooperation on HTA and aimed at "contributing to the development of content and structure of a possible 3rd Joint Action on HTA". It highlighted how distinct tasks should be defined and attributed to the strategic level and scientific/technical level "while ensuring synergy between the levels with a clear separation of their remits and mandates". It emphasized the need for a transition from "piloting of cooperation activities to routine implementation and uptake of the joint output in national/regional HTA production processes". It also introduced three levels of commitment for partners, each associated with specific responsibilities and duties (EUnetHTA 2014:3)[162]. Finally, in the final technical report of the JA2, regarding the hosting facility of the future HTA sustainable structure, an assessment of potential options was suggested and which should also include "definitions of the role, function and specific tasks of the coordinator/coordinating facility to support permanent cooperation" and explore sustainable funding mechanisms (EUnetHTA 2016:4).

The contribution of JA2 regarding the organisation and governance of a future sustainable network for HTA cooperation in Europe was thus primarily focused on the formulation of recommendations. These were however less explicit than the business model delivered in JA1, except for the level of commitments proposed by JA2 and which would nourish the reflections on the EU level, as we will see in the next section. Moreover, no references have

---

162   The first level of commitment regarded sharing and exchange of information produced and methods applied individually by participating organisations. On the second level, partners would commit themselves to contribute to the development, support and application of common tools (e.g., databases, models for structuring and reporting of HTA information, capacity-building activities) and scientific methods (e.g., methodological guidelines and templates) to support HTA production processes. On the third level, they would commit themselves to contribute to the production of joint assessment reports and application of the results of joint assessment reports in the national/regional HTA production processes (EUnetHTA 2014: 11).

been made to the reflection process of JA1 and its proposed business model. Not even when discussing the financial aspects of the sustainable mechanism (e.g. no reference to the proposed credit system of the business model of JA1). The recommendations would limit themselves to a statement that "an appropriate, feasible mechanism of financing permanent operations of such a system needs to be identified" (EUnetHTA 2016: 4). Since part of this question was being reflected upon in the EU HTA Network, EUnetHTA focused in the JA2 still on seeking co-funding for the continuation of its activities via the EU budget (e.g. Health Programme, Horizon 2020, structural funds) which was still being considered key to secure sustainability of the EUnetHTA cooperation (EUnetHTA 2014: 7).

Hence, besides the formulation of recommendations, no concrete advancement regarding the governance and organisation of a future sustainable network on HTA cooperation would be made in the JA2. Once more, the objectives established for the second Joint Action would spill over to the third Joint Action which will run from 2016-2020. Here again, as in the EU-netHTA project and the JA2, a specific WP 1 on 'Network coordination' would be dedicated to this aim. Indeed, besides the coordination of the activities of JA3, the Work Package 1 would aim at providing "scientific and technical coordination support for European collaboration activities in HTA to the integration of the HTA activities in the whole life-cycle of technologies, which lead to the development of a final sustainable model for the scientific and technical mechanism of a permanent cooperation in HTA" (www.eunethta.eu). The difference with the previous Joint Actions is thus that EUnetHTA will reflect only upon the scientific and technical part of the sustainable cooperation as reflected in the first deliverable listed and which stated the establishment of a sustainable model for the scientific and technical mechanism of a permanent European cooperation on HTA (www.eunethta.eu).

6.4.1.2 Procedural policy instruments: Communication

Communication efforts in EUnetHTA followed a two-fold strategy: internally and externally. Internal communication projects were targeted at providing a basis upon which other activities could be developed and should ensure internal cohesion of the EUnetHTA undertakings. In this regard, various tools have been developed across the Joint Actions such as a clearing house function, an internet and intranet website and several databases (e.g. POP, EVIDENT). Internal communication efforts have first been targeted at exchanging relevant information regarding HTA itself. Indeed, HTA reports on the same technology or key policy question could show important variation across countries. The aim was thus to ensure a degree of harmonisation and standardisation regarding the structure of the reports as well as the underlying assessments. As such, information which would be relevant for other agencies could be more easily extracted (EUnetHTA 2009:15).

From the establishment of a Clearinghouse functionality in the EUnetHTA project (EUnetHTA 2009:11), new tools have been developed in JA1 and JA2 such as the POP database permitting to enhance the efficiency of technical and scientific information exchange systems necessary to undertake joint work or support local assessments. Indeed, this tool permitted all agencies to be aware of all Present and Ongoing Projects (POP) of EUnetHTA members, which should not only enhance cooperation efforts but also reduce duplication of efforts (www.eunethta.eu/pop-database/). This tool has been of high importance as it represented an essential element in the establishment and implementation of joint assessments and has been continuously updated alongside other internal communication tools and methods. Indeed the intranet, internet and the information management infrastructure will be regularly restructured across the three Joint Actions, allowing a better support "to the piloting of collaborative production of HTAs by partner agencies, and facilitate the tasks and team working of the other WPs" (www.eunethta.eu). Hence, internal communication means were developed to support the key-activities of the network. This could aim at facilitating the information flow between the Work Packages and the governance structures such as the Secretariat and the Executive Committee. It could also aim at offering technical support linked to initiatives of joint work as for example the POP database. Similarly, the EVIDENT database has been established to support cooperation in evidence collection and share information on reimbursement and assessment status of new technologies or requests regarding additional evidence (studies) on technologies (see further on EVIDENT: www.eunethta.eu).

External information efforts of EUnetHTA were aimed at disseminating the activities and outcomes of the network so as to enhance the awareness about HTA and the cooperation efforts on the European level in this regard. Dissemination had already been identified in the EUR-ASSESS project as important for HTA development. This item remains meaningful enough to dedicate in each Joint Action a specific Work Package to it (i.e. WP 2 in JA1, JA2 and JA3). Throughout the years the activities will diversify and intensify. As such dissemination has taken place by means of promotional materials and social media, the publication of articles in scientific journals, the presentation of EUnetHTA at scientific conferences and (stakeholder) Forums (EUnetHTA 2013: 37-40); www.eunethta.eu).These dissemination activities have been a mean to take stock of the activities done in the network on the development of tools, methodologies and new initiatives or members. Moreover, it permitted to bring HTA cooperation in the spotlight and attract the attention of policymakers and stakeholders.

It should be highlighted that the organisation of conferences also allowed to shape discourse and peer-education on certain issues (e.g. REA, Early Dialogues, Regulation proposal). Moreover, this was also an opportunity for members to exchanges informally, create new relationships on which future collaborations could be built. Knowing each other better also

contributed to establish trust which has been often recognised as an important element to successfully develop joint work. It also allowed members to resolve particular problems by being able to communicate more easily and learn from the experiences of others (e.g. Personal interviews 1, 6 19). Finally, it contributed to the involvement of stakeholders in the project "to ensure that the results of the project are applicable and appropriate" to them. In this regard, the WP2 on Dissemination of the Joint Action 3 aimed at developing a "post-2020 model of European HTA network in terms of effective communication with the key stakeholders". To this end, it is also been envisaged to establish a stakeholder analysis and registry (https://www.eunethta.eu/ja3-archive/work-package-2-dissemination/).

6.4.1.3. Procedural policy instruments: Capacity-building

The relationship between dissemination and capacity-building is at many levels quite narrow which explains why it has always been integrated in the Work Package on Dissemination in the Joint Actions. As for dissemination, capacity-building follows a two-fold objective: internal training of EUnetHTA partners on the various tools and methodologies being developed and external training of stakeholders and agencies with less experience in HTA. Though the EUnetHTA Project (2006-2008) still dedicated a specific WP 8 to support countries without or with a limited institutionalisation of HTA, the latter has been integrated in the general capacity-building activities in the Joint Actions (EUnetHTA 2013; www.eunethta.eu). Moreover, capacity-building also proceeded for an important part via peer-education where the more experienced partners would share their knowledge and experience to less experienced members of the network (Personal interviews 1, 11, 19, 22, 28, 30). "*The way I view it is you get out what you put in. Like we went from being a brand-new agency, with no track record at all, to now being probably one of the most experienced members of the network*" (Personal interview 19).

Besides peer-education, capacity-building has taken place though the development of tools and training materials such as a handbook on HTA capacity-building aiming to provide guidance and support on how to establish HTAs. Training seminars and e-learning courses accompanying the HTA tools and methodologies developed also sought to respond to the various needs of the members of the network (EUnetHTA 2009: 151-176). The aim here was to increase the awareness and "understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholders" (www.eunethta.eu). In order to assess the needs of members, the network proceeded by the implementation of surveys so as to better understand how new tools or methodologies were being perceived by the end-users as well as specific needs of agencies that could be addressed by international cooperation (Moharra et al.2008: 28-29).Throughout the last Joint Actions specific attention has been given to capacity-building of stakeholders and newly established HTA agencies. This

also aimed at enhancing the impact of HTA reports in national decision-making processes by producing best practices among EUnetHTA members (EUnetHTA 2013a 33-48).

6.4.1.4. Procedural policy instruments: Evaluation

The evaluation processes in the EUnetHTA project and Joint Actions have been an integral part of the projects and also an explicit requirement from the EC Commission. Evaluation of the HTA cooperation could be made on two different levels: an evaluation on internal processes (mainly project implementation), and evaluation on external processes (e.g. consultations process of different proposals made by EUnetHTA the EU Commission or other actors). Part of the internal evaluation processes have been organised in a formal way and were conducted by a specific WP on Evaluation (following the requirements of the grant agreement). This evaluation regarded mostly the implementation of the project's strategic objectives and the sub-objectives defined in each WP. As such all tools and methods were being examined. The evaluation tools were mainly surveys, semi-structured interviews and documentary analysis. A comprehensive outline of the results of these evaluation processes will be given at the end of this chapter in the section on the fifth phase of the policy cycle (evaluation).

However, often internal evaluation has been conducted in a more or less informal way applying some form of single or double-loop learning processes (see chapter 4). "*I think EUnetHTA is a learning organisation. So, we do evaluate; how did that go and where could we potentially find weaknesses and address them the next time. (…) I think it is probably mostly that kind of learning by doing and developing the way that we do things*" (Personal interview 19). On-going internal evaluation leads to an adaptation of the process on the basis of the interim results. "*The entire EUnetHTA works that way*" (Personal interview 1). Indeed, the many pilot projects that have been set-up, have been adapted following formal and informal evaluation processes. Moreover, exchange of experiences in EUnetHTA - but also in other international HTA-related societies - also make up part of the evaluation processes to compare progress or situations dealt with in other agencies (e.g. Personal interviews 6, 30). Hence, soft governance evaluation methods have been applied in EUnetHTA, even though this has never been officially organised that way.

Regarding the evaluation on external processes, EUnetHTA has participated in several consultation processes. On can cite here in particular the public consultation process launched in 2016 by the EU Commission regarding the different scenarios of the future HTA cooperation in Europe and the participation of members and stakeholders in the preparatory phase of the Commission Proposal for a Regulation on HTA cooperation. For a more consistent approach in our analysis, we will discuss the latter as well in the final section of this chapter.

6.4.2. Policy implementation in EUnetHTA: substantive policy instruments

In the previous section we have examined the procedural instruments used by EUnetHTA in the form of Organisation, Communication, Capacity-building and Evaluation. All these processes have can potentially influence the substance of the policy outputs (Howlett, Ramesh and Perl 2009: 169). In this section, we will examine the instruments used which are directly concerned by the substance policy output. Although the various outputs have been developed at different points of time, we will adopt in this section the HTA approach of the life-cycle of a health technology, ranging from: Horizon Scanning, Joint Scientific Advice, joint work (i.e. methodologies, tools and assessments), (additional) evidence generation and uptake of joint work in national settings.

Already in the EUnetHTA Project (2006-2008) the question of (early) access to new health technologies has been raised. This question will remain high on the agenda throughout the subsequent projects and Joint Actions. Indeed, highly innovative and promising technologies with the potential of bearing a high value for the health care system often also represent high costs and their impact on the health systems is still uncertain. Market approval is based on quality and safety evidence collected in controlled setting (e.g. RCT) and analysed according to clearly defined data (see chapter 5). Obtaining coverage for new technologies requires often additional data on clinical effectiveness, cost-effectiveness, impact and quality of life which again requires time and money to collect. Hence, once a promising technology is identified it can take long before sufficient evidence is gathered permitting to make a decision on its market authorisation and coverage.
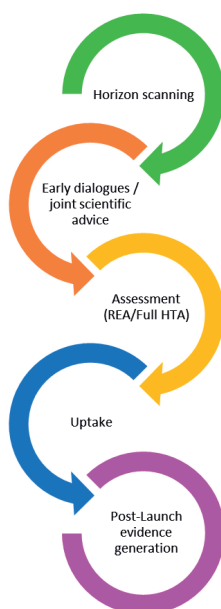
Figure 6.1. Assessment process based on health technology life-cycle

Since the launch of the EUnetHTA project, an increasing number of EU Member States had recourse to a new mechanism called "access with evidence generation" (AEG) herewith allowing a temporary access to the market for some health technologies whilst requiring simultaneously the generation of additional evidence to reduce uncertainty about the technology. This mechanism required thus to anticipate and gather relevant data as early and as quickly as possible to ensure the technology is safe and efficient. If, initially, 'evidence generation' was being dealt with in EUnetHTA at the stage between market approval and national regulatory processes, gradually a life-cycle approach will be adopted comprising initial evidence generation (Early Dialogues) and post-launch evidence generation (including real world data). As with the other instruments developed, this process will develop in stages from Horizon Scanning (early awareness and alert systems), joint work in the form of use of common tools and methodologies, Relative Effectiveness Assessments and full HTAs. Output of collaborative work is often considered being of use when effective uptake of that work in national settings can be observed. In this section, we will outline the main policy instruments that have been developed by EUnetHTA in this regard and which have implied an ever-closer collaboration with the EMA.

6.4.2.1. Substantive policy instruments: Horizon Scanning
Providing timely access to new health technologies requires often a so-called *Horizon Scanning* exercise to identify among all new and emerging technologies, those technologies

which seem the most promising, even if not all evidence has yet been generated to feed into the regulatory processes. Horizon Scanning can be defined as "the systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society" (www.eunethta.eu). Several Horizon Scanning Systems (HSS) have been developed over the course of years in Europe and abroad, such as Euroscan, an international network focusing, amongst others, on the development of methods for the early identification of health technologies (www.euroscan. org)[163]. Horizon Scanning is closely connected with other stages preparing an HTA such as topic identification, selection and prioritisation. The importance to prioritise the assessment of health technologies had already been underscored in the very first project of HTA collaboration (EUR-ASSESS, see chapter 4).

In 2006, EUnetHTA addresses the issue of Horizon Scanning in a dedicated Work Package combining it with additional evidence generation. During the EUnetHTA project and the first Joint Action, both topics were however dealt with in two different strands of the same Work Package 7. Strand B focusing on the early identification of new and emerging technologies. Strand A concentrating its attention on the definition of conditions for providing timely access to promising technologies with evidence generation (EUnetHTA 2009:116). The first EUnetHTA initiatives regarding Horizon Scanning were aimed at developing a systematic review on existing Horizon Scanning programs and their working processes. Collaboration herein was established with other organisations such as EuroScan. The added value the EUnetHTA project aimed to achieve in this field was to develop a standardised form for information sharing, making it available to a wider audience (EUnetHTA 2009: 117).

During Joint Action 1, no real Horizon Scanning activities, as such, have been implemented as the efforts in Strand A were concentrated on developing a database on evidence generation on new technologies. This 'EVIDENT database' contained information on additional studies requested by European HTA bodies and gathered furthermore information on assessment and reimbursement of new technologies (EUnetHTA 2013:113). Stand B had focused on the development of the 'POP database' gathering information on ongoing and planned projects/assessments of new pharmaceutical and non-pharmaceutical technologies (EUnetHTA2013:114). These databases, which had been developed using several consultation

---

163 Other HS systems that have been developed in Europe and elsewhere are for example: EuroScan; HTAi – via the HTAi IG DEA interest group on disinvestment and early awareness; BeNeLuxA/IHSI; The Nordic Pharmaceutical Forum; Cross-regional collaborations (e.g. Spain and Italy); the Canadian HTA agency (CADTH); the Australian Institute for Safety Compensation and Recovery Research (ISCRR).

methods among EUnetHTA members, were considered to be an important tool to reduce the duplication of work among HTA agencies and foster collaboration on assessments.

Both databases could be considered as offering support to a Horizon Scanning activity since they permitted to present an overview of assessment projects planned as well as request for additional evidence made by agencies on some health technologies. This approach was however fully targeted on the need of HTA agencies and not necessarily on the need of the European health systems. The latter would be more interested in knowing what would be in the pipelines of pharmaceutical and medical device companies so as to prepare for e.g. potential health budget impacts. EUnetHTA, however, at this stage of development, needed to first allow for a comprehensive overview of planned and ongoing projects of HTA agencies and was less focused on pipe-line products.

In Joint Action 2, the importance of collecting evidence throughout the entire life cycle of health technologies will be underscored. However, again attention will be directed to other stages of evidence collection and in particular towards the so-called Early Dialogues which will be outlined in the next section. Indeed, the final report states that "By 2019 a standard process should be implementable for European HTAs, that would cover appropriate genera-tion and assessment of evidence throughout the entire life cycle of health technologies (from Early Dialogues, through early assessments, additional evidence generation and assessment of technologies already established in the market to technologies which may be already out-dated and could be replaced by newer, safer and more effective ones)" (EUnetHTA 2016:4).

Hence, although acknowledged of being an important exercise of HTA by EUnetHTA mem-bers, Horizon Scanning had never been a priority topic for EUnetHTA till 2016 (Personal inter-views 20, 24, 29). In Joint Action 3, this will however slightly change, as specific attention will be given to Horizon Scanning which will be treated separately from other evidence collection activities. Indeed, the WP7 will focus specifically on evidence collection (Early Dialogues and post-launch evidence collection), whereas Horizon Scanning will be integrated in the WP4 on joint production. As such, one of the objectives of this work package will be to "develop and refine a system of Horizon Scanning, topic selection and prioritisation in close collaboration with the Liaison Committee and relevant Work Packages" (www.eunethta.eu/ja3-archive/work-package-4-joint-production/).

The increased attention given to Horizon Scanning could partly be explained as a result from the Commission proposal for a Regulation on HTA and which included a specific chapter on Horizon Scanning in relation to the early identification of emerging technologies (Euro-pean Commission 2018). Horizon Scanning became more widely used in different settings and several HSS had been developed in Europe all seeking to increase the timeliness and

relevance of the activities they would support. Moreover, Horizon Scanning also served to better evaluated new medicines in the industry's pipeline that could potentially have an important impact on the health budgets. Although pursuing similar objectives these systems would differ in their management, operational and administrative structures as well as their customer profiles. As such some would respond to needs of health systems other would seek to support procurement processes besides reimbursement decisions. EUnetHTA would seek to develop a new Horizon Scanning system aimed at responding to the needs of HTA agencies working in a European collaboration (Personal interviews 15,17)

In July 2018, as a response to the EU proposal for a Regulation on HTA cooperation and preparing the post 2020 scenario, the JA3 WP4 made recommendations for a new HSS which had been submitted to the EUnetHTA members as well as relevant stakeholders. These recommendations sought to cover several stages to be performed before the actual joint assessment and included: Horizon Scanning (HS), Topic Identification, Selection and Prioritisation (TISP). This system should support HTA activities throughout the technology lifecycle including early dialogue with technology developers, initial assessments, planning and additional evidence generation and reassessment (EUnetHTA 2018a:12).

Criteria for topic selection would be based on economic or resource impact, potential health benefits, severity or burden of disease, population size and the importance to policy and/or health care. During the prioritisation process, additional criteria would be applied so as to retain for assessment those technologies having a greater impact on the system's or network capacity for assessment. The criteria proposed by EUnetHTA and in line with the scope of the EU proposal would focus on unmet medical need; potential impact on patients public health, or health care systems (e.g. burden of disease, budget impact, transformative technology); cross border potentials; union-wide added value (e.g. relevance to a large number of Member States); the resources available to perform assessments (EUnetHTA 2018a:23).

Although present in the workload of several EUnetHTA work packages since 2006, Horizon Scanning has never been a priority topic for the network. It is only in the Joint Action 3 that this topic receives new attention and becomes an integral part of an innovative model, based on a life cycle approach of health technologies. The integration of Horizon Scanning activities in the Commission proposal on HTA cooperation most probably also has played a role in the renewed attention for this topic in EUnetHTA. Moreover, the attention given by regional intergovernmental collaborations to Horizon Scanning could also have had an impact herein. Indeed, increasingly governments would start to develop the HSS to better evaluate the arrival of new products on the market and which could have an impact on the health budget. As we will outline below, some countries had decided to collaborate on economic evaluations of technologies, including in their efforts also Horizon Scanning activities.

6.4.2.2. Substantive policy instruments: Early Dialogues

Once a technology has been identified and prioritised for assessment, another process can be initiated in the pre-licensing phase of market entry. This process has been developed at different places and by different organisms and therefore responds to different denominations such as; (parallel) scientific advice, Early Dialogues or joint scientific consultation. The aim of this process is to establish a structured dialogue between pharmaceutical and medical device companies on the one side and regulatory and/or HTA bodies on the other, to provide information about the evidence and information needs of HTA bodies and regulators. Indeed, as outlined in chapter 1, the evidence requirements for regulatory agencies such as the EMA and national HTA bodies can differ. Although accepted for EU market entry, a technology could see it commercialisation being delayed by additional evidence requests of HTA bodies. Hence patient access for innovative medicines or medical devices would be slowed down.

Although developed after the initiatives on additional evidence generation, which would target more specifically post-launch evidence, the initiative on Early Dialogues has evolved as one of the most successful EUnetHTA products. Single HTA Early Dialogues had been already developed by some HTA bodies since 2009 (e.g. NICE, GB-a). In 2010, Tapestry Networks, an American organisation, launched a multi-stakeholder project which would lay down the foundations of future initiatives in the field of parallel scientific advice or Early Dialogues. The initiative was based on recommendations of earlier projects seeking to develop stakeholder understandings regarding diabetes Type 2 and breast cancer (Bergmann et al. 2014).

The working groups of these projects concluded that public and private stakeholders in the drug development systems lacked "sufficient information to support and assess the development of innovative medicines that address unmet needs at reasonable cost" (Bergmann et al. 2014: 305). Based on their recommendations, six pilot projects have been launched from 2010 to 2012, implementing multi-country, multi-stakeholder consultations on drug development. These projects permitted the establishment of common meetings between regulators, health technology assessors, payers, patients and medical experts aiming to deliver a joint advice regarding the drug development (Tapestry Networks 2012).

In 2010, a similar initiative had been initiated by the EMA. The so-called parallel scientific advices allowed for concertation between a pharmaceutical company and two or three HTA bodies. The process sought to enhance the understanding of stakeholder data needs (including patients') and the differences between regulators and HTA bodies (Shan and Carter 2019). Hence, developers could receive simultaneous feedback on their development plan from the regulators and HTA bodies who would give, if possible, a common response. However, if their positions would diverge too much, each individual HTA body would give its contribution about evidence required (Tafuri et al. 2016; Personal interview 29).

Hence, when EUnetHTA started its activities on Early Dialogues in 2012, experience in the matter existed but was still rather limited. The approach EUnetHTA sought to adopt, differed from the previous initiatives in the sense that it extended the number of HTA bodies participating in the discussions (6 to 10 HTA agencies in the first projects) (Harousseau et al. 2015). Moreover, EUnetHTA sought to reach a concerted *single* contribution of HTA bodies after a joint consultation between the industry, the regulators and the participating HTA bodies. "*We wanted to create a model which would be more effective in terms of performance and more collaborative*" (Personal interview 29). To this end, the common consultations with all stakeholders around the table would be preceded by meetings of HTA bodies to "*see how far we could go in our coordination, in our common responses etc.*" (Personal interview 29). In cases where no common response could be given because of the regulatory disparities that could not be overcome, a common response would be edited, indicating however the reserves expressed by specific parties facing specificities in their countries which should be taken into account by the developers (Personal interview 29).

At first, a small budget was provided to finance three Early Dialogues. Highly motivated, some HTA bodies initiated however two preparatory projects which they would finance themselves. As feedback of agencies and developers was highly positive, eight pilot projects have been implemented instead of the three initially foreseen (Personal interview 29). Hence, in order to extent the initiative, more budget was required. As the Joint Action was already set in motion and could not be amended in terms of objectives and budget, a separated project has been developed under the denomination of "Shaping European Early Dialogues – SEED". Supported by the recommendations of the Health Forum, the European Commission decided to support this initiative by setting up a call for tenders which contained a certain number of specifications to which the project had to respond.

Some of these specifications aimed at ensuring the sustainability of the Early Dialogues and followed a soft governance approach (e.g. single / double loop learning approaches, stakeholder consultations etc.). Although the Commission did have a say over the content of the project, it did leave the opportunity to the project initiators to further amend the approach based on learned lessons and past experiences.

For the Commission representatives, the parallel scientific advices and Early Dialogue did respond to a real need and also permitted to face a certain 'battle of powers' that existed at the European level between regulators and national/regional HTA bodies, each having their own expectations and requirements. The projects initiated by EMA and EUnetHTA did offer an opportunity to put all stakeholders around the table, "*start talking to each other*" and map out possible scenarios for parallel HTA scientific advice and regulatory scientific advice (Personal interview 8). Hence, besides the scientific reasons, there was also a political need to

support the initiative: "*there was this opportunity – because EMA was a difficult case – and then we said: why don't we try to find a hook for them to start talking to each other? So, we issued a call for tender*". (Personal interview 8).

With the Commission financial support, the SEED project avoided the "premature death" of a highly successful initiative. "*The success had exhausted all our resources and we could not respond to all the requests. The SEED project avoided that [discontinuation of Early Dialogues] and allowed us to continue and to make new propositions for the future*" (Personal interview 29). The SEED initiative, which started its first pilots in 2012, also allowed to install a sort of junction with the EUnetHTA Joint Action 2 launched the same year (Harousseau et al. 2015, Personal interview 29). The first pilots were followed-up by eleven Early Dialogues (9 on pharmaceuticals and 2 on medical devices) which were implemented during the Joint Action 2 (2012-2015) and exceed the number of Early Dialogues initially foreseen (Personal interview 29).

Membership of the SEED consortium and participating HTA bodies was overlapping with EUnetHTA. Hence, although in terms of participation, the SEED consortium resembled the membership profile of EUnetHTA, it remained a separate administrative entity. Moreover, some HTA agencies (e.g. GB-a) could be participating in the SEED project but not in the EUnetHTA Joint Action (Personal interview 29). This collaborative approach included besides HTA agencies and the industry also representatives of the EMA with whom a certain number of projects had been carried out in parallel, whilst the majority of Early Dialogues regarded multi-HTA bodies (EUnetHTA 2015b: 4). "*We said, we first have to know how to work together before starting to work with the EMA*" (Personal interview 29).

Participation was voluntary, advice was not binding and confidential which contributed to the success of the project amongst the partners from the industry who adopted a very positive approach to the project: "*The motivation was there because often when you ask for reimbursement for a product, you notice that you have the market approval but the reimbursement authorities will have certain other requirements or do not agree with primary or secondary endpoints and you only figure that out at then. That is far too late because there is not much you can do about it.*" (Personal interview 16). Moreover, organising a dialogue between representatives of clinical departments of the industry, the EMA and HTA agencies was also helpful for internal industry processes: "*It was internally a real eye-opener for people of clinical departments and also regulatory who normally only exchange with EMA. They could see what the requirements are of reimbursement authorities. But it was also an eye-opener for representatives of EMA and the reimbursement authorities*" (Personal interview 16).

Indeed, before the parallel regulator-HTA bodies scientific advice organised by EMA since 2010 and the SEED project, there had been no systematic exchanges on the issue between the EMA and HTA bodies. Both the initiatives on parallel scientific advice, initiated by EMA, and the Early Dialogues implemented by EUnetHTA, demonstrated however that evidence needs of different stakeholders could be aligned within single trial designs or development programmes while respecting their respective areas of authorities and competences (Tafuri et al. 2016). Hence, since 2012, EMA and EUnetHTA have started to collaborate more intensively on the issue of evidence generation. Starting with bi-annual meetings, exchange has become more frequent and several collaborative projects have been put in place.

Pilots on the side of EMA and of EUnetHTA have been implemented comprising the collaboration of both bodies where simultaneous feedback was given to medicine developers by the regulators and HTA bodies. The aim was to streamline data requirements in a single development plan satisfying the needs of the regulators (risk/benefit evaluation) and HTA bodies (value assessments). EMA assessment reports (e.g. EPAR) have been adjusted to address the needs of HTA bodies. New common approaches have been investigated to collect robust data for post-authorisation processes. The use of patient registries[164] have been examined in this regard. The collaboration between both bodies also regarded the development of the pilot projects on rapid relative effectiveness assessment of pharmaceuticals, discussed above. Finally, a discussion has been initiated regarding the wording of therapeutic indications (www.ema.europa.eu).

Ultimately, these initiatives have led to the establishment in July 2017 of a new common EMA-EUnetHTA platform for parallel consultation. This initiative replaced the parallel scientific advice procedures. An importance difference in the new approach consisted in the fact that a single contact point had been created for the manufacturers which did not have to contact anymore EMA, EUnetHTA and/or HTA bodies individually. Consultations could take place before or after market authorisation. The objective would still be the same: give developers of medicines simultaneous and coordinated advice on their development plans and herewith facilitate the alignment of data requirements which would satisfy the needs of both regulators and HTA bodies. An EUnetHTA-led Early Dialogue Secretariat would become in charge of centralising the recruitment of HTA bodies participating in the procedure, which would also include patient and health care professionals (EMA 2017; www.ema.europe.eu). Hence, starting at different places in different venues, the various initiatives of parallel scientific advice and Early Dialogues have, to date, developed into a common procedure where guidelines, templates, fees etc have been developed and are implemented in a harmonised

---

164 A patient registry collects information about patients who are affected by a particular condition (www.ema.europa.eu).

manner between the EMA and EUnetHTA. An Early Dialogue Working Party has been es-
tablished which consists of European experts who are in charge of the evaluation of the
applications and the drafting or revision of guidance (www.ema.europe.eu). Five HTA bodies
have a full seat in this structure[165], HTA bodies which are not members of the EDWP could
participate in some Early Dialogues depending on their area or expertise and availability
(EUnetHTA 2018:20). The Joint Action 3 would foresee the implementation of 33 to 35 Early
Dialogues, a number which seemed easily attainable as many applications arrived in the
course of the Joint Action (EUnetHTA 2018).

The synergies created by the cooperation between the EMA and EUnetHTA most likely
encouraged other initiatives seeking to establish closer cooperation between the HTA arena
and organisations, such as, the Heads of Medicine Agencies, the Commission Expert Group
on Safe and Timely Access for Medicines to Patients (STAMP) or the Network of Competent
Authorities responsible for Pricing and Reimbursement (NCAPR) (European Commission
2014b; 2016d). In the light of these developments a reflection paper (European Commission
2016a) had been written in 2016 on request of the EU HTA Network, and shortly after,
a synergy group has been established. The aim of the latter was to provide an overview
of activities carried out by different organisations and institutions and which could either
overlap or where collaborative work would be of interest. The reflection paper had already
identified in this regard issues, such as, the definition of unmet medical need, Horizon Scan-
ning, novel study designs. Hence, the idea was here to examine whether synergies could
be created among agencies or institutions working in similar areas regarding market entry,
post-marketing activities (e.g. evidence generation, 'late dialogues'), or in any other area
(e.g. initiatives on patient involvement, personalised medicines or orphan drugs). The work
of the synergy group was still in its very early stage at time of this research, but it started the
reflection for further steps to be taken in this regard (personal interview 26).

6.4.2.3. Substantive policy instruments: Joint work

Reducing duplication of efforts in order to promote more effective use of resources laid at the
heart of all European cooperation efforts in HTA since 1992. Considering the high disparity
between countries, the first projects (EUR-ASSESS, HTA-Europe) sought to gain insights in
the different methodologies used and establish best-practices recognised by the partners in
the different projects. From there, common tools and methodologies have been developed
by the subsequent projects. These aimed at proving Member States with objective, reli-
able, timely, transparent, comparable and transferable information which could be used in

---

165 HTA bodies with a full seat in 2019: HAS (France), G-BA (Germany), NICE (UK), AIFA (Italy), NIPN
(Hungary), two HTA bodies would share a seat: RIZIV-INAMI (Belgium), ZIN (The Netherlands)
(EUnetHTA 2018:20).

decision-making processes (European Commission 2016:4). However, to reduce duplication, one of the most important objectives is not only to exchange information but also to be able to establish *joint assessments* which could effectively be used in national decision-making processes.

Already since the ECHTA/ECAHI project, a distinction had been made between the development of common tools, methodologies on the one hand and joint assessments on the other (ECHTA/ECAHI 2001). EUnetHTA will proceed by a similar approach dealing with these issues in different work packages. In 2014, the term 'joint work' has been introduced and refers to a rather broad description including the development of common methodologies, tools and joint health technology assessments but also comprises literature reviews, structured information for rapid or full HTAs, Early Dialogues or scientific advice on R&D planning and study design (European Commission 2016: 4).

To lay the basis of a common approach and methodologies, the EUnetHTA project partners have started by adopting a new definition of HTA, amending herewith the widely used definition framed by INAHTA[166]. As such, the EUnetHTA definition would define Health Technology Assessment as: "*a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific metho*d*"*. (EUnetHTA 2008b: 13)

Addressing the problem of importing assessment results of HTAs done by different HTA agencies, the network partners first sought to develop a common HTA reporting structure. The need for standardisation in this regard had already been underscored by the previous European projects such as EUR-ASSESS and ECHTA/ECAHI (Lampe et al. 2008). The EUnetHTA project responded to this need by developing a reporting model permitting to establish a basis for the uptake of assessment elements in other health settings. Building upon work established by the early European cooperation projects, the Work Package 4 of the EUnetHTA Project developed a so-called *Core HTA model* comprising the nine domains originally identified in the EUR-ASSESS project, adding initially to these the domain of 'accuracy', but which disappears at a later stage (Lampe et al. 2008b: 71-83). The domains comprised in 2008: 1. Current use of the technology (implementation level) 2. Description

---

166 INAHTA definition of HTA: Technology assessment in health care is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health Technology (INAHTA 2007).

and technical characteristics of technology 3. Safety 4. Accuracy 5. Effectiveness 6. Costs, economic evaluation 7. Ethical aspects 8. Organisational aspects 9. Social aspects 10. Legal aspects (Lampe et al. 2008b:18). In a later stage these domains will be reframed as: 1. Health problem and current use of technology (CUR) 2. Description and technical characteristics of technology (TEC) 3. Safety (SAF) 4. Clinical effectiveness (EFF) 5. Costs and economic evaluation (ECO) 6. Ethical analysis (ETH) 7. Organisational aspects (ORG) 8. Patients and Social aspects (SOC) 9. Legal aspects (LEG) (EUnetHTA 2016a:7).

The model was characterised by including an ontology of HTA, structured according to basic concepts as Domain, Topic and Issue, all three-combined forming a so-called *Assessment element*[167].The *Assessment elements* would be further described in detailed in an *Element card* which would be generic in nature and could thus be used for the assessment of different technologies categories. An *Element card* included information about transferability potential, importance, information sources, reference materials and the relation of elements to one another. Inclusion in the common core HTA model would depend on the transferability of the assessments as well as on their importance since not all elements defined in the ontology would be relevant for or transferable to other settings (Lampe et al 2008b: 25-26).

The EUnetHTA project proposed two ways to use the HTA Core Model. One could either consider all domains of the Core Model, as it gave a summary of the findings of each domain which had been gathered in a multidisciplinary process. The second way allowed for a selective use of the assessment elements. In any case, no recommendations for use or non-use of the technology would be given. The Model has first been developed for what was considered as the most commonly assessed health technologies: medical/surgical interventions and diagnostic technologies. However, considering the variety of existing technologies, different forms of the model have been developed at a later stage to meet the specificities of other technologies (Lampe et al. 2008b: 16). Indeed, several pilot projects have been implemented since 2006. The experiences and lessons learned regarding the scientific assessment of the technologies have been taken into account in the subsequent versions of the HTA Core Model which has been adapted accordingly (see for details Pasternack 2009; Lampe 2009 and EUnetHTA 2015c; 2016).

During the Joint Action 1 (2010-2012), the main concepts of the HTA Core Model would be kept mostly unchanged and the model would continue to be a methodological framework for the production and sharing of HTA information. It was still based upon: 1) an ontology

---

167 This approach permits to address for each of the domains, specific topics and within these topics, specific issues. Similar *Topics* can be addressed in different *Domains* and similar I*ssues* may exist in different *Domains* (Lampe et al. 2008b).

containing a set of generic questions defining the contents of an HTA, 2) methodological guidance assisting in answering the questions and 3) a common reporting structure enabling standardised reporting of HTAs (EUnetHTA 2013: 52). The main novelty would be the development of an online tool and services facilitating the production sharing and use of the Core Model[168]. Moreover, the elements cards have been replaced by so-called '*results cards*'. These contained the answers defined by the assessment elements and would be organised into '*collections*'. The collections could be either an official EUnetHTA assessment such as a standard 'core HTA' or a 'rapid HTA' (comprising only the first 4 domains). They could also refer to any other type of collection freely established by the user. Finally, the handbook developed at an earlier stage and which was an aid to the use of the HTA Core Model has been updated and made available online (EUnetHTA 2013: 53-55).

The Joint Action 2 followed up on the work described above by developing a set of guidelines for the production of full Core HTAs. The underlying rationale remained based on the belief that sharing and collaborating on HTA would enhance efficiency and relevance of information for all users, avoid duplication and increase uptake of joint work. As such, besides the policy guidelines developed in JA1, a common set of procedures and standards will be developed during JA2 to ensure internal coordination and organisational aspects of common core HTAs[169]. Finally, the Work Package 8 of the JA2 was dedicated to the maintenance and update of the HTA Core Model infrastructure according to the different applications of the HTA Core Model (e.g. pharmaceuticals, medical devices, diagnostics) (EUnetHTA 2016a).

As discussed above, following the recommendations of the Pharma Forum, EUnetHTA had been designed as network to develop Relative Effectiveness Assessments (REA). The Joint Action 1 will follow-up on this recommendation by adjusting the HTA Core Model to REA. One of the main adaptations regarded the introduction of a rapid model which would be limited

---

168 The process of producing information into the online HTA Core Model was split up into five phases: 1) Project definition (setting up the project, as well as its scope and participants); 2) Protocol design (selecting relevant questions and formulating the to match the scope); 3) Research (finding answers to the questions); 4) Entering results into a collection of core HTA information (consists of results cards and general texts for the whole collection); 5) Viewing and submitting results (emphasis on viewing at this point) (EUnetHTA 2013: 52).

169 The JA2 guidelines outline how the project should be organised by dividing the project group into different working teams, each working on different domains. Each of these teams is headed by a primary investigator (PI) who is responsible for the overall coordination and for the delivery of the final HTA production process. The PIs are assisted by one or more investigators. Besides the active researchers, each team is assisted by a group of internal reviewers who need to come from another organisation in another country than the investigators. Finally, an editorial team has to be set up for each HTA Core project (EUnetHTA 2015c:12-13).

to the first four domains of the Core HTA Model[170] (EUnetHTA 2013: 75). The domains have been however adapted to include only the items relevant and feasible for rapid assessment. The domain on cost and economic considerations has been excluded based on the recommendations of the High Level Pharmaceutical Forum. The remaining domains (ethical, organisational, social and legal domains) have been replaced by a short checklist permitting a quick assessment of these issues (EUnetHTA 2013: 82). A (rapid) Relative Effectiveness Assessment (REA) has been defined as "an assessment of a specific technology within a limited timeframe in comparison with one or more relevant alternative interventions. It may assess a new pharmaceutical launched onto the market, or (re)assess a pharmaceutical for a new indication or when new relevant data are available" (Kleijnen et al. 2012).

Considering the specific environment of pharmaceuticals where market authorisation needs first to be received from the European Medicine Agency, the model for REA sought to be in line with the regulatory processes already in place[171]. As such, the submission file by the marketing authorisation holder and the European Public Assessment Report (EPAR) would constitute the primary sources of information for the REA. If needed, this would be complemented by a full systematic literature search in reference databases. Specific guidelines for this model have been developed and regularly adapted (EUnetHTA 2013:82). Hence, as the extent of applications of the Core Model and the model on Rapid REA developed, so have the guidelines associated to them. In the course of 2008-2016, many guidelines have been developed focusing each on a specific issue of a specific application of these models[172].

Despite the work realised to develop and adapt the models according to the needs and based on feed-back of those who tested them, no real generalised use of either the Rapid REAs or a full core HTA has been observed till the end of the Joint Action 2. Even the implementation of pilot projects did not face the same enthusiasm observed in the Early Dialogues, in particular on behalf of the industry partners (Personal interview 15). Indeed, agencies having tested

---

170 The four domains investigated in a rapid relative effectiveness assessment are: Health problem and current use of technology; Description and technical characteristics of technology; Safety and Clinical effectiveness (EUnetHTA 2013: 75).

171 One of the underlying reasons to adopt a rapid model of assessments relates to the Transparency Directive requiring some countries to assess pharmaceuticals within a limited period of time (90-180 days).

172 Besides the guidelines on each of the domains treated in the Core Model other examples are: Methods for health economic evaluations - A guideline based on current practices in Europe; Endpoints used for Relative Effectiveness Assessment Clinical Endpoint; Endpoints used in Relative Effectiveness Assessment Safety; Comparators & Comparisons, Direct and indirect comparisons; Internal validity of randomised controlled trials; Meta-analysis of diagnostic test accuracy studies (see for an extensive list http://eunethta.eu/eunethta-guidelines).

the HTA Core Model found that the approach represented "a major shift in the content and work processes of a traditional HTA" (Pasternack et al. 2009: 26). Working with other agencies thus implied a change of habits and procedures and required trust building between HTA bodies who would participate. Moreover, some agencies found that working with HTA bodies on a common HTA process did not always result in a gain of time as the reports often had to be adapted to local needs or requirements (e.g. Personal interviews 19, 20 22, 27).

The implementation of the pilots testing the core-HTA model and the REAs allowed for feed-back of peers who underscored certain challenges that needed to be overcome (e.g. Huic et al. 2013). Whilst problems related to practicalities could more easily be dealt with, the problems of a legal and scientific nature continued to slow down the willingness or capacities of some HTA bodies to take part in common core-HTAs or REAs (e.g. Personal interviews 19, 22, 27). One of the difficulties was related to the heterogeneity regarding the status of HTA bodies in their respective countries. Some would be working under direct orders of the ministries, with assessment procedures and rules laid down in formal legal processes. Others would be able to decide independently on issues such as the choice of assessments and the methodologies used, making it easier to participate in a common assessment procedure (e.g. Personal interviews 11, 19, 20, 22, 30). Hence the room of manoeuvre to adapt to common assessments varied according to nature of the HTA bodies.

Aware of these challenges EUnetHTA has sought to address the technical, legal, logistic and administrative problems. As it could not impose the use of the models or joint assessments upon the network members, it has mostly concentrated its focus on increasing the quality of the project implementation to ensure the quality of the assessments. Since the first pilot core-HTAs in the EUnetHTA project, several collaborative models have been tested. The envisaged improvements focused on issues such as the organisation of the work (divided across agencies or not), communication means used during an assessment, methodologies, timeliness, etc. (EUnetHTA 2013:59). Each pilot project was evaluated internally and feed-back of peers was used in the new pilots. Changes could concern organisational matters (e.g. interaction between domain teams) but also touched upon items such as topic selection, methodological guidance, suitability of the models for all applications, and planning exercises (EUnetHTA 2013).

Disagreement existed whether the quality of the model and its outcomes would be sufficient to allow for a broad use among all members or European HTA agencies. The model that has been applied during Joint Actions 2 and 3 operated according to the principle that one organisation served as authoring institution and as such became the lead author in the project. Others were selected as co-authoring institutions. They were assisted by reviewers from two to five different institutions. To some, this model still needed to be further

improved to ensure a proper uptake in national agencies. "*If you get a report for reviewing which is not ready, where half of the things are not provided, you cannot do a correct review. (…) Another [remark] is, if you have different ways of researching the literature in different reports, then you have to re-check all the time whether this is the right procedure. You can also see that the way and the quality of these different research procedures differ. If I need something, if we want to share something, we need to know what we get. If we have to check each paper very, very thoroughly, it is worthless, it is the same as any other systematic review. So, we cannot rely on and we cannot build on this activity*" (personal interview 22).

Moreover, as outlined above, the HTA process has to be understood within the wider process of technology development and market access. As such HTA often has to respond to specific requirements of ministries or regulatory institutions. These requirements will influence the scientific approach chosen. Hence, although the establishment of trust amongst HTA bodies seems to be an important element to develop, it cannot resolve in itself the methodological disparities: "*We believe that everywhere in Europe and in the world there are really good scientists. They know their work but they are all working on different processes and different demands, different cultural demands and different political demands and requirements. These differences are those where we have a problem with*" (personal interview 22).

Others also emphasise that the lack of participation and use of the outcomes of common HTAs is not only related to issues of quality, trust or willingness but also has to be related to the contextualisation of an HTA: "*There is always a core of evidence which is the same across all these reports. It's about what is the evidence available, what does the evidence look like, what is the result of that evidence that you will see in any HTA report, probably what is the core of that evidence. But then, there is all the discussion and the analysis around it, which probably starts to become unique to reach in HTA reports. I have always felt that we could create a core of information which is relevant to everyone and we would probably save a small amount of time if we weren't all writing out the characteristics of all the clinical studies that have ever been done and presenting their results. But it is never going to get rid of that individual interpretation and analysis that you then need to fit into your decision-making framework. You can't 'uncontextualise' that bit*" (personal interview 27).

When looking at the nine domains of the core-HTA model, the last five are those in which context plays an important role[173]. Since the Joint Action 3, the focus of EUnetHTA shifted

---

173   The nine domains of the HTA Core Model are: 1. Health problem and current use of technology 2. Description and technical characteristics of technology 3. Safety 4. Clinical effectiveness 5. Costs and economic evaluation 6. Ethical analysis 7. Organisational aspects 8. Patients and Social aspects 9. Legal aspects (EUnetHTA 2016a:7).

exclusively to the routinisation of REAs[174]. Indeed, the domains constituting a relative ef-fectiveness assessment would be considered as segments where harmonisation could be achieved (personal interview 15). Economic, social, ethical and legal aspects of an assessment could be considered as part of the appraisal process by some HTA agencies or Member States where reaching common grounds would be an even bigger challenge in particular because of the need for contextualisation. Hence, although voluntary cooperation on domains laying outside the REAs remained a possibility within EUnetHTA, the focus of the EUnetHTA col-laborative approach in the JA3 would be laying purely on the clinical side (personal interview 15).

Since the introduction of REA in EUnetHTA, there had been some concern on how this would affect the other work of EUnetHTA (e.g. Core-HTA model). Nevertheless, during Joint Actions 1 and 2, both models coexisted well while being developed in parallel as they were used for different purposes. The adhesion of new agencies, where assessment of pharmaceuticals played an important role did, however, impact the internal approach: "*Their tradition was more about safety and effectiveness. They were not so keen in general to look at other collaborations. So, there has been an internal challenge on how to fix the use of different national needs and of different process needs together*" (personal interview 18).

The Commission proposal for a Regulation on HTA cooperation in Europe would build on the approach that has been developed over the years in EUnetHTA and would propose European cooperation on relative effectiveness assessments, by including mandatory aspects in the proposal. Cooperation on other HTA domains would remain voluntary (European Commis-sion 2018). Although, the other domains would still be recognised as important amongst the EUnetHTA members, the Commission proposal could have, according to some, a big impact on the further collaboration developments: "*Now, of course if this Commission proposal*

---

174   The rapid REA take place in four phases: project planning (protocol), assessment, review and con-sultation. Each of them comprising specific sections. As such the project planning phase comprises issues such as preliminary assessment of the draft submission file, scoping, search of information, formulating research questions, and planning methodologies. At the end of this phase, a final project plan is being developed comprising timelines and a list of all relevant questions to be addressed in the assessments as well as the methodologies intended to be used. The assessment phase includes finding answers to the questions using the outputs of the protocol phase, the methodological guidance in the REA Model, and the guidelines. As indicated by its name, the review phase is concerned by reviewing the assessment and comments and suggested from other reviewers are collected. The consultation phase permits to consult all stakeholders in the process (EUnetHTA members, the company applying for market authorisation physicians and/patients). Additional comments and opinions can be collected here (EUnetHTA 2015a: 12).

goes through as it is, there is a risk that it will leave agencies to work only on the first four domains" (personal interview 18).

6.4.2.4. Substantive policy instruments: Additional Evidence Generation

Randomised controlled trials (RCTs) are commonly considered as the gold standard for evidence generation in technology assessments. However, in some case RCTs are either not available or not sufficient to inform decision-makers as they primarily address the questions of safety and efficacy under specific (controlled) circumstances. However, sometimes decision-makers would need more information regarding the efficacy and safety in a real-world environment within a specific target group which has or not been taken into account in the RCTs. Additional Evidence Procedures (AED), seek therefore to gather, in a limited time-frame, relevant data to confirm or infirm expectations. The way in which these procedures take place varies between countries in Europe and different policy frameworks and mechanisms have been developed allowing temporary access to promising technologies whilst requesting additional evidence to reduce uncertainty. These procedures could take the format of so-called 'conditional reimbursements' or 'managed entry schemes' (e.g. Klemp, Frønsdal and Facey 2011; Van de Wetering, Van Exel, Brouwer 2017).

At the start of the EUnetHTA project, no institutionalised collaborative framework existed in this area where exchange of experiences and information mostly proceeded via inform e-mail exchanges and person to person communication in informal networks (EUnetHTA 2009: 122). To allow for a better understanding of the European disparities regarding AEG procedures, the EUnetHTA project - through its WP7 Strand A - first sought to provide an overview of the various national experiences, to identify the main barriers to evidence generation and to develop collaboration among HTA-agencies involved in these mechanisms. Following an in-depth study on national experiences, a 5-step policy framework has been developed. Coordination, methodological guidance, funding and a regulatory framework were identified as critical success factors (EUnetHTA 2009 ;136).

To promote a more efficient exchange system which would be less time-consuming and ensure more accuracy in the information and data to be exchanged, WP7 developed the so-called Eiffel toolkit, a web-based instrument permitting to structure the collaboration in the field of AEG. The collaboration was organised on three levels: (1) sharing information, (2) coordinated action, (3) joint action. The website allowed to either request information or post information via structured standardised forms stored in a database containing all available information (EUnetHTA 2009: 122). This tool has been further developed during the EUnetHTA collaboration project and the JA1 (EUnetHTA 2013: 105).

During the JA1, criteria have been developed for the selection and prioritisation of new technologies which would be relevant for AEG. These criteria were aimed at HTA doers, study funders and other stakeholders and ensured a transparency of selection making (EUnetHTA 2013: 113). The EVIDENT data-base discussed in the previous sections and which served as an aid to Horizon Scanning activities also served to support AEG. Besides the information regarding studies being planned or considered in an HTA body, the database also contained information on additional studies requested by HTA bodies in Europe and could even give information on assessment and reimbursement of new technologies in EU Member States (EUnetHTA 2013:113).

During the JA3, the topic of AEG will be dealt with in Strand B of the Work Package 5 which also addressed the issue of Early Dialogues. The general idea here would be to consider evidence needed for HTA throughout the life cycle of a technology. Early Dialogues did, in a sense, depart of the traditional HTA approach - considering only the evidence delivered by the manufactures – by identifying at an early stage evidence which would be required. Conversely, indicating evidence gaps post market authorisation would be a traditional activity of HTA bodies, however, till then, no joint approach between HTA bodies would have been adopted. In the Joint Action 3, the idea would therefore be to build upon the experience of the Early Dialogues and establish so-called 'late dialogues' where post-marketing evidence generation could be discussed between several HTA bodies and manufacturers (personal interview 29). As such, 'Post-Launch Evidence Generation' pilots (PLEG-pilots) have been implemented seeking to address the issue of evidence gaps and managed entry agreements by adopting a collaborative approach.

As in other fields of collaboration, the challenge would be to agree upon a common framework and accepted evidence as the procedures would still highly differ. As such, registries for, example, would be accepted as post-launch evidence in Italy where their data collection would be financed and run by an HTA body (i. e. AIFA) whereas this would not be possible in other countries. Here again, differences in procedures would often stem from the different statuses of HTA bodies (e.g. integrated or not in regulatory bodies) (Personal interview 29). As in Early Dialogues, the PLEG-pilots would be implemented in collaboration with the EMA. However, no joint advice or opinion would be given in these projects. The first pilots implemented would target specifically on the use of registries and real-world data in the areas of rare diseases and cancer (EUnetHTA 2018). The tools developed would be based on the PARENT Joint Action[175] which worked specifically on the issue of patient registries.

---

175   The Cross Border PAtient REgistries iNiTiative (PARENT), is a Joint Action which has been financed and implemented under the EU's Health Programme 2008-2013.

6.4.2.5. Substantive policy instruments: Uptake

In chapter 1, we have outlined the relation between HTA and national policy-making processes since HTA seeks to provide input in regulatory processes such as pricing and reimbursement of health technology, the establishment of clinical guidelines or hospital investments. Strengthening the link between HTA and health care policy-making in the EU Member States, is an objective which has been on the European HTA cooperation agenda since 1992, when the EUR-ASSESS project started to be elaborated. Indeed, the founders of the first HTA cooperation initiatives in Europe already underscored the importance of securing a strong relationship between the collaborative HTA project and domestic decision-making processes as, in their opinion, this would also strengthen the development for HTA as such (see chapter 4).

The HTA-Europe project (1997-1999) further addressed this issue by publishing a book giving an overview of HTA practices and use in domestic decision-making processes of several European countries (see chapter 4). In 2006, as HTA was still a relatively young discipline but manifesting a fast development in many countries, the HTA-Europe project would be updated by the EUnetHTA project. As such, the Work Package 6 of the EUnetHTA project would publish in 2008 the book: *Health Technology Assessment and Health Policy-Making in Europe. Current status, challenges and potential* (Garrido et al. 2008). This publication established a systematic overview of the relation between HTA and policy-making in the EU Member States and highlighted the needs of HTA consumers aiming at providing input for policy processes[176].

Ensuring the use of collaborative HTA projects outputs in national decision-making processes, implied the uptake of those outputs in the HTA bodies operating in the domestic policy-making processes. The notion of 'uptake' refers to the use of collaborative HTA work in national-decision-making processes. Although the aim to facilitate the use of collaborative HTA outputs has been present since the EUnetHTA project, it is only during the Joint Action 2 that a clear definition of the concept has been given. As such, 'uptake' points to a broad understanding of use of collaborative HTA products and regards "the general implementation of any EUnetHTA output in a national context and may include the usage and implementation of the EUnetHTA tools and Joint Assessments" (www.eunethta.eu). Hence, 'uptake' is not just limited to the use of joint assessments but also includes all other tools and methodologies developed by the EUnetHTA Network and used in a local/regional/national setting (e.g.

---

176   The publication underscores the need for collaboration on HTA in Europe and outlines the policy processes in the EU countries under scrutiny. The relation between HTA, policy-making and regulatory processes is being examined. It also presents the state of play of HTA in Europe and brings to the fore the needs and demands from policy-makers (Garrido et al. 2008).

use of the POP Database for local reports, submission templates, guidelines, the production of a local HTA report on the basis of the HTA Core Model or EUnetHTA guidelines).

Several tools have been developed to facilitate uptake of EUnetHTA outputs. The EUnetHTA project would develop a toolkit permitting to adapt the results of an existing HTA to a regional or national setting. The aim here was "to enable an HTA agency in one setting to make use of an HTA report produced elsewhere, thus saving time and money" (EUnetHTA 2011a:6). This toolbox comprised checklists, questions and resources enabling to assess the relevance, reliability and transferability of report. The users of the toolbox could determine whether e.g. the policy and/or research question posed in a report was sufficiently similar to the questions posed in its own setting. It could also assess the quality of the report and determine whether the information was applicable to the target setting and could thus inform policy-making[177]. The toolkit has been revised several times throughout the project and the subsequent Joint Actions and key elements of the adaptation toolkit had been integrated in the HTA Core Model online. Each revision resulted from feed-back of peers via evaluation rounds, in-house reflexion processes or surveys[178] (EUnetHTA 2013:55).

As the first Joint Action focused on the establishment of tools and methodologies to undertake joint work, less attention was being given to the specific issue of uptake in national decision-making processes. Whilst the JA1 still had to develop and test the methodologies, it is only during the Joint Actions 2 and 3, that the issue of 'uptake' will become increasingly important. Indeed, in JA2, a specific WP 5 has been dedicated to the issue of "applying the HTA Core Model for Rapid Assessment for national adaptation and reporting". The aim here was "to test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network) (www.eunethta .eu).

---

177 For this purpose, the toolkit comprised two sections: speeding shifting and main toolkit. The speedy shifting focuses on the relevance of the report for adaptation. The main toolkit regards questions of reliability and transferability (EUnetHTA 2011a).

178 Before publishing the final deliverable in 2008, two evaluation rounds were organised to test different versions by means of a questionnaire, in-house reflection processes and a Delphi survey. Several agencies have tested the Adaptation toolkit by selecting one or more HTA reports from a different country to assess whether it fulfilled the needs of their own health services. Evaluation of the applicability of the toolkit has also been done by testing the toolkit on the first Core HTA on Drug eluting stents elaborated by WP 4. Finally, group work with WP 5 members on five topic areas and face-to-face or telephone interviews further completed the evaluation process of the Adaptation toolkit (www.eunethta.eu).

During the Joint Action 2 the concept of 'National Adaptation' will be introduced pointing to a specific type of national uptake. It focused in particular on the use of *joint assessments* results (. i.e. full core-HTA or Rapid REAs) in a national or regional setting. Several modalities have been developed to support this, such as: summarising (i.e. Core HTA report is being summarised and used as background information), updating searches (i.e. search is being based on the original joint Core HTA search and further updated), adapting (i.e. systematic extraction of relevant HTA information from a joint assessment) or adopting (i.e. use of an assessment without making any changes in the content)[179]. Examination from the twelve Rapid REA pilots implemented in the JA2, showed more than seventy cases of national uptake (www.eunethta.eu/national-uptake).

Despite these examples of uptake, the general feeling amongst the agencies, EUnetHTA and the Commission was that the use of joint work was too low (Personal interviews 8, 9, 15). The governance structure of EUnetHTA, as an independent network without any established legal status, could however not impose the integration of the new core-HTA or REA model into the procedures of the national HTA bodies. It would thus be fully depended on the willingness of each HTA agency to adopt or not the framework and methodologies of the core-HTA model or the REA model. Adapting to common EUnetHTA methodologies and tools seems to have been done more easily by HTA agencies in small and middle-sized countries. Often their relative independence or strong ties with the ministries would be an asset in this regard. HTA expertise in these countries would be often concentrated in HTA bodies and representatives of ministries would be more inclined to take advise of representatives of HTA bodies to determine the course of action of HTA bodies. In bigger countries such as France, the UK or Germany, changing legal or methodological aspects or procedures regarding HTA seems to have encountered much more difficulties. Moreover, in small or medium sized countries, the executive functions within an HTA body would often be carried out by representatives present in EUnetHTA executive or lead functions which facilitated decision-making regarding the adaptation of the local model to the EUnetHTA model (e.g. Personal interviews 11, 19, 22, 27).

However, even those bodies having formally adopted internal procedures according to EUnetHTA standards, did face internal difficulties as their employees had to adapt to new habits and procedures. "*We have decided to adapt our HTAs in such a way that they would fit in the Core-HTA model with another layout. It was maybe accompanied with weeping and gnashing of teeth in the home base of our researchers (…) but you do need the authority of the chief of the institution to be able to do that*" (personal interview 20). Hence, since

---

179 To determine whether a report is based on national adaptation an explicit reference to the EUnetHTA joint assessment has to be made (www.eunethta.eu/national-uptake).

the EUnetHTA project, researchers having participated at the Core HTAs agreed that the general concept and structure of the Core HTA was feasible and that the content produced was useful for local HTAs. However, in practice, it remained difficult to increase the number of projects and see the results of those projects been implemented in the national settings.

This had in particular consequences for the industries' approach regarding the (rapid) REAs and full core-HTAs. Conversely to the Early Dialogues, the enthusiasm of manufacturers to participate was rather limited. Several reasons could be brought forward to explain this situation. Most often, the lack of uptake has been brought forward as an explanation why manufactures hesitate to participate in these projects: "*submitting files for a European assessment which in the end will not be used by the Member States, or will just be looked at a bit, then put aside before they start doing their own national assessments… All advantages the industry sees in this process will be realised only if the reports will be used. If they are not used, it is a duplication of efforts for the industry: two processes, two times more work, conclusions on a European level which will differ of those on the national level. That makes it a rather complex issue without offering any advantage, zero advantage for the industry. So as long as the process remains voluntary for the agencies, it should be voluntary for the industry as well*" (personal interview 24).

During the Joint Action 3 a specific work package (WP7) would be dedicated to the issue of 'national implementation and impact'. A systematic analysis would be made regarding the use of EUnetHTA tools, methodologies in national HTA bodies. Through internet surveys, qualitative interviews and focus groups, the members of the work package would seek to better understand the impact of EUnetHTA products in national HTA assessments and how joint assessments would be implemented in the different European countries (EUnetHTA 2019). This analysis would examine both the use of EUnetHTA output for assessment purposes and for dissemination activities and would regard the joint or collaborative assessments published under JA3 (4 assessments of pharmaceutical technologies and 18 of other technologies (EUnetHTA 2019a)). The reports published in 2019, near the end of the Joint Action 3, pointed to an increase in use of EUnetHTA outputs for pharmaceutical technology assessments compared to Joint Action 2 (220 in JA3 of which 53% for assessments and 47% for dissemination purposes). For other technology assessments, 105 uses of assessments have been reported, with a majority in dissemination (EUnetHTA 2019a: 6).

When uptake took place, the implementation reports showed that most often the EUnetHTA assessments would be used as background information or additional information. Agencies would also use assessments and add local information or elements related to budget impact, cost-effectiveness analysis as well as organisational, legal or ethical aspects. Often assessments would also be used to inform the evaluation of a company submission (EUnetHTA 2019: 19).

For non-pharmaceutical technology assessments, the studies showed that most often the EUnetHTA outputs would be used without changes other than a translation. Hence, the work carried out by EUnetHTA would replace the agencies' work (EUnetHTA 2019: 19). This would be less the case in pharmaceutical technology assessments. The reports, furthermore, underscore a good topic selection as the assessments' topic are generally within the remit of the agencies (EUnetHTA 2019a: 10). At the end of the JA3, some 20 countries reported using EUnetHTA JA3 assessments. The reported number of uptake marked a significant difference compared to JA2 (EUnetHTA 2019a: 18).

The 2019 implementation study is however interesting as it would assess in detail the parts of EUnetHTA assessments used by HTA bodies and the challenges and barriers they would encounter when using EUnetHTA outputs. Regarding the former, HTA bodies would most often have recourse the domains of corresponding to EUnetHTA REAs: i.e. clinical effectiveness, safety, health condition and use of technology and description of technology (EUnetHTA 2019:20). The collaborative work would mostly be used as background information. Additional information regarding issues as budget impact, cost-effectiveness analysis or ethical, legal and organisational information would be added (EUnetHTA 2019a: 19). Barriers to uptake, as highlighted in the report, would point to the language requirements (i.e. use of national language as pre-requisite) as well as issues of the use of a specified reporting structure and the timing of the availability of EUnetHTA assessments as well as the fact that different assessment elements would be needed (EUnetHTA 2019: 21; EUnetHTA 2019a:21). For other technology assessments, barriers cited would concern language requirements, a different scope of assessments compared to the national assessment, as well as timing of the EUnetHTA assessment availability and too restrictive included evidence in the EUnetHTA REAs (EUnetHTA 2019:22).

6.4.3. Policy implementation of EU HTA cooperation processes

In this section we will examine the policy implementation of European HTA collaboration as it has developed on the EU side. We have seen in the sections above how, since 2008, HTA cooperation has been dealt with in line with the Cross-Border Health Care Directive. From 2008 till 2014, policy implementation regarded mostly the insertion of means to support HTA cooperation in the public health Programme. As of 2014, policy implementation regarding HTA collaboration on an EU level would take mostly place through the EU HTA Network and structured by means of two multiannual work plans (MWP). The implementation of the course of action suggested in these plans would be done in close cooperation with the Joint Actions 2 and 3 run by EUnetHTA. This would be coherent with the way governance of European HTA cooperation had been outlined in the Strategy paper of the EU HTA Network which we have described above.

Whist the EU HTA Network would be responsible for the strategic orientation of HTA co-operation, EUnetHTA would act as its technical and scientific arm. Moreover, the first MWP (2014-2016) recalled that "In line with Art 15(7) of Directive 2011/24, measures adopted to implement this MWP shall not interfere with Member States' competence in deciding on the implementation of Health Technology Assessment conclusions and shall fully respect the responsibilities of Member States for the organisation and delivery of health services and medical care" (European Commission 2013b:2).

Part of the work established by the EU HTA Network will be the preparation for a legislative proposal on HTA Cooperation as discussed above in the section on policy formulation. As at the time of writing this proposal still needed to be adopted we will examine in this section which have been the points of discussion and how these are related to the objectives and projects implemented by the different networks which have been involved in European HTA cooperation.

6.4.3.1. The EU HTA Network Multiannual Work Plans

One of the first activities implemented by the EU HTA Network has been the development of a Multi Annual Work Plans (MWP). The first MWP which would run from 2014-2016 and has been developed during the Joint Action 2, outlined three key tasks which would be in line with the substantive policy instruments described above in the examination of EUnetHTA. The first MWP key task regarded the follow-up of the Joint Actions and the establishment of a sustainable cooperation on a scientific and technical level between HTA authorities and other players. Here we do find back the main objective pursued already in the early cooperation initiatives and by EUnetHTA: setting up a sustainable network for HTA cooperation in Europe.

The difference with the approach of the former initiatives is that the EU HTA Network will envisage a sustainable cooperation outside the existing project-based approaches by seeking to establish a structure including high-level national policy-making authorities, as would be proposed in the Commission Proposal for a Regulation on HTA Cooperation. Indeed, as underscored by a Commission representative, the question that increasingly came to the forefront in discussions on HTA cooperation was: "*Can we rely on voluntary self-governance to strengthen this cooperation? (…) Because the problem is all about predictability, stability and planning. So, we can keep on relying on projects that last four years and need a year and a half for negotiations, half a year to start, they work for three years maximum and then half a year to close down. Is this something cost-effective and actual useful for Member States?*" (Personal interview 8).

The second key task in the MWP 2014-2016 would underscore the importance of uptake and re-use of joint HTA production. However, the EU HTA Network would limit itself at this stage solely to the formulation of recommendations "on what is necessary to enable competent authorities to increase re-use of joint HTA work at national/regional level". It would also underscore the importance to encourage the industry to participate in joint work (e.g. of pharmaceutical rapid assessments) and to encourage national authorities to promote such joint work (European Commission 2013b: 6). We have seen how this issue will be taken up in the work plan of the third Joint Action where a specific work package will seek to advance on the issue of uptake and re-use of joint production (see above).

The third key task of the first MWP addressed the topic about the interaction between regulatory authorities and HTA bodies. The aim here would be to streamline the different processes in order to speed up patient access to treatment. Hence, synergy and de-fragmentation between regulatory authorities (EU and national level) and HTA bodies should be targeted according to the EU HTA Network. Besides improved patient access to treatment, improving business predictability and reduce administrative hurdles for technology providers and regulators still underpinned the EU HTA Network approach in seeking more synergy between Regulators and HTA agencies "while safeguarding the criteria applied for placing technologies on the EU market" (European Commission 2013b: 4). This issue too, would be further worked out in the third Joint Action as described in the section above.

The second and third key tasks have been implemented by means of the publication of reflection papers and have served as a basis for the work undertaken by EUnetHTA, in particularly in the Joint Action 3. The reflection paper on 'Reuse of joint work in national HTA activities had been adopted in April 2015 underscoring the importance of this issue for the usefulness of the overall HTA cooperation process. It will also determine the approach the Commission will adopt while preparing its Proposal for a Regulation on HTA cooperation in Europe linking sustainability of the network with uptake of joint work:

"To enable the move from piloting to long term sustainability of "Joint Work" and more broadly the cooperation at EU level on HTA, it is essential to ensure the usefulness of the cooperative work. The usefulness of the cooperation is also reflected by the extent to which Joint Work, i.e. the "products" of the cooperation are valued and used by national and regional HTA bodies as well as by other stakeholders, for example patients, health care providers, payers (statutory health insurance) and industry. Only if national/regional HTA bodies and stakeholders can benefit from joint work in their national activities will they continue to invest resources in the cooperation after EU funding from the Health Programme ends. If the reuse is not happening to the desired extent, there is the risk that the EU cooperation remains an interesting exercise but with limited value for national/regional HTA activities.

Thus it will not be meeting the final objectives set out in Directive 2011/24 including, supporting Member States in providing "objective, reliable, timely, transparent comparable and transferable information on the relative effectiveness […]" and avoiding duplication of assessments" (Art 15.2)."

The reflection documents would assess the different methodologies and tools that had been developed by EUnetHTA and which so far did not bring the desired results according to the authors of the document. The options envisaged in the paper to increase uptake of joint work would serve as a basis for the work carried out in the Joint Action 3[180]. Specific attention was also given to the life-cycle approach as still disparities among the HTA bodies in Europe existed. Although, according to the authors of the paper, these differences should be respected they also believed that the life-cycle approach in evidence generation (pre- and post-launch) should benefit from a closer cooperation between regulators, HTA bodies, payers and providers[181] (European Commission 2015c: 8). Similarly to the other subjects mentioned above, the life-cycle approach would be further elaborated in the Work Package 5 of the third Joint Action including herein the Early Dialogues as well as post-launch evidence generation and registries (www.eunethta.eu/ja3-archive/work-package-5-life-cycle-approach-to-improve-evidence-generation).

The second HTA Reflection paper, adopted by the HTA Network in November 2016, dealt with the topic of "synergies between regulators and HTA issues on pharmaceuticals". The reflexion made here sought to build further on the work establish by the SEED project and the Early Dialogues developed by EUnetHTA, as well as on work undertaken in the EMA and initiatives such as the IMI projects and the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP). As starting point of the reflection process, the authors of the paper considered that "stronger synergies between developers of health technologies,

---

180 The Reflection document referred for example to the establishment of a professional project management process and of a mechanism (including standard operating procedures) permitting a transparent topic selection and prioritisation process. Moreover, it recommended the implementation of a process facilitating the expertise by clustering (e.g. specific bodies are responsible for the assessment of specific types of technology assessment and are assisted herein by experts and appropriate stakeholders). Finally, an evaluation process measuring the uptake and the added value of European HTA cooperation has been recommended. Moreover, the reflection paper also made some specific recommendations regarding joint assessment reports, the HTA Core Model, Submission templates, Methodological standards for HTA, training material and ICT tools (POP database, EVIDENT database) (European Commission 2015c: 5-8).

181 In this respect, it highlights the necessity for cooperation between networks such as the Safe and Timely Access to Medicinal Products Expert Group (STAMP) and the EMA (European Commission 2015c: 8).

regulators, HTA bodies and decision makers can contribute to a timely and comprehensive access to information and data throughout the entire life cycle of health technology (from start to end) which can result in important benefits for healthcare systems" (European Commission 2016a: 2). Three phases in this regard are being identified: the pre-marketing phase, market entry and the post-marketing launch phase.

The pre-marketing phase would explore ways to develop successful initiatives as the Early Dialogues and would aim at developing a single model for parallel advice, suitable for both regulatory and HTA needs[182]. Suggestions related to the second phase aimed at developing actions to support the production of joint work and ensure early exchange of information between regulators and HTA bodies. Information exchange between the EMA and HTA bodies could take place through the establishment of a legal arrangement for a structured process where assessments would include data relevant for HTA. Regarding the third phase, reflection was focused on post-marketing studies with the potential use of Real World Data (RWD). The idea of "late dialogues" was also evoked permitting to facilitate collaboration with technology providers in the post-marketing phase[183] (European Commission 2016a: 5-6). All these reflections have been further used in the Joint Action 3 which has sought to implement some of these proposals in pilot projects as outlined in the sections above. Moreover, these reflections will also lay at the basis of the Commission proposal for HTA Cooperation in Europe (European Commission 2018).

The second Multiannual Work Programme (2016-2020) adopted by the EU HTA Network at time of the start of the Joint Action 3, stipulated that "The HTA Network is expected to act as key strategic forum to contribute to defining the possible scope, sustainability and governance of the European cooperation on HTA, beyond Joint Action 3. (…) During the coming years, one of the main objectives for the HTA Network should be to take an active role in clarifying and ensuring conditions for a sustainable functioning of the scientific and technical cooperation when the EUnetHTA JA3 ends in 2020" (HTAN 2016:3). Moreover, it is underscored how at the time of drafting the work plan the third Joint Action was just being launched. Therefore again, the repartition of tasks between the EU HTA Network and EUnetHTA should still remain the same: the former focusing on the political and strategic objectives taking care not to duplicate activities foreseen by the Joint Action or other relevant initiatives but instead create synergies between them (HTAN 2016: 2).

---

182   Attention here would also be given to the definition of unmet medical needs, evidence limitations, Horizon Scanning programs etc. (European Commission 2016a).

183   Some other areas where collaboration between regulatory and HTA bodies could be useful have also been identified such as orphan medicinal products, personalised medicine and vaccines (European Commission 2016a: 6).

Although not specified as such in the document, under "other relevant initiatives" one could understand regional (intergovernmental) initiatives which had been launched between several EU Member States and which would target Horizon Scanning activities, joint assessments and in some cases even cost-effectiveness analysis and price negotiations. In most of these cooperation structures, membership would overlap with EUnetHTA membership. The main difference in initiatives such as; the Beneluxa Initiative[184], the Finose collaboration[185], The Valetta declaration[186], or the Visegrad + 2[187] would be the strong implications of relevant national ministries in those. These initiatives have been developed independently of the European Commission at a time where a new Commission proposal was being prepared. As it was unclear how these initiatives would further develop, the Commission would adopt – at least officially – a rather neutral position towards them even if it did attend meetings of some collaboration initiatives (Grubert 2018; www.globalpricing.com).

The EU HTA Network will therefore focus on delivering concrete outputs regarding the sustainability and governance of European governance. In this regard, different actions will be undertaken by the European Commission as described in the sections above (e.g. section 6.2.2.3.0) and which follow the classical path of the development of a new legislative Com-

---

184 Beneluxa is an initiative created in 2015, which "aims for sustainable access to, and appropriate use of, medicines in the participating countries". It seeks to "increase patients' access to high quality and affordable treatments". The cooperation activities take place in areas such as Horizon Scanning, mutual recognition of HTA, information sharing and policy exchange and pricing and reimbursement. In 2019, the following countries had joined the network: Belgium, the Netherlands, Luxembourg, Austria and Ireland (www. Beneluxa.org).

185 The Finose collaboration refers to a memorandum of understanding signed in June 2018 between national HTA agencies in Finland (Fimea), Norway (NoMA) and Sweden (TLV) aiming to produce joint assessment reports containing both clinical and economic assessments. Although Denmark had participated in a 2017 memorandum of understanding of high-priced hospital medicines, it did not take part in the Finose collaboration as its reimbursement decision-making system differed too much from the other three countries (Grubert 2018; www.remapconsulting.com).

186 The Valetta Declaration signed in May 2017 by Cyprus, Greece, Italy, Malta, Portugal and Spain established a collaboration in the field of the assessment and procurement of new medicines. The area of activities are: joint clinical assessments, economic evaluations and joint price negotiations; sharing information to input price negotiations and contracting; sharing information and best practices around biosimilar pricing and reimbursement; sharing pharmaco-therapeutic / effectiveness assessments of drugs; Horizon Scanning. The focus is on drugs with a potential high impact on national budgets such as oncology drugs, orphan drugs, biosimilars. Other countries which have joined the group since are Croatia, Ireland, Romania and Slovenia. France has been granted an observer status (Grubert 2018; www.infarmed.pt; www.remapconsulting.com).

187 The Visegrad+2 group comprised the Czech Republic, Hungary, Poland, Slovakia, Croatia and Lithuania who agreed in March 2017 to cooperate to ensure fair and affordable access to medicines for their citizens (Grubert 2018).

mission proposal. Following the Inception Impact Assessment published in 2016, the public consultation, which ran till January 2017, and the Impact Assessment published in January 2018, the European Commission publishes its Proposal for a Regulation on HTA cooperation in Europe outlined in section 6.2. In the next section we will focus our analysis on some key issues of debate in discussions on the Commission proposal involving the different stakeholders in the HTA cooperation process.

6.4.3.2. The Commission proposal for a Regulation on HTA cooperation

Section 6.2 on the EU policy formulation process has outlined the Commission proposal for a Regulation on HTA cooperation in Europe. In this proposal, HTA cooperation is organised according to four pillars: Joint Clinical Assessments (JCA), Joint Scientific Consultations (JSC), the identification of emerging health technology and voluntary cooperation. To be implemented, the proposal should be adopted by the European Parliament and the Council with qualified majority, according to the Ordinary Legislative Procedure applicable in this case. This proposal brings to the fore some new key-player in the field of HTA cooperation: the European Parliament and Council.

As the first institution having to pronounce itself on the proposal, the European Parliament will propose a series of amendments first discussed in the ENVI Committee before being submitted to a vote and adopted in the plenary assembly of the European Parliament in October 2018. The debates on the text proposed, revealed the different controversial standpoints present among the Member States, some of which already had been expressed by stakeholders in the aftermath of the proposal's official publication. Indeed, although the European Economic and Social Committee delivered a positive opinion in May 2018, some countries (i.e. Czech Republic, Germany, France and Poland) had already raised their concern as regards the respect of the subsidiarity principle as outlined in the section on policy formulation (Council 2018)[188].

Although the proposal on HTA cooperation was a new topic on the European Parliament's agenda, the issue of HTA had already been debated several times in this institution. In its 2017 resolution on EU options for improving access to medicines, for example, the Parliament had already called on the Commission to propose a legislative framework on HTA, underscoring that "health technology assessments (HTA) must be an important and effective instrument for improving access to medicines, contributing to the sustainability of national healthcare systems, allowing for the creation of incentives for innovation, and delivering high therapeutic added value to patient; (…) the introduction of joint HTAs at EU level would

---

188 All countries, except Poland, had submitted a reasoned opinion in this regard (Council of the European Union 2018).

avoid the fragmentation of assessment systems, the duplication of efforts and the misalloca-tion of resources within the EU" (European Parliament 2017: 29). Moreover, the resolution also brings to the fore the importance of relative effectiveness assessments and the need to harmonise transparent HTA criteria in this regard and to put in place a "European classifica-tion system" to chart the therapeutic added value of new medicines. It also calls upon the Commission to strengthen Early Dialogues. (European Parliament 2017: 15).

As underscored by a Commission representative, inter-institutional cooperation permits a topic to be discussed in the different political venues. As such, Council conclusions are often prepared in cooperation with Commission representatives as has been the case in HTA cooperation: "*It is a rather small world so, of course, at the more technical level, we talk to each other. When the Council makes a conclusion, the Commission is involved, it is consulted … it didn't come out of the blue for us and you will see a lot of connections between the different conclusions, these documents, the documents of the HTA Network. So, it is not a coincidence that all the three institutions have HTA as a topic. And the same with Parliament, at technical level they ask advice, opinions. (…). The three institutions have different timings and objectives. Only when there will be an initiative form the Commission, there will be a formal process between the institutions*" (Personal Interview 8)

The amendments adopted in the first reading of the Parliament demonstrate again the interest of this institution for this topic. The point of view of the Parliament will however differ from the approach the Commission had adopted in drafting the proposal by taking an Internal Market approach. The European Parliament will indeed attempt to reintegrate a public health approach in the Regulation proposal. As such, the first amendment seeks to enlarge the legislative basis from referring not only to Article 114 TFEU regarding the estab-lishment and functioning of the internal market but also to Article 168 (4) TFEU regarding measures setting high standards of quality and safety for medicinal products and devices for medical use (European Parliament 2018). Similarly, instead of adopting the statement in the Commission proposal considering the development of health technologies as "a key driver of economic growth and innovation in the Union", it proposes to add the qualification of the development of HTA as a "key to achieving the high level of health protection that health policies must ensure, for the benefit of all citizens" (European Parliament 2018).

Other amendments adopted in the first reading are of a more technical nature, precising some aspects of HTA, such as, amendment 10 underscoring the need for health profession-als, patients and health institutions to have a better knowledge about the added therapeutic value of a new medicine compared to existing ones. Indeed, the Parliament confirms in its amendments its support to harmonise HTA criteria "to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of

innovation and value for the patients", already expressed in earlier official statements and in which it advocated "to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests" (e.g. European Parliament 2017a).

The Parliament also stresses how HTA could be a tool for promoting high-quality innovation "steering research towards addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities" (European Parliament 2018). Other items, related to the importance of HTA, have been highlighted such as the possibilities for improved patient access to medicines, efficiency in use of resources, sustainability of health systems, more efficient research and greater predictability for the sector improving herewith its competitiveness (European Parliament 2018).

Many amendments seek for more explicitly in the text of the proposal which was considered by some as being too vague and leaving to many areas open for discussion or decisions taken by means of delegated or implementation acts (e.g. Personal interviews 11, 12, 15, 17, 21). Moreover, regarding the rules to be established in joint assessments, the parliament stresses the need to guarantee the highest quality standards and the alignment to the best available practice, avoiding herewith a convergence towards the lowest common denominator and having more experienced HTA bodies used to apply higher standards having to accept lower requirements (European Parliament 2018).

As to the mandatory aspects of the Regulation, the European Parliament proposed to give the right to Member States to complement the Joint Clinical Assessments with additional clinical evidence and analyses (e.g. different comparators). The case of orphan medicinal products has also been introduced in the text. The Parliament moreover argues for the need "to move towards a centralised authorisation system that assesses devices on the basis of safety, efficacy and quality" as, due to the increasing amount of medical devices addressing clinical conditions, more HTA cooperation would be needed to address to lack of clinical evidence in some cases. (European Parliament 2018).

With regard to the governance structure, the Parliament proposes that Joint Scientific Consultations (JSC) could be conducted with the Coordination Group or with working groups set up for this purpose. Precisions regarding what these JSC should address are also given (e.g. clinical study design, comparators based on the best medical practice) as well as the evidence necessary to conduct the consultations (European Parliament 2018). Moreover, it is being proposed to establish a system of charges for health technology developers which would request JSC and JCA for research on unmet medical needs. The Parliament proposed

furthermore to add a new article regarding the establishment of a structured dialogue with stakeholder groups by means of a stakeholder forum.

The original text of recital 31 proposed to consider, two years after implementation of the Regulation, the possibility establish a Union agency and introduce a fee-paying mechanism for health technology developers. The European Parliament amends the text by deleting this possibility in the Regulation proposal. Instead, it proposed to submit an Impact Assessment study after the transitional period, which should evaluate, amongst others, "the progress made in relation to patients access to new health technologies and the functioning of the Internal Market, the impact on the quality of innovation and on the sustainability of health systems, as well as the appropriateness of the scope of the joint clinical assessments and the functioning of the support framework" (European Parliament 2018).

The Commission proposal also foresaw a certain role for the Commission in having the final say on inclusion or non-inclusion of a health Technology after a JCA. Indeed, in the Commission proposal, in case the Commission would conclude that a modified approved JCA report and summary report would not comply with the substantive and procedural requirements of the Regulation, the Commission would have a right to decline the name of the health technology in the List foreseen by the Regulation. The European Parliament, in its amendments, proposes to restrict this right to only express itself of the procedural requirements laid down in the Regulation and in case of a negative opinion leave the health technology on the list, accompanied by the negative opinion of the Commission. As foreseen in the original proposal, the European Parliament confirms that, in case of the latter, the mandatory obligation of using the results of the JCA would not apply to the other Member States.

The European Parliament endorses the standpoint of the Commission stating that the the principles of subsidiarity and proportionality do apply in this case as the objectives of the Regulation "namely to approximate the rules of the Member States on carrying out clinical assessments of the health technologies falling under the scope of this Regulation, cannot be sufficiently achieved by the Member States alone but can rather, by reason of their scale and effects, be better achieved at Union-level" (European Parliament 2018). This approach has not been shared by all Member States which would have to pronounce themselves in the first reading of the Council.

As in the case of the European Parliament, the ENVI committee would coordinated the preparatory work regarding the adoption procedure of the Regulation proposal, the Working Party on Pharmaceuticals and Medical Devices, would do so at the Council level including in its work the examination of the Parliament's position. Several meetings have been organised

in this regard throughout 2018 and 2019 and were still ongoing at the time of writing our research conclusions (Council 2019).

In the future several scenarios may take place regarding the adoption procedure. The most likely is that the Council will add amendments of it own, in which case the text would return to the European Parliament for a second reading. Either the Parliament will adopt the Council amendments in which case the proposal would be adopted as such. The European Parliament has however a right to introduce new amendments in this second reading which would then be needed to be adopted by the Council in its second reading. In case of disagreement between the Council and the Parliament a so-called 'trilogue' could take place between the Commission, the Parliament and the Council seeking to find a comprise suitable for all. The next section will highlight some reactions of the different stakeholders which had been involved in the process since the first HTA cooperation projects. These reactions do also reflect many of the issues raised in the institutional debates.

6.4.3.3. Reactions on the Commission proposal for a Regulation on HTA cooperation

Although the initiative from the Commission to submit a proposal in the form of a Regulation came as a surprise for most observers and stakeholders, the need to frame the cooperation and establish a legal basis for it had been expressed many times before (e.g. Personal interviews 4, 6, 17). Indeed, as underscored by some: "*The Commission used the EUnetHTA network to reach a consensus on what HTA should become in Europe. But it remains a network of experts and Member States are represented but it is not a forum where you can implement these things on a short-term basis*" (Personal Interview 17). The different scenarios presented in the consultation initiatives of the Commission also had prepared most actors in the field on the possibility to create new structures on which a sustainable cooperation could take place. What came as a surprise, however, were the mandatory aspects related to the proposal for a Regulation under EU-law. *"It was a surprise; we didn't see it before it came out. I think, to a certain extent, people didn't internalise what it means to put the cooperation on a legislative basis until they actually saw the proposal (…). "Then, when they saw what putting on a legislative basis meant, in terms of what the requirements of that were, I think they considered them to be more far reaching than they anticipated"* (Personal interview 19).

Overall, smaller EU Member States seemed to adopt a more positive approach to the proposal which is explained, according to some, by the fact that the gain in financial and project management may be more important in countries with less personnel and smaller structures dedicated to HTA. "*We recognise as a small country with limited HTA resources and finances, the added value of such a cooperation and we really support it. (…) Just voluntary work is*

not an option" (Personal interview 11). Agencies or countries supporting the Commission proposal would often bring forward the same arguments used by the Commission, such as, the need to avoid duplication and the gain of time and resources related to that. Also, the need for a better uptake would be underscored as well as an improved access for patients to innovative medicines. Other arguments brought to the fore were related to relative effectiveness assessments. Some underscoring the fact that the part of clinical effectiveness would be the 'easiest' to collaborate on, as the majority of Member States would often look at the same comparators (e.g. Personal interview 11, 12, 19). Other stressed that the results of relative effectiveness assessments could be used in the national processes for cost-effectiveness and other economic evaluations and would therefore bring added value (e.g. Personal interview 11).

Although fears for a reduced quality of assessments have been expressed (e.g. personal interview 22), some observers actually underscored how a framework, as the one proposed by the Commission, could actually enhance the quality of HTA. In particular the cooperation on the Joint Scientific Consultations could make a difference, as it would prepare the ground for the Joint Clinical Assessments. In this view, agencies could require (more) robust evidence from the industry which should be able to present solid data to support their efficacy and relative effectiveness. In case they would default on this, a negative opinion could be issued regarding their product. *"I think this should be the goal from the cooperation with EMA and HTA, but this is still not present in the narrative"* (Personal interview 13).

Moreover, to guarantee scientific robustness, some believed that, as the Coordination group of the proposed structure would be responsible for the scientific work, Member States would have to appoint scientists in this group. These would be responsible for giving a strategic direction and would be maybe less driven by policy objectives (personal interview 19). Moreover, since much of the proposal had been based on the work developed and implemented by EUnetHTA, some welcomed the fact that the instruments used, would be those with which they would already be familiar. Other positive remarks towards the Regulation proposal were related to the role of the stakeholders in the process. Even though much of the actual implication of stakeholders still had to be defined by means of delegated acts, some believed that it would actually give the Commission "power to work with different stakeholders to define which place they will get in the new structure" (Personal interview 12).

The absence of clarification upfront, regarding some issues which would have to be defined at a later stage in delegated or implementing acts, was a point of discussion. Some actors in the HTA arena would be reassured by these matters while, to others, these would trigger concern: "T*he Regulation [proposal] has preferred to install a lot of freedom of defining mechanisms, methods and frameworks. So, the Regulation [proposal], as such, leaves still*

many things open and some Member States fear this openness - or misinterpret this openness as a grab for power, which it is not. It is, I think, actually, the opposite intention. It is meant to empower Member States to define in a later stage the actual day to day business" (Personal interview 15). Others, however, would adopt the opposite standpoint and would fear that Member States would lose control over the issue (e.g. Personal Interview 17, 21). *"What do you include in the Regulation, which conditions? And which guarantee do you include in it, especially for the Member State 'drivenness' (…) and what do you leave to the Commission in the delegated and implementing acts? (…) When it is about competence distribution, then one has to ask oneself whether you should leave this to the implementing acts or whether you wouldn't have to attach this simply to the Regulation"* (Personal interview 17). Reference is being made to other legislative texts (e.g. Falsified Medicines Directive) in which delegated and implementing acts also had to be defined after the adoption of the text. *"We see now that the Commission is filling in all kind of details which go much further than what we thought the text was about. This gives eventually much more power to the Commission which in turn produces much more uncertainty towards the field"* (Personal Interview 17).

The presence of a certain number of elements to be defined in delegated or implementing acts also triggered concern regarding the quality of the assessments: *"as the rules haven't been defined, some fear that it will not offer an equivalent [quality] level of what could exist at the national level"*(Personal interview 21). According to others, however, this argument refers to a lack of trust that exists among Member States regarding the different methodologies and processes used in HTA: *"P eople think that whatever way they set up their system, they think themselves that it is the best one" (Personal interview 19).* The latter is considered by some as something which is not necessarily justified: *"So the perception of what constitutes a good assessment may differ a lot between two countries. But often it may be because of the people that are working there. So, the people, may have different perceptions or preferences. There is nothing objective about it. It is not really a scientific argument; it is more about people's preferences and national habits. (…) I think the key issue is going to be: is it okay, in general, to use European joint work? That is the big thing" (Personal interview 18).*

What the different agency representatives often did agree upon was the fact that, if the proposal would be adopted, it would change the work habits considerably: *"It is very different to work independently from working as part of a network as that is the way you do business. (…) It would require a lot of change at a country level"* (Personal interview 19). People underscore how work at a national/regional level follows specific timelines, reporting structures, reporting languages and prioritisation issues etc. *"All of that has to change to the common methodology. Now, I don't see that as an insurmountable obstacle, but it would change the way we do what we do"* (Personal interview 19). Others refer to the highly

regulated environment in which HTA takes place and which is difficult to change: "*People are used to act in some way according to the law (…). There are doubts if this obligatory use of common clinical assessments will fit this structure*" (Personal interview 30). "*The proposal forbids any amendment or additional clinical assessment and I am not sure that we can do that. (…) There are different national processes and national requirements from the health care system which require perhaps the inclusion of other studies and we cannot close assessments like this*" (Personal interview 22).

To some, shifting joint work on clinical assessments to a mandatory level, simply comes too soon. "*We are not ready yet. Why trying to go so fast? It is possible to share scientific work, but no mandatory joint assessments*" (Personal interview 22). Others believe that JCA would not necessarily reduce the work of some agencies who would anyhow need to go through a company's submission evidence procedurally: "*They can introduce EUnetHTA assessments or pan-European clinical assessments reports into that process, but most of them can use only small bits of it as part of their approval process of the company submission. So, it is not really saving any of them any resources. It is not really deduplicating any of their work*" (Personal interview 27).

Some fears have been expressed regarding the impact the mandatory process, proposed for clinical assessments, could have on the other domains of HTA (remaining on a voluntary basis in the Commission proposal). Some believed there could be a risk that collaboration on other HTA domains would be reduced. "*I know that within EUnetHTA there are quite many people that are interested in working in all of the domains but there is also this type of approach saying: let's just do the clinical stuff and then we are done with it*" (Personal interview 18). Others however have another opinion on the issue and believe that countries which already do a full assessment would continue to do so and only use the part of joint clinical assessments in their national processes, as it constitute often an input for the economic evaluation (e.g. Personal interview 19).

These dual views on the Regulation proposal can partly be explained by the fact that people, on the one hand, recognise that the cooperation does offer opportunities and a more solid legal framework. On the other hand, although it regards only a small part of the full HTA process (i.e. relative effectiveness), some fear that if decision-making on clinical effectiveness falls outside the national boundaries, it could have an impact on the remaining domains of the evaluation process and on the control of Member States herein, especially when it comes to timeliness and the quality of the advice (e.g. Personal interview 17). Timeliness is indeed one of the topics that often came to the fore in the different debates on the Regulation proposal. Although the Commission has sought to align this to the Market authorisation process of the EMA, for some this would still not be satisfying as it would delay national

processes, and thus delay patient access (e.g. Personal interview 27). Some would argue that for countries with a slow patient access process, the Regulation would actually speed up the availability of the medicines to patients. However, as underscored by others, timeliness is not only depending on the HTA part of the process but often also depends on the pricing and reimbursement processes: "*the delay is probably currently more in the appraisal and decision-making and not in the assessment*" (Personal interview 27).

Finally, doubts are being expressed upon the abilities of the Commission to coordinate the work through its secretariat. "*They will never have the means to manage this network (…). This is a very technical and managerial exercise which is not administrative. That requires specific skills that need to be developed*" (Personal interview 20). Others also refer how public health issues are often not the priority of the EU which may then affect the budget allocated to these issues (Personal interview 21). The reference to the possibility to create a Union Agency on HTA, as stated in the Commission proposal, is considered to some like an eye-opener regarding the real intentions of the Commission behind this initiative: "*So, that is the whole story. We are going towards an 'EMAbis', which will operate as the EMA driven by strong industry interests*" (Personal interview 20). The belief that industry interests would underpin the proposal has also been strengthened by the fact that EFPIA, a pharmaceutical umbrella organisation, supported the Commission proposal (Personal interview 24; EFPIA 2018). According to some observers, this has raised the question among HTA actors, whose interests the proposal would serve most: the industry or the Member States? (e.g. Personal interview 13).

The pharmaceutical industry indeed welcomed the proposal as it would allow to align evidence generation in Europe and create consistency, transparency and synergies in clinical assessments permitting to expedite patient access to medicines and create greater predictability on evidence generation requirement (EFPIA 2018). The medial device industry, however, would take a quite different stand on the proposal. Indeed, several questions have been raised as the regulatory situation of medical devices differs from the pharmaceutical one. First, the HTA process of medical devices follows different paths according to the EU Member States. Countries who do have an HTA process for medical devices will run an assessment only on a few products. The difference between the Member States can be explained by the fact that the aims of an HTA as well as the timing, the scope of products and evidence requirements of an assessment will differ.

Whilst HTA of pharmaceuticals will serve as an input in regulatory and pricing decision-making processes, this not necessarily the case for medical devices. In the UK, for example, HTA will serve to provide guidance, or to make a productivity analysis to decide about the scope of patient groups or cost-effectivity issues. France will adopt a different approach

which would be close to HTA of pharmaceuticals and inform, amongst others, reimbursement decision-making processes. Germany will start assessments only for specific products requesting reimbursements. As the aim of assessments will differ across counties, so will the timing of those assessments vary. In France, for example, it will take place at market access, in the UK this may happen at a later stage after market access. Medical device representatives, therefore, fear that, due to these different approaches, it will become very difficult to have a standardised approach towards HTA in medical devices (Personal interview 23). Moreover, some underscore that the development of a device and its use, once it has been marketed, will differ from pharmaceuticals. New technological developments can influence the latter and as such evaluation of devices is a continuous process requiring to frequently update the information about them. Hence, they wonder what the added value of the Regulation proposal would be for the assessments of medical devices especially considering the number of countries which do not have a specific HTA process for devices in place (Personal interview 23).

Hence, the mandatory approach is here too a matter of concern. As underscored by some, "*the proposal does not allow to refuse one of the pillars. Either one has to participate in everything or nothing*" (Personal interview 24). The fact that this scenario has not been presented in the consultation process has astonished many players in the HTA field (e.g. Personal interview 24, 27, 30). "*Maybe a Directive would have been enough. Maybe it is too early for a Regulation. I think that some recommendations, like in a Directive, may be even more effective than a strict Regulation. But on the other hand, only voluntary involvement will maybe not destroy EUnetHTA, but [it could lead to] only active organisations which will remain present and some less active which will go out saying that they have no benefit of this structure*" (30). The inter-institutional debate will seek to advance on the various issues outlined above as many of these reactions may come up either in Council or in the Parliamentary discussions on the topic. The debate the Commission proposal has triggered, leads again to the question whether HTA cooperation should remain voluntary or should be structured into a more stringent framework. Implicitly it calls for answering the question whether HTA cooperation in Europe can be sustainable in a voluntary framework following soft governance principles.

6.4.3.4. Intergovernmental cooperation initiatives on HTA

While the European Commission and EUnetHTA continued to seek for a model guaranteeing sustainable HTA cooperation in Europe, several intergovernmental initiatives had been established focusing on HTA-related issues in a regional context. These initiatives all had their own legal framework and procedural arrangements but shared the fact that they often resulted from a governmental initiative, gathered participating countries with similar public health systems and focused primarily on the issue of affordable access to medicines. Hence, instead

of pursuing a mandatory 'one-size fits all'- approach, as put forward in the Commission proposal, these initiatives offered a cooperation structure where Member States remained free to opt-in or withdraw. All these cooperation initiatives are still in their early stages of development, therefore no solid analysis about their efficacy and effectiveness could yet be made. However, the rise of these initiatives which came almost simultaneously with the Commission implementation of the EU HTA Network and the subsequent work towards the Regulation proposal, requires attention when examining the governance of HTA cooperation in Europe.

One of the main reasons triggering the establishment of these initiatives could be found in the rising medicines prices creating a new challenge to health systems of even high-income countries. This rationale already laid at the basis of the HTA cooperation initiatives examined above (see also chapter 1 and chapter 4). However, since the mid-2010s, the price increase of innovative medicines was explained by higher development costs, novel action mechanisms and a drug development focus targeted on smaller-sized patient populations (e.g. orphan drugs, oncology) (Paris and Colbert 2017). Hence, to gain bargaining power in the price negotiations with pharmaceutical companies, some countries sought to join forces. This cooperation was not only directed towards clinical effectiveness assessments to reduce process costs, it also targeted cost-effectiveness evaluations and joint price negotiations, to reduce reimbursement costs.

The various initiatives such as the Beneluxa-initiative[189] established in 2015, The Valetta Declaration[190] signed in 2017, the Visegrad+2 group[191] created in 2017 and FINOSE[192] set up in 2018, all aimed at achieving affordable treatments and ensure fair patient-access to high quality treatments[193] (Eatwell and Swierczyna 2019). Most of these initiatives included in their cooperation efforts similar activities as those implemented by EUnetHTA, using even EUnetHTA tools and guidelines, such as, Horizon Scanning, information sharing and best practices, clinical assessments (e.g. personal interview 17; www.beneluxa.org; Grubert 2018). However, a point of distinction would be the joint price negotiations constituting a key-objective in these initiatives and which would be absent in EUnetHTA or the EU HTA Network. Indeed, to EUnetHTA, pricing and reimbursement decision-making had always been considered as a Member-State competence which should be respected. "*For us as*

---

189 Beneluxa is an initiative created in 2015, which "aims for sustainable access to, and appropriate use of, medicines in the participating countries". It seeks to "increase patients' access to high quality and affordable treatments". The cooperation activities take place in areas, such as, Horizon Scanning, mutual recognition of HTA, information sharing and policy exchange and pricing and reimbursement. In 2019, the following countries had joined the network: Belgium, the Netherlands, Luxembourg, Austria and Ireland (www. beneluxa.org).

190 The Valetta Declaration signed in May 2017 by Cyprus, Greece, Italy, Malta, Portugal and Spain established a collaboration in the field of the assessment and procurement of new medicines. The area of activities are joint clinical assessments, economic evaluations and joint price negotiations; sharing information to input price negotiations and contracting; sharing information and best practices around biosimilar pricing and reimbursement; sharing pharmaco-therapeutic / effectiveness assessments of drugs; Horizon Scanning. The focus is on drugs with a potential high impact on national budgets such as oncology drugs, orphan drugs, biosimilars. Other countries which have joined the group since are Croatia, Ireland, Romania and Slovenia. France has been granted an observer status (Grubert 2018; www.infarmed.pt; www.remapconsulting.com).

191 The Visegrad+2 group comprised the Czech Republic, Hungary, Poland, Slovakia, Croatia and Lithuania who agreed in March 2017 to cooperate to ensure fair and affordable access to medicines for their citizens (Grubert 2018).

192 The Finose collaboration refers to a memorandum of understanding signed in June 2018 between national HTA agencies in Finland (Fimea), Norway (NoMA) and Sweden (TLV) aiming to produce joint assessment reports containing both clinical and economic assessments. Although Denmark had participated in a 2017 memorandum of understanding of high-priced hospital medicines, it did not take part in the Finose collaboration as its reimbursement decision-making system differed too much from the other three countries (www.fimea.fi; Grubert 2018; www.remapconsulting.com).

193 Similar initiatives have been established such as the Baltic Partnership Agreement (2012) including Latvia, Lithuania, Estonia, Romanian; the Bulgarian Initiative (2015) with Romania, Bulgaria; Sofia Declaration (2016) Bulgaria, Croatia, Estonia, Hungary, Latvia, FYR Macedonia, Romania, Serbia, Slovakia, Slovenia; the Spanish and Portuguese initiative (2017); the Nordic Council (2017) with Denmark, Finland, Norway, Sweden and the Nordic Pharmaceuticals Forum/ NLF (2015) including Denmark, Iceland, Norway, Sweden. (Ataíde and Granzow 2018).

EUnetHTA, there is a clear line and we didn't cross that line. We stay in the framework of clinical assessments. Anything in the other domains will always remain national Member States' mandate" (personal interview 15).

Hence, different clusters of countries cooperating in HTA, including economic evaluations and price negotiations, developed in Europe since 2015. The rise of these regional clusters raises the question about the effectiveness of EUnetHTA; "*One could say that [these regional initiatives] are HTA+ cooperation structures and that is a pity as we did have EUnetHTA for that. (…) So, it is a bit regretful, but maybe it says something about the success of EUnetH-TA*" (personal interview 13). Indeed, as underscored by Beneluxa initiative representatives, developments in EUnetHTA were sometimes considered to be too slow. Horizon Scanning is cited as an example: "*As Member States, we need to be well prepared to make decisions. In fact, for years we are lagging behind the facts. (…) we need this now and EUnetHTA is not delivering a lot* (personal interview 17). Moreover, the regional initiatives offer the advantage of being in full control of the process: "*It has to do with the fact that you have a hold on your own information needs and what you do to fulfil these. In EUnetHTA, it remains to be seen whether you receive the information you would need*" (personal interview 17).

Referring to the Commission proposal which also included a pillar on Horizon Scanning, the Beneluxa-initiative representatives indicated not to be in a position where they could wait for years before something would be set up. "*It is not our intention to have our own little thing, because we too, would prefer doing a pan-European horizon scan which would be used by everybody. But we do start to work on it now, because we need it*" (personal interview 17). Moreover, finding the resources at a national level for an identified (domestic) need is sometimes easier than obtaining and sharing a pan-European budget. Hence, the underlying dynamics of the regional initiatives, based on strategies elaborated to respond to concrete policy needs, allows for faster/more efficient decision-making processes. Communication flows are shorter as direct communication between health ministries easily takes place. For governmental representatives, the dynamics and pace necessary to come to a decision in EU policy processes does often not correspond to the national political need. "*We need specific instruments for that and we need thus completely different dynamics and pace (….) A cooperation such as Beneluxa is essentially a political intervention, a more strategic intervention. So, it is driven by different impulses and different interests*" (personal interview 17).

As we have outlined above, appraisal processes are often considered to be context specific which makes some countries or HTA bodies reluctant to cooperate in a joint European assessment/appraisal model. Examining the number of HTA bodies or governmental institutions having signed one or more regional cooperation agreements in the field of economic evaluations and joint price negotiations shows nevertheless that a strengthening of the

cooperation efforts is not to be ruled out in these areas. Indeed, as underscored by an HTA agency representative: "*If the drug company is using the same model across X number of countries and extrapolating them with data, why would you not look at doing collaborative appraisal of that model? (…) If you have countries where it makes sense to do joint work in the economic domain leading to the opportunity to do joint work at pricing and reimbursement level, it would make sense for countries to work at the economic level because they have similar health systems and an economic model wouldn't be any different between the countries*" (personal interview 19).

Others underscore the importance of bargaining power in the negotiations with pharmaceutical companies and to a lesser extent with medical device companies. Especially smaller-sized countries would potentially benefit from such a cooperation (personal interview 22). However, fears have also been expressed that this situation could also lead to health systems developing at different speeds and increasing inequality in health care in Europe (personal interview 25). Finding convergence between Member States with similar health care systems is easier and therefore maybe also more attractive to some than an overall pan-European approach. Moreover, some believe that these regional cooperation structures could also serve as a hub for others, either by joining existing initiatives, if their interests would be served by that. Or, simply by making new arrangements between a group of agencies having the same needs at a given time (personal interview 27).

We have seen how representatives of the pharmaceutical industry welcomed the European Commission proposal for a Regulation where joint clinical assessments would become mandatory. This industry is however much more reluctant to the regional initiatives seeking to work on common cost-assessment evaluations and price negotiations. The context specificity of those assessments is often be brought to the fore as an argument not to pursue these type of cooperation initiatives (e.g. personal interview 24). However, as in EUnetHTA assessments, here too, industry representatives fear that even if companies would participate in joint economic assessments, appraisals and price negotiations, some countries would still after the common process decide to re-evaluate the technology at the national level. "*There is nothing we can do about it because, in any case, they do not ask for our opinion. They will collaborate all the way to price negotiations and eventually reimbursement. (…) If they need to cooperate, well they should do it effectively*" (personal interview 24).

Hence, after having already been examined in the EUR-ASSESS project in the mid-1990s, the topic of cooperation in areas as economic evaluations and coverage is back on the agenda. Too sensitive to be dealt with in an EU legislative framework, it seems that Member States actually do identify benefits to strengthen cooperation efforts in this area as long as they remain in full control over the process and can chose to opt-in or out an assessment procedure.

The overlapping memberships of countries and HTA bodies in several European networks or regional clusters raises the question whether sooner or later *a rapprochement* between some of those initiatives will not become inevitable as conflict of interest and/or engagements may arise in the future.

6.4.4. Conclusion policy-implementation in European HTA cooperation

In this section we have outlined the many procedural and substantive instruments developed throughout the EUnetHTA project and Joint Actions as well as instruments developed on an EU-institutional level. These instruments have been developed to reach the objectives set out by these networks and discussed in the section on policy-formulation. The overall objective remained the same throughout the various initiatives: developing a sustainable network for HTA cooperation in Europe. The procedural instruments which have been implemented by EUnetHTA since 2006, have targeted organisational, communication, capacity-building and evaluation matters. The substantive instruments regarded the development of HTA-related activities such as Horizon Scanning, Early Dialogues, joint work, post-launch evidence generation and uptake. On an EU level, implementation activities were closely associated with the legislative proposals impacting HTA cooperation. As such, at first implementation activities regarded the work plan of the EU HTA Network. Part of these activities regarded the reflections and preparation for a new Commission proposal on HTA cooperation in Europe.

In our examination of the first procedural instrument (i.e. Organisation) we have seen how EUnetHTA has sought to develop different (business) models to ensure sustainability for the cooperation efforts and how in 2014 a new entity has been set up at EU level by means of the EU HTA Network. The developments taking place on the EU level will become intrinsically linked to the organisational developments of EUnetHTA which will become the scientific and technical arm of the newly created policy-oriented EU HTA Network. This set-up and division of responsibilities would, in the perception of the Commission, be of temporary nature, as the Commission proposal on HTA cooperation in Europe would foresee the establishment of a new coordinating body at EU level with Member States' appointed representatives and assisted by a Commission-led secretariat.

Hence, although the reflections developed by EUnetHTA regarding the organisational structure of a sustainable HTA network in Europe have not, as such, been implemented, we have seen how some aspects of this reflection process have been retained in the Commission proposal on HTA cooperation. We can cite as an example the activity centres of the business model developed in JA1 which share similarities with the pillar structure of the future cooperation system as proposed by the Commission in its Regulation. The Joint Action 2 and 3 will limit their contribution on organisational aspects of a sustainable HTA cooperation model to the formulation of recommendations. Indeed, due to the changing nature of the

network, their work became primarily focused on developing the scientific and technical coordination of HTA activities and products which will become the core-substance of the Commission Regulation (i.e. JSA, JSC, identification of emerging health technologies and voluntary cooperation). Hence, the development of a sustainable structure for HTA cooperation in Europe has since the JA2 be shifted to the EU HTA Network and has eventually led to the Commission proposal for a Regulation on HTA cooperation in Europe.

The second procedural instrument of EUnetHTA regarded internal and external communication means. The internal communication activities within EUnetHTA aimed at ensuring smooth effective information flows and contribute to establish internal network cohesion. As such, various instruments have been implemented such as the POP – and EVIDENT data bases, intra- and internet sites and information management infrastructures facilitating information exchange between work packages, the secretariat and the governance structures of the network. These instruments also contributed to ensuring cohesion in reporting formats of the outputs produced by EUnetHTA. The external communication efforts took place through dissemination activities such as the publication of promotional material, scientific publications, participation at and organisation of conferences and (stakeholder) forums.

As in the early cooperation projects (e.g. EUR-ASSESS), which had already emphasized the importance of dissemination activities to support HTA development in general, EUnetHTA also sought to enhance awareness of HTA and attract the attention of policymakers and other stakeholders on the cooperation efforts. The dissemination activities have moreover also played an important role in shaping discourse and peer-education on certain issues such as Relative Effectiveness Assessments or Early Dialogues. Through the informal contacts and exchanges which took place during conferences and workshops, personal relationships have been established facilitating the establishment of trust between members and hence allowing members to become more efficient in their collaboration on joint work. It is hard to measure the part of awareness created by EUnetHTA regarding HTA cooperation in Europe. However, the communication instruments created, and the formal and informal communication means developed, certainly have contributed in the production of EUnetHTA outputs and on which an important part of the Commission proposal has been based (e.g. HTA methodologies, Early Dialogues, joint REAs).

The third procedural instrument we have identified regarded capacity-building. In EUnetHTA, this has been implemented in a two-fold strategy: internal training of members on tools and methodologies developed by the network and external training of stakeholders and agencies having less experience in HTA. Peer-education and exchange of best practices have played an important role herein with the more-experienced members sharing their knowledge with less-experienced members. Several instruments have been developed to support capacity-

building activities such as the organisation of training seminars and workshops, e-learning and the publication of a handbook. These outputs resulted from needs expressed by the members through internal formal and informal evaluation processes. As in dissemination, capacity-building has, from the start, be considered of importance not just for internal net-work purposes but also to increase the impact of HTA in national decision-making settings. Indeed, as in the early cooperation initiatives, after 2006 capacity-building was associated to the belief that if the quality of the outputs would increase, so would be the uptake of them.

The fourth procedural instrument regarding evaluation is, to some extent, closely related to capacity-building. Evaluation in EUnetHTA was driven by two processes: internal and external demands. Internally, the evaluation could take place in a formal and informal way. The formal evaluation process would focus on the implementation of the project objectives as required by the grant agreements and examining the state of play of tools, methodologies and pilot projects being implemented. Informal evaluation took often place during the implementa-tion of the activities of the work packages and often fed into learning processes. As we have seen above, some qualified EUnetHTA as a 'learning organisation' which operated via single or double-loop learning processes. Adaptation and adjustment based on evaluation processes form an integral part of these processes. At the time of the Joint Actions, external evaluation processes have been also organised, often upon request of the European Com-mission (e.g. public consultations). EUnetHTA's input in those has been of high importance, in particular regarding the development of the Commission proposal for a Regulation on HTA cooperation.

The second part of this section examined what could be considered as the core-activities of EUnetHTA: the substantive policy instruments which have been classified above according to the life-cycle approach of a technology (i.e. Horizon Scanning; Early Dialogues; Joint work; Additional evidence Generation and Uptake). Although present since the early days of HTA collaboration, Horizon Scanning has never been a real priority for EUnetHTA. The EUnetHTA project would address this issue only by seeking to establish a systematic overview of existing Horizon Scanning Systems and their working processes. Joint Action 1 did not give real attention to this topic as the Work Package to which Horizon Scanning activities had been attributed, primarily dealt with the establishment of the EVIDENT and POP data bases. The importance of Horizon Scanning will be underscored in Joint Action 2 but, here too, atten-tion of the Work Package involved was focused on other activities (e.g. Early Dialogues). The Joint Action 3 will treat Horizon Scanning separately from other evidence collection activities and would integrate the topic in the Work Package on Joint Production, herein developing a new model respecting a life-cycle approach of health technologies.

Several factors seem to have contributed to this increased attention of Horizon Scanning by EUnetHTA. In the first stage of HTA cooperation development, Horizon Scanning was not a priority topic. The increased attention for the topic since the Joint Action 3 can be explained by the fact that, with the progress made on methodologies and tools for joint work, resources (e.g. time and manpower) became available to address other parts of the life cycle of a health technology. Moreover, attention on behalf of the Commission given to Horizon Scanning may also have played a role. Indeed, the third pillar of the Commission proposal for HTA cooperation regarding the 'early identification of health technologies', refers to Horizon Scanning.

The latter followed a more general trend which one could observe in regulatory processes as several regional intergovernmental cooperation initiatives (e.g. Beneluxa, The Valette declaration) started to integrate this exercise into their collaborative frameworks. Whereas, in EUnetHTA, Horizon Scanning was important to anticipate on assessments that could be done jointly, this exercise in the intergovernmental cooperation initiatives, sought to gain a better insight on new drugs and devices entering the market and which could potentially impact the health budgets. In a sense, Horizon Scanning remains a young field of activity within HTA cooperation structures. The approach chosen in each of these structures will therefore also vary, since the aims pursued will differ. Future developments may require establishing synergies between these approaches – should this respond to needs of regulators and the HTA arena.

Although similar initiatives existed before the launch of the SEED project by EUnetHTA members, the Early Dialogues, established by EUnetHTA, have permitted to develop syner-gies between the Regulatory authorities and the HTA arena. The aim was to align data requirements in a single development plan which would responds to both the needs of the regulators and of the HTA bodies. Success factors were multiple and rested upon the fact that the dialogues brought mutual benefits to the participating actors. Indeed, cooperation from industry was assured as the project would offer predictability in their development plan. Coordinated and simultaneous advice given to the developers by the regulators and HTA bodies before market authorisation would facilitate data alignment and implementa-tion of (expensive) clinical studies which would better match assessments requirements. This coordinated approach would also facilitate the assessment processes from both regulatory and HTA bodies and created favourable conditions to speed up the process of market- and thus patient access.

Voluntary participation and the non-binding advice certainly helped to overcome potential barriers any of the participating actors could have in the Early Dialogues. Moreover, the governance structure put in place to coordinate the activities and the cooperation between

EUnetHTA and EMA, has allowed for a smooth implementation of the Early Dialogues which would often outnumber the initial projects planned. From an ad hoc cooperation project between EUnetHTA members, the Early Dialogues have developed as one of the most successful initiatives of the network creating synergies with European regulatory authorities. Representing the second pillar in the Commission proposal for an HTA Regulation on HTA cooperation in Europe, it did not trigger any controversial debate. On the contrary, the positive experience of the pilot projects and the governance structures put in place smoothly running the projects led to a general consensus on this topic.

Joint work has been defined as comprising common methodologies, tools, joint assessments, literature reviews, and scientific advice. To enable the implementation of joint health technology assessments the EUnetHTA network has started to work on the methodologies and tools that lay at the basis of these assessments. Besides instruments such as the EVIDENT and the POP-database discussed above, HTA Core Model has been developed and would represent one of the key instruments to achieve joint assessments. The model would comprise nine domains which could be assessed jointly. Handbooks, online tools and services have been developed and updated to facilitate the use of the HTA Core Model which has first been tested and regularly adjusted by means of pilot projects.

The introduction of Relative Effectiveness Assessments in EUnetHTA following the recommendations of the Pharmaceutical Forum in 2010, has given a new dynamic to EUnetHTA's work which would however impact the implementation of the HTA Core Model. Indeed, collaboration on the first four domains of the Core Model as is the case in the REAs, seemed to be more attractive to HTA bodies, as there was less need to contextualise. Collaboration on issues such as cost-effectiveness, social, ethical and legal issues appeared to be more difficult to achieve. Conversely to the Early Dialogue projects, EUnetHTA faced difficulties to find participants to collaborate on Core HTA or REAs pilot projects. On behalf of HTA bodies, several reasons have been brought to the fore making participation difficult for some of them. Often domestic legal constraints have been a barrier, as these would require adaptation of national processes to the EUnetHTA assessment models and processes. Even when legal or administration barriers would be overcome and participation in the joint assessments was being decided by the top management of an agency, difficulties to adjust to the models have been noticed. However, feasibility of implementing the model would be confirmed by participants in joint REAs or full HTAs, even though this would not always result in the expected workload reduction, as only small parts of the joint assessments could be used in the local setting and further adaptation would be required in many cases.

The lack of participation in joint assessments and the lack of uptake of the results of joint work have been a profound matter of concern since the Joint Action 2. Despite the different

tools to facilitate uptake and the studies implemented to understand the reasons for the lack of it, no significant advance has been made in this regard. As the cooperation in EUnetHTA was entirely based on voluntary participation, the network could not impose the use of its outputs to the network members. Moreover, the lack of uptake would impact the willingness of industry partners to participate in this process as, rather than deduplicating efforts, it would actually add up their workload. Reasons identified for the low uptake of EUnetHTA are multiple and point to issues such as legal constraints, timing of the availability of the reports, reporting formats and language requirements, willingness to adapt. No consensus exists whether these barriers would be surmountable.

The very nature of the EUnetHTA network and of the EU HTA Network rooted in voluntary self-governance did not allow them to impose practices on their members. The soft governance means used, such as, discourse, persuasion, exchange of best practices and peer-education, have not permitted the EUnetHTA network to obtain from its members commitment to use on a broad scale the output of its products in their local and national assessments. The European Commission has considered the latter as reason to invoke the subsidiarity principle as, after two decades of cooperation on Member State level, the main objectives of creating a sustainable network and ensure use of its outputs had not been reached.

Its proposal to move the cooperation efforts in some fields (e.g. Clinical effectiveness) on a mandatory level, had not been welcomed by all actors in the field. The discussions on the Commission's initiative revealed how the fear for loss of control of regulatory process still dominated Member States' positions. It is interesting to notice how regional intergovern-mental initiatives dealing, amongst others, on HTA and pricing issues have flourished in years leading up to the Commission proposal. To Member States and HTA bodies participating in these cooperation agreements, the latter were often considered as more reassuring as they operated on a voluntary basis. The flexible nature of the agreements would allow them to concentrate their efforts only on products and assessments considered of importance for them for national health system or health budget purposes. The similarity of their health systems, health markets and/or social insurance schemes would facilitate cooperation in mat-ters and avoid some the barriers encountered in EUnetHTA (e.g. legal constrains, timeliness, participation national regulatory authorities etc.). Moreover, would Member States not be satisfied with the cooperation initiative, they could simply step out.

Whilst the Commission has sought for a compulsory one size fits all model, the regional intergovernmental initiatives proposed an opposite more voluntary 'tailored-made' approach to Member States. The choice of the Commission is in line with the traditional Community approach seeking to have a level playing field. Although initiatives in the EU exists where Member States can opt-in or not (under certain conditions) a cooperation framework (e.g.

The EURO zone, the Schengen agreements), the question remains whether this could lead to unequal development schemes across the EU Member States in the case of health policy. A voluntary opt-in system, as had been at times suggested, could entail the risk exists that health policy and access to health would develop at different speeds and would lead to an increase in health inequalities in Europe. To avoid this, the Commission has thus chosen for Regulation applicable to all keeping mandatory cooperation restricted to clinical assessment and leaving the possibility for further cooperation open on a voluntary basis. However, to do so, it had to disrupt health technology assessment from one of its natural bases (i.e. health policy) to enshrine it firmly in the remaining one: industrial policy. As such, the structure proposed in the Commission initiative may lack solidity at its very basis, refraining stakeholders from putting their trust and support in it.

Hence, the least one could say about the Commission proposal for a Regulation on HTA cooperation in Europe, is that it has opened a debate permitting to clarify actors' positions. Indeed, before this proposal, opinions converged about the usefulness of streamlining HTA processes and practices. However, by putting the cooperation in a mandatory legislative framework, the aims pursued by the Commission in supporting such a cooperation became more explicit. Keeping efforts at the level of exchange of best practices and providing methodological guidance seemed to be below the Commission's expectations. However, as the debates on the proposal are still ongoing and a final decision still has to be made by the Council and (eventually) by the European Parliament, the question remains to see whether the preparatory work of the various projects and Joint Actions will have been sufficient to lift up the cooperation structure to another level. We have seen in this section how the Parliament became more involved in this issue and supported the initiative by framing it into a public health policy issue. The outcome of the debates in the Council will show how Member States will approach this proposal. Although involved in HTA cooperation through the Joint Actions and different high-level policy networks since more than 2 decades, it seems that, at ministerial level, people were not entirely prepared for this proposal (e.g. Personal interviews 17, 22, 27, 29, 30). Many of the reactions we have outlined above from different actors in the HTA field, could very well be echoed in the Council debates. It remains to be seen whether a compromise position will be found and on which basis HTA cooperation will be framed in the future EU setting. The future will show whether the amendments of the Parliament and the Council will be able to convince all parties involved of the benefits such a legal framework would offer to the health systems and end-users of health technologies: the patients.

In the following section, we will examine the how HTA cooperation has been developed by looking at it through the lens of the last part of the policy cycle on Evaluation. We will again follow the same structure as in the other sections of this chapter by analysing first how

evaluation has played a role in the EUnetHTA project and Joint Actions before we turn to the cooperation efforts on the EU level.

6..5. EVALUATION IN EUROPEAN HTA COOPERATION

6.5.1. Evaluation in the EUnetHTA network

Setting up a formal evaluation process in projects and Joint Actions has been a prerequisite specified in the grant agreements of the EU Commission. In the EUnetHTA project and the Joint Actions, the evaluation was done by members of the project organised in a dedicated Work Package (WP) on evaluation. The main task of this WP was to evaluate whether and to which extent the strategic objectives of the projects and the sub-objectives of the working groups had been reached. This structure comprising similar objectives will be repeated throughout the EUnetHTA Joint Actions as it has been part of the grant agreements framing the cooperation and its financial support. As such, in each EUnetHTA Joint Action, one Work Package will be exclusively dedicated to evaluation processes (www.eunethta.eu).

Whilst in the EUnetHTA Project an external independent evaluation process had been scheduled (but not implemented), in the Joint Actions, only internal evaluation processes (performed by staff directly involved in the project work) where required by the EU Commission (EUnetHTA 2013b: 17; Lund et al. 2008). The evaluation tools were a combination of electronic surveys, semi-structured interviews and documentary analysis to assess the working of the project and identify any difficulties. The surveys targeted besides the Partners also the Steering group, participants of the Stakeholder Forum and the Secretariat. Regular feedback was given to the Commission and the project participants. In each project, specific questions had been formulated to steer the evaluation process.

As such, in the EUnetHTA Project, a certain number of factors had been identified to evaluate the success of the project in establishing the framework for developing an effective and sustainable network. These factors were: Production of deliverables in a timely manner; Effective working collaboration between Work Packages; High degree of member participation in the Work Packages; Effective communication; Sustained commitment to Project; User and stakeholder satisfaction with new routines and practice; Perceived added-value (Lund et al. 2008). Whilst the deliverables have been produced within the required deadlines, the evaluation revealed some key challenges to be addressed in the future. It is interesting to notice here, how these challenges identified in the early days of the EUnetHTA network, have remained presented throughout the cooperation efforts and became one of the underlying reasons of the Commission to present its proposal for a Regulation on HTA.

As such the EUnetHTA project underscored how the tools that had been developed, still had to be tested in a real-life situation. Due to the large number of participants and the heavy workload, cooperation across Work Packages varied. Developing a more effective collaboration across WPs was however important due to the interconnectivity of the tools to be developed. Within the Work Packages, participants did not show an equal degree of participation. Face to face meetings were considered as an effective mean to remediate to that but difficult to organise especially in groups with a large number of participants. Sustained participation was shown only by a small group of core-participants (Lund et al. 2008:4-6). The project also revealed some difficulties such as the effort needed to explain the HTA Core Model to all actors. Moreover, the question remained regarding the use of this model as it was already clear that politics or "old habits" could hamper the development of this model across the organisations. Moreover, the starting levels of HTA knowledge among the participants different also generating different expectations, needs and goals. Differences also existed at the level of financial capabilities, interests, organisational structures and competencies (Lund et al. 2008: 24).

The evaluation however did highlight the members' commitment to the project who indeed declared perceiving benefits in the collaboration in particularly through the exchange of knowledge, experiences and the development of tools (Lund et al. 2008; EUnetHTA 2009:21). Participants confirmed their belief that EUnetHTA could reduce duplication of reports provided that the tools would be further developed. The adaption tools were considered as potentially facilitating multinational use of HTA-reports. The produced handbook would help new HTA organisation to develop their activities. The policy study permitted a better understanding of the current situation. A structured monitoring/information system that was put in place would allow to get a better insight in new and emerging technologies. The establish communication platform and clearinghouse function would permit to strengthen the national and international position of organisation. English should remain the working language. Overall, "no one has expressed any doubt about EUnetHTA's usefulness or expected discontinuation" (Lund et al. 2008: 5).

Hence, at the end of the EUnetHTA project, participants would see an added value in EUnetHTA. However, as most of the work was still in an initial stage of development, this belief still had to be confirmed via tangible outputs. Concerns for the repartition of competences between work of a European structure and local authorities were at time already brought to the fore as members underscored how "EUnetHTA should remain a network and should not become a centralised organisation as inevitably, this would result in undermining local/national autonomy" (Lund et al. 2008: 30).

The evaluation of the Joint Action 1 addressed in particular the question whether the project had achieved its overarching objective of putting "into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level". It examined in particular whether EUnetHTA had been able to develop "a general strategy and a business model for sustainable European collaboration on HTA". Moreover, as the importance to further development of HTA tools and methods had been outlined by the previous project, focus on the latter was one of the evaluation priorities. As such, part of the evaluation process would examine the application of those in the field (EUnetHTA 2013b:10).

The evaluation done in this JA was mainly conducted through self-completion questionnaires and documentary analysis. The conclusion of the process was that the project had produced the majority of the deliverables planned. However, as regarding the overarching strategic objective "Using the definitions provided by project participants and stakeholders it appeared the JA had not been successful in meeting this objective" (EUnetHTA 2013b: 172). A second Joint Action was therefore planned "before evolving into the permanent network in 2015" (EUnetHTA 2013b: 172). The business model developed has been valued by most of the participants and it was expected that it would be further developed in the following JA2. Similarly, the evaluation shows the necessity to further develop the different EUnetHTA tools and methods. Whilst only fifty percent of the participants considered that "the JA had achieved what they wanted", many did indicate that they did benefit from added value such as networking, informational sharing and improved awareness of HTA developments (EUnetHTA 2013b: 173). Some also reported to have recourse to the new tools developed and the expected that their use of the HTA Core Model, the POP database and the EVIDENT database would increase in the future. Further training on these tools was however considered a necessity (preferable in face-to-face meetings) (EUnetHTA 2013b).

The evaluation objectives of the Joint Action 2 remained focused on testing the capability of EUnetHTA to produce structured core HTA information and apply it in a national context. As such, the various models and tools developed have (again) been examined. The Joint Action 2 concludes that (still) further improvement of the tools and methodologies should be pursued. Moreover, the development of methodological guidelines should be "strategically re-organised with a focus on implementing partnerships with recognised scientific societies and scientific projects relevant to HTA" (EUnetHTA 2016: 4). Most barriers already identified in the earlier projects regarding difficulties related to uptake have been brought to the fore (EUnetHTA 2016: 3). However, with the establishment of the EU HTA Network, means to overcome those would be examined in cooperation with the EU-level policy network.

Indeed, since the creation of the EU HTA Network, EUnetHTA which will see part of its objectives (e.g. reflect upon a sustainable structure on HTA cooperation) being shared with

the newly established entity. Evaluation will therefore essentially be focused on the objectives set at the start of the project. As such, evaluation processes have highlighted how the Joint Action had been able to deliver expected results in terms of pilot projects and methodological guidelines and tools and urges to move into the direction of the routinisation of common assessments[194]. The various studies implemented at EU level will take over part of the evaluation process regarding the implementation of EUnetHTA's tools, methodologies and assessment models as we will examine in the section below. In particular, the question regarding the establishment of a sustainable structure will be examined in a broader EU-led framework, including in this exercise external organisations as well as other European institutions (e.g. European Parliament). Here too, we will see how some of the issues already identified in the EUnetHTA project and Joint Action 1 and 2 will again be underscored by studies commissioned at the EU level.

6.5.2. Evaluation in EU setting

The evaluation processes of any policy or is often closely related to other parts of the policy cycle and in particular to the policy formulation process as the former can serve as input for the latter. In the case of HTA, the process set in motion by the Commission to propose a new legislative instrument for HTA cooperation in Europe, has proceeded by several studies commissioned by the Commission. Besides serving the policy-formulation process as we have seen in section 6.2., these studies have also allowed to evaluate the cooperation process as such. Many of the evaluation instruments used by the Commission have therefore already been discussed in other parts of this chapter. In this section we will therefore only focus on how some conclusions of these evaluation processes have been used to support the Commission policy orientation regarding HTA cooperation in Europe.

---

194 The final technical report will highlight the following outputs of the JA2: "Twelve REAs (6 on pharmaceutical and 6 on other technologies); Three Core HTAs; Eleven Early Dialogues (9 on pharmaceuticals and 2 on medical technologies); Five methodological guidelines; Evidence submission templates for pharmaceuticals and medical devices; An updated and upgraded application package of the HTA Core Model; More than 40 instances of the national uptake of the results of the joint work performed in EUnetHTA JA2; A suit of process and procedural guidance to support various types of joint activities within the framework of European cooperation on HTA; Recommendations on the implementation of a sustainable cooperation on HTA"(EUnetHTA 2016: 2-3). In the Joint Action JA3 80 joint reports and 35 Early Dialogues would be foreseen besides developing further guidelines, models and methodologies (www.eunethta.eu).

Till 2013, the evaluation processes of HTA cooperation in Europe would be strictly related to EUnetHTA activities and other related HTA projects financed by the Commission[195]. As outlined in section 6.5.1., various evaluation studies had been carried out to monitor the progress made by EUnetHTA. These studies would highlight the challenges HTA cooperation would be facing as well as the progress made. Many barriers to achieve sustainability of HTA collaboration and the uptake of collaboration outputs had already been identified in the early days of EUnetHTA, and confirmed throughout the Joint Actions, as discussed in the previous section. However, specific evaluation processes would take place on an EU-level regarding the implementation of the Health programme financing EUnetHTA projects and Joint Actions. The report on the 2008-2013 Health programme has amongst others investigated on the interest and influence of various stakeholder groups regarding projects financed by this programme.

Based on findings drawn upon case studies of various projects amongst which EUnetHTA, the reports highlight the importance of governmental policymakers. It points to their high level of influence and generally low level of interest in health programme outcomes. Underscoring how HTA would be one of the few topics of high interest to policy-makers, the report draw attention upon the fact that "a failure to effectively engage policy-makers when this would have been desirable is a common thread across many projects and Joint Actions. It is therefore a key priority to find ways in which their (often limited) interests can be taken advantage of in order to raise their awareness and ideally secure their backing for the implementation / use of the various novel approaches, interventions, data sets etc. produced by the HP" (European Commission 2015: 46). This advice has been followed to a certain extent with the creation of the EU HTA Network which sought to gather high-level policymakers to reflect upon the strategic orientation of HTA cooperation in Europe. We have seen, however, in the previous sections of this chapter how membership of this network would often overlap with EUnetHTA. Moreover, instead of high-level policymakers, often ministries would send representatives with "technical HTA skills'.

In 2013, to feed its reflection process on achieving sustainability of HTA cooperation in Europe, the European Commission – by means of the Agency for Health and Consumers- asked the organisation *Ecorys* for an independent report on the state of play of HTA

---

195 Other projects financed through the FP7 projects were ADHOPHTA - Adopting Hospital Based Health Technology Assessment in EU; ADVANCE_HTA - Advancing and strengthening the methodological tools and practices relating to the application and implementation of Health Technology Assessment (HTA); INTEGRATE-HTA - Integrated health technology assessment for evaluating complex technologies; MEDTECHTA - Methods for Health Technology Assessment of Medical Devices: a European Perspective (European Commission 2015d: 76)

cooperation. The aim pursued was to provide an economic and governance analysis "on alternative solutions for the set-up of a permanent secretariat for future cooperation in the field of HTA, taking into account possible synergies and costs for the Commission" (Ten Have et al. 2013: 7). The conclusions of the study again highlight that the "main bottlenecks are the organisational complexity of working with many partners in one network. Also, major differences in decision-making structures, data requirements and the level of conduct and implementation of HTA in individual EU Member States seem to obstruct intensifying the current collaboration. Although the will for increased collaboration clearly exists, efficiency gains can be made" ((Ten Have et al. 2013: 41). Barriers perceived among HTA players to have the coordination of the collaboration being hosted in the Commission or in a subordinated agency had also been identified in this study. But no acceptable solution had been presented as all scenarios presented pros and cons. The report already pointed to the conciliation difficulties between efficacy and effectiveness on the one hand and scientific robustness and expertise on the other (Ten Have et al. 2013: 41-42).

The Inception Impact Assessment (IIA) led by the European Commission in 2016 gives a clear evaluation on an EU level of the state of play of HTA Cooperation by then and will serve the formulation process of the Commission proposal for a Regulation on HTA cooperation. Once more it is highlighted how most Member States share the vision that HTA cooperation could be beneficial for the national health systems and how the instruments developed by EUnetHTA have allowed for capacity-building, exchange of information and development of resources and specialised expertise. Support on behalf of the Council[196] and the European Parliament[197]. have been highlighted as well as the position of various stakeholder groups which became, according to the IIA, increasingly interested and supportive to collaboration on HTA.

However, the low uptake and coexistence of parallel national HTA processes showed that the objectives reducing duplication of work of HTA bodies, as set by EUnetHTA, had not been achieved. Explanatory reasons brought to the fore we again the different procedural frameworks, methodologies and data requirements in Member States as well as (lack) of administrative capacity (European Commission 2016: 9-11). Hence, the IIA would conclude that "It is not rational to invest public funds into HTA cooperation at European level, if the uptake of the work is not improved and the duplication of efforts is not avoided" (European

---

196 E.g. Council conclusions on Personalized medicine for patients (2015/C 421/03); Council conclusions on innovation for the benefit of patients (2014/C 438/06); Council conclusions on Personalized medicine for patients (2015/C 421/03).

197 E.g. European Parliament resolution on the Commission Work Programme for 2016 (2015/2729(RSP)).

Commission 2016:9). We have seen how this rationale laid at the basis of its future proposal for a Regulation on HTA cooperation.

The Public Consultation, which was held from October 2016 to January 2017 confirmed most of the findings in the IIA regarding the disparity that exists among HTA bodies in the (clinical and economic) methodologies and HTA procedures and how this still led to divergent outcomes of HTA reports, duplication of work, a decrease in business predictability, and a disincentive for innovation (European Commission 2017). Opinions regarding a future HTA framework have also be collected as discussed above (see also European Commission 2017). Many of these items have been re-discussed in the Impact Assessment, published simultaneously with the Commission proposal and which also based its conclusions on additional studies held[198]. Having presented various scenarios for future collaboration as discussed in the sections above, the Commission would surprise most key-players involved by proposing a mandatory structure which had not, as such, been submitted to stakeholders in the consultation processes or assessment report. Since the publication of its proposal, the Commission has continued to organise stakeholder meetings either with individual stakeholders or via the stakeholder pool of the EU HTA Network. As the proposal has not received a warm welcome by various actors in the field and triggered quite some discussion at a high-policy level in national governments, the European Commission continued to provide information about its standpoint and gathered information regarding actors' positions on the issue. At the time of writing no final conclusions can be drawn upon the actors' positions and the outcome of the Commission proposal. However, the move of the Commission has allowed to get a better picture of the issues at stake for all actors involved as well as the limits of a mandatory approach of harmonisation.

6.5.3. Conclusion evaluation in European HTA cooperation

In this section on policy evaluation, we have seen how various formal and informal evaluation procedures have been implemented since the EUnetHTA project started in 2006. It is interesting to see how the first evaluation processes already revealed the barriers associated to the lack of uptake and thus the inability of EUnetHTA to reach one of its main objectives. Whereas at first, the limited participation of members in pilot project was identified as an explanatory reasons, soon other more structural reasons were brought to the fore: legislative and procedural national framework, financial and administrative capacities, lack of trust in quality of joint assessments, need for capacity-building, resistance to change etc. Hence despite the continuous support for cooperation, expressed by HTA bodies, Member States and

---

198 Mapping of HTA methodologies in EU and Norway; Mapping of HTA national organisations, programmes and processes in EU and Norway (https://ec.europa.eu/health/technology_assessment/eu_cooperation_en) (European Commission 2017b; 2017c).

even taken up in official declarations of the European Parliament and the Council, more than a decade later, none of these barriers seems to have been overcome by the means implemented in EUnetHTA, neither by the establishment of the EU HTA Network which sought to involve high-level policymakers on the topic. Similarly, the establishment of a sustainable structure for HTA cooperation has not encountered consensus among key actors despite the various studies, public consultations and assessments implemented to advance on this issue. The Commission proposal based on these evaluations would even come up with a structure which had not been evaluated as such amongst the players concerned which would trigger fierce debates in many fora.

6.6.   CONCLUSION

In this chapter we have outlined by means of the five stages of the policy-cycle the developments regarding HTA cooperation in Europe since 2006. The aim of this chapter was to lay down the data in a comprehensive manner so as to allow for a more structured examination of it. Indeed, as we have seen in chapter 4, HTA cooperation started as a rather simple initiative by HTA doers and has developed into a complex undertaking including many actors on several policy-making levels. From a rather unknown technical subject in the 1990s, HTA has become a well-known political 'hot item' in European and national public policy debates. Whist in the early days, HTA cooperation sought to develop and strengthen HTA activities, as such, on a national level, it has developed in the last decade to a competence's distribution issue between the EU and the Member States.

This process has come as a surprise for some. However, the data in the present chapter demonstrates how this process has taken place through, what could be considered as, small insignificant steps forward in each stage of the policy-cycle. In the section on agenda-setting, we have seen how gradually new actors entered the scene, influencing the agenda-setting process and herewith the course of action of the cooperation process. Indeed, from an exclusive HTA arena agenda point, HTA entered formally the EU agenda at time of the High Level Group on healthcare and medical services to finally being discussed in the formal Council and European Parliament regulatory decision-making processes. The role of the Commission has been preponderant herein and has also led to the transformation of the network in terms of membership, governance structures and policy objectives. Soft governance has been, in essence, the means by which it has done so. However, to ensure the continuity of the cooperation, it proposed mandatory ('hard governance') regulatory means.

In terms of membership several observations can be made. Whilst the EUnetHTA project would be essentially made up of members stemming from HTA arena, this would change

with the Joint Action format were the membership approach would seek to include more actively the ministries of health who should appoint partner organisations. Direct ministerial implication remained however quite low as the members appointed would be mostly HTA bodies' representatives. The relationship between the latter and their home-base would vary. HTA agencies from smaller states would often send top-executives whereas those from medium-sized to larger EU countries would send middle-management staff. This would have repercussions on the transfer and use of EUnetHTA tools and methodologies at the national level, as top-management would be in a better position to adapt local habits to EUnetHTA guidelines.

Moreover, top-executives of smaller-sized countries would also have easier access to representatives of ministries of health. As such, information flows between agencies and ministries would be more frequent. As technical expertise related to HTA questions would often lack at ministerial level, these countries would also send the representatives of their HTA bodies to represent their country in international networks or meetings. Hence, when an official standpoint of the ministry would be requested regarding international HTA matters (e.g. proposal for a Regulation on HTA cooperation), advice on behalf of HTA agency representatives would be asked.

Lack of direct governmental implication in HTA cooperation has been one of the underlying reasons which led the Commission to set up a new EU HTA Network aiming to gather national representatives at a senior policy-making level. Herewith, the Commission sought to facilitate and improve the uptake of joint work. In practice, however, overlap in terms of membership between both networks would be the case with both networks being mostly composed by HTA doers instead of HTA policy-makers. Under impetus of the Commission, stakeholder policy will also be developed, first in EUnetHTA but lacking real consensus regarding their level of engagement resulting thus in various experiences according to the projects and Joint Actions in which they were involved. The Stakeholder Pool established in the EU HTA Network did respond on paper to a balanced stakeholder involvement policy. However, in practice, the weight of the different stakeholder groups seems to have been unequal, with some (e.g. industry) having a longer culture of exchange and lobby activities with European institutions than others and thus more weight (at least in the perception of other stakeholder groups). Membership in the networks has thus shifted from a rather closed HTA-arena representatives, to more heterogeneous networks. The introduction of new actors has been of importance by the impact it would have on the other stages of the policy-cycle as new views of the cooperation initiatives would nourish the debates.

These changes would in particular affect the influence the Commission would have on the cooperation efforts. Indeed, whilst the EU HTA Network was conceived to be member-state

driven, in practice, the Commission found itself in a position to steer the course of actions as it was presiding the meetings, leading the secretariat and setting up the agenda. Moreover, the setup of this network would also alter the governance functions of EUnetHTA since HTA strategic policy-making would be shifted to the EU HTA Network, herewith taking over the traditional role of the EUnetHTA Plenary assembly, relegated since then, to a merely informative function. Even if the other EUnetHTA governance bodies will remain in place, EUnetHTA will have to follow an agenda set by the EU HTA Network. Indeed, since the setup of the EU HTA Network, it had been decided that the EUnetHTA would fulfil the role of scientific and technical arm of the newly established network and should remained focused on the cooperation outputs. The EUnetHTA secretariat will even become integrated in a Directorate in the Joint Action 3 which will work closely with the secretariat of the EU HTA Network (i.e. Commission representatives).

The room of manoeuvre for the Commission to support the cooperation process was provided by the Cross-Border Health Care Directive in which HTA cooperation had been inserted as one of the flanking measures allowing for the setup of the EU HTA network. As the objectives of the EU HTA Network closely followed the objectives of the previous HTA cooperation initiatives, this network would become the forum to discuss the model for the establishment of a sustainable network for HTA cooperation in Europe. Previous business models and ideas developed in Joint Action 1 and 2 have only to a limited extent nourished the debates. Basing itself of the forum created by the EU HTA Network, the Commission will put forward its plans to structure the HTA cooperation into an EU legal framework. The Inception Impact Assessment, public consultation, and Impact Assessment will all be discussed in the network and will serve as a basis for the Commission to elaborate its proposal for a Regulation on HTA cooperation. This process built further upon the work of EUnetHTA, as through the exchange of best practices, peer education, and discourse, a common approach regarding HTA cooperation had been developed within the HTA arena. However, this approach needed to be further disseminated in other policy circles and in particular amongst decision-makers on a national and European level.

At first, the belief had been shared amongst EUnetHTA partners, that their network would become the sustainable cooperation mechanism to which the Article 15 in the Cross-Border Health Care Directive referred. Once the EU HTA Network had been set up, the latter seemed to be the future sustainable network structure. However, the Commission proposal follows a different path whereby both networks could be abolished (i.e. EUnetHTA and the EU HTA Network) and drive the cooperation efforts in a sustainable manner based on an EU regulatory framework through the establishment of a high-level coordination group or even, potentially, a Union agency. As such, HTA cooperation enters on the agenda of other

European institutions such the Council and the Parliaments which had already gradually be involved in the discussion on HTA cooperation in Europe.

Bringing in new actors in the cooperation process has impacted the policy-formulation process and objectives to be pursued. Especially since the establishment of the EU HTA Network and the search for a sustainable framework for cooperation, a new approach would be adopted by the Commission in its proposal for a Regulation on HTA cooperation. Whilst the overall objective of setting up a sustainable framework for HTA cooperation, remained the objective to ensure uptake of common HTA outputs, establishing the proposal on an Internal Market basis would introduce new (market-orientated) objectives. It is not clear what underpins the choice of the Commission to pursue this dual approach based on Internal Market harmonisation objectives, on the one hand, and public health objectives on the other. At present, the debates in the Council and in the Parliament will decide whether the Commission approach will be adopted fully or partially.

Finally, regarding the governance policies, the Commission has operated by shifting gradually from a voluntary soft governance approach, to a mandatory EU regulatory framework to ensure uptake of joint work. At first sight, one could herewith implicitly conclude that this move demonstrates the limits of voluntary soft governance cooperation frameworks in the field of HTA cooperation to reach harmonisation of practices. However, the reasons for the disappointing amount of joint work outputs and the lack of uptake, brought to the fore by commissioned or internal studies, do not fully explain the difficulties to reach the objectives set. Neither do they fully explain the positive results in Joint Scientific Advice. Moreover, the rise in regional cooperation initiatives which - conversely to the Regulation proposal approach – do integrate cost-effectiveness assessments and joint price negotiations could cast doubts upon the Commission approach to structure HTA cooperation the way it has been presented in the Regulation proposal.

In the next chapter, we will therefore examine the data set out in this chapter against the theoretical framework outlined in chapter 3. The aim will be to identify the role of soft governance in structuring HTA cooperation in Europe and in particular in reaching (or not) the objectives set by the various networks. This analysis based on the data set out in chapter 4,5 and 6, should allow us to answer the research questions framed in the introduction.

PART C

ANALYSIS

7 | Data Analysis

"National sovereignty withers when entrapped in the forms of the past."
Jean Monnet, Memoirs

7.0.   INTRODUCTION

After having set the theoretical framework in part A of this thesis and organised the data gathered in the research in part B, we will analyse in part C the data by using the research framework set out in chapter 3. This research framework is structured so as to allow detailed network analysis and builds further upon the notion of networks as a medium for the implementation of soft governance instruments. It is framed around three central concepts: governance networks, network governance and metagovernance. The chapter is structured in three parts. The first part examines general and specific characteristics of the HTA networks. It will base the analysis on soft governance-related factors impacting the typology of governance networks and as such integrated in our research framework: incentives, membership, resources and governance modes. The analysis should enable us to determine whether in the case of European HTA cooperation networks, governance networks can be identified. This part will also seek to determine which factors related to typology of networks have played a role in structuring HTA cooperation by soft governance means in a European framework.

The second part will focus on network governance of HTA cooperation networks. It will base the examination on soft governance-related factors impacting the effectiveness of governance networks in terms of goal attainment. In chapter 3 we have integrated in the research framework four factors potentially impacting goal attainment of governance networks: social interaction, governance instruments, management and external events. Each of these factors will be examined according to their particular features listed down in the research framework (see below). Goal attainment can be explored by looking at process, outputs and outcomes. In this chapter will seek to identify how each of these factors had an impact on the HTA cooperation process, the outputs that have been produced by the networks and the outcomes that have been identified as a result of cooperation initiatives.

Both the typology of a governance network as the effectiveness of network governance inform about the presence of a form of metagovernance regarding European HTA cooperation networks. This will be explored in the third part of this chapter. The implication of the European Commission in HTA cooperation networks has been present since the very first initiatives. This section will build further on the analysis made regarding the typology of governance networks and the effectiveness of network governance by highlighting the role of the Commission herein. The aim is to determine whether a form of metagovernance has been present in the development of European HTA cooperation networks.

The conclusion of this chapter will resume the main findings of the research based on the research framework It will highlight which soft governance-related factors in governance networks, network governance and metagovernance have had an impact on the develop-

ment of HTA cooperation in Europe. These will used to answer the research questions in the final chapter of the thesis, presenting the overall research conclusions, policy recommendation and subjects for further research.

METAGOVERNANCE				
GOVERNANCE NETWORKS *Typology*		*NETWORK GOVERNANCE* *Effectiveness* (Goal attainment)		
Network formation	*Incentives* *Strategic calculations* *Support/constrain*	**Social interaction**	*Learning processes* *Shared values and understanding* *Trust* *Goal consensus*
Membership	*Public, private, non-profit* *Relation home organisation-network* *Open/closed* *Homogeneous/heterogeneous*	**Governance instruments**	*Policy instruments* *Legislative and regulatory instruments* *Political instruments* *Financial instruments*
Resources	*Financial* *Natural/physical* *Social/political* *Human*	**Management**	*Competences* *Styles (project/process management)*
Governance modes	*Horizontal power distribution* *Asymmetric power distribution* *Centralised power distribution*	**External events**	*Ideological* *Legal* *Political* *Economic*

Table 7.1. Thesis research framework (2)

7.1. GOVERNANCE NETWORKS: TYPOLOGY OF EUROPEAN HTA COOPERATION NETWORKS

In part A of this thesis, we have outlined how networks present an adequate forum for the implementation of soft governance and have been used by the EU has a manner to pursue specific policy objectives. The data gathered in part B of the thesis has brought to the fore how the first HTA networks emanated from an HTA arena initiative at time of the Maastricht Treaty which marked the beginning of an official EU public health policy. At first, the HTA networks had no other relationship with the EU than through the request of financial support. This has however evolved into the establishment of an EU HTA network in which the role of the Commission became preponderant. This section will examine the attributes of the different networks that have been established in the course of the years and determine whether they respond to the characteristics of so-called governance networks.

In chapter 3 we have outlined key characteristics of networks influencing the typology of networks. In the present section we will use the data of part B of the thesis on the basis of these characteristics to first define the typology of the networks that have contributed to the development of HTA cooperation in Europe. We will focus in particular on the networks of the early cooperation initiatives which we will consider for the purpose of this analysis as a single entity (EUR-ASSESS, HTA-Europe and ECHTA/ECHAI), EUnetHTA and the EU HTA

Network. The aim of this section will be to identify the similarities and differences between those networks and determine whether and to which extent they can be considered as governance networks. Moreover, we will seek to assess whether the typology of a network has had an impact on the process of establishing a sustainable framework for HTA cooperation in an EU setting. In doing so we will follow the structure of the research framework regarding the typology of networks based on the following elements: network formation, membership, resources, and governance. In the research framework outlined in chapter 3, each of these elements correspond to several attributes which will be used to structure our analysis in the present section.

7.1.1. Network formation of European HTA cooperation networks

In chapter 3, we have outlined several factors influencing network formation such as contextual incentives, strategic calculations and support or constrain given to network formation. Contextual incentives could refer to issues such as interdependencies in terms of resources or strategic externalities or the need to deal with wicked problems. Strategic calculations and choices to form or participate in a network can be made for various reasons such as securing action capabilities or compensate for limited rationality or the presence of a cheap exit strategy. As such, strategic games such as the free rider problem, the assurance problem or the generosity problem can occur. Finally, support or constrain linked to dual loyalties towards the network and its home-organisation can lead to a constant search to balance between the need for more cooperation and the desire to maintain sovereignty and control over its course of action (see section 3.5.1).

The networks established in the early cooperation initiatives resulted from endogenous developments within the HTA arena, motivated by shared needs of developing knowledge and capacity on HTA. Hence the *contextual incentives* leading to the establishment of the first project-based networks laid in the diversity of approaches in a relatively young policy field. HTA arena representatives felt the need to enhance the quality and quantity of HTA, avoid duplication and allow a better allocation of resources. No intervention of actors outside the HTA arena has been identified. However, European Commission support has been determinant to launch and maintain the project. The first initiative had already been reformulated upon Commission guidance to allow funding acceptance. Moreover, the request of ECHTA/ECHAI project coordinators addressed to the European Commission to formalize EU support for HTA cooperation, would represent a first step towards the establishment of a sustainable network structure, supported by the EU and seeking to move away from a project-based approach (4.4.3).

The incentives for the Commission to support HTA cooperation in the 1990s differed however from incentives identified in the HTA arena and were related to the limited competences

of the EU in health policy and the desire to develop more efficient and cost-effective health systems in the Member States (section 4.2.2). No contextual incentives on behalf of Member States have been identified at this period, of time, in our research. Besides a cheap exit strategy, no real strategic calculations have been found for the creation of the first EUR-ASSESS network and the subsequent projects (HTA-Europe, ECHTA/ECAHI). By developing their knowledge on HTA through collaboration, network members essentially sought to strengthen the position of HTA in national decision-making processes.

The contextual incentives to establish the EUnetHTA network closely followed those of the early cooperation initiatives as development of HTA knowledge and expertise and duplication of efforts across Member States remained a concern for HTA agencies. Capacity-building of countries having limited experience in HTA became more important in the course of the years. The inclusion of HTA as topic in the HLG and allowing for the HTA to qualify as political priority for the EU has been however a new factor playing a role in the establishment of EUnetHTA (6.1.1) as was the inclusion of HTA cooperation in the Cross-Border Health Care Directive in the 2008 Commission proposal facilitating the continuation of the network in the form of Joint Actions (6.1.1). Previous collaboration experiences served as a basis for the setup of the network which pursued similar objectives. Finally, the political support of the HLG and the financial support of the Commission also contributed to the establishment of the EUnetHTA network (6.1.1).

Strategic calculations would be more present in EUnetHTA compared to the previous projects. Still voluntary based, the cheap exit strategy remains present. However, other calculations also came to the fore which explain the need for support looked after, not only on behalf of national and European public authorities but also on behalf of organisations such as the WHO (6.2.1.1). In the early 2000s HTA was increasingly considered of importance to address challenges in national health systems, facing, amongst others, rising health-care costs. It remained however a complex issue in terms of expertise and the role it should have in national decision-making processes. By creating EUnetHTA, the project initiators envisaged to establish stronger ties between the domestic policy-making level and HTA. For network members, cooperation seemed to offer more advantages than to continue the work in isolation. The incentives of the European Commission to support the EUnetHTA project were still in line with their position in the 1990s and aimed at strengthening the health systems. However, the importance of lifting HTA to the (European) policy-making level became an active strategy which became increasingly important over the years (6.1.1.; 6.1.2.).

Network formation	Early HTA initiatives	EUnetHTA	EU HTA Network
Incentives	• Limited knowledge knowhow HTA useful for developing efficient and cost-effective health systems • Limited use HTA in MS • Address rising health care costs MS • HTA diversity and duplication	• HTA diversity and duplication • HTA Capacity-building • HTA is EU political priority • Continuation of collaboration efforts • Commission support	• Develop efficient and cost-effective MS health systems • Rising health care costs • HTA duplication & lack of sustainability EUnetHTA • Lack of uptake EUnetHTA outputs • Develop policy level input • Legal framework
Strategic calculations	• Cheap exist strategy • Compensation limited knowledge	• Cheap exit strategy • Assurance problem • Cooperation>maintain sovereignty	• Enter MS health systems • Develop EU health policy • Establish link HTA-policy makers • Co-steer HTA cooperation
Support/constrain	• Home-organisations informed • Public authorities informed • No loyalty concurrence	• Support from Home organisation • Support MS Public authorities • Support international public authorities • EU support	• Support EU legal framework • Support MS public authorities

Table 7.2. Network formation European HTA cooperation networks

Similarly, to the establishment of EUnetHTA, the contextual incentives of the EU HTA Network were related to the previous network experiences. However, in this case, the network establishment resulted from an EU initiative. As sustainability of HTA cooperation had not been achieved through the work of EUnetHTA, the Commission sought to establish a new network at a Member State policy-making level. The adoption of the Cross-Border Health Care Directive would give the Commission a legal basis and framework to establish a new network (5.1.3). In a sense, this approach was also in line with the formal request of the ECHTA/ECAHI representatives to establish a sustainable and properly funded coordinating body for EU-wide network on HTA asked for more than a decade earlier (4.4.3). HTA cooperation had developed into a complex policy issue touching upon different policy fields involving actors on multiple levels. The strategic calculations at this point of time are based on the belief that HTA needed to be lifted at a higher policy-level to ensure effective action leading to the realisation of the cooperation objectives. Moreover, by coordinating the secretariat and co-presiding the Network, the Commission had an opportunity to steer the direction of this network (6.3.2.). Developing EU public health (into new fields such as timely patient access) and strengthening the health systems would further underpin the efforts of the Commission to steer the cooperation process.

7.1.2. Membership of European HTA cooperation networks

When examining membership policy in the different HTA cooperation networks, distinct approaches can be identified. In the first EUR-ASSESS, project members had been invited by the project initiators basing the membership upon geographical (EU) criteria (distinct from membership in existing international societies) (4.1.1.). Members were (except for Germany) exclusively representatives of the HTA arena. In the subsequent projects of the early cooperation efforts, membership would be somehow extended, but the approach remained the same (predominantly HTA body representatives) (4.1.1; 4.3.3). The relationship of the network towards the home-organisation of members was of low intensity, although members would sit in middle- to top management ranked positions. Their involvement should be mainly considered as a personal contribution to the network and did not necessarily reflect the interests of their home-organisations (at least not officially), even if support for participation was given and backed by the ministry.

Membership	Early HTA initiatives	EUnetHTA	EU HTA Network
Public, private, Non-profit	• HTA arena (mostly public)	• HTA arena • Few ministries (6)	• Public authorities responsible for HTA
Relation home organisation-network	• Low	• Depending on size MS - Small MS: strong - Big MS: Low	• Unclear, no transparency on membership
Open-Closed (socially & cognitively)	• Socially closed • Cognitively rather open	• Project, JA1, JA2 socially closed, cognitively rather open • JA3, socially and cognitively open	• Socially Closed, Cognitively open • No transparency on membership
Homogeneous/ Heterogeneous	• homogeneous	• homogeneous: project, JA1, JA2 • heterogeneous: JA3 • Stakeholder pool heterogeneous (but no formal members)	• unclear • Stakeholder pool heterogeneous (but no formal members)

Table 7.3. Membership European HTA cooperation networks

These early cooperation networks could be characterised as closed networks in a social understanding as members could participate only upon invitation of the project initiators and (in most cases) with the approval of the respective health ministries (3.5.3; 4.3.3.). No representatives of a ministerial level did take part in the first networks, which could be qualified as *networks of peers*. Although, the networks did not exclude any potential partners, the restrictive public knowledge about the new project-based network did not allow any easy access to potentially new members (4.3.3). The early cooperation networks established in the 1990s did demonstrate cognitive openness. Awareness regarding the outside reality was even driving the cooperation efforts both regarding the objectives pursued by the network as well as the availability of the means necessary to do so. Members participated and rep-

resented the network in other HTA-related international societies or cooperation structures with a shared value system (4.1.1). However, no other stakeholder groups participated in the network which could be qualified as being homogeneous in its membership structure, consisting predominantly of HTA bodies representatives sharing similar profiles and academic and professional backgrounds (4.1.1.).

Membership in the EUnetHTA network differed across the different projects and Joint Actions. As such, in the EUnetHTA project, membership represented predominantly the HTA arena. The project distinguished itself from the Joint Actions in terms of membership by the number of partners outside the EU (and outside Europe such as Israel, the USA, Canada) as well as by the inclusion of international organisations (Annex 4). The main partner being the beneficiary of the European Commission grant was the Danish Health and Medicines Authority which remains so till the Joint Action 3, which will be led by the Zorginstituut Nederland. The Joint Action 1 counted 35 partner organisations, again mainly representing the HTA arena from EU countries. Membership remained very similar in the Joint Action 2 which counted 39 partner organisations under which 3 Ministries of Health (of Malta, Cyprus and Slovakia) like in the Joint Action 1 (Malta, Spain and the Czech Republic) (Annex 4). The Joint Action 3 will mark a difference in terms of membership as it will open the network and include 81 partner organisations. Profiles of the member organisations will be more varied and not limited to HTA agencies and include members, such as, academic institutes, national medicines agencies, insurance funds, public health organisations or institutes. The number of Ministries of Health taking officially part in the cooperation remains low and concerns only small countries (Cyprus, Czech Republic, Slovak, Republic, Croatia, Slovenia and Ukraine). Apart from the Joint Action 3, the network structure of EUnetHTA is quite homogeneous. Socially, the structure remains closed, as membership is only possible upon recommendation of the ministries and concerns mainly HTA bodies. Cognitively, influences from external organisations do have an impact on EUnetHTA either via members participating in international societies or via the European Commission-led expert groups (5.3.3.2.; 6.4.2.3.; 6.4.2.4.)

Membership of the EU HTA Network remained unclear. The rules of procedures stipulated that members could be either representatives of national authorities or bodies responsible for HTA and designated by participating Member States (6.2.2.1.) Minutes of the meetings never precise the nature of the country representative participating in the meetings (HTA body, ministerial representative or other). Data collected through personal interviews indicated that overlap between EUnetHTA members and the EU HTA Network often existed (6.2.2.1.). The network remained closed as participation was possible only upon invitation and subsequent approval of the ministries. Moreover, transparency was lacking as to whom would take part in the network meetings. Strong ties still existed with the Joint Action 3 representatives. Due to lack of transparency, it is difficult to examine whether the network is homogeneous or

heterogeneous, although the former seems to be the case. The Stakeholder pool, gathering umbrella organisations from different stakeholder groups would bring heterogeneity in the network structure even though, these are no formal members of the network and do not take part in the network meetings[199]. Relation between the representatives and their home-organisation is, for the same reasons, unclear. Especially the information flow between the network and Member States' ministries cannot be clearly identified and no public record is available. Conversely to the early cooperation networks and EUnetHTA, the EU HTA network has been setup upon the initiative of what would become a metagovernor (i.e. the European Commission). The official membership structure should also distinguish this network from EUnetHTA and the early initiatives as it was not meant to be a network of peers. In practice, it has been difficult to verify this information and overlap between EUnetHTA and the EU HTA Network has been reported in terms of membership. The strong policy orientated objectives of EU HTA Network and the participation of policymakers should, at least theoretically, put it more firmly in the category of governance networks established to pursue public policy aims defined by public authorities.

7.1.3. Resources of European HTA cooperation networks

Resources of networks can vary between different type of means such as financial, natural/physical, social/or political and human resources. In the HTA networks that have existed since the early initiatives, all these resources have played a role in the development of European cooperation in HTA. Financial means to set up and pursue the cooperation efforts mainly came from two sources: the European Health Programme of the European Commission and national governmental support (mostly in-kind). The former was given through grants which have been drastically adjusted upwards since the Joint Actions. As such, the grant approved by the European Commission for each Joint Action doubled compared to the previous Joint Action[200]. Time dedicated to HTA cooperation projects has been taken into the budgets of the participating HTA bodies, often financially supported by national public authorities. Development of tools, publications and organisation of meetings, seminars and conferences would be financed through the budget allocated by the European Commission grant. This would remain through the various projects since the early initiatives till the Joint Action 3. Costs of secretariat activities and personnel would be covered by funds stemming from the

---

199 Stakeholders would be represented by specific organisations who would be allowed to participate at the end of the EU HTA Network meetings for presentation purposes (6.3.1.2.2.).

200 As such the grant approved by the European Commission for the Joint Action 1 was at the level of 2 903 897,79 € for a project duration of 37 months. The Joint Action 2 received financial support up to 6 599 777,00 € for a project duration of 42 months and Joint Action 3: 11 999 798,74 €. (https://webgate.ec.europa.eu/chafea_pdb/health/projects/724130/summary).

European Commission grant. Costs of secretariat premises would be covered by the hosting HTA body (6.3.1.2.1).

Resources	Early HTA initiatives	EUnetHTA	EU HTA Network
Financial	• European Commission	• European Commission • National public Authorities	• European Commission • National Public Authorities (?)
Natural/Physical	• National public authorities (secretariat premises ECHTA/ECAHI)	• National public authorities (secretariat premises)	• European Commission (secretariat premises)
Social/Political	• --	• High level expert groups • Health Council • International societies and organisations	• European Commission • National public authorities
Human	• HTA representatives	• HTA representatives • European Commission representatives	• European Commission representatives • External personnel

Table 7.4. Resources European HTA cooperation networks

Our research has not identified specific social or political support, apart from the HTA community itself, in the early cooperation initiatives. This will however change in the interlude period (2001-2006) with where high level expert groups such as the HLG on health services and medical care or the Pharmaceutical Forum increasingly offer support which will also be translated in political support by means of official statements of representatives of national public authorities, the European Commission and the Health Council as well as in draft legislative proposals of the Commission, some of which have been adopted by the European Parliament and the Council (5.1.2.2.; 5.3.3.1.; 5.3.3.2.; 6.1.1; 6.1.2.;6.2.2.; 6.2.2.3). The EU HTA Network distinguishes itself from the other networks as its establishment resulted from a European Commission initiative itself based on the Cross-Border Health Care Directive. Support from national public authorities was thus implicitly present. Social support was closely associated to support of the same kind to the EUnetHTA network (6.2.2).

Human resources have played an important role in the development of HTA cooperation in Europe. Much of the work implemented depended directly on the know-how of HTA body representatives who dedicated much time and energy in the network projects. Investment of the latter grew accordingly with the setup of new networks. Indeed, the number of new projects implemented by the networks has developed over the years requiring the investment of more people to implement them (4.4; 6.4). Since part of the work of the EU HTA Network has been implemented through the EUnetHTA network (the scientific and technical arm), human resources have been shared. Work related to the development of studies preparing the Commission legislative proposal was often done by Commission personnel or external persons commissioned (and paid for) by the European Commission.

7.1.4. Governance modes of European HTA cooperation networks

Governance modes in the early cooperation projects such as EUR-ASSESS and ECHTA-ECHAI were characterised by a non-hierarchical coordination method. Although formal governance entities did exist (i.e. Steering Committee, Executive Committee, Subgroups) all members participated in the decision-making process formally or informally (4.3.1.). Although the project initiators had an important role to play in terms of implementation and decision-making and a project coordinator had been appointed, the project heavily depended on the commitment of all for the implementation of the work. No hierarchical status structure existed, and all members interacted on an equal basis which was also reflected in the Steering Committee comprising all members (4.3.1.). Appointment of subgroups members was based on expertise. The Executive Committee resulted from practicalities linked to management and implementation functions (4.3.1.). Whilst the HTA-Europe project was based on the same governance structure as in EUR-ASSESS, the ECHTA-ECHAI network will differentiate itself from its predecessors by creating a Secretariat (4. 3.1.). However, offering administrative and organisational support, this body did not fundamentally alter the governance approach of the early initiatives which could be characterised as a *participant-governed network* as defined in section 3.5.3.

Governanc Modese	Early HTA initiatives	EUnetHTA	EU HTA Network
Power distribution	• Horizontal coordination • Equal status participants	• Horizontal coordination • Differentiated status participants • No equality in authority members	• Member State horizontal coordination • BUT Important (top-down) Commission influence on agenda and policy setting, financial and human resources
Steering mechanism	• Decentralised collective self-governance • Participant-governed	• Lead-organisation governance	• Network Administrative Organisation

Table 7.5. Governance modes European HTA cooperation networks

The governance structure of the EUnetHTA network shows still many characteristics with the early HTA cooperation initiatives. However, points of distinction can also be identified over time within the different Joint Actions. As such, a main difference between the ECHTA/ECAHI project and the EUnetHTA project has been the designation of a 'main partner' of the project. Resulting from a contract condition to be fulfilled, this appointment did affect the governance practices in EUnetHTA. The Secretariat would also be hosted in the premises of the main partner giving the latter a coordination role in which it distinguished itself from the other project partners (6.3.1.1.). The main partner chaired the Steering Committee responsible for the strategic orientation of the project and was also member of the Executive Committee. Moreover, as the formal contact point, it became also a privilege interlocutor of the European Commission (6.3.1.1.). Hence, through its leading role, its (informal) weight upon the network decision-making processes also distinguished it from the other members.

The Standard Operating Procedures of the EUnetHTA Collaboration and Joint Action 1 as well as the Consortium Agreement integrated in the Joint Action 2, reflected a few differences with the former projects. As such, membership would be differentiated between 'EUnetHTA Partners' and 'EUnetHTA Associates' (6.3.1.2.1). The formal agreements also clearly defined the responsibilities of each as well as the terms of engagements and consequences in case of breach of the agreements (6.3.1.2.1). Besides formal differentiation in membership, weight upon decision-making processes also differed amongst the EUnetHTA Joint Action partners according to seize and weight in national decision-making structures and personal investment in EUnetHTA (6.3.1.2.1). Moreover, due to their role in the network structure, Lead Partners, united in the Executive Committee had significant influence in the network (6.3.1.2.1). The Executive Committee counted since the Joint Action 2 also a Commission representative amongst its members which did not hold any voting rights but could, informally, influence decision-making of the network.

Governance in the Joint Action 3 will distinguish itself from the previous Joint Actions by the role of the main partner which will be transformed in a 'Directorate' composed of a Director's office and a Secretariat. The name change reflected a change of governance practices from a more horizontal soft governance approach in the previous projects and Joint Actions to a more top-down hierarchical governance approach in the Joint Action 3. Although this could have pointed to more authority of the lead-partner over the project, the data has shown that, in practice, EUnetHTA became subordinated to the EU HTA Network. Hence, EUnetHTA could be characterised till the Joint Action 2 as Lead-Organisation Governance. Although much of the governance structure remains in place in the Joint Action 3, much of the governance, policy orientation and project implementation of the EUnetHTA Network will be determined by the EU HTA Network (6.2.2.2).

The EU HTA Network resulted formally from the implementation of Article 15 of the Cross-Border Health Care Directive. Governance structures have been determined by the legislative text and work organised according to the Multiannual Framework adopted by the network members. As chair of the network, responsible, amongst others, for setting the agenda and running the secretariat, the European Commission (DG Santé) could be characterised as the administrative entity establishing a rather centralised governance practice. Its role in coordinating the work and offering financial, physical and human resources, allowed for a certain degree of sustainability. Expertise to reflect upon a long-term sustainability cooperation structure has been gathered through EUnetHTA on the one hand and specialised EU commissioned studies on the other, all financed by DG Santé (6.2.2.3.1; 6.3.2.). With the establishment of the EU HTA Network, the policy-setting role of the EUnetHTA Plenary Assembly has been shifted to the former, alongside the transformation of EUnetHTA to a technical and scientific arm of the EU HTA Network. As such, governance of EUnetHTA for an important part shifted to the EU HTA Network.

The 2018 Commission Regulation proposal outlined the potential establishment of a Member State-led coordination body, co-chaired by the Commission, which should govern the future HTA cooperation structure and take the policy decisions. The Commission would host the cooperation structure and be responsible for running the Secretariat. Other key functions such as the official Commission approval for publishing results on the lists were also foreseen in the initial proposal. The creation of a Union agency for HTA envisaged by the Commission, after a transitional period, indicated a potential desire to move towards a similar structure as the EMA (6.3.2.). Although stakeholder participation has always been promoted by the Commission in HTA cooperation, the position and influence given to the latter by means of the Stakeholder pool would remain limited, with some stakeholder groups having more influential weight on decision-making processes than others (6.3.1.2.2; 6.3.3.).

7.1.5. Conclusion typology European HTA cooperation networks

This section has analysed the various networks seeking to establish sustainable European cooperation in HTA. The examination has proceeded according to (governance) network characteristics outlined in chapter 3 and constitute the first part of our research framework. The aim of the analysis was to identify the governance structures of HTA cooperation networks and to see whether these correspond to characteristics of governance networks. If indeed (some) of these networks could be qualified as governance networks, the following step would be to examine how these relate to the soft governance approach of the post 2000 EU health policy.

In section 3.4.1. we have outlined a list of general characteristics of governance networks as brought to the fore in the literature on governance networks. The analysis made in this section allows us to compare the characteristics of the HTA cooperation networks with the general characteristics of governance networks. The table below brings to the fore that all three network structures examined do correspond to governance networks.

Indeed, all networks resulted from a desire of social actors to develop knowledge and experience in HTA. Cooperation could enhance HTA quality and quantity in domestic decision-making processes, herewith strengthening the national health systems in Europe. As such, the networks aimed at contributing to a public purpose. The examination of the networks' typologies has permitted to further distinguish the specific characteristics of the network structures. Section 7.1.1. has outlined the similarities and differences regarding the formation of these networks, each resulting from the emergence and interaction of the previous network(s). Contextual incentives, for example, differed and reflected consequences of work produced or not in the previous networks. Some incentives, however, were consistent in all network formations, such as the rising health care costs and the need to contribute to the efficiency and cost-effectiveness of the health systems. The voluntary basis of cooperation,

allowing for a cheap exit strategy, also played a role in each. Fluctuating incentives would be related to new policy contexts in either the Member States or the European Union as well as to strategic calculations to gather in an HTA cooperation network.

Characteristics Governance Networks	EUR-ASSESS, HTA-Europe, ECHTA/ECHAI	EUnetHTA (Project, JA1, JA2, JA3)	EU HTA Network
More or less stable pattern of relationships of social actors clustering around policy problem/resources, emerging, sustaining and changing though interactions[1]	+	++	+
Stable horizontal relations of interdependent, autonomous actors (public private, civil society), not necessarily equal in authority and relationships[2, 3]	+/-	++	+
Interaction through negotiations based on deliberation, learning and common understanding[2]	++	++	+/-
Interactions in regulative, normative, cognitive and imaginary framework[2]	+/-	+	+
Self-regulating within limits set by external agencies[2]	+	++	+
Actors aggregate different resources[4]	+	+	+
Contributes to public purpose[2,3,4]	+/-	+	++

Table 7.6. Attributes Governance Networks applied to European HTA cooperation networks
[1]Klijn and Kloppenjan (2016), [2]Sorenson and Torfing (2007), [3]Klijn (2008), [4]Huppé, Cneech and Knoblauch (2012)

The horizontal soft-governance coordination approach certainly favoured support from public authorities in Member States, which remained in control of their domestic health policies. Although no hierarchical top-down governance structure characterised any of these networks, we have seen that some member organisations would enjoy more authority than others, often depending on the size of the agency and the country of origin. One can cite as an example hereof the main partners, the European Commission and some HTA agencies of (size-wise) bigger EU Member States. Due to the need to enhance knowledge and capacity on the one hand and the fact that HTA corresponded to a small policy-field requiring specific expertise, members remained interdepend to fulfil the goals of the cooperation and to reach their own objectives when joining the networks.

Network members came predominantly from the (public) HTA arena, especially in the projects till the EUnetHTA Joint Action 3. The homogeneity of the networks resulted in a shared normative framework which remained a cognitively open network. This did not necessarily mean that a common approach towards specific projects would be systematically shared by all members and their home-organisations (e.g. quality requirements of joint work). Indeed, depending on the relationship between the network and the home-organisations, different standpoints towards proposed solutions or practices would remain. This would be observed

more often in (size-wise) bigger EU Member States. By sending top-management representatives, stronger adhesion to joint work would be found in HTA bodies of smaller countries.

Stakeholders from the non-profit and private sectors increasingly took part in the cooperation process, however, with unequal influence and participation. Public authorities mainly took part in the process by formally appointing members to the networks. Officially, the EU HTA Network should be composed of ministerial representatives, in practice however, the membership structure of this network seemed to resemble strongly the EUnetHTA network. Self-regulation was the rule but needed to respond to specific procedures specified in grant agreements, supervised by the European Commission which secured an important part of the financial resources. Other resources, such as in-kind contributions (e.g. personnel costs, premises) were covered by national authorities.

The governance modes implemented in all HTA networks were based on soft governance and voluntary cooperation. However, each network did display distinct characteristics in terms of governance structures. From a participant-governed network in the early initiatives, to a lead-organisation governance in EUnetHTA, European HTA cooperation has been organised in the EU HTA Network via a network administrative organisation, with the European Commission acting as metagovernor`. The role of the Commission in the development of HTA networks has been determinant. From a simple grant allocator in the EUR-ASSESS project, to a full-fledged partner of the Joint Actions, the Commission did indirectly take part in steering the governance processes regarding the typology of the governance networks. As such, it has had an influence on the strategic calculations to pursue the cooperation initiatives, on its membership structure (e.g. openness, heterogeneity, stakeholders), on the available resources (financial support) as well as on the governance structures.

Having identified the network characteristics of each of the three main HTA cooperation networks, the next section will examine to which extent these networks have been effective in reaching the goals set.

7.2. NETWORK GOVERNANCE: EFFECTIVENESS OF EUROPEAN HTA GOVERNANCE NETWORKS

As outlined in chapter 3, soft governance modes have often been used by European institutions to implement specific policy processes through governance networks. In section 3.6. we have framed the notion of effectiveness and recalled that effectiveness in governance networks cannot be measured in the same way as effectiveness of states and markets (Jessop 2002: 236). We also have defined effectiveness of networks in terms goal attainment (3.6.2.)

which can be analysed through *process*, *outputs* and *outcomes*, all three being interrelated (3.6.1.) *Processes* can be examined by, for example, looking at negotiations that take place between actors or a network's adaptation capacity. Trust, learning processes, shared values and understanding can play a role herein (3.6.2.) *Outputs* can be observed in the form of concrete, desired and targeted 'products' of the collaboration efforts. Measurement can be done by comparing the results to the goals set or the needs expressed (3.6.2.) *Outcomes* have been defined in the research framework as (un)desired effects of the cooperation efforts and can be divergent in nature (e.g. evolving social situation, developed problem-solving capacity or creation of new private or public entities) (3.6.2.).

To attain the overarching goal, sub-goals may be set as intermediate steps. The dynamics of goal pursuit could be represented as a chain of goal attainment. Goal attainment being understood as 'the action or fact of achieving a goal towards which one has worked' (3.6.1.). In the outline of the research framework we have indicated that this encompasses in our understanding goal setting and goal achievement (3.6.1). In the following sections we will examine effectiveness of HTA cooperation networks in the light of goal attainment as defined in chapter 3. We will do so by applying the elements highlighted in the research framework which allow to examine goal attainment through process, outputs, and outcomes.

The research framework includes the following factors which bear the potential to impact effectiveness of network governance: social interaction, governance, management, and external events. In this section we will look at each of these factors individually through the scope of specific features laid down in the research framework. Social interaction will be examined by focusing on learning processes, shared values and understanding, trust and goal consensus. Governance instruments will be explored by considering procedural and substantive policy instruments as well as legislative, political, and financial instruments. Impact of management on effectiveness of network governance will be analysed in this section by concentrating the examination on particular skills required for such undertakings by network managers as well as to the management style (i.e. process management versus project management). Finally, the section will present an overview of external events having had an impact on HTA cooperation and occurring in the time-lapse of the examination period of the HTA networks.

The aim of this analysis is to identify whether these factors were present in the European HTA cooperation process and whether they have played a role in the goal attainment process of European HTA cooperation networks. We will then examine to what extent social interaction, governance, management and external effects have had an impact on 1) the process of establishing a sustainable network (overarching goal), 2) the production of cooperation outputs (sub-goals) and 3) cooperation outcomes.

7.2.1. Social interaction in European HTA governance networks

Internal processes supporting or restraining cooperation in a network can be affected by *social interaction.* As such, social interaction has a potential impact on goal attainment, a process which takes place, amongst others through cooperation. Social interaction can take place in various ways. Attributes of social interaction included in our research framework comprise t*rust, shared values and understanding, learning processes* and *goal consensus*. (3.5.1.). In this section we will examine to which extent these have been identified in the HTA cooperation networks and how they have favoured (or not) the *process* of establishing a sustainable network, the production of *outputs* and contribute to the development of specific *outcomes*. Although we will examine each of the social interaction attributes in a separate manner, the distinction is rather artificial as they are all interconnected and can mutually influence each other.

Moreover, each constituent of social interaction, can be affected by various elements related to the *typology of a network* (see section 7.1.). As such *incentives* and *strategic calculations* in network formation can affect the degree of *trust* or *goal consensus*. Similarly, an *open or closed network* can affect social interaction as it will have an impact on the number of *members* and their profiles. Moreover, *homogeneity or heterogeneity* of a governance network can impact the degree of *shared values and understanding* as well as *trust, learning processes* and *goal consensus*. Hence, even though we will examine the various attributes of social interaction separately, we will at times refer to interrelated features of other influencing factors regarding the typology or effectiveness of governance networks. In the following sub-section, we will first examine social interaction through the scope of *learning processes* and *shared values and understanding*. The next sub-section will focus on *trust* and *goal consensus*.

7.2.1.1. Social interaction: learning processes & shared values and understanding in European HTA governance networks

In governance networks based on soft governance and deliberative decision-making processes, social interaction plays an important role with regard to goal attainment. As outlined in chapter 3, these networks cannot rely upon a hierarchical top-down decision-making structure. Instead, decisions are being made by deliberation and negotiation which take place in a regulative, normative, cognitive and imaginary framework. Such a framework favours learning processes and shared understandings on issues which will be of importance in reaching common decisions and developing policy instruments to reach the goal set (3.7.1.).

Learning processes in HTA cooperation networks often took place in the form of exchange of knowledge and information, allowing to establish best practices in HTA bodies and in Member States (4.2.1.). Attention went in particular to individuals and organisations having

less experience with HTA. Peer-education was here most common where more experienced partners would share their knowledge with less experienced ones. However, formalised learning processes have been implemented as well and led to the production of specific tools and training materials (e.g. handbook on HTA capacity-building, training seminars and e-learning materials) (6.4.1.3.; 6.4.2.3.).

These learning processes had a dual outcome. On the one hand, they would allow for the production of capacity-building tools which would facilitate the production of joint work such as methodologies, joint core-HTAs and joint REAs. On the other hand, they have contributed to the development of a common understanding on the needs and goals of HTA cooperation. Moreover, values could be transmitted through learning processes and become more largely integrated in the network community. These shared values and common understanding would, amongst others, be reflected in the formulation of objectives which, *in essence*, have remained the same since the early cooperation initiatives (6.2.1.) In this sense, learning processes did contribute to the goal consensus process regarding the establishment of a sustainable European HTA cooperation network and the various tools which should be developed to support this overarching goal.

As these learning processes mostly concerned HTA doers, the impact they had on *shared values and understanding* also predominantly remained within the HTA arena. Our research has not identified any specific social interaction processes towards representatives of ministries of health or other governmental institutions. The latter are however key actors in HTA processes as they will have to decide upon the use of HTA outputs in domestic pricing and reimbursement processes. Methodological and quality issues regarding HTA have a direct impact on the outcome of HTA and indirectly also impact regulatory processes since the HTA reports are used as input in pricing and reimbursement decisions on the national level. In this sense, policymakers at ministerial level would be concerned by HTA cooperation processes and could have been more actively involved in them.

Although the need for social interaction with ministerial representatives has been recognised by the networks, no specific activity has been established in this regard by them. This raises however questions as to the reasons and consequences hereof, especially with regard to the EU HTA Network. Interaction with policy-makers could have been expected in this case, since this network was conceived as a policy orientated network. Nevertheless, no particular learning processes or exchange of knowledge and experiences seem to have been envisaged nor established with ministerial representatives, to date. Explanatory arguments could be found relating to both the ministries and the networks. Considering the specific expertise required to understand HTA processes, ministries would often delegate their involvement in HTA networks to agencies' representatives. Moreover, networks would implicitly count upon

HTA agency representatives to ensure the development of learning processes targeted at ministerial representatives.

In cases where social interaction between HTA agencies and ministries has been observed, it would be correlated to the size of the agency's home-country and the management level of the HTA body-representative, active in the networks. The smaller the country and the higher the management-level, the more intense social interaction between ministries and HTA bodies would be. Moreover, personal relationships between representatives of the ministries and HTA agencies also seem to have played a role in the development of social interaction at this level (6.4.2.5.).

Consequences of low social interaction intensity between ministries and HTA cooperation networks, could be measured in domestic and European regulatory and legislative processes. Qualitative data of our research points to potential impact of social interaction – or the lack thereof – on the adoption process of the Commission proposal for an EU Regulation on HTA cooperation. Considering the role of the Council in the EU legislative processes, social interaction could have had an influence on the positioning of EU Member States towards the proposal. We have seen in part B how some Member States have adopted critical standpoints regarding this proposal which would not always reflect the positioning of their countries' HTA agencies, having participated in the process for many years (6.4.3.3.). More developed social interaction processes between the networks and ministerial representatives could have allowed to overcome the obstacles encountered at earlier stages in the collaborative processes. However, social interaction cannot solely explain the positioning of Member States on the Commission proposal as other aspects also played a role herein.

The inclusion of stakeholders in the cooperation processes, although initiated in the first Joint Action, became effective only in the Joint Action 2 and triggered disappointments in Joint Action 3 (6.3.1.2.2; 6.4.1.3.). Indeed, predominantly composed of HTA bodies, active stakeholder participation in the network activities was restricted. Projects were carried out by the network members and stakeholders would mostly be involved on a consultancy basis. This model, were little interaction would take place with the general network on a continuous basis, would have an impact on the development of learning processes and the establishment of a set of common values and understanding among stakeholders' umbrella organisations and their members. The latter is of importance in the development of joint work and the uptake of it in a domestic setting.

Moreover, by enlarging the membership of the networks (e.g. JA2 & JA3), disparities arose not only among stakeholder groups but also within some stakeholder groups. Indeed, the data has brought forward how disparities could exists between umbrella stakeholder organi-

sations participating in the network and their members. As such, HTA network values could be adopted by the umbrella organisations but would not be diffused to their members. Consequently, positioning of umbrella organisations, members of HTA networks, would not necessarily reflect the position of the stakeholder group as a whole. An example hereof could be found in EFPIA, which would consider joint work in HTA as valuable and beneficial for the pharmaceutical industry. This idea would however not always be shared by their own member organisations who would consider these issues only from a side-line and would not necessarily see sense in cooperating in joint assessments (6.3.1.2.2.).

Social interaction, or lack thereof, with some stakeholder groups has impacted the goal attainment process in several aspects. Inclusion of stakeholders in the HTA cooperation governance processes has been strongly supported by the European Commission. One of the objectives of the creation of a Stakeholder Forum was to persuade a wider group of stakeholders in HTA cooperation of the benefits of collaboration and the setup of a sustainable structure for European HTA cooperation. Through exchange of information, knowledge and experiences, it was hoped common values on the issue would be further shared. However, opinions diverged regarding the inclusion of stakeholders in the HTA processes and positions often reflected national practices (6.3.1.2.2.).

Despite the stakeholder policies implemented in EUnetHTA and the EU HTA Network, no harmonised stakeholder approach has been adopted in 2020. Divergent Member States' positions regarding the level of stakeholder inclusion still characterises the debate. Hence, decisions regarding the level of stakeholder inclusion in the European HTA networks undergoes influences from national processes. These varies according to the governmental perspectives on health technologies, considered either as an element of public health or seen as products serving economic growth (6.3.1.2.2.). Moreover, our analysis has not been able to identify any horizontal stakeholder interaction across the different stakeholder groups. No solid unified position or concertation regarding stakeholder policy on behalf of all stakeholder groups (payers, patients, health care providers and industry) has been observed.

To conclude, learning processes have allowed for the development of a set of shared values and understanding among HTA agency representatives representing the members of the HTA networks. Present since the first collaborative initiatives, learning processes have undergone a development process whereby, besides informal exchanges of experiences and peer education, learning became increasingly structured in the form of capacity-building tools and processes. Moreover, these processes also underpinned the production of specific tools and methodologies, designed as sub-goals to prepare the establishment of a sustainable structure HTA cooperation in Europe. As such, social interaction, by means of learning processes and shared values and understanding, have had a *positive impact on the goal*

attainment process and the *production of specific HTA collaboration outputs* allowing for the development of joint work.

Social interaction between the European HTA networks and policymakers has been observed only in some cases. Lack of social interaction stemmed from the specificity of HTA whereby ministries often delegated their presence to HTA body representatives. European networks did not actively pursue interaction with governmental institutions implicitly assuming this would take place on the agency level. Consequently, social interaction between the networks and ministries was of a low intensity level and did not allow diffusion of learning processes and common values and understanding.

Moreover, the qualitative data of our research points to a correlation regarding social interaction between agencies and governmental institutions and the size of the home-country and the management representation level participating in the HTA networks. Hence, absence of routinised *social interaction* between policy-makers and HTA collaboration networks has *negatively impacted the goal attainment process* of the HTA networks.

Social interaction	EUR-ASSESS, HTA-Europe, ECHTA/ECHAI	EUnetHTA				EU HTA Network
		P	JA1	JA2	JA3	
Learning processes						
HTA Arena	++	+++	+++	++	+	-
Policymakers	-	-	-	-	-	No data available
Stakeholders	-	-	-	+/-	+/-	-
European Commission	+/-	+	++	++	+	+
Shared values and understanding						
HTA Network	+++	+++	+++	++	++	++
HTA Network-Policymakers	-	-	-	+/-	+/-	No data available
HTA Network-Stakeholders	-	-	-	+/-	+/-	+/-
Stakeholders-Stakeholders	-	-	-	+	+/-	+/-
HTA Network-Commission	++	++	++	+++	++	+++

Table 7.7. Social interaction in European HTA networks
(learning processes & shared values and understanding)

Social interaction as regards stakeholder groups seems to have taken place only in a vertical manner between the HTA network governance structures and the different stakeholder groups. Impetus to establish and deepen the relationship with stakeholders has mainly stemmed from Commission officials. Stakeholder policy predominantly remained at an informative or consultancy level and excluding any decision-making role in governance structures. Impact of learning processes to develop a system of shared values and understanding

remained limited as no real active role was given to stakeholders. Moreover, there where these learning processes took place and interaction did positively impact shared values and understanding, it would often remain at the umbrella organisation level and not further disseminate to their members. Hence, due to restricted stakeholder involvement in the cooperation process, effect of social interaction remained limited. In this sense, *learning processes have had only a limited impact on goal attainment* of the HTA networks.

7.2.1.2. Social interaction: Trust and goal consensus in European HTA governance networks

The importance of *trust* among actors cooperating towards a common goal is often brought forward in discussions on cooperation mechanisms. *Trust* has been explained in chapter 3 as reflecting the willingness of network members to accept vulnerability based upon positive expectations of each other's intensions or behaviours (Provan and Kenis 2008:238). Measuring the degree of trust, as well as its impact on such cooperation mechanisms, can however become a hazardous experience as it implicitly relates to sentiments, such as, reliance, confidence, beliefs in abilities or statements made. Disregarding the examination of *trust* in cooperation processes could however lead to a flaw in a research on cooperation mechanisms as this seems often to be related to goal consensus.

Trust among members of *participant-governed networks* (horizontal power distribution) tends to be generally higher than in *lead-organisation networks* or *network-administrative organisations* and contributes to cooperation and goal achievement. However, reaching collective goals can also be set in type of networks with a lower trust density. In chapter 3 we have also highlighted how trust is manageable and plays a role in generating collectively negotiated decisions. Moreover, trust can also be influenced by the typology of networks. As such, in homogenous networks, composed of actors with similar professional, educational or cultural backgrounds, members may be more inclined to trust each other and share common values and beliefs than in heterogeneous networks (3.5.1.).

Trust has not been equal across all HTA cooperation networks and seems indeed to have affected the goal setting and goal attainment processes. In the early cooperation initiatives, qualified as 'participant-governed networks', membership of the network corresponded to a sort of 'community feeling' and trust in the cooperation process and the network was high (4.6.). The 'dual leadership' of the project coordinators also indicates a certain level of trust between them. Indeed, if in EUR-ASSESS David Banta would demonstrate a high level of personal investment in the project and would stand more in the forefront of the project, Egon Jonsson would take over that position in the ECHTA/ECAHI project without this affecting the cooperation imitative and project outcomes (4.1.). The level of trust present in the early cooperation initiatives is also reflected in the decision-making processes which

similarly resulted mostly from informal dialogues and exchanges between members at different venues and at different points of time. Decisions were officially adopted by consensus in the governance bodies, after having been discussed and agreed upon in informal arenas. No tensions regarding potential disagreements about the objectives set and the manner to achieve them, have been reported (4.3.1.).

Similarly, *goal consensus* in the early cooperation initiatives was easily found. The overarching objective of the early cooperation initiatives regarded the establishment of a European network for HTA cooperation. The sub-objectives were conceived as means to achieve this goal. The main objective found consensus among the networks' members, all sharing the belief that it would strengthen capacity- building and dissemination of HTA use and results. The impact of informal dialogues on the consensus-based decision-making processes in the (formal) governance structures, indicates how members had 'positive expectations of each other's behaviour and intensions' (4.2.1.; 4.3.1.) The homogeneity of the network is found to have had a positive impact on trust and goal consensus processes in the early cooperation initiatives (7.1.2.).

The level of trust among members of EUnetHTA has fluctuated in the course of years. In the EUnetHTA project and first Joint Action, trust amongst network members and trust in the goal setting and goal attainment process, tended to be stronger than at later stages of EUnetHTA. The inclusion of an article on HTA cooperation in the Cross-Border Health Care Directive (2011/24/EU) has reinforced the trust-building process regarding the network's objectives. The homogeneous structure of the network in its early days has had a positive impact on the trust building process. Conversely, the more heterogeneous the network became, the more signs of mistrust would appear regarding the feasibility of the project objectives (7.1.2.). Lack of trust would be expressed regarding issues such as, process and product quality and timeliness of product outputs. As such, the need and feasibility of essential cooperation features (e.g. joint assessments, uptake of joint work) would be questioned (6.4.2.3.; 6.4.2.5.). Hence, network structure has had an influence on the trust-building process of the HTA cooperation networks. Network homogeneity has displayed a positive impact on trust building, whilst network heterogeneity negatively impacted the latter.

Besides trust building, the network structure also affected the *goal consensus* process. We have seen above, how EUnetHTA has gradually enlarged membership, whereby the membership structure became more heterogeneous. Although, this process can lead to enhanced knowledge and capacity, it could also lead to an 'efficacy paradox' as discussed in chapter 3 (Voss et al. 2006) (3.5.1.). Knowledge expansion and innovation do, on the one hand, enhance the problem-solving capacity of a network. On the other hand, the diversity of membership also makes it harder to achieve consensus on the solutions proposed (3.5.2.).

This efficacy paradox has been observed in EUnetHTA. Since the EUnetHTA project till the first Joint Action, *Goal consensus* was present in, what was then, a homogeneous network. Consensus on implementation strategy or solutions proposed to specific problems, was generally the case (6.2.1.1.; 6.3.1.1). In the later stages, when EUnetHTA membership was less homogeneous, goal consensus was more challenging to achieve. Although, by joining the network, members implicitly adhered to the general objective of establishing a sustainable network for HTA cooperation, consensus was harder to find on the means to achieve this. Certain topics, such as, duplication of efforts, became openly questioned, which had not been the case before. Similarly, some members put doubts on evaluation results regarding (low) uptake as reported by the European Commission and EUnetHTA representatives. Moreover, the idea that HTA collaboration *should* lead to more uptake of joint work was not anymore unanimously shared (6.4.2.5.).

We have outlined in chapter 6 that uptake of joint work was entirely voluntary. The network could therefore not impose use of joint work to its members. Horizontal coordination implicitly relied on trust in members' willingness and abilities to implement the collective outputs produced. We have seen that in small and middle-sized countries, integration of EUnetHTA tools and methodologies, as well as participation in joint HTAs, was higher than in (size-wise) bigger EU Member States. This depended partly on management and governance decisions from HTA agencies and partly on trust building processes.

Trust in HTA networks' joint work can also be connected to the management level of HTA body representatives participating in the HTA networks. Smaller agencies often sending top-mangers to the networks, bigger agencies usually having middle-management representing them. By co-developing the joint tools, methodologies and assessments and being trained by network members, top-management representatives would be more inclined to adapt their internal agency working habits to EUnetHTA standards (6.4.2.5.). Moreover, they would have the authority to adapt the internal processes accordingly. Hence, trust and goal consensus seem to correlate these governance and management decisions.

Moreover, trust - or the lack thereof - would also impact (active) participation of members in the development processes of common tools, methodologies and assessments. In the section on joint work (6.4.2.3.) we have seen how the investment in work packages was not equal across the EUnetHTA members and how the lack of involvement of some agencies resulted from the lack of trust in the quality of the work produced as well as doubts casted upon the reduction of efforts in joint HTA. The latter would furthermore explain the low uptake (see also 6.4.3.3). Hence, although uptake of joint work depends on many factors as discussed in section 6.4.2.5., trust - or the lack thereof - in the quality and usefulness of EUnetHTA tools, co-impacts this process.

Trust and goal consensus also affected uptake via (lack of) stakeholder participation and adherence to the networks' objectives. Our research has highlighted how the pharmaceutical industry had difficulties finding member organisations willing to cooperate in EUnetHTA joint assessments pilot projects. Many companies feared that participation would enhance their workload and, due to the low uptake, did not have trust in the potential benefits the process would offer them. Although goal consensus on HTA cooperation was present, lack of uptake would lead to a lack of trust, which in turn negatively impacted the production of joint work (outputs) (6.4.2.3.; 6.4.2.5.)

As outlined in the sections above, no direct implication of national decision-makers has been observed in our research and expert opinion would essentially be provided by network members (predominantly HTA agencies' representatives). Although, in the EU HTA Network, there was room for a better inclusion of high-level policy makers, in practice, membership of EUnetHTA and the EU HTA Network often overlapped. As no transparent information has been available at time of the data collection regarding the nature of the participants in the EU HTA Network meetings, it is difficult to make an assessment regarding the level of trust and goal consensus of potential policymakers participating in this network.

To overcome the lack of goal achievement (both regarding sub-goals as the overarching goal), the Commission was of the opinion HTA cooperation needed EU action to eliminate obstacles to HTA convergence. It therefore proposed a Regulation on HTA cooperation with mandatory elements of uptake (6.2.2.3.1.). The Regulation proposal was based on results of a public consultation process and impact studies, justifying, according to the Commission the content of the proposal and the application of the subsidiarity principle. This Regulation proposal stumbled however on fierce opposition of some Member States. Some positions reflected opinions already expressed within EUnetHTA regarding the quality of some tools (e.g. joint HTAs), often considered inferior to their national standards (6.4.3.3.). Other critical reactions were related to the quality of the consultation process and the interpretation of the results. Trust, or the lack thereof has thus also played a role in the adoption process of the HTA Regulation proposal (6.4.4.).

Moreover, lack of trust in the Commission intentions with the Regulation proposal has been expressed with regard the implementing and delegated acts. Some Member States feared that by leaving some key issues to be decided upon at a later stage, they would lose grip on the system. This would explain their reluctance to enter in vertical governance schemes leaving no possibility to opt-out. Hence, goal consensus as regard the setup of a sustainable structure for HTA cooperation as well as consensus on the means to reach that goal, diminished once the proposal was submitted to bigger target audience. The development of salience for regional HTA cooperation initiatives (e.g. Beneluxa) could be interpreted as

a response to the EU-led proposal, as these new initiatives would offer the possibility to Member States to remain in full control and cooperate with countries having similar health systems and HTA practices (6.4.3.4.).

For a better comprehension of the impact of social interaction on the effectiveness of HTA cooperation networks, it is also important to assess social interaction between the HTA networks and the EU Commission. In the early cooperation initiatives, trust still needed to be developed between both arenas. However, by granting financial support, it is safe to ascertain that a certain level of trust on behalf of the Commission was present at this stage of the networks' development process (4.4.2.). Similarly, the ECHTA/ECHAI network's call to the Commission, to create a sustainable network for HTA cooperation, also testifies of a certain level of trust on behalf of the HTA arena representatives towards this EU institution (4.4.3.). The establishment of the Joint Actions in which the European Commission receives a bigger role, implicitly points to a solid relationship between the partners based on mutual trust. Similarly, the partnership also indicates goal consensus as both sides of the partnership subscribe the same contract. Through various processes of exchange of information and experiences, shared values and understanding about HTA cooperation developed. EU Commission representatives acquired a better understanding of HTA issues, and HTA arena representatives better understood the role HTA could play in the EU public health landscape.

Social interaction	EUR-ASSESS, HTA-Europe, ECHTA/ECHAI	EUnetHTA				EU HTA Network
		P	JA1	JA2	JA3	
Trust						
HTA Network	+++	+++	+++	++	++	++
HTA Network-Policymakers	+	NA	-	+/-	+/-	No data available
HTA Network-Stakeholders	NA	NA	+/-	+/-	+/-	+/-
Stakeholders-Stakeholders	NA	NÁ	+/-	++	+	++
HTA Network-Commission	+++	+++	+++	+++	++	+++
Goal consensus						
HTA Network	+++	+++	+++	++	++	++
HTA Network-Policymakers	+	+	+	+/-	+/-	No data available
HTA Network-Stakeholders	NA	NA	+/-	+	+	+/-
Stakeholders-Stakeholders	NA	NA	+/-	+	+/-	+/-
HTA Network-Commission	++	+++	+++	+++	++	+++

Table 7.8. Social interaction in European HTA networks
(Trust and Goal consensus)

7.2.1.3. Conclusion social interaction

We have seen that social interaction has been developed in its various aspects throughout the cooperation process since the early 1990s. However, this process has limited itself es-

sentially to the HTA arena. The early cooperation initiatives responded to a homogeneous network structure where membership was mostly composed of HTA doers. Goal consensus was easy to attain, decisions were taken by consensus and implementation methods had not been contested. In EUnetHTA, a similar membership structure characterised the EUnetHTA project and Joint Action 1, displaying similar results in terms of goal consensus and adhesion to policy decisions and implementation. However, with the enlargement of the network to new members of various profiles, opinions diverged as to the desirability, feasibility, and strategy of reaching the overarching objective. Hence, whilst homogeneity has demonstrated a positive impact of the diffusion of learning processes, shared values and understanding, trust and goal consensus, heterogeneity has negatively affected the latter.

Social interaction with stakeholders has mostly been developed in a vertical way (network-stakeholder group) since the Joint Actions, but only to a certain extent. A horizontal development of social interaction (stakeholder group-stakeholder group) may have taken place at some points resulting from individual efforts but has not been organised in an institutional way. The Stakeholder Forum and Stakeholder Pool of EUnetHTA and the EU HTA Network, have contributed to instil a certain degree of social interaction favouring the development of learning processes, shared values and understanding, trust and goal consensus. However, its impact on reaching the overarching goal of the network seems quite limited.

Moreover, representatives of (health) ministries, which ultimately would be representing their Member State in the formal decision-making fora regarding the institutionalisation of HTA cooperation in Europe, have not been included in the process of establishing social interaction. The debates on the 2018 Regulation proposal of the Commission would display disparities among Member States positions. These did not necessarily reflect opinions held by their HTA bodies representatives, members of the EUnetHTA network. Lack of social interaction can partly explain this phenomenon.

Throughout the development process of the HTA networks, learning, shared values and understanding, trust-building and goal consensus processes have also taken place within the European arena. These have contributed to frame or re-frame policy problems and seek for common solutions underpinned by European support (3.5.1.). The Commission proposal to insert HTA cooperation in the Cross-Border Health Care Directive allowing for the creation of the EU HTA Network was the first attempt of the Commission to create a sustainable HTA cooperation network. The Commission proposal for a Regulation on HTA cooperation, has been another mean to attain that goal.

As long as cooperation remained voluntary, support of Member States and most HTA agencies was assured. However, this would change once some aspects would potentially become

mandatory. Hence, although the need for HTA cooperation was shared by most network members and stakeholders, no consensus existed regarding the manner in which this should take place. Debates on the issue would essentially point to a lack of trust towards the quality of the assessments and the need and/or feasibility of generalised uptake of joint work. The cooperation process had not succeeded in creating consensus on a Member State level to shift part of Member State HTA competences to an EU-level (6.4.3.3.).

This section has outlined how social interaction plays an important role in the effectiveness of European HTA cooperation networks. It has underscored how social interaction has taken place to a certain degree and with certain actors in the field. As such, its impact on the establishment of a sustainable cooperation framework has remained limited as the social interaction with certain groups and in specific fields was of low intensity. The main reasons identified in this regard, point to the (non-) inclusion of key-actors in the process as well as the manner in which these processes have taken place (vertical versus horizontal processes). Social interaction has however had a positive impact on *the creation of outputs in the form of new common tools and methodologies and to some extent in the production of joint assessments*. The impact of social interaction – or the lack hereof – is important, in particular in the *production of (un) expected outcomes* such as the proposal for a Regulation in the field of HTA cooperation, the opposition created towards the latter and the establishment of regional cooperation initiatives.

Social interaction	Establishment sustainable network (process)	Production outputs	Cooperation outcomes
Learning processes	+	+++	++
Shared values & understandings	+	+	++
Trust	+	++	+++
Goal consensus	+	++	+

Table 7.9. Social interaction in European HTA networks

7.2.2.   Governance instruments in European HTA governance networks

In this section we will focus our attention on aspects of network governance laying outside the spectrum of social interaction and examine how governance through the use of specific policy, legal, political, economic and financial instruments have affected effectiveness of European HTA cooperation networks in the sense of goal attainment. As these instruments are based on soft governance, some of the characteristics brought to the fore will overlap with elements discussed in the section on social interaction.

7.2.2.1. Policy instruments in European HTA governance networks

The manner in which policy decisions will be translated into concrete actions to reach the goal set, depends, amongst others, on the instruments chosen. In chapter 4 and chapter 6 we have analysed the policy-implementation process according to the use of policy instruments. These policy instruments have been classified into *procedural* and *substantive policy instruments*. The former referring to instruments affecting policy processes associated with the delivery of policy outputs and the latter referring to instruments bearing the potential to influence the substance of policy outputs (4.4.1.). As procedural instruments we have identified in the HTA cooperation networks, instruments related to organisation, communication, capacity-building and evaluation. Substantive policy instruments have been related to joint work, uptake and the life-cycle approach (4.4.1.; 4.4.2..; 6.4.1..;6.4.2.).

In this section we will first examine the networks' procedural instruments and how they relate to HTA cooperation processes, outputs and outcomes. It will inform about the policy instruments' potential in structuring the European HTA cooperation process and will serve as input to answer the thesis research questions. The second part will focus on the substantive policy instruments implemented through soft governance. It will inform us about their potential in creating common tools, methodologies and practices underpinning European HTA cooperation. Moreover, it will address the potential of these policy instruments to establish synergies between HTA and EU regulatory processes.

7.2.2.1.1. Procedural policy instruments

In European HTA cooperation, the instruments used to implement policy objectives have been based on soft governance. When examining the governance approach in terms of organisational matters, we have identified two distinct processes. The first regarding the internal governance of the HTA cooperation networks. The second regarding the governance of external processes aiming to establish a sustainable HTA cooperation structure (e.g. Cross-Border Health Care Directive (2011/24/EU). In chapter 6 we have highlighted how both processes have often been intertwined as the project-based networks were, for a long time, being considered to become the future sustainable network. This has impacted the goal attainment process in several ways. In this section we will focus on both processes distinctively by examining the instruments used in the internal and external processes separately.

The analysis of the internal processes regard policy instruments used in the *organisation* of the HTA cooperation networks aiming to offer organisational support to the realisation of the project objectives. Organisational policy instruments underpinned *project* implementation and should be distinguished from instruments used to steer the *process* of establishing a sustainable framework for European HTA cooperation. At times, however, confusion between both has been identified. This has had an impact on the instruments used to steer the internal network coordination.

In the early cooperation initiatives, internal project coordination was clearly separated from the process of establishing a sustainable HTA cooperation framework. Network steering instruments were fully based on soft governance, characterised by horizontal coordination, and excluding all forms of hierarchical command-control organisational governance. The creation of Subgroups, pursuing specific objectives, resembled organisational structures functioning upon so-called management by objectives (4.2.1.). Whilst the project had set the goal of creating a sustainable HTA cooperation structure, steering activities were primarily focused on the achievement of the sub-objectives, set by the network members without any interference from other (political) arenas. Commission intervention has been observed in the ECHTA/ECAHI project, by its request of the addition of a project objective to the grant proposal submitted. However, reasons underpinning the request were essentially related to grant allocation and did not concern project content as such (4.2.3.).

The internal organisational of the EUnetHTA project and of the EUnetHTA Joint Action 1, would be similar to the first networks. Although, the soft governance steering mechanisms would change from a participants-governed organisation to a lead-organisation governance structure, the coordination of the networks would remain distinct from the - to be established – sustainable HTA cooperation framework. The latter is highlighted by the distinction made between 'network coordination' from 'network development', dealt with in different work packages (6.4.1.1.). The establishment of workgroups pursuing the realisation of sub-objectives still functioned according soft governance steering mechanism, coordinated by a secretariat operating through a lead-organisation.

External governance processes will gradually impact the internal organisational processes. We have seen how the integration of HTA cooperation in the Cross-Border Health Care Directive will create confusion regarding the role of EUnetHTA and later of the EU HTA Network. At first, EUnetHTA has been considered as being the – to be established – sustainable HTA network. Later, the EU HTA Network will be seen as such. Although the establishment of the EU HTA Network will bring some clarity as to the role of EUnetHTA (becoming the scientific and technical arm of the latter), this would not resolve the question regarding the status of the EU HTA Network and whether it should be considered as the future sustainable network or not. The internal organisation of the EUnetHTA Joint Action 2 was focused on alignment with the Directive. By becoming the technical and scientific arm of the EU HTA Network, its status has been clarified. This also had an impact on the organisational aspects. EUnetHTA would see its objectives and work programme being decided upon by the EU HTA Network which would also affect the governance modes and instruments used, even though, on paper, much remained the same.

With the establishment of the EU HTA Network, governance of European HTA cooperation, *in practice*, seems to shift towards a more Commission-steered governance mechanism. Policy instruments used were: expert-level committees, stakeholder participation, impact assessments, public consultations. Whilst these instruments all remain soft governance instruments, some of those have been implemented in the light of establishing a Regulation proposal, stepping away of the soft governance approach by proposing a legal framework based on hard law. Hence, throughout the development stages of EUnetHTA and the EU HTA Network, the boundaries between the use of soft governance and 'hard governance' policy instruments became increasingly blurred.

The Regulation proposal, foreseeing the establishment of a new cooperation structure partly based on mandatory aspects of Joint Clinical Assessments, underscores how the Commission considered soft governance modes not efficient enough to reach the overarching goal of creating a sustainable HTA cooperation network allowing convergence of practices (6.4.3.2.). Despite the more centralised soft governance modes implemented till then, the Commission believed part of the cooperation efforts would need to shift to a form of hard governance. This rationale justified the choice of a Regulation as legislative framework, rather than other legislative means, such as, a Directive.

To counter arguments related to competence division in health care between the EU and its Member States, the Commission referred to the subsidiarity principle. The Inception Impact Assessment already highlighted the benefits of European HTA cooperation but underscored how instruments used in the networks, based on voluntary cooperation and horizontal steering mechanisms, did not permit to achieve the objectives set and that an increased level of cooperation to reach synergies and reduce duplication in HTA would be better pursued at EU level (6.2.2.3.1.). In other words, according to the Commission, voluntary cooperation could lead to the production of concrete outputs in terms of joint work, it could however not ensure the use of those in national regulatory processes. After years of voluntary cooperation at Member State level failing to accomplish the establishment of a sustainable European HTA cooperation structure, the Commission considered that EU action, comprising mandatory (hard governance) elements was required.

Hence, the internal organisational processes of the examined HTA cooperation networks, functioned according to soft governance principles. External processes have had an impact on internal organisational processes and have often led to the establishment of new structures. During the collaboration process, the goal of establishing a sustainable HTA cooperation framework has increasingly been mixed with the networks' project-based goals conceived to support the establishment of the sustainable HTA cooperation structure. The European Commission will seek to achieve the overarching goal, initially by creating the EU

HTA Network before proposing a Regulatory framework. Herewith, it will operate a shift from a soft governance approach to a coordination structure comprising hard governance implementation aspects.

A second procedural policy instrument can be identified in the internal *communication* means that have been developed to support the key-objectives of the networks. Communication in the early HTA networks was rather informal. In EUnetHTA, communication instruments would be reinforced. The various databases would allow for a more efficient communication and would support joint work (e.g. joint assessments, evidence generation). Internal communication means (e.g., intranet for network members) facilitated exchanges on technical or substance matters. External communication, such as, dissemination of network activities and products, has been present since the early cooperation initiatives. Specific work packages have been dedicated to this aim. The organisation of seminars and conferences have certainly contributed to framing HTA cooperation in a wider environment. Whilst these activities did contribute to increased stakeholder information regarding HTA cooperation and the (legal) developments in the EU health policy field, impact on decision-makers has not been observed in our research.

Capacity-building has been another procedural policy instrument aiming to reach the goals of the HTA networks. The impact of capacity-building and learning processes on social interaction has been underscored in the previous section. Capacity-building instruments such as training seminars, handbooks, and peer-education have been present since the early cooperation initiatives and have contributed in HTA networks in the development of shared values and understanding (4.4.1.). These instruments were based on a soft governance approach and have contributed in developing common understanding towards the need for HTA cooperation among certain actors in the HTA arena. Section 7.2.1. has however also outlined how capacity-building, or the lack thereof among certain actors (e.g. national policymakers) has negatively affected the goal containment process.

Finally, as fourth procedural policy instrument, *evaluation* processes, often instilled by EU grant approval procedures have been implemented and allowed for single and double loop learning processes. Single loop learning processes were standard procedure in the development of many tools and methodologies such as the POP database, the EVIDENT database, the handbook for HTA, joint REAs, core HTAs as well as the Early Dialogues (6.2.1.; 6.4.1.; 6.4.2.). However, double loop learning processes leading to governance and/or organisational changes also have been observed. Most visible are the changes established from one Joint Action to another and the ones leading to creation of the EU HTA Network. The establishment of new governance bodies such as the secretariat in the ECHTA/ECAHI project (4.3.1.) or the 'directorate' on the third EUnetHTA Joint Action (6.3.1.2.1.) are other examples hereof.

However, the Commission proposal for a Regulation could also be interpreted as resulting from double loop learning processes since EUnetHTA experiences in HTA cooperation have been used to develop a new framework pursuing the initial network goals (6.2.2.3.2.).

In this section we have examined the procedural instruments used in the various networks. We have looked in particular at instruments based on organisation, communication, capacity-building and evaluation as these were instruments used in all networks and on which the data collection has been structured. To conclude this section, the following observations can be made: *Organisation has had positive impact on the process of collaboration* by the setup of networks based on soft governance mechanisms, setting objectives which remained consistent throughout the cooperation. However, o*rganisation has had a negative impact on the process of cooperation* due to the lack of clarity and certainty about the future of the project-based networks which slowed down the process of establishing a sustainable frame-work, still not established to date. *Organisation had a mitigated impact on the production of network outputs* as it did offer a framework to develop tools and methodologies necessary for collaborative work on HTA but did not contribute to the generalized used of these in local settings. *Organisation did contribute to the production of (unexpected) outcomes of the networks,* such as, the 2018 HTA Regulation proposal and the development of regional (intergovernmental) cooperation structures. These could be considered as unexpected results partly occurring as a consequence of the non-establishment of a sustainable cooperation structure by the HTA networks and the lack of uptake of their outputs.

Governance	Establishment sustainable network (process)	Production outputs	Cooperation outcomes
Procedural policy instruments			
Organisation	+ & -	+/-	+
Communication	+	+	-
Capacity-Building	+	+	NA
Evaluation	+	+	+
Substantive policy instruments			
Horizon Scanning		-	+
Early Dialogues		+++	+++
Joint work		+/-	+
Evidence generation		+	++
Uptake			+

Table 7.10. Procedural policy instruments in European HTA Networks

The impact of *communication* on the cooperation process has been *positive on the col-laboration process* as such, particularly through external communication means in the form of dissemination of outcomes and the organisation of conferences. Internal communication

means have had a *positive impact on the production of outputs* as they facilitated exchanges on technical issues and network activities.

Capacity- building has been examined though instruments such as training seminars, handbooks and peer-education which differed from learning processes in social interaction. The latter could be considered as an *outcome* of capacity-building tools. In this regard capacity-building had a *positive impact on the production of outputs and on outcomes* and positively contributed to the goal attainment *process*.

Similarly, the *evaluation* exercises of the networks *contributed to the collaboration process* by preparing organisational adjustments or adapt content, tools and methodologies. In this sense *it also positively contributed to the production of outputs* such as joint work. As the internal evaluation also highlighted the discrepancies in the process of establishing a sustainable framework for HTA collaboration in Europe, it did have an influence on the elaboration of an HTA Regulation proposal, which could be considered as an *outcome* of the networks' collaborative initiatives.

As underscored above, procedural instruments can have an influence on the substance of the policy outputs. In the following section we will examine substantive policy instruments in relation to their contribution to the European HTA cooperation process, outputs and outcomes.

7.2.2.1.2. Substantive policy instruments

In chapters 4 and 6 we have examined substantive instruments developed by the HTA networks and which contributed to the production of the networks' outputs. These outputs where often comprised in the sub-goals set by the networks and considered necessary to achieve the overarching goal of creating a sustainable HTA cooperation network. In chapter 6 we have explained how these outputs have been developed at different points of time. However, as they all correspond to a certain phase in a health technology life cycle, we will proceed the analysis by respecting these phases: Horizon Scanning, Joint Scientific Advice, joint work (i.e. methodologies, tools and assessments) (additional) evidence generation and uptake of joint work in national settings (6.4.2.).

Horizon Scanning

Horizon Scanning has been an activity addressed in the first HTA networks under the denomination of 'priority-setting' (EUR-ASSESS) or 'Clearing-House function' (ECHTA-ECHAI) (4.4.1). At the time, other collaborative frameworks, such as 'Euroscan', already existed and recourse to those was strongly encouraged by the networks. Indeed, this would allow them to focus on other aspects of the collaboration (e.g. harmonisation of methodologies). Nevertheless,

the importance for a concerted approach on Horizon Scanning had been underscored and the Subgroub on priority setting of the EUR-ASSESS project had even highlighted the need to work with stakeholders at this stage "to ensure commitment to the process and the outcomes" (4.4.1.). Stakeholders were however absent in the initial HTA networks. Even though their participation had been encouraged by the Commission representatives at a much later stage, it had never been specifically associated to Horizon Scanning.

Horizon Scanning had however been addressed in the EUnetHTA project where it aimed at establishing a systematic review of practices and start collaboration with organisations such as Euroscan and establish a common form for information sharing. In this project, horizon scanning had been defined as "the systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society" (6.4.2.1). Despite defining the activity, no real Horizon Scanning projects have been implemented till Joint Action 3, where the topic received renewed attention. It built upon some instruments developed in Joint Action 1, such as the EVIDENT database. Hence, although recognised as being important for HTA, Horizon Scanning has never been a priority topic for EUnetHTA (6.4.2.1.). Collaborative work produced by the HTA cooperation networks in this area remained thus limited.

It is interesting to notice how the absence of Horizon scanning outputs produced by EUnetHTA has actually given an incentive to regional cooperation initiatives (e.g. Beneluxa) to fill this gap. Domestic policymakers increasingly needed visibility regarding products in the industrial pile-line to better anticipate their potential budgetary and public health impact. Horizon Scanning has also been included in the Commission proposal for an HTA Regulation. Moreover, by including Horizon Scanning in the proposal for an HTA Regulation proposal, the Commission too, considered the activity as one of the pillars of HTA cooperation and implicitly recognised its importance in the HTA cooperation process.

The EUnetHTA Joint Action 3, will finally give renewed attention to the topic by developing an innovative Horizon Scanning system (HSS). The proposed HSS would link Horizon Scanning to topic identification, selection and prioritisation. This was actually already the approach discussed in EUR-ASSESS. To date, in terms of outputs, EUnetHTA has not (yet) produced an instrument allowing to support HTA collaboration by means of a HSS. Instead it joined a new organisation, the International Horizon Scanning Initiative (IHSI), launched by Beneluxa and which secretariat is hosted by the Zorginstituut Nederland (ZIN) sharing herewith personnel also involved in EUnetHTA (https://ihsi-health.org/team/).

Impact of Horizon Scanning on the collaboration process and outputs has not been identified in this research. This can be explained by the low number of Horizon Scanning activities

being developed in HTA cooperation networks. Importance of Horizon Scanning on HTA cooperation has been underscored by the Commission which inserted the topic in its HTA Regulation proposal. Moreover, other (regional) HTA cooperation organisations did launch Horizon Scanning initiatives to respond to a need of policy-makers. This could be considered as *(un)expected outcomes* of the European HTA networks which did not (sufficiently) address this topic.

Early Dialogues
The initiative on *Early Dialogues* has developed as one of the most successful EUnetHTA outputs. Indeed, starting as an 'ad hoc activity' of EUnetHTA members, not foreseen in the EUnetHTA Joint Actions before 2012, the initiative quickly outgrew the expectations of the project initiators. Several reasons have been brought to the fore to explain this phenomenon. First, establishing concerted dialogues between regulators and HTA agencies on the evidence requirements in the early phases of drug development, responded to a real need of all stakeholders involved. It offered enhanced visibility for the industry as well as for the assessors. As the process was still based on soft governance principles, proposing voluntary participation and voluntary use of the recommendations, adherence to the project on behalf of the industry was high. This consolidated the output production of Early Dialogues.

Moreover, Commission support was assured since the latter saw an interest in establishing collaborative mechanisms between the EMA and the European HTA networks. The development process of the Early Dialogues also applied soft governance principles leaving the process to be adjusted according to lessons learned from past experiences. Stakeholder participation has been present from the start and included, besides the industry, also representatives of patient organisations (6.4.2.2.). The positive experiences of stakeholder participation in Early Dialogues have been shared with other HTA related discussions about stakeholder participation (e.g. stakeholder participation in REAs).

Finally, the success of the Early Dialogues can also be related to the presence of a shadow of hierarchy. The non-observation of scientific advice given by the HTA agencies and the European regulatory agency could lead to the non-approval of market access or have consequences on the pricing and reimbursement negotiations. Requirements which should be observed by the technology developers could thus be imposed by the regulators and/or assessors at a later stage. The threat hereof, certainly favoured adherence to the process on behalf of the industry.

The Early Dialogues have led to several outputs and outcomes which have affected the HTA cooperation process as a whole. As outputs we can first list the many concerted scientific advises given to manufactures and used by the industry in their development process. The

establishment of a common platform for parallel consultations with a single-entry point, allows for coordinated advise on manufacturers' development plans, facilitating herewith the alignment of data requirements between regulatory and HTA agencies. The adjustment of EMA assessment reports (e.g. EPAR) to HTA needs can be cited as another output. Moreover, the establishment of a formal Early Dialogue Working Party coordinating the collaboration efforts is another example hereof (6.4.2.2.).

The process of collaboration has also led to certain outcomes. Through Early Dialogues, cooperation between the EMA and HTA bodies has been established, which did not exist as such before. Indeed, the research has underscored how representatives of both arenas were not used to collaborate. The projects around Early Dialogues allowed for a better mutual understanding of the needs and challenges faced by each in this area. Cross-institutional learning processes have taken place based on the exchange of experiences. As stakeholder participation had been well developed in EMA regulatory processes, EUnetHTA could take advantage of the lessons learned. The synergies which have been established between both arenas favoured development of further collaboration initiatives in other fields (e.g. collaborative projects in the field of post-launch evidence generation, inclusion of patient registries in data collection) (6.4.2.2.). Finally, collaboration in Early Dialogues did also produce (unforeseen) outcomes in pharmaceutical companies, such as, enhanced collaboration between departments within a given company, not used to collaborate on these issues. Being confronted with external assessment bodies, worked as an 'eye-opener' to some, creating a better comprehension of the needs of each pharmaceutical division and leading to more efficient cooperation at subsequent stages of the market access process (6.4.2.2.).

Joint work
At the core of the European cooperation efforts in HTA lays the production of joint assessments. These should serve as input in domestic decision-making processes regarding pricing and reimbursement of health technologies. The aim to produce joint HTAs had been already expressed in the EUR-ASSESS project recognising the need to develop common methodologies and establish a common reporting framework (4.4.1; 6.4.2.3.). The ECHTA/ECHAI project made a distinction between the development of common tools and methodologies on the one hand and joint assessments on the other. EUnetHTA would adopt a similar approach by addressing these items in different work packages. The term 'joint work' would be introduced only during the Joint Action 2 and would refer not just to joint methodologies, tools and assessments but would also comprise literature reviews, structured information for rapid or full core-HTAs, Early Dialogues and scientific advice.

Chapter 6 has outlined the different implementation stages of joint HTA production, transferrable into the national settings. Adopting a new HTA definition can be cited as one

of the outputs produced by EUnetHTA, creating herewith a basis and legitimisation of the cooperation efforts. The Core-HTA model has been a milestone in the development of joint assessment and responded to the needs expressed in the early cooperation initiatives for a standardised model. Similarly, the adaptation of the Core-HTA model for REAs is another important output produced. To ensure adequate implementation of the joint assessments, numerous methodologies and guidelines produced. Finally, tools such as the POP database and the EVIDENT database, were essential to support joint HTA production and constitute joint work of the HTA networks (6.4.2.1.; 6.4.2.3.).

Hence, concrete outputs have been produced and tested in pilot projects (6.4.2.3.). Many of these corresponded to sub-objectives of the cooperation networks (6.2.1.). They were considered necessary to achieve the overarching goal of establishing a sustainable network as they would constitute the basis for all collaborative work. By re-qualifying EUnetHTA into a scientific and technical arm of the EU HTA Network, the European Commission acknowledged the need for the development of common tools, methodologies and guidelines as pre-requisite for the production of joint assessments and other forms of joint work. Although essential in the process of establishing a sustainable cooperation process, to date, most outputs have been implemented in a pilot project format and their impact thus remains limited.

Production of joint work, on the one hand, implicitly acknowledges the possibility to reach convergence in HTA through soft governance cooperation mechanisms. On the other hand, the limited uptake of joint work in national settings as well as the lack of consensus regarding the need, the quality and the adaptability to domestic settings, restrains its impact on the goal achievement process of the networks. The impact of joint work as substantive policy instrument on the process of establishing a sustainable framework for European HTA cooperation is thus mitigated. This conclusion should, however, be taken with caution as it is time-related. A transition from pilot projects to routinisation of joint work could still take place in the future, provided that the uptake challenges would be overcome. Moreover, the fact that regional HTA cooperation initiatives have recourse to EUnetHTA processes of joint work (6.4.3.4.) would support the argument that these outputs may have a wider impact than initially anticipated and thus do contribute to HTA cooperation in Europe and the establishment of more sustainable systems.

Additional Evidence Generation
The importance of collaborating on *additional evidence generation* had been discussed initially in the EUnetHTA project. To date, the outputs produced by the EUnetHTA network and the EU HTA Network are rather limited. The Eifel toolkit could be cited as an output contributing to the establishment of additional evidence frameworks, but still in a pilot project format. The work on Early Dialogues and the synergies established with the EMA in this field, further

contributed to the development of a new coordinated approach in Post Launch Evidence Generation Projects (PLEG) (6.4.2.4.). These projects, though finding themselves in an early development stage, seem to respond to a need expressed by several stakeholder groups. Conversely to the Early Dialogues, cooperation on PLEGs comprises rather delicate issues, such as, the use - or not - of patient registries and real-world data (RWD). As standpoints on these issues differ among Member States, it remains to be seen whether a common approach can be adopted leading to establishment of a common framework applicable to national settings. Hence, additional evidence generation, as a substantive policy tool, has to date not had a significant impact on the process of establishing a European HTA cooperation framework.

Uptake
Talking about uptake first needs to clarify what one understands by this term. If initially the HTA networks targeted the use of joint assessments in national settings, this aim has been adjusted in the course of the cooperation process. *Uptake* has been defined during the Joint Action 2 as "the general implementation of any EUnetHTA output in a national context and may include the usage and implementation of the EUnetHTA tools and Joint Assessments" (6.4.2.5.). This definition would clearly impact the rate of uptake measured in evaluations, as it would comprise many more features of joint work. As such, use of the POP-database for local reports, or use of some aspects of a core-HTA or REA would already qualify as 'uptake' (6.4.2.5.). The concept of 'national adaptation', introduced in Joint Action 2, would target more specifically the use of *joint assessments* results in national or local settings (i.e. REAs or full core-HTAs) (6.4.2.5.). However, here too, partial use of the assessment results would qualify as uptake.

Opinions diverge regarding the figures brought forward on uptake (6.4.2.5.). Part of the difficulties in assessing uptake is related to evaluation methods. As outlined in chapter 6, measuring uptake of joint work in medical devices or pharmaceutical products requires different approaches and need to take into account the different market access processes. Moreover, evaluation studies carried out so far have proceeded according to different definitions of uptake. As such, figures brought forward are not necessarily comparable, making the it difficult to assess an evolution in the uptake process. Nevertheless, the last study made by EUnetHTA during JA3 did point to a significant increase in uptake compared to JA2. Barriers to uptake, highlighted in this study, pointed to language requirements, reporting structures, timing of assessment availability, need for different assessment elements or assessment scope. Previous studies had pointed to additional barriers such as legal constraints (6.4.2.5.).

Uptake has thus been a critical matter in HTA cooperation. The (perceived) lack of uptake has had an impact on the Commission decision to propose a mandatory legislative proposal

for HTA cooperation. The opposition expressed by Member States towards the mandatory uptake of clinical assessments results, demonstrated how this is still an issue of content. The latter seems to result from the voluntary uptake approach adopted for years in the HTA networks and which had led to disappointing results. Uptake lays at the heart of the negotiations on the proposal for an HTA Regulation and it would be premature to draw conclusions at this stage. At first sight, the soft governance coordination approach proposing uptake on a voluntary basis, seems limited in the case of the European HTA networks examined in this research. However, in the sections above, we have underscored how some aspects of soft governance, such as social interaction, have not been implemented in a generalised manner, leaving some key-actors outside these processes.

Hence, concluding that soft governance cannot ensure uptake seems premature. Aspects related to the typology of governance networks, as well as some features related to network governance (e.g. social interaction, legislative instruments, management, external events) seem to play a role in the level of uptake. Hence, presence or absence of these elements in the cooperation process may have influenced the outcome of uptake. We can however draw the conclusion that the impact of uptake on the process of establishing a sustainable framework in HTA cooperation is of high importance and is intrinsically linked to the sustainability of the process. To date, the (perceived) lack of uptake has had both a positive and negative impact in terms of outcomes. On the one hand it has instilled doubt in the feasibility of reaching the overarching networks' goals and has had a negative impact on the adherence of some key-actors to the routinisation of joint work. On the other hand, it has underpinned the Commission decision to propose a Regulation as legislative instrument, seeking to secure uptake by mandatory means.

7.2.2.2. Legislative and regulatory instruments in European HTA governance networks

Our research has brought to the fore how national legal frameworks regarding HTA, presented real challenges in some countries (e.g. Poland, Germany) to EU HTA cooperation which, so far, have not been overcome (6.4.2.3.). Collaborating on joint assessments was not just a matter of consensus on methodologies and work processes. The simple nature of HTA agencies, working independently or taking direct orders from ministries, would also play role herein as they were bound - or not - to follow specific procedures. The cooperation processes set in motion in EUnetHTA have not been able to always take these into account, making it for some agencies difficult or impossible to use the EUnetHTA outputs as these would not fulfil the legal requirements applicable in their home countries (6.4.2.3.).

Moreover, the nature of the assessments (i.e. REAs or Core-HTAs) would also present more or less difficulties in terms of legal constrains. As we have outlined in chapter 6, a core-HTA

comprises nine domains, some of which (e.g. cost-effectiveness) are considered by Member States as being part of the appraisal process in pricing and reimbursement decision-making processes. Besides the resistance of some Member States to delegate this part of the assessment processes outside the Member State, it also presented challenges linked to the need for contextualisation of assessments. Indeed, as outlined in chapter 6, uptake of EUnetHTA outputs was not only a matter of trust in the quality of the processes or willingness to adapt national procedures, the outcome of an HTA also needs to be inserted in a national context which, according to some network members, is unique (6.4.2.3.).

Focusing on relative effectiveness aspects of HTA has been the EUnetHTA strategy since the Joint Action 3 and has also laid at the core of the Commission proposal for an HTA Regulation. Indeed, the idea was to circumvent those assessment domains which would be more inclined to encounter legal restrains in domestic markets. It was thought that the clinical effectiveness domains would trigger less opposition by Member States and would ease the uptake thereof. It is interesting to notice that the biggest discussion issue of the Commission Regulation proposal, remained the mandatory uptake of clinical effectiveness assessments. Moreover, the regional cooperation initiatives (e.g. Beneluxa) have developed their strategy by cooperating on these domains which seemed to be problematic in EUnetHTA and the EU HTA Network (e.g. Cost-effectiveness). Hence, although legal constrains have constituted a real obstacle to the development of joint assessments, it cannot, in itself, explain the reason of the low uptake[201].

Being bound by a specific legislative framework seems however to play a role in the sense that cooperation in areas where such a framework was not present or still in the process of being established, cooperation and uptake of outputs seemed more successful. We can cite as examples hereof Horizon Scanning activities as well as the work done in cooperation with the EMA on Joint Scientific Advice/Early Dialogues. Even in the field of Additional Evidence Generation, which is linked to a highly regulated field, cooperation seems to encounter (so far) less resistance by agencies participating in the networks. This could be explained by the fact that these fields are in development in most countries and that the exchange of experience herein actually contributes in establishing the legal frameworks which will regulate these activities. Moreover, in the field of Joint Scientific Advice, the presence of a shadow of hierarchy would also play a role as explained above. Finally, the establishment of a synergy group could create favourable conditions for the development of collaborative outputs in this field and the adjustment of legal frameworks should this be required

---

201 One should however underscore at present, the regional cooperation initiatives are still too young to present solid data regarding uptake of their outputs.

By creating links with established regulatory agencies (e.g. EMA) new frameworks have been developed, acceptable to all players. It remains a question to see whether a similar approach can be found in the so-called late-dialogues or other additional evidence generation processes as, here too, one could wonder whether a common approach to new types of evidence (e.g. Real World Data), will be found. The path followed with the Early Dialogues seems promising but was successful as it regarded cooperation with an established European Agency having authority in market access regulation procedures and would create conditions for the shadow of hierarchy to apply. Should late-dialogues seek to develop a commonly adopted framework applicable to all Member States, similar obstacles as in REAs could be encountered.

The debates around the HTA Regulation proposal demonstrate the impact of the EU legal framework on the cooperation processes. Indeed, some members have expressed their opposition on the simple fact that the EU entered a field where competences laid exclusively by the Member States (6.4.3.3.). The arguments for the application of the subsidiarity principle have not convinced all actors as some would refute the Commission argument that twenty-five years of cooperation showed that Member States alone did not permit to reach the objectives on which all had agreed (i.e. sustainable network of HTA cooperation in Europe). Hence, the soft governance approach, based on voluntary cooperation, exchange of best practices, capacity-building and persuasion, has so far not allowed to shift the competences division in the HTA policy field as foreseen by the treaties.

Legislative and regulatory instruments have had a *negative impact on the process of collaboration* as the legal constrains observed by some HTA agencies in some countries prevented them from take into account the collaboration outputs in their domestic regulatory processes. However, in some areas (e.g. Early Dialogues) the *presence of shadow of hierarchy would have a positive impact on the process of collaboration* as well as on the production of collaboration outputs. The creation of the HTA Network synergy group could be cite as an example of an attempt to overcome disparities related to domestic legislative and regulatory frameworks.

7.2.2.3. Political instruments in European HTA governance networks

Governance networks are often established to respond to specific policy questions. Hence, interdependencies between networks and/or between state actors and networks often develop (3.7.5.). Use of political instruments by various actors concerned by a policy issue can be targeted to support or constrain network activities. When analysing effectiveness in terms of goal attainment in HTA cooperation networks, it is of interest to examine the role of political instruments herein. In this section we seek to identify which political instruments have been used in the governance of HTA cooperation initiatives. As there are many different

political instruments available, we seek here to highlight those that have been identified in our research and seek to determine in which way they have contributed or not to goal attainment.

Our research has brought to the fore several procedures and processes that could be quali- fied as political instruments. *Agenda alignment* has been one of the first instruments used by the European Commission. We have seen in chapter 4 how the Commission has identified HTA cooperation as a mean to enter the health systems and has decided to support the initiatives. It has integrated HTA cooperation in the health programmes facilitating herewith also funding opportunities for HTA cooperation (4.1.3.; 4.2.3.). Agenda alignment has also played a role in securing further support for HTA cooperation and *inter-institutional cooperation*. Integrating HTA cooperation in the various *expert committees* (e.g. HLRP, HLG, G10, Pharmaceutical Forum) has permitted on the one hand to streamline agenda-setting processes as well as to push HTA cooperation further on the EU political agenda (5.1.2.). This instrument has had positive outcomes for HTA cooperation as we have seen how HTA has been qualified as a political priority and how it made its entrance in Council Conclusions allowing for further Commission proposals in the field of HTA cooperation.

The integration of HTA cooperation in the flanking measures of the Cross-Border Health Care Directive (2011/24/EU) can be cited as an outcome of agenda alignment. This has not only allowed for the establishment of the EU HTA Network, but also led to positioning of the European Parliament on the issue of HTA. Agenda alignment has again been used to create synergies between EUnetHTA and the EU HTA Network (6.2.2.2.). The Regulation proposal on HTA cooperation is, to date, the last outcome of agenda setting and agenda alignment processes including herein all European and national decision-making actors. Hence, agenda alignment has played a very important role in pursuing the objectives set in the various HTA cooperation networks. It has been key in the reaching sub-objectives and setting new ones. It has had a positive effect on the capacity of the networks to approach the overarching goal through the establishment of a chain of goal attainment (3.4.1.).

Agenda alignment has however not been a stand-alone process but has been accompanied by the implementation of other political processes. Besides the use of *expert committees* mentioned above and which have been very important during the interlude period of HTA cooperation (2001-2006), *stakeholder involvement* can be mentioned as another political instrument used (6.3.1.2.2.). We have seen how the latter has been instilled mainly upon Commission initiatives and how this has permitted to integrate other perspectives on HTA cooperation. Stakeholder integration was conceived to extend support for HTA coopera- tion and allow for processes which would fit needs and expectations of the various actors involved in HTA. We have highlighted above how some stakeholder groups have been more

present in the cooperation processes than others, and how there was a low representation of national actors involved in regulatory and decision-making processes (6.3.1.2.2.; 6.3.3.). Hence, stakeholder involvement has clearly had an impact on goal attainment. It has permitted to involve more actors in the process and extend the support for the creation of a sustainable network on HTA cooperation.

Consultation processes implemented in particular during the run-up to the Regulation proposal can also be cited as political instrument. These processes included online surveys, targeted at a large public ranging from representatives of the HTA agencies, to academics, civil servants and citizens. Consultation processes also comprised face-to-face meetings with stakeholders and Commission representatives as well as informal exchanges during conferences and working meetings with various actors in the HTA arena (6.2.2.3.1.). As the consultation processes were aimed at structuring a future strategy for sustainable HTA cooperation, they clearly had an impact on the goal attainment process. The nature of the impact is however mixed. Indeed, by reaching out to various actors, the Commission sought to define the terms of the proposal in such a way it would correspond to needs and expectations of the actors in the field. However, the evaluation process of a consultation is never a neutral exercise. We have seen in chapter 6 how some actors have the impression their needs have not been fully understood and others believing their interests have not been respected (6.2.2.3.2.).

The reactions on the Regulation proposal highlight the mixed opinions in the field towards the Commission suggestions and underscore how some opinions expressed during the consultation process have not been taken into account. It seems that the Commission has underestimated the level of disagreement towards some elements in the Regulation (e.g. mandatory uptake of clinical effectiveness assessments) (6.4.3.3.). The impact on the process outcome hereof may be quite important as fierce opposition could halt the process. Hence, consultation processes have had a mixed impact on HTA cooperation. One the one hand it has allowed to contribute to develop discourse and goal consensus regarding HTA cooperation and has legitimized a Commission proposal. However, by not taking into account some of the opinions expressed, opposition towards the proposal may not be overcome and political will may not be united to adopt the proposal in its original form.

Institutional communication is another political instrument that has come to the fore in our research. We will focus here only on official communication actions to distinguish this from any other communication actions that could fall into social interaction and which have been discussed above. Since the early days of HTA cooperation, the Commission has used official communication means to support and secure further development of HTA cooperation. These communication actions would follow the classical means available to the Commission.

Inserting HTA cooperation in official documents such as the Health program, Council conclusions or European Parliament reports, and motions or other legal documents has legitimized action on behalf of the Commission.

Finally, the establishment of *partnerships* can also be cited as a political instrument used by the European Commission to support HTA cooperation. The Joint Actions made available for the cooperation have had a very significant impact on the developments. Indeed, moving from a project-format with the Commission as main funder to a Joint Action, still a project-format but with the Commission becoming a full partner, allowed for more political and financial support also on behalf of Member States (6.2.1.2; 6.3.1.2.). Moreover, partnership creation with the EMA in the field of Early Dialogues has certainly be facilitated by the Joint Actions and the fact that the Commission took part in it (6.4.2.2.). Hence, the political weight given to HTA cooperation through participation of the Commission has had a positive impact on the cooperation initiatives in reaching the sub-goals of developing joint methodologies, tools and joint assessments as well as in the creation of synergies with European regulatory processes (6.4.2).

Recourse to *political instruments* such as agenda alignment, stakeholder involvement, consultation processes, (institutional) communication and the establishment of partnerships has had a *positive impact on the process* of HTA collaboration. The establishment of a partnership between the European Commission and the HTA arena in the form of Joint Action has had a *positive impact on the production of outputs*. *Agenda alignment* and Institutional communication and partnerships have positively impacted the creation of *outcomes* such as the Regulation proposal in the field of HTA collaboration.

7.2.2.4. Financial instruments in European HTA governance networks

Establishing a sustainable network for HTA has been, since the beginning, the overarching goal of the cooperation initiatives. Sustainability of a network will also depend on the financial resources available, which, in governance networks, often depend on the political support. The main financial instrument used by the Commission to support HTA cooperation has been the EU (Public) Health Program. We have seen above how objectives of the EU (public) health programs and those of the HTA cooperation project have always been aligned so that the projects could qualify for funding (4.2.; 6.2.). EU funding however has been essential for the development of the cooperation processes and the production of outputs. It has been complemented by national funding sources, mainly consisting of the allocation of HTA agencies' personnel.

The biggest challenge in reaching the overarching goal of creating a sustainable HTA cooperation structure has been to secure funding sources, other than those coming from the

EU health programs. Different strategies and business models have been developed in the course of the projects but which, to date, have not been implemented (6.4.1.1.). Proposals for industry contributions have also been made. The Impact Assessment made by the European Commission underscored the costs of assessments made at a national level and the gain to pull assessments together. It also underscored how EU support would be withdrawn should uptake of joint assessment be insufficient (6.2.2.3.1.). However, the financial instruments cannot be dissociated from political decision-making and the establishment of a legal framework regarding HTA cooperation. As underscored in our research, as long as joint assessments are not mandatory or are not commonly used in the Member States, industry will hesitate to make financial contributions for a process in which it has no interests as this would be a duplication of time, efforts and financial investments (6.4.2.5.).

Governance	Establishment sustainable network (process)	Production outputs	Cooperation outcomes
Legislative & Regulatory instruments	-	- & +	-
Political instruments			
Agenda alignment	++		++
Stakeholder involvement	+/-		
Consultation processes	+ & -		
(Institutional) communication	++		+
Partnerships	+++	+	++
Financial instruments	++ & -	+++	+/-

Table 7.11. Legislative, political and financial instruments in European HTA cooperation networks

Hence, on the one hand, due to the *financial instruments* available through the EU Health Program, the *process* of HTA cooperation has been able to develop and has led to *the production of concrete outputs*. At the other hand, due to this financial support available, no real incentive allowed for the search of independent sustainable business models. In this sense the financial instruments have negatively impacted the cooperation process. As long as cooperation could continue on a voluntary basis, uptake would continue to depend on national decision-making procedures, preventing sometimes uptake of joint work (see above). With a low uptake, incentives for the industry to financially contribute to joint assessments would be absent. Hence, whilst financial instruments are crucial to the goal attainment set by all HTA cooperation networks, their efficacy will remain intertwined with political support and the establishment of a legal framework. Without the latter, HTA cooperation will likely follow the same course as most projects funded by public authorities which often disappear after public funding stops (3.5.2.).

7.2.3. Management in European HTA governance networks

In chapter 3 we have outlined how there is a correlation between effectiveness of networks and management. However, as no consensus exists in the literature about what effective management methods would be, we will focus our analysis only on management competences and management styles. The aim is to examine how these avec evolved in the different HTA networks and how they have affected effectiveness of these networks in terms of goal attainment.

7.2.3.1. Management competences in European HTA governance networks

Management competences are diverse and are often associated to skills of network managers such as facilitation, coordination and mediation skills to guide interaction processes among actors in the network. We have seen in our research that network managers have played an important role in the development of HTA cooperation and how some of these managers or project leaders could be qualified as 'policy entrepreneurs'. Management of HTA cooperation by *policy entrepreneurs* has been identified in both the HTA arena as in the EU health policy arena, from the first HTA cooperation activities till the EUnetHTA Joint Action 2 (4.1.3.; 4.6.; 5.4.; 6.2.1.1.).

The research has underscored the importance of establishing a link between policy makers and networks to create a place for HTA in national and European decision-making processes (e.g. 6.2.1.1). The latter results from the very nature of HTA often considered as a bridge between research and decision-making (1.1). Hence, establishing and leading an HTA network required a specific skill-set comprising, besides management skills, also a technical and political comprehension of HTA itself. As knowledge of, and experience in, HTA laid primarily with 'HTA doers', the cooperation initiatives naturally developed into *networks of scientists managed by scientists* (6.4.1.1.). This regarded both the general management positions as well as the management of the work packages (i.e. Lead-Partners being representatives of HTA agencies). Even though the EUnetHTA secretariat till the Joint Action 2 did count among its project managers, people trained in project management, these still came from an HTA background (6.3.1.2.). This would change in Joint Action 3, were an external project manager would be appointed having no previous links to HTA (6.3.1.2.1).

Policy entrepreneurs have played an important role by allowing HTA cooperation to enter the national and EU agenda setting processes. We have seen above how this has secured political and financial support. Management of HTA cooperation networks required thus to have a solid knowledge of HTA itself and abilities to translate this into policy objectives. In the first development phases of the HTA networks, management by HTA scientists has been effective in terms of attaining sub-objectives (e.g. development of tools, methodologies, network coordination, project implementation, recognition of necessity of cooperation

amongst national policymakers). However, it is questionable whether this approach has been effective enough in the later stages of the project (e.g. low implementation of REA pilot projects, long transition period of pilot projects to routinisation, low uptake of joint work, no consistent data collection regarding project implementation, no establishment of a sustainable network) (6.4.). Although reasons for lack of effectiveness in attaining sub-objectives have various explanations and depend on different factors, management does seem to have played a role in addressing those factors.

Ensuring the transition from a project-based approach into lasting sustainable network has been the biggest challenge and main goal of all network initiatives (6.4.1.1.). We have underscored in the section above that confusion has long existed whether EUnetHTA would become the sustainable HTA network mentioned in the Cross-Border Health Care Directive. The establishment of the EU HTA Network has further increased uncertainty as the new structure itself did not offer any sustainability but needed to propose a legislative basis for such a sustainable network. This had an impact on the management of the existing HTA networks. In the Joint Action 1, the idea prevailed that EUnetHTA would become the sustainable network. Coordination of EUnetHTA and the development of a new business model were therefore dissociated in the JA1. In all other EUnetHTA projects and initiatives, both sub-objectives (i.e. coordination of EUnetHTA and establishment of a sustainable (new) network) were managed within the same work package (6.4.1.1.). The uncertainty that existed during the Joint Action 2 has certainly not favoured effective goal attainment as to establishing a sustainable network. During Joint Action 3, the status of EUnetHTA had been clarified as it became the scientific and technical arm of the EU HTA Network, limiting its contribution regarding the establishment of a sustainable HTA network to the formulation of ideas and recommendations. (6.4.1.1).

Management of the EU HTA Network has been difficult to assess in the research. One can only underscore that the secretariat was coordinated by the Commission. Management of the network activities could be resumed in the preparation of a new legislative proposal of the Commission and was thus part of Commission activities (6.2.2.3). A concrete outcome hereof has been the official Commission proposal of a Regulation on HTA cooperation (6.2.2.3.2.). Following its publication, continuous efforts on behalf of Commission representatives to explain the proposal to different stakeholders involved have accompanied the process throughout the adoption phase. Activities of the EU HTA Network since the Commission proposal also mainly regarded only stakeholder meetings. Hence, since its establishment, management processes of the EU HTA Network seem to have been led by Commission institutional processes and Commission representatives (6.4.3.).

This section underscores how *management competences* have had an impact on the goal attainment of HTA networks. *A positive impact* both on the *process of HTA cooperation as well as in terms of outcomes* of this process, has been observed in the first networks benefiting from management skills implemented by *policy-entrepreneurs,* securing political and financial support by EU and domestic policy-makers. *Mixed results* have been observed in the later development stages of EUnetHTA where *outputs have been disappointing* and where management has suffered from the simultaneous pursuit of a policy goal and technical and scientific sub-goals. The scientific profile of the managers of the early cooperation projects seemed to have favoured goal attainment as profound understanding of both HTA and policy-processes were necessary. The expansion of the network during the last Joint Actions required however different management skills differentiating technical and scientific project implementation of policy objectives. The establishment of the EU HTA Network seems to have tried to establish this differentiation by separating policy orientation from technical and scientific HTA activities. It remains questionable whether this new structure has been successful as the future of EUnetHTA and the EU HTA Network will depend on the outcome of the adoption process of the HTA Regulation proposal still under debate at the time of writing.

7.2.3.2. Management styles in European HTA governance networks: project management versus process management

Management can affect goal attainment which is the reason why this aspect has been integrated into the research framework outlined in chapter 3. However, a systematic analysis of the management of HTA networks would require different research instruments than those we have used. As this has not been the prime target of our research, we will limit ourselves in this section to underscore some aspects which have born the potential of playing a role in goal effectiveness. The extent of their impact however will not be dealt with in the present research and remains a subject for further examination.

In the literature, no consensus exists whether a particular management style would lead to more or less effectiveness of a governance network. Often *project management* has been compared to *process management*, each referring to different goals and attributes (3.5.3.). One of the main differences between both is that projects are specific, time-limited, and target a particular goal. Implementation takes place through different phases whereby the project is initiated, defined, planned, executed and closed. *Process management* often refers to an on-going process whereby people can operate according to standard operational procedures defining the manner in which a goal can be attained, whereas *project management* defines the steps that need to be taken to achieve the goal.

Our research has allowed to identify the presence of both project management and process management in the HTA cooperation networks. Establishing a sustainable HTA cooperation refers to a *process* which should be on-going, and management hereof would refer to *process management*. The setup of an HTA project, limited in time and reaching specific goals in terms of output, was conceived to allow for the process of cooperation to be established and maintained throughout the years. *Project management* would thus characterise these time-limited projects. In the early cooperation initiatives, as well as in EUnetHTA, no strict differentiation has however been made between the *process* of cooperation and the *projects* to establish this cooperation. These networks were often considered by their project managers and other members, as the framework in which the cooperation process would take place (6.4.1.1.). Hence, although the cooperation *projects* implemented aimed at establishing a cooperation *process,* both objectives have been mixed in the implementation phase, which has contributed to negatively impact goal attainment of HTA cooperation as defined in the various HTA networks.

With the establishment of the EU HTA Network it seems that a differentiation between both has been made to some extent. By reframing EUnetHTA as a project limited in time and pursuing objectives which should serve the establishment of a sustainable cooperation framework, the Commission distinguished process management from project management. The EU HTA Network would operate on the basis of process management in the quest to establish a sustainable HTA cooperation framework. EUnetHTA would become a project herein, operating via project management. The legal framework proposed by the Commission would allow for cooperation *process* to develop.

Our research has brought to the fore that network members often perceived the project-based framework of Joint Actions to be an obstacle in establishing a sustainable framework. Indeed, the HTA cooperation initiatives since the beginning have taken place in the form of a project, limited in time, finances and personnel. Administrative procedures (submission, reporting and fundraising), indispensable in the implementation of projects are however time-consuming and reduce effective time of project implementation. Hence the time and budget limited framework could not match the objective of creating a sustainable cooperation framework. Hence, by searching to transform a project into a process, the chances of being effective in goal attainment were slim. By creating the EU HTA Network, the Commission disentangled both and would subordinate the project to the process goals.

The HTA Regulation proposal sought to establish a legal framework in which a cooperation *process* could be developed. Such a framework could create visibility for the organisation of time-limited projects in terms of project objectives, administrative support and financing. As such, cooperation projects could take place and would refer to one of the four pillars of

the proposal (Joint Clinical Assessments, Joint Scientific Advice, Identification of emerging health technologies, Voluntary cooperation). This proposal has, as we have outlined above, created new obstacles but relating to different issues, primarily the question of the division of competences between the EU and the Member States (e.g. mandatory uptake of Joint Clinical Assessment results).

A legal framework at an EU-level, would also have the potential to serve as a support for other (regional) cooperation initiatives. Framing a cooperation *process* implicitly creates room for development. If a full mandatory approach would not be acceptable to key-actors in the process, other (intermediate) solutions could be envisaged without compromising the over-arching goal. However, in the initial debates of the HTA Regulation proposal, the discussions seemed to be framed along the traditional community *versus* intergovernmental approaches. Indeed, the Commission had adopted in this case a community approach at a time where this comprised risk. As we will outline below, external events, such as the rise of Euroscepticism could affect EU decision making in the field of HTA. Moreover, in terms of process and project management, one could consider the adoption of the Regulation proposal as a project in itself. This would however contain the risk to lose sight of the *process* it should frame. A process allows for more creativity and room of manoeuvre in the setup of sub-goals than a project which is bounded by time and resources. At a time where the European integration process is severely being challenged (e.g. Brexit, rise of Eurosceptic parties in national governments), creativity on behalf of the Commission could allow for innovative problem-solving approaches to arise.

Management	Establishment sustainable network (process)	Production outputs	Cooperation outcomes
Competencies			
Policy entrepreneurs	+		+
Management of scientists by scientists	-	++ & -	-
Styles			
Process management & project management	+ & -	++ & -	-

Table 7.12. Management in European HTA Networks

Project management as used in the early cooperation initiatives in EUnetHTA has on the hand have *positive impact on the collaboration process* as it has allowed for the goal setting process to take place. Moreover, the project-based approach also allowed for the *production of some collaboration outputs* such as common tools, methodologies and pilot joint assessments. On the other hand, the confusion between the project aims and the process aim has led to a *mixed approach of management styles* which *has negatively impacted the cooperation process and outcomes.*

7.2.4.   External events affecting European HTA governance networks

Examine governance networks requires to take into account the broader environment since external events may require the network to adapt. External events can have diverse origins and can be of an economic, political, ideological or institutional nature. In this section we will focus our examination on some events which have come to the fore in our research and which have had an impact on one of the networks we have analysed. The events listed in this section do not seek to be exhaustive, as other events not identified in our research may have occurred.

HTA cooperation has developed against a background of the European integration process. *Ideological approaches* related to the latter seem to have impacted HTA cooperation to a certain extent. The initial project proposal of what would later become the EUR-ASSESS project, had been submitted in 1992, the same year of the signature of the Maastricht treaty which founded the European Union (2.1.1.). Under impetus of the Delors Commission, the European integration process gained new interest on behalf of Member States and citizens. European cooperation projects where often welcomed both in the domestic policy field as, of course, on the EU level. EUR-ASSESS has certainly benefited from this pro-European atmosphere but still had to overcome the difficulty of finding funding for a project in a policy field that hardly existed at the EU and domestic level. Moreover, the start of the EUR-ASSESS project corresponded to the initiation of a European public health policy (4.1.2.). We have seen in chapter 4, how the first proposal for European cooperation in HTA matched Commission intentions to enter to health systems of the Member States (4.1.2.). A window of opportunity was thus created which allowed the first projects to be implemented.

In our research we have highlighted several *legal developments* which have laid down the basis for HTA cooperation to develop. First, we can cite here the Maastricht Treaty (1992) in which for the first time an article on public health had been included (2.1.1.). This article gave way for an official European public health policy to be developed. Based on the latter, a health program has been adopted which has also become the main funding source for HTA cooperation (4.2.2.). Second, the Lisbon Treaty (2007) has had a particular influence on HTA cooperation as it legitimized European cooperation projects in the field of health care based on soft policy means. We have seen, how this has given the possibility to the European Commission to propose a Directive on Cross-Border Health Care in which an article on HTA cooperation has been included. (5.1.3.). Based on this article, the EU HTA Network could be established (5.1.3.3.). Finally, the 2018 Commission proposal for a Regulation on HTA cooperation could, if adopted, be a milestone in the history of HTA cooperation framing the cooperation process in a sustainable manner. To date, this proposal is still in its adoption process and results needs to be awaited.

Several *political developments* have also had an impact on HTA cooperation in Europe. Following the adoption of the Maastricht treaty, a specific Directorate for health has been established moving health policy from a unit level in DG enterprise to DG Sanco. This allowed for the development of an official EU public health policy. HTA has been identified by the Commission representatives as being important for EU public health and the sustainability of the health systems. Similarly, in the aftermath of the adoption of the Maastricht treaty, the EMA has been established (5.2.2.) and becoming the pharmaceutical gateway to the European Market. We have seen how the EMA has played an important role in creating synergies between the HTA arena and the European regulatory arena by means of Joint Scientific Advice (6.4.2.2.).

The EU governance turn in the early 2000s has created favourable conditions for the establishment of expert networks such as the High Level Group on health services and medical care (5.1.2.2.), the G10 process on medicines (5.3.3.1.) and the Pharmaceutical Forum (5.3.3.2.) which have on the one hand allowed for HTA to enter on the EU agenda and qualify HTA as a political priority for the EU. HTA as such has been included in official Council declarations securing herewith the inclusion of HTA in the EU Health programme (pre-requisite for obtaining EU funding). Besides the Council, the European Parliament also supported HTA cooperation by integrating it in its search to improve access to medicines (6.4.3.2.). Moreover, this institutional player also incorporated HTA in its motions and resolutions whereby it enhanced the political weight of HTA in the European policy-making processes. The implication of the European Parliament in the adoption process of the HTA Regulation proposal has also permitted the introduction of new amendments and the adoption of the text in the EP's first reading (6.4.3.2.).

External events	Establishment sustainable network (process)	Production outputs	Cooperation outcomes
Ideological approaches	++		
Legal developments	++		
Political developments	+++		
Economic developments	++		

Table 7.13. External events in European HTA Networks

Finally, particular *economic developments* also have had an impact on HTA cooperation in Europe. In chapter 1 we have outlined how HTA has partly developed as a consequence of rising health care costs. This rationale became even more valid the more the cooperation process developed. The financial crisis of 2007 has once more underscored the need to contain health care costs and as has enhanced the perceived need for European HTA cooperation. This period coincides with the establishment of the first Joint Actions which,

as we have seen, included the Commission as full partner and received formal support on behalf of the Member States. Finally, high prices of pharmaceuticals in specific disease areas also triggered reaction on behalf of domestic regulatory and reimbursement institutions and could be considered as one of the triggers for the regional cooperation initiatives to develop and to include in their cooperation agreements costs-effectiveness assessments, price negotiations and Horizon Scanning (6.4.3.4.). Whilst working on the basis of EUnetHTA tools, these cooperation initiatives could be considered by some Member States as an alternative to EUnetHTA and/or the future European legal framework. These regional networks could therefore compromise the collective Community approach aimed at in the HTA Regulation proposal as it offers EU Member States a flexible framework where the national competences will not be endangered. In this sense it has positively impacted HTA cooperation as such but negatively impacted the networks' developments. It is too early to make projections on the potential of these regional initiatives in establishing a sustainable HTA cooperation framework.

7.2.5. Conclusion effectiveness of European HTA governance networks

In this section on effectiveness of HTA governance networks we have examined HTA cooperation by confronting it to four factors potentially impacting goal attainment: social interaction, governance instruments, management, and external events. We have underscored which role each factor has played in the process of establishing a sustainable network of HTA cooperation as well as in the production of collaboration outputs and outcomes.

The examination of social interaction has brought to the fore how this process has taken place mainly within the HTA arena and to a lesser extent in the EU Commission. Social interaction has been observed on a much lower level of intensity within some stakeholder groups and reached predominantly members of umbrella organisations. Social interaction between the HTA arena and representatives of ministries has been identified in this research only in some cases and stood in relation with the level of management representing the HTA arena in the HTA cooperation networks.

The level of social interaction within the HTA arena and between the HTA arena and the EU Commission has had a positive impact on the effectiveness of the networks in establishing common tools, methodologies and (pilot) joint assessments. The low level of social interaction between the HTA arena and ministerial representatives has negatively impacted effectiveness in establishing a sustainable HTA cooperation framework. Moreover, the latter has contributed to unexpected outcomes such as the development of (intergovernmental) regional HTA cooperation initiatives.

The impact of governance instruments on the effectiveness of the European cooperation networks has been examined by focusing on (procedural and substantive) policy instruments, legislative and regulatory instruments, financial instruments and political instruments. The examination has brought to the fore how procedural policy instruments have been effective in advancing the process of establishing a sustainable network of HTA cooperation through internal communication and evaluation processes and to a certain extent through internal organisational processes. However, the implementation of the latter has also negatively contributed to the effectiveness of the networks as no clear distinction had been made between project goals of the network and the goal of creating a sustainable collaborative framework.

Substantive policy instruments have been effective in creating collaborative outputs such as common tools, methodologies and to a certain extent (pilot) joint assessments. However, use of these outputs in domestic decision-making processes remained very limited. Domestic legislative and regulatory frameworks have mostly had a negative impact on the effectiveness of European HTA networks as adjustments to new commonly developed tools often appeared challenging. On the other hand, these instruments positively impacted the effectiveness of the networks in creating synergies between the EU regulatory framework and the HTA arena. Presence of a shadow of hierarchy furthermore contributed to the effectiveness of reaching the goals set in this area.

Political instruments identified in the research (i.e. agenda alignment, stakeholder involvement, consultation processes, institutional communication and partnerships) positively impacted the effectiveness of the HTA cooperation networks in the process of establishing a sustainable framework for European cooperation. With the exception of the partnership established between the European Commission and the HTA networks, these instruments had little impact on the production of cooperation outputs. However some of these instruments such as agenda alignment, institutional communication and consultation processes positively impacted effectiveness of HTA networks by contributing to outcomes such as the insertion of HTA cooperation objectives in the public health programme, the insertion of HTA cooperation in the Cross-Border Health Care Directive and the Commission Regulation proposal for HTA cooperation.

The main financial instrument identified has been the public health program, funding the essential part of the networks' projects. This instrument has had both a positive and negative impact on effectiveness of the networks. On the one hand, financial resources were essential to start and pursue the cooperation initiatives producing joint work. On the other hand, by remaining available, no real incentives would be created to seek for alternative sustainable funding sources.

The presence of policy entrepreneurs in the early cooperation initiatives and in the EUnetHTA Project, positively impacted effectiveness in creating goal consensus and translating the objectives in concrete project-based objectives. However, by developing into 'networks of scientists managed by scientists' the goal attainment process had been negatively impacted. Moreover, the confusion as regards the status of the networks (becoming or not the – to be created – sustainable network), led to a mixed management approach where no clear distinction would be made between process and project management.

Finally, our analysis has brought to the fore a few external events which have positively impacted the effectiveness of the networks in terms of goal attainment. These would related to ideological approaches as well as legal and political developments which have contributed pursuing the process of establishing a sustainable network for HTA cooperation in Europe. Some economic developments such as the rising health care costs related innovative health technology developments as well as financial crisis have had a positive impact on the development of the HTA cooperation networks.

7.3.   METAGOVERNANCE AND EUROPEAN HTA COOPERATION NETWORKS

The European governance approach adopted with the White Paper on European governance (2001) comprised recourse to networking as governance instrument. The interest of networking was recognised by the impact it could have on addressing complex policy problems comprising multiple actors on multiple policy levels. The relationship between Europe and networks is however often asymmetrical in which the presence of the shadow of hierarchy may play a role. Networks, however, can also been used by private actors to seek access and influence the institutional level (see chapter 3). According to the White Paper on governance, cooperating with networks through the use of soft governance, could "enable them to contribute to decision-shaping and policy execution" (European Commission 2001b). The EU could have recourse to networks in various ways ranging from simple (financial) support to tighter forms of relationships aiming to develop specific policy objectives. The manner whereby the European Commission uses governance networks to implement specific policy objectives can relate to metagovernance.

The data outlined above in the sections on the typology of governance networks and effectiveness of network governance also informs about the role of the European Commission in the cooperation processes. In this section we will therefore only highlight to what extent the implication of the European Commission can be regarded as metagovernance. In section 3.2. on metagovernance we have underscored that no standard form of metagovernance

exist. In the academic literature different perspectives are indeed presented as to the exact role of a metagovernor.

The role HTA cooperation could play in the development of a European public health policy had been identified in an early stage by representatives of the European Commission. As HTA was considered a mean to enter the domestic health system, salience for the matter has grown (4.1.2.) As such, serving European public health policy, support to HTA cooperation would be secured essentially by financial means (grants via the EU public health programme). Moreover, support-lending policies has further been structured through agenda-alignment and associated actions (e.g. inserting HTA objectives in the EU public health programme).

From 2001 to 2006, HTA cooperation has been promoted and supported essentially upon initiative of the European Commission through its high-level expert networks. These networks have permitted HTA to enter on the EU decision-making agenda. First, by inserting HTA as a topic in the High Level Process of Reflection on Patient Mobility and Healthcare. Then, proposing it as a priority topic of the High Level Group on health services and medical care, securing herewith the launch of the EUnetHTA project (5.1.2.). Moreover, by playing a crucial role in the content development of the European Cross-Border Health Care Directive, the HLG has indirectly also contributed to the insertion of HTA cooperation in this legislative framework. As such, the establishment of the EU HTA Network can be seen as an additional outcome of this expert network.

Similarly, as underscored by Commission representatives, a new health article, initially conceived for the Constitutional Treaty (2004) and finally adopted in the Lisbon Treaty (2007) was entirely drafted according to a soft governance approach allowing the European Commission to lend support and coordinate cooperation initiatives such as HTA (5.2.). Developments in the field of the pharmaceutical sector have also played an important role in European HTA cooperation. Indeed, the choice of EUnetHTA as dedicated network to implement joint REAs resulted from a European Commission initiative, launched in the G10 process on medicines and then further developed in the Pharmaceutical Forum. We have outlined above how REA has become central in HTA cooperation. Renamed as Clinical Effectiveness Assessment, it has furthermore been integrated as one of the four pillars of the Commission proposal for a Regulation on HTA cooperation.

From financial support and policy alignment processes, the European Commission has stepped up its involvement in HTA cooperation by proposing to EUnetHTA the Joint Action cooperation format in which the Commission became an active partner. Its influence on agenda setting, financial support and informal decision-making processes has become of increasing importance and was determinant for the cooperation process to proceed. The

establishment of the EU HTA Network has even more changed the role of the European Commission in HTA cooperation. Although Member States are represented in this network, it is the Commission who presides the meetings of this policy-orientated network and who sets the agenda. We have outlined in chapter 6 how the activities of this network have been mainly driven towards the publication of the proposal for a Regulation on HTA Cooperation. The latter has been prepared through the implementations of various studies, surveys, consultation procedures, conferences and Impact Assessment studies, all of them financed by the European Commission who also provided administrative support for the network.

When referring to descriptions of metagovernance as published in the academic literature, the Commission involvement shows many traits with what has been qualified as forms of metagovernance. As such, it has had a "major point of leverage to shape what happens via networks: public policy" (O' Tools 2007:223). Scholars also have pointed how international institutions can influence networks through informal instruments and affect the position of network actors. Moreover, the role of international institutions regarding information diffusion could potentially affect motivations and commitments of network members. The latter could further impact the functioning and output production of the network (3.2.). In the sections above we have seen how this could be applied to the role of the European Commission in the HTA cooperation networks. Similarly, the establishment of connections between networks and key actors involved in a particular policy process, as underscored in the literature, has also been observed in HTA cooperation. The latter has not only played a role in the high level expert groups, the establishment of synergies between the EMA and EUnetHTA can also be cited as an example hereof.

The influence of a metagovernor can also be expressed by persuading network actors of the greater value of network cooperation compared to the pursuit of self-interested calculations. Through build-up of trust, commitment and good faith, participants perceptions can shift in favour of the establishment of stable and durable network solutions (3.2.). In the sections above we have highlighted how social interaction and the establishment of relations of trust have been quite high with the European Commission. Strong adhesion to the Commission Regulation proposal has also been identified among individual EUnetHTA members and did not always reflect their home-organisations for reasons explained above.

Hence, the manner in which the Commission has participated in supporting and steering the cooperation efforts whereby HTA cooperation has turned into a European policy field, shared all characteristics with metagovernance. As underscored by Triantafilou (2007:1950), although a metagovernor can influence the course of action of a network as well as its governance approaches, it does not have the ability to control the outcomes of political processes of networks. In the case of HTA cooperation, the current debate on the adoption

of the Regulation proposal does illustrate this point. The production of joint assessments, considered for a long time as insufficient by the Commission, is another example of the limited influence of the latter over the network outputs. It does furthermore display how the Commission has used a soft governance approach to prepare hard legislative proposals. Finally, the data gathered on HTA cooperation within an EU framework confirms how the European Commission, in the case of HTA cooperation has governed *in* networks rather than *by* networks (3.1.2.). Although the networks remained independent, the presence of a shadow of hierarchy has, at times, influenced the positioning of network actors.

7.4. CONCLUSION

In this chapter we have analysed the data outlined in part B based on the research framework developed in chapter 3. This research framework has allowed detailed network analysis and has been established upon three central concepts: governance networks, network governance and metagovernance. Networks have been considered as a forum in which soft governance instruments can be implemented. The data gathered in part B sets out the development of several HTA cooperation networks which have developed in Europe since the early 1990s. In this chapter we have concluded that these distinct networks could be qualified as governance networks and corresponded to the general characteristics of governance networks outlined in chapter 3 (see also table 3.1.). As such, all three networks demonstrate a rather stable pattern of relationships of social actors clustering around the need for more (European) cooperation in the field of HTA. Actors remained autonomous but displayed inter-relationships among them. Although equal in membership status and engaging in horizontal governance relationships, members of the networks were not all equal in terms of authority and weight in decision-making processes. Negotiations took place based on deliberation, learning processes and the development of a set of common understanding. The networks activities had created a regulative normative, cognitive and imaginary framework in which the interactions took place. Self-regulation was the rule within the boundaries of the project frameworks and within various degrees of influence of external actors (e.g. European Commission). The actors aggregated different resources important for the cooperation initiatives to be pursued. These initiatives were considered contributing to public purpose.

The different HTA *governance networks* which have been established since the first European HTA collaborative project did show disparities as regards their typology in terms of incentives, membership, resources and governance practices. Although all networks aimed at contributing to a public purpose, the formation of the three main networks examined, showed however dissimilarities as to the contextual incentives, strategic calculations and support and constrain perceived. Incentives to join the networks were related to capacity-building, reduc-

tion of assessment duplication and increased impact of HTA on national decision-making processes. Voluntary engagement and its related cheap exit strategy favoured participation as members could decide upon their investment level or cease further cooperation at any time. The support of the European Commission, HTA agencies and the implicit support of domestic policy-makers further positively affected the incentives to participate in the collaboration initiatives.

Whilst membership was mostly composed of HTA bodies in all networks, the degree of homogeneity and the networks' openness to other members has evolved throughout their development processes. The degree of interaction between the networks and home-organisations varied among members and pointed to a correlation between the size of the country of origin and the HTA body management level represented in the network. The smaller the country and the higher the agency management level represented in the networks, the stronger the relationship and interaction between the networks and the home-organisations. Stakeholder participation was absent in the first initiatives and after that fluctuated in terms of intensity of collaboration. Moreover, participation was not equal among the different stakeholder groups. No active participation of representatives of public authorities has been recorded in our research.

Financial resources were provided for by means of EU (public) health programme grants as well as by in-kind contributions of HTA agencies of domestic public authorities. The level of contribution and financial resources available, highly differed among the networks and in the different development stages (e.g. Joint Actions) of the same network. Although the financial resources available facilitated the cooperation initiatives, the nature of these resources also constituted a barrier to create a financial sustainability of the networks and of the HTA cooperation process. Recurrent grant support did not produce a real incentive to search for independent sustainable means to finance the cooperation initiatives. Moreover, the project grants reinforced the project-based approach, creating insecurity about long-term continuation of the cooperation process and requiring additional time-consuming project-based administrative activities (grant application, evaluations and reports). At times, the projects became considered as the cooperation process itself, leading to the adoption of a mixed management approach.

Other forms of resources have been of importance to develop the network activities and did vary amongst the networks. As such, the level of expertise has been important for capacity-building and learning processes to develop. The level of expertise being interdepended with the capacity-building processes, contribution of human resources in terms of expertise thus diverged across the various networks. Physical and human resources (e.g. premises and

administrative support) provided for by national authorities or agencies have further played an essential role enabling European HTA cooperation to develop.

The networks' governance modes all corresponded to soft governance steering mechanisms based on voluntary participation. However, each new cooperation network has functioned according to distinct governance modes which ranged from participant-governed networks, a lead-organisation governance structure to a configuration sharing many characteristics of a network-administrative organisation. The voluntary aspect of participation has ensured HTA bodies and public authorities to remain competent in national decision-making processes regarding the use - or not – of outputs produced by the networks. The horizontal self-steering governance approach displayed however its limitation as to the degree of convergence sought. Indeed, the more centralised the power-distribution, the more convergence of tools, methodologies and practices achieved.

The role of the European Commission as metagovernor further confirmed the limitations of a governance structure entirely based on horizonal governance steering modes. The increased participation of the Commission in structuring the strategic objectives of the networks has been largely accepted by the network members. However, resistance has been expressed to the HTA Regulation proposal which sought to step outside soft governance modes by framing part of HTA cooperation into hard law and (corresponding) top-down decision-making processes. The establishment of regional cooperation initiatives (e.g. Beneluxa, Visegrad+2) although cooperating in sensitive domains of Member State competences seem to indicate salience for an intergovernmental form of cooperation (rather than an EU community cooperation format) where commitment is decided upon by the Member States, and opting-out of the process always possible.

Regarding *network governance* examined by focusing on effectiveness of the governance of European HTA cooperation networks - considered in the light of goal attainment - the following conclusions can be drawn. Factors, such as, social interaction, governance instruments, management and external events have had an impact on the effectiveness of European HTA cooperation in reaching the objectives set. This impact has been observed in terms of process, output and outcomes of the cooperation initiatives.

Social interaction has taken place mainly within the HTA arena and, on a lower intensity level, with stakeholders and public authority representatives. It had a positive impact on the effectiveness of the networks in terms of establishing common tools, methodologies and (pilot) joint assessments. The effect of social interaction has been observed in the development of learning processes, mainly on the HTA agency level. Moreover, through the exchange of experiences and capacity-building exercises, a set of common values and understanding has

been developed, contributing to goal consensus and the build-up of trust. Social interaction has played a role in the evolution of the networks from an epistemic community essentially based on the collaboration of peers to networks interconnected to and co-steered by European institutions. The diffusion of a set of common values and understanding regarding HTA cooperation proceeded from the HTA arena to Commission representatives and has been further diffused to high level expert networks. Consequently, political support to the cooperation process and infusion of new approaches (e.g. REAs) within the networks has occurred.

Lack of social interaction between social actors has however also been observed. The relatively closed structure of the networks prevented some key-players (e.g. policy-makers, stakeholders) to take actively part in the networks. As such, social interaction could not – or only in a limited manner - take place on these levels. When present, stakeholder interaction in the network mostly took place on a vertical level (network-stakeholder group). Horizontal stakeholder relationships across the various stakeholder groups (patients, payers, health care providers and industry) has not been observed on significant levels.

Moreover, the build-up of trust and goal consensus amongst domestic policy-makers has not been observed in our research. Similarly, no learning processes, nor a shared set of common values and understanding have been established with these social actors. The latter has had a negative impact on the process of creating a sustainable HTA cooperation framework in Europe and securing support for an HTA Regulation proposal in this area. Moreover, it has contributed to the development of unexpected outcomes such as the establishment of regional (intergovernmental) cooperation initiatives.

Governance instruments also have had an impact on the effectiveness of HTA cooperation networks both in a positive as in a negative way. As such, procedural and substantive policy instruments have impacted the process of cooperation through internal communication, evaluation and capacity-building processes allowing for single and double loop learning processes. This has led on several occasions at restructuring the cooperation efforts into new entities or cooperation approaches and giving a new impetus to the cooperation process as such (e.g. creation of EUnetHTA and the EU HTA Network; moving from projects to Joint Actions). Substantive policy instruments have played a positive role in the cooperation process as concrete outputs have been produced in terms of tools, guidelines, and common assessments. However, some substantive policy instruments (e.g. Horizon Scanning) did not respond to domestic policy needs or were not produced in a timely manner. This contributed to disappointments in the cooperation process, mistrust in the quality of the outputs and the creation of separate regional (intergovernmental) cooperation initiatives seeking to alleviate the problems. As in social interaction, governance instruments have not (enough) included

active participation of stakeholders and national policy-makers. This has had an impact on the uptake of joint work.

Uptake of the collectively developed tools remained disappointing, creating doubts upon the feasibility and thus legitimacy of the overall goal of establishing a sustainable framework for HTA cooperation. As regards political instruments, positive and negative impacts on the HTA cooperation process in Europe have been found. Agenda alignment, inter-institutional communication and partnership development mostly having positively contributed to the cooperation process and the production of concrete cooperation outputs in terms of tools, methodologies and joint work. These instruments also paved the way for the establishment of regulatory frameworks at an EU level, offering support to HTA cooperation in Europe. Negative impacts of political instruments have been observed particularly in areas of domestic regulatory frameworks, creating tensions and legal uncertainty regarding uptake of joint work in some Member States. Financial instruments also had both positive and negative impacts. Repeated grant renewal through the EU Public health programme ensured continuity of the cooperation initiatives but did not generate networks' need to establish an alternative sustainable financial mechanism for a European HTA cooperation framework.

In terms of management, positive impacts on the cooperation process has been found in the presence of policy-entrepreneurs and in the project leaders' capacity to well understand the complexity of HTA and contribute to the production of concrete outputs. However, by having a network of scientists managed by scientists, no active participation of other key-actors in HTA has taken place, preventing the network from integrating in their approach insights of external actors, such as policy-makers. Moreover, the mixed management approach between process and project management has also negatively impacted the goal attainment process of establishing a sustainable HTA cooperation framework. Uncertainty about the networks' vocation to become or not the future sustainable HTA cooperation framework has led, at times, to inconsistency in the management approach.

Finally, various (ideological, legal and economic) external events have also been identified as having impacted the effectiveness of HTA cooperation in reaching the goals set. Treaties such as the Maastricht Treaty and the Lisbon Treaty have had a positive impact on the cooperation processes. The Cross-Border Health Care Directive has paved the way for the establishment of EU HTA Network. Similarly, economic and financial crisis and rising health care cost further triggered the need for cooperation.

As regards the role of the European Commission in the HTA cooperation process in Europe, the following conclusions can be drawn. Active supporter of the cooperation efforts since the first European HTA network, its participation in the cooperation process has gradually

evolved. As a full-fledged partner of the Joint Actions, it has played an important role in structuring HTA cooperation in Europe. Besides political weight given to process and constructing the strategic orientation of it, its recourse to political, financial and legislative instruments has been determinant. As such, agenda alignment has permitted HTA cooperation to be put on the European decision-making agenda, receive support from high-level expert committees, enter the public health programme allowing for financial support and being inserted as flanking measure in the Cross-Border Health Care Directive (2011/24/EU). The latter has led to the establishment of the EU HTA Network, preparing the legislative road to the HTA Regulation proposal made by the Commission in 2018 and which adoption process is, to date, still running. The manner in which the Commission has participated in supporting and steering the cooperation efforts whereby HTA cooperation has turned into a European policy field, shared all characteristics with metagovernance.

This chapter has examined data from our empirical research on European HTA cooperation process on the basis of the central concepts of thesis research framework: governance networks, network governance and metagovernance. Through network analysis, this approach has allowed to identified soft governance-related factors impacting the development of European HTA cooperation. In the next chapter, we will draw the overall conclusions of the research.

8 | Conclusion

"Statesmen are concerned to do good,
and above all to extricate themselves from awkward corners;
but they do not always have either the taste or the time for using their imagi-
nation.
They are open to creative ideas
and anyone who knows how to present such ideas
has a good chance of having them accepted."
Jean Monnet, Memoirs

8.0.   INTRODUCTION

This research has addressed the governance of European cooperation processes in the field of Health Technology Assessment (HTA). It aimed at examining how these processes have been structured within the framework of the European Union. Cooperation in this field sought to establish convergence of practices so as to enhance the quality and quantity of assessments as well as their input in domestic decision-making processes. As such, it sought to reduce duplication of similar assessments in the EU and contribute to the development of more effective and efficient EU health systems. In twenty-five years of cooperation, several projects have been implemented aiming to develop common tools, methodologies and assessment models and establish a sustainable HTA cooperation framework in Europe.

Salience for HTA cooperation on behalf of the European Commission has been present since the early cooperation initiatives emanating from within the HTA arena. However, since HTA is considered as a policy domain falling under the exclusive competences of EU Member States, EU support for convergence policies in the field of HTA is restricted by the Treaties to support lending and coordination policies. This research has sought to explore how HTA cooperation has been developed within an EU framework and to what extent it has been structured through soft governance.

The commonality between all cooperation initiatives studied in this research was networking. The intrinsic characteristics of networks offer favourable conditions for the implementation of soft governance modes and instruments. Networking has also been integrated in the new governance approach of the European institutions since the turn of the century. As such, EU support to HTA cooperation networks matched the new EU governance approach.

To examine the role of soft governance in structuring HTA cooperation within the EU framework we have proceeded through network analysis. This approach allowed to connect HTA cooperation networks with EU soft governance modes applied in health policy. To this end we have developed a research framework structured according to three main concepts of networks: governance networks, network governance and metagovernance. The framework furthermore comprised soft governance-related factors potentially impacting a governance network's typology as well as factors potentially impacting the effectiveness of network governance. Effectiveness has been defined in the sense of goal attainment, comprising goal setting and goal achievement.

A thorough examination of the development of the main European HTA cooperation networks has been made. For a systematic analysis of these, we have organised the data collected by means of five stages of a policy cycle (agenda-setting, policy-formulation, policy

decision- making, policy implementation and policy evaluation). This approach has enabled data collection and analysis capturing governance approaches in organisational development, steering modes, policy-instruments, managerial styles and social interaction.

The examination period covered three distinct development stages of European HTA cooperation. The first, running from 1992-2001, regarded the initial cooperation efforts with the implementation of the projects EUR-ASSESS, HTA-Europe and ECHTA/ECAHI. The second, taking place from 2001 to 2005, addressed developments in the field of EU health policy which have been essential for the further development of HTA cooperation within the framework of the European Union. The third covered the period since 2006 and regarded the attempts to setup a sustainable structure for HTA cooperation in Europe though networks such as EUnetHTA and the EU HTA Network.

As the research topic finds itself at the crossroad of two academic research fields – European governance and health policy –, Part A of this thesis has contextualised HTA within both fields and set out the theoretical basis of our research framework. In Part B we have outlined the data according to the three research periods mentioned above. Part C has analysed the data on the basis of the research framework. The present chapter will address the general conclusions of the research and will answer the research questions defined in the Introduction of the thesis. It will also underscore the strengths and limitations of the research, formulate research- as well as policy recommendations.

The research questions formulated in the introduction of this thesis comprised an overarching research question (RQ):
- *Research Question: To what extent has soft governance structured HTA cooperation within the framework of the European Union?*
  To delimitate the scope of this question, three sub-research questions have been formulated, focussing each on a specific area of HTA cooperation:
- *Sub-Research Question 1: Can convergence and harmonisation of HTA tools, methodologies and practices be achieved through soft governance in an EU setting?*
- *Sub-Research Question 2: Can national uptake of joint work in HTA be achieved through the use of soft governance in an EU setting?*
- *Sub-Research Question 3: Can synergies be established through soft governance between HTA and European regulatory processes of pharmaceuticals?*

This chapter will present the conclusions of the research as follows: the first section will outline the role of soft governance in European HTA cooperation regarding the specific areas targeted in each sub-research question. The second section will answer the overarching research question regarding the extent in which soft governance has structured HTA

cooperation within the EU framework by setting out its impact. The latter will be addressed in three ways: 1) areas of 'positive' impact of soft governance on the European HTA cooperation process in terms of goal attainment; 2) areas where a positive impact of soft governance has not been found or only in a limited way; 3) explanatory factors for the absence of positive soft governance impact regarding goal attainment.

Following these sections, limitations of the research will be indicated as well as areas were further research would be necessary. Policy recommendations in the field of European HTA cooperation will be proposed in the last part of the chapter and precede the final concluding remarks.

8.1. ACHIEVING CONVERGENCE, UPTAKE AND SYNERGIES THROUGH SOFT GOVERNANCE IN EUROPEAN HTA COOPERATION

The research has demonstrated that HTA cooperation in Europe has been steered mainly through HTA networks. These networks operated according to soft governance modes and aimed at the establishment of a sustainable HTA cooperation framework allowing for convergences of HTA practices in Europe and avoid duplication of efforts. Several soft governance instruments have been implemented to support that goal and will be outlined in detail in the sections below. The Open Method of Coordination, although reflected upon as potential instrument, has not been implemented as such.

To understand to what extent soft governance has shaped the cooperation efforts within the framework of the European Union, we have delimited the scope of this research to three areas in which HTA cooperation has taken place: development of common tools, methodologies and practices; uptake of joint work; synergies between the EU regulatory framework of pharmaceuticals and HTA. In the following sections we will address each of these areas by answering the three sub-research questions. The input will be used to answer the overarching research question and draw the general conclusions of the research.

8.1.1. The role of soft governance in convergence and harmonisation of HTA tools, methodologies and practices in an EU setting

One of the key-objectives of the collaborative HTA initiatives was the convergence of HTA practices and the production of joint work which could be used in national regulatory decision-making processes, herewith reducing duplication of work and enhance quality and quantity of HTA Europe-wide. This objective has remained in essence the same throughout all HTA cooperation networks. The data we have collected and examined brings to the fore

that concrete European collaborative HTA outputs have been produced in the form of common network tools, methodologies and practices. Examples hereof are the Core-HTA model, the (Rapid) REAs model, the POP-database, the EVIDENT data base, numerous guidelines, handbooks and other capacity-building tools. A substantial number of joint assessments have been produced within the networks, although often still in pilot format. Routinisation of joint (REA) assessments has been pushed only in Joint Action 3, more than twenty years after the start of the first cooperation initiatives. Moreover, although the networks have been able to develop joint work and create convergence in certain tools, methodologies, and assessments, not all members of the networks would adhere to the outputs produced. Finally, convergence of tools, methodologies and assessments underpinned the overarching objective of the networks to establish a sustainable HTA cooperation framework.

Soft governance has played a role in establishing some degree of convergence of tools, methodologies and practices within the HTA networks examined. The first argument to underpin this conclusion relates to the organisational framework in the form of governance networks. The establishment and functioning of European HTA cooperation networks serving the purpose of seeking convergence of HTA outputs, entirely follows a soft governance approach. These networks have been qualified as *governance networks* operating on the basis of soft governance principles such as voluntary participation of autonomous actors engaging in horizontal relationships where different levels of authority and weight in decision-making processes have been observed. Cooperation processes were based on deliberation, learning-processes and the development of a common set of values and understanding. Moreover, receiving political, administrative and financial support from internal and external actors, these networks contributed to a public purpose recognised on both the domestic as the European level.

Specific aspects related to the typology of these governance networks have been identified as impacting the development of convergence in HTA outputs, translated in the form of tools, methodologies, and joint assessments. These aspects are associated to the network formation process, membership structure, resources and governance modes.

In terms of network formation, voluntary participation stimulated by incentives such as deduplication of work, (personnel, financial and time) investments, peer-education and exchange of best practices, have been decisive for the setup of the networks. The homogeneous membership structure creating networks of peers, has favoured the establishment of a set of common values and understanding, pre-requisite to the production of joint work. Available financial resources through the EU (public) health programme have permitted the production of pilot projects systematically evaluated through single- or double loop processes. Expertise, increasingly present in the HTA cooperation networks, has been of prime importance for

the development of tools and guidelines. It has also played a crucial role in capacity-building processes necessary for the establishment and implementation of joint assessments. Other resources, such as, administrative support, availability of premises and administrative human resources further strengthened collaborative work aiming convergence of practices.

Convergence of practices requires adherence to the goal setting and goal attainment processes. As entirely voluntary cooperation initiatives, convergence of tools, methodologies and practices would rely upon soft governance steering modes of the networks. The HTA governance networks distinguished themselves by the steering modes implemented, ranging from horizontal power distribution (e.g. EUR-ASSESS, HTA-Europe ECHTA-ECHAI functioning as Participant-Governed Networks), asymmetric power distribution (e.g. EUnetHTA functioning as Lead-Organisation Governance) to centralised power distribution (e.g. EU HTA Network/ Governance structure in the HTA Regulation proposal sharing many traits of a Network Administrative Organisation). A correlation between the degree of convergence and the steering modes has been observed. The more centralised the governance modes, the more convergence of tools, methodologies and practices targeted and attained.

Soft governance underpinning the development of convergence of tools, methodologies and practices have also been observed in *network governance*-related aspects such as social interaction, governance instruments, management and external events. Social interaction has been an important factor favouring the production of joint outputs. In particular learning processes and the development of a set of common values and understanding have been of high importance when developing collaborative tools. Consensus building, exchange of experience and best practices have favoured the production of joint work. Trust building has been another crucial element in producing outputs such as guidelines, joint assessments or common databases.

The soft governance instruments used, such as, internal communication, peer-review, single and double loop evaluation processes, further strengthened the convergence processes. Moreover, the political, financial and regulatory instruments have created a framework allowing continuation of the projects aiming the convergence of HTA outputs. By requalifying EUnetHTA as the scientific and technical arm of the EU HTA Network, emphasis has been put on the need for routinisation of joint work. The latter should support the overarching objective of creating a sustainable HTA cooperation framework.

The (project) management approach organised in Work Packages based on voluntary participation of network members, has had a dual impact on the process of convergences of practices. Although 'management of scientists by scientists' offered the advantage to induce the necessary expertise to establish convergence of tools, methodologies and practices, it

also prevented input from other actors, in particular those involved in domestic decision-making processes. Moreover, the voluntary participation of agencies in the various work packages did not necessarily reflect their support to convergence of practices. As such, the joint work generated as a network did not necessarily represent adherence to this work by individual HTA bodies.

Finally, impact of soft governance on the convergence of European HTA tools, methodologies and practices has been observed in relation to the presence of a *metagovernor* (i.e. European Commission). Social interaction has played an important role in securing support for the cooperation initiatives on behalf of the European Commission developing its own policy agenda for HTA cooperation. Through policy instruments such as inter-institutional agenda alignment and high level expert networks, the European Commission has been able to influence the course of action by offering political, financial and administrative support aiming the convergence and harmonisation of HTA practices. By creating the EU HTA Network, the European Commission has instilled a new impetus to achieve this aim. In particular, its proposal for a Regulation on HTA cooperation in Europe, comprising mandatory aspects regarding Joint Clinical Assessments highlights how the European Commission sought to steer the cooperation efforts towards HTA harmonisation in Europe.

To conclude, convergence of HTA tools, methodologies and practices can be achieved in an EU setting through soft governance. The research has brought to the fore specific soft governance features operating through governance networks, network governance and metagovernance and which have impacted the process of convergence of tools, methodologies and practices in a positive or negative way. As such, convergence is favoured by the establishment of governance networks based on voluntarism, soft governance steering modes, discourse, learning, capacity-building and the build-up of a set of common values and understanding. Moreover, convergence will be easier to achieve in a homogeneous, closed network structure comprising strong network-home organisation relationships. Available resources will support convergence processes. Soft governance steering modes impact the degree of convergence achieved. The more centralised the governance modes, the more convergence obtained.

Social interaction between network members provides the basis for learning-processes, shared values, trust and goal consensus, essential for the development and implementation of joint work. Management of a network of scientists by scientists had a dual impact on convergence by accelerating the development of common tools and methodologies and practices but decelerating adherence to the joint work by external actors not taking an active part in the networks. Presence of a metagovernor, by means of the European Commission, operating essentially through soft governance has been essential for the establishment of convergence.

Finally, although a certain level of convergence has been achieved, no harmonisation of HTA tools, methodologies and practices has been observed in our research, despite the presence of soft governance modes and instruments implemented through governance networks. Harmonisation of certain aspects of HTA has been targeted by the European Commission basing the process however on hard legislation rather than on soft governance.

8.1.2. The role of soft governance in national uptake of joint work in HTA

'Uptake' refers to the use of joint work in domestic decision-making processes. Debate regarding the exact level of uptake in national settings is still on-going. Systematic use of HTA outputs produced by the HTA governance networks has not been observed. Generally, uptake is considered to be rather low. Various studies, carried out in the past and presented in this research, have pointed to challenges such as quality, linguistic, legal, technical or time-liness matters faced by the networks or HTA bodies to ensure uptake. The present research has examined the issue of uptake by taking another perspective and examine to what extent soft governance has played a role in the level of uptake measured. As such, several factors related to *governance networks*, *network governance and metagovernance* have come to the fore. These can be associated to the presence or absence of soft governance instruments in the processes seeking to ensure uptake.

Due to the division of competencies between the EU and its Member States regarding the organisation and management of domestic health systems, processes of uptake have been steered by soft governance, based on voluntarism and the absence of hierarchical top-down decision-making. Uptake of joint work could therefore not be imposed by the HTA governance networks. Domestic HTA bodies remained in charge of the HTA processes and were sole decision-makers as to include or not joint work in their assessments. The outcome of these decisions would impact diffusion of joint work in national regulatory processes. Several factors have been identified in our research as potentially impacting this decision-making. First, the management level of HTA agency representatives participating in the network activities, has come to the fore as a favourable factor in uptake. Qualitative data gathered in our research points to the fact that the higher the management level of an HTA agency representative involved in an HTA cooperation network, the better the chances to adjust to new tools, methodologies and other forms of joint work.

Second, the *membership* structure of the HTA cooperation networks can (partly) explain the disappointing levels of use of collaborative HTA outputs in domestic settings. The relationship between the governance networks and their members' home organisations has, in many cases, been qualified of low intensity. S*ocial interaction* would in these circumstances remain limited to the network level and its effects (e.g. learning processes, setup of a common set of values and understanding, trust building and goals consensus) could not be produced in

representatives of home organisations not involved in the HTA governance networks. Adherence of home organisations to joint work produced in HTA networks would consequently be harder to secure.

The third explanatory factor regarding the disappointing levels of uptake of joint work is to be found in the low level of active involvement of domestic ('hard') policy-makers. As HTA matters are often considered being technical issues requiring specific expertise, ministries tend to delegate representation in HTA collaborative initiatives to HTA agency representatives. The size of the agency, the degree of interaction with the ministry, as well as the management level represented in the collaborative initiatives, all impact uptake. Our research has found that participation of senior HTA agency executives in the establishment of collaborative tools, methodologies and assessments created favourable conditions for uptake due to knowledge of, and trust in the outputs produced. Furthermore, senior HTA agency executives possessed the authority necessary to adapt domestic HTA processes and operate internal change. Consequently, chance for uptake of joint work would increase.

Moreover, social interaction between ministerial representatives and HTA bodies tended to be higher when senior agency representatives were involved in the HTA networks. The level of social interaction would have an impact on learning and capacity-building processes within the ministry as well as on the trust-building and goal consensus processes regarding HTA cooperation. Adherence of 'hard' policy makers to HTA collaboration becomes crucial in the development of new EU legislation since the ministerial level plays a decisive role in the adoption process of new legislative proposals. Hence, even if recourse to hard legislation is made to ensure uptake though mandatory means, soft governance remains of importance to prepare decision-making processes in sensitive, technical and complex issues, such as HTA.

Finally, limited stakeholder participation in the development of joint work may also impact the uptake of it. Participation of stakeholders in the HTA cooperation networks has mostly been restricted to informative purposes rather than to collaborative purposes. Social interaction in the networks between HTA bodies and stakeholders has been rather limited. Transversal social interaction between stakeholder groups themselves has not been intense either. As a result, goal consensus has not always been observed amongst all stakeholder groups and salience to participate in pilot projects has, at times, been below expectations. Similarly, learning processes, the development of a set of common values and understanding, trust-building in the quality of the processes and their outputs, also have been impacted by the low level of social interaction.

Hence, no active soft governance instruments and steering mechanisms have been implemented in HTA collaborative processes seeking to ensure uptake of joint work in domestic

HTA decision-making processes. Nevertheless, this research has established that soft governance could play an important role in favouring the diffusion of joint work in national HTA and domestic pricing and reimbursement processes. Based on the data gathered in this research, there is no clear indication that soft governance *alone* would be sufficient to guarantee uptake of joint work in national settings. However, soft governance could provide solutions to overcome the challenges to uptake as recorded in various studies and relating to issues of quality, timeliness, legal constrains, linguistic barriers and other technical problems. Social interaction has come to the fore in our research as an important element to ensure political and peer support, necessary to surmount technical and strategical obstacles preventing uptake to occur. Moreover, even in cases where EU hard legislation would be used to support uptake of HTA joint work in domestic settings, soft governance would still be necessary to ensure adherence of EU Member States and national HTA bodies to the new legislative framework proposed.

8.1.3. The role of soft governance in the establishment of synergies between HTA and European regulatory processes

The research has outlined how the process of European cooperation in HTA has led to the establishment of synergies between the HTA arena and the EU regulatory framework in the field of pharmaceuticals. To date, a common EUnetHTA/EMA platform exists, offering to manufacturers the possibility to request via a single entry-point Joint Scientific Advice on behalf of HTA bodies and the European Medicines Agency. Dedicated governance bodies have been created to coordinate the latter, such as, an Early Dialogue Working Party and a Early Dialogue Secretariat. European and domestic regulatory processes and European Public Assessments Reports have been adapted accordingly.

Factors related to soft governance having positively contributed to the establishment of these synergies between the HTA arena and the EMA are related to the typology of HTA governance networks as well as to effectiveness of HTA network governance. As such*,* membership homogeneity of the network has played an important role. Early Dialogues comprised mainly three actors: HTA bodies, the pharmaceutical industry, and the EMA. The needs expressed were shared by the three social actors, each operating in a separated environment. Hence, goal consensus was easy to achieve. Conversely to other EUnetHTA outputs produced, the Early Dialogues have been set up by associating each partner and stakeholders closely to the project. Adherence of the industry participants was high due to the adequacy between the participants' needs and the product outputs as well as the presence of a shadow of hierarchy. As such, the outcome of Joint Scientific Advice would allow industry representatives to adapt the product development process so as to be compliant with the requirements of the assessors. However, by refraining from doing so, a company would risk seeing its market access procedure be delayed.

Other factors having played a role in successfully creating synergies between the two arenas, were the available *resources* in expertise, (administrative) manpower and availability of premises. Political support on behalf of the Commission as well as of the HTA bodies themselves and EU Member States, has further favoured the smooth implementation of the cooperation initiatives.

As all key-actors were involved in the process, social interaction could take place between them. Learning processes and the development of a common set of values and understanding underpinned the establishment of trust in the process and in the partners. Capacity-building and evaluation processes further strengthened the establishment of synergies between the two arenas. As an entirely new initiative, some governance instruments such as the creation or adaptation of legislative and regulatory frameworks could be tailored to the needs of the HTA bodies and the EMA. Since no other similar system existed on a national level, no domestic legislative hurdles blocked further development. Moreover, process and project management have been dissociated. Each project serving as input for the larger process to be developed.

To conclude, soft governance has played an important role in the establishment of synergies between HTA and European regulatory processes. In this respect, the membership structure of the networks, the soft governance steering modes and availability of various types of resources has favoured the development of the process. Social interaction and the inclusion and active participation of stakeholders has further reinforced the synergies which have developed. Presence of a shadow of hierarchy consolidated adherence to decision-making and, as such, sustainability of the cooperation initiatives.

8.2. TO WHAT EXTENT: DOMAINS AND EXPLANATORY FACTORS

In the previous section we have examined the role of soft governance in three different areas of HTA cooperation: convergence of tools, methodologies and practices, uptake of joint work or synergies between the HTA arena and EU regulatory processes of pharmaceuticals. We have highlighted in each specific area, which soft governance-related factors were associated to either a positive or negative impact regarding goal attainment of the HTA networks. The overarching goal of all networks being the establishment of a sustainable structure for HTA cooperation in Europe. Several sub-goals served as means to reach the overarching goal. The conclusions drawn permitted to answer the sub-research questions of this thesis.

In this section we will build upon these conclusions to address the overarching research question regarding the extent to which soft governance has structured HTA cooperation within

the framework of the European Union. To this end we will first address domains where a positive impact of soft governance in European HTA cooperation has been observed and underscore the reasons hereof. We will then highlight domains where a positive impact of soft governance in terms of goal attainment *has not* been observed. Finally, explanatory factors for the absence of positive impact of soft governance on European HTA processes in terms of goal attainment, will be underscored. The domains of impact of soft governance covering the three main areas of HTA cooperation display the extent to which soft governance has structured HTA cooperation within the framework of the European Union.

8.2.1. Domains and explanatory factors of positive impact of soft governance in European HTA cooperation

Impact of soft governance in structuring HTA cooperation within the EU framework has been examined in this research through a network analysis by focusing on typology and effectiveness of HTA networks in terms of goal attainment. We have outlined how effectiveness can be measured in terms of processes, outputs and outcomes. In this section we will highlight the domains where goal attainment has been found and in which where soft governance has played a role.

Our analysis has brought to the fore five domains where a positive impact of soft governance has been measured in the European HTA cooperation networks.

These areas are:
1) **Goal setting process of European HTA networks.**
   The objectives set since the first HTA cooperation projects have been consistent and allowed HTA actors to remain united around a common goal, securing herewith the continuity of cooperation efforts. Social interaction, through learning processes and the development of a common set of values and understandings, has been an important factor herein. Horizontal coordination, and voluntary cooperation with a cheap exit strategy have favoured the continuation of cooperation efforts. Moreover, the availability of continuation of funding sources and the administrative support received from the Commission has also played a decisive role herein. Finally, the political support, translated in Council declaration, EP motions and Commission programmes has secured the development of the projects. The inclusion of HTA in legal frameworks (e.g. Cross-Border Health Care Directive) further assured continuation of the projects.

2) **Development of HTA cooperation tools, methodologies and joint assessments.**
   Common tools and methodologies have been developed in the networks. These were mostly related to support joint assessments (REAs or common core-HTAs) which initially were carried out as pilot projects and in a later phase became more routinised. Develop-

ment of those resulted from learning processes, peer-education and exchange of best practices and evaluation through pilot projects. Procedural governance instruments (e.g. communication, evaluation) supported the development of substantive governance instruments (e.g. REAs, Early Dialogues, joint core HTAs) as the latter should prepare the establishment of a sustainable framework for HTA cooperation. The new repartition of the networks' roles since the creation of the EU HTA Network, where EUnetHTA became the scientific and technical arm of the former, further highlights how the substantive governance instruments were needed to reach the overarching goal.

Even though, no sustainable HTA cooperation framework exists to date, goal attainment of sub-goals (i.e. development of common tools (e.g. POP database), methodologies (e.g. HTA framework guidelines, handbooks) and practices (e.g. joint REAs, common core-HTA) has been demonstrated in this research. Factors favouring convergence were relate to network structure (homogeneity and closeness) as well as governance modes (the more centralised, the more convergence). Social interaction would support learning-processes, shared values and understanding, trust and goal consensus, essential in the development of joint work. Project management had a two-fold impact on convergence. The expertise shared in a network of peers accelerated development of joint work, but lack of active stakeholder involvement decelerated adherence of external actors not involved in the process. As metagovernor, the European Commission actively supported convergence strategies, pushing the process even into the direction of a hard regulation proposal. As such, it has used its influence to steer HTA networks from the outside and use soft governance to pave the way for hard regulation.

3) **Limited uptake of common HTA tools and methodologies in national HTA processes.**
EUnetHTA tools and methodologies have been used in national HTA processes, in some EU member states. Although no general uptake of joint work has been observed, the research did bring to the fore how some countries did use EUnetHTA tools, methodologies or (elements of) joint assessments in national HTAs. Social interaction did impact uptake there where it took place. Implication of top-management representatives of HTA agencies allowed for learning processes and shared values and understandings to be transmitted to the domestic HTA agencies. Presence of top-level managers in the networks' activities allowed for adaptation processes to be decided upon in the domestic settings. Trust in the EUnetHTA outputs was a consequence of participation in the development of those. Through communication between top managers of HTA agencies and ministerial representatives, benefits of social interaction were transmitted to the ministerial level, in some countries, favouring acceptance of European tools and methodologies in domestic

HTA procedures. Overall impact of joint work in national HTA decision-making processes remained limited though, as we will further discuss in the section below.

4) Use of EUnetHTA outputs by regional cooperation networks (e.g. Beneluxa).

Regional cooperation processes, although establishing separate cooperation structures have developed their common activities using tools and methodologies of EUnetHTA. Moreover, membership overlap between EUnetHTA and regional cooperation initiatives allowed to build upon shared values and understandings and experiences in HTA cooperation. Although this can be considered as an unforeseen outcome of the previously established HTA cooperation networks, it does underscore effectiveness of them in the production of common tools and methodologies based on a soft governance approach.

5) Establishment of synergies between EUnetHTA and the EMA.

To date, a common platform has been established for parallel consultations between EUnetHTA and the EMA. The synergies which have been established between both arenas result from soft governance processes. Dialogue between the HTA and regulatory arena (comprising internal-industrial dialogue), exchanges of experiences and best practices, voluntary cooperation, and horizontal coordination have underpinned the collaboration processes and still characterise the functioning of the common platform. Network homogeneity favoured goal consensus. Stakeholders inclusion has been a specificity of the initiatives and impacted adherence and commitment to the initiatives. The latter was however also impacted the presence of a shadow of hierarchy. Although not compulsory, non-compliance with joint scientific advice could have costly consequences for technology procedures during market access processes. The concordance between the needs and the outputs produced further favoured adherence to the cooperation initiatives. Similarly, the relatively less-complex content of Early Dialogues (compared to a full HTA based on the nine domains of the Core Model) certainly further contributed to the successful establishment of synergies in this area. Social interaction has been determined and was favoured by the inclusion of all key-actors of the processes. As such learning processes and capacity-building could take place and were diffused to external actors. Other factors positively impacting synergies between the two arenas, were related to available resources (financial, human and administrative) and political support on behalf of national and European public authorities. The latter facilitated legislative and regulatory adaptation to the new initiatives.

8.2.2. Domains of absence of a positive impact of soft governance in HTA cooperation

The main goal established by all networks was the setup of a sustainable framework for HTA cooperation in Europe. Such a framework should facilitate the uptake of joint work produced

in a collaborative HTA framework. To date, no sustainable European HTA framework has been established and uptake of joint work in domestic decision-making processes remains limited. The first and overarching objective has been pursued by means of soft governance modes and instruments. Regarding uptake of joint work, recourse to soft governance is less evident although the few development processes seeking to establish uptake did point to a limited use of soft governance.

Hence, a positive impact of soft governance in terms of goal attainment has not been measured in the following two areas:

1) **No establishment of a sustainable European framework for HTA cooperation**

   HTA cooperation has remained project-based with each project and Joint Action being a follow-up of the previous one. The creation of the EU HTA Network turning EUnetHTA into its scientific and technical arm marks a point of departure in this regard. As a policy orientated network, the EU HTA Network would examine how a sustainable framework for HTA cooperation could be established, de facto demonstrating that no such a framework had been created throughout the previous projects. The 2018 Commission HTA Regulation proposal should produce the legal conditions for such a framework to be created, and herewith also established that no such a framework existed. Hence, soft governance has allowed the development of European HTA cooperation networks, which have prepared (some of) the instruments necessary for a sustainable framework to function. However, to date, soft governance approaches have not led to the creation of such a framework. The Commission Regulation proposal is an attempt to remedy to this. (Intergovernmental) regional cooperation initiatives can be considered as alternative ways to establish a sustainable cooperation mechanism. All proposals have used the outputs of the cooperation processes set in motion in the networks analysed.

2) **No systematic uptake of joint work in the EU Member States**

   The Commission HTA Regulation proposal came as a response to the absence of a sustainable HTA cooperation framework *and* to what was considered by the Commission as a lack of uptake of joint work in national HTA processes. Besides a continuation of voluntary cooperation in the field of Joint Scientific Advice and Horizon Scanning and joint assessments, the Commission proposed a mandatory approach for Joint Clinical Assessments. Herewith, it implicitly acknowledged that soft governance would not be sufficient to ensure convergence of practices in joint assessments. By limiting the mandatory uptake to the clinical aspects of assessments, it hoped for a better acceptance of EU Member States as these fields would not directly touch upon economic matters. This did not prevent Member States considering the proposal as a breach of the subsidiarity principle. Although much attention has been given by the European Commission and

the networks to explanatory reasons for the lack of uptake in national HTA processes, no clear strategy to favour uptake has been identified in this research. Mostly, uptake should result from the transmission of common values and understandings from the networks to the HTA agencies comprising herein also qualitative and methodological issues. As such, one can consider that the approach regarding soft governance was underpinned by soft governance principles and instruments, even more so, as no hierarchical top-down governance approaches have been implemented. Hence, although soft governance was the underlying steering mechanism seeking to secure uptake of joint work in the EU Member States, no dedicated 'uptake-strategy' based on soft governance instruments has been developed in the various European HTA networks.

8.2.3. Explanatory factors for the absence of positive soft governance impact regarding goal attainment

Establishing a sustainable framework for HTA cooperation allowing for the use of joint work in national pricing and reimbursement processes has been the main objective since the early cooperation initiatives. The lack of goal attainment and the related lack of uptake underscore a lack of effectiveness of the HTA networks in this regard. Explanatory reasons for both are interconnected. In the section above we have highlighted how soft governance has not been identified as having a positive impact in these areas in terms of goal attainment.

In our research we have identified the following factors related to soft governance which had an impact on the outcomes of HTA networks regarding the lack of goal attainment:

1) **Underrepresentation of domestic policymakers in European HTA cooperation networks.**

Active participation of policymakers has been missing in the HTA networks. Importance of this key-actor in HTA processes had already been underscored in the EUR-ASSESS and in the HLG project. However, in practice, participation of a policymaking level was limited to the nomination or approval of HTA agencies in the HTA cooperation networks. The absence of policymakers in networks' activities also prohibited social interaction to take place. Consequently, impact of learning processes and capacity-building could not take place with policymakers nor could common values and understanding or trust be built up amongst them. Information about progress of network activities would depend on the relationship between HTA agencies and the ministries and the level of HTA representation in the HTA networks. As HTA serves as input for national regulatory processes regarding pricing and reimbursement of health technologies, this policymaking level should play an important role in the European cooperation of HTA. Finally, the adoption of any EU regulatory proposal has to be approved by the domestic health policymakers represented in the Council of the European Union. The active participation of ministerial representa-

tives in European HTA networks could have secured domestic support for cooperation initiatives or could have disclosed in an early stage potential hurdles for any regulatory proposal in this regard. Moreover, the degree of involvement of governmental representatives is one of the distinctive traits between EUnetHTA and regional HTA cooperation initiatives.

2) **Limited stakeholder policy in European HTA cooperation networks**
Four stakeholder groups have been identified in HTA governance networks: industry, patients, payers and health care providers. The involvement of stakeholders in HTA networks' activities has however been limited and inequal across stakeholder groups. Industry and patient umbrella organisations have been most active and influential in the cooperation processes. Payers and health care providers have played a very limited role in the cooperation efforts. The early cooperation initiatives as well as the European Commission have often underscored the importance of including stakeholders in the cooperation processes but with limited effects. Three conclusions can be drawn as regards stakeholder policy:

2a) **Stakeholder involvement was limited to informative rather than collaborative purposes**.
In the HTA networks, no consensus existed as to the degree of participation of stakeholders in the networks' activities. National policies still dominated the members' positioning on the matter. Diversity could be explained by the adoption of an economic or public health perspective in stakeholder involvement. Depending on the perspective, some stakeholder groups could be more or less influential than others (e.g. industry in an economic perspective; patients in a public health perspective). As stakeholder participation was limited, social interaction was minimal. Learning processes were difficult to establish as was the development of a set of shared values and understandings. The level of trust in active stakeholder involvement in HTA processes would depend on national experiences and no particular trust building processes have been developed at a European level. Moreover, there where social interaction did take place to a certain extent, it often concerned only the umbrella organisation, participating in the EUnetHTA activities. Transmission of social interaction benefits to member organisations was difficult to achieve. Consequently, awareness of HTA cooperation in Europe and adherence to HTA networks' goals by a large set of stakeholder organisations was, most often, very low.

2b) **Stakeholder coordination has mainly taken place at a vertical level (network-stakeholder**).
No particular stakeholder coordination process has taken place at a horizontal level (stakeholder-stakeholder). The latter could have allowed for the development of a more inclusive stakeholder policy and the establishment of learning processes leading to the development of shared values and understandings and the build-up of trust. Goal con-

sensus regarding both the ultimate aim of HTA cooperation as well as consensus on the role of stakeholders in this process could have reinforced the cooperation process as a whole and allowed for a stakeholder approach dissociated from national practices.

2c) Partial representation of reimbursement organisations ('payers') in European HTA networks. Payers play a crucial role in HTA processes and in European HTA processes are constituted of social security systems and mutualities. The stakeholder group representing 'payers' in EUnetHTA and the EU HTA Network refer in fact only to additional reimbursement schemes which often do depend on decision-making processes of social security organisations. As outlined above, domestic policymakers, often key-actors in reimbursement decisions, did not actively participate in the networks and would therefore not approach joint tools, methodologies and assessments in the same way as those who were involved in the processes.

3) Ineffective interaction between HTA networks and members' home organisations

Social interaction remained at the level of network members and dissemination of its effects in home organisations was limited. Learning processes, the establishment of shared values and understandings, trust building and goal consensus would essentially take place at a network level. This would have several consequences on uptake of joint work. Depending on the size of the agencies, dissemination of the outputs of cooperation activities in the home organisations would be more or less intense. This seems to be correlated with the management-level representing an agency in the HTA Networks. The smaller the agency, the higher the management representation level in the HTA networks, the more network activities transmission into the home-organisation, the more chance of uptake of joint work. Indeed, integration of elements of collaborative processes would follow (top)management decision-making. The bigger the agency, (proportionally) the less transmission of information on network activities and its outputs to home-organisation's employees and the less uptake of joint work. Middle-management representatives of (size-wise) bigger agencies, participating in the networks would have more difficulties to transmit social interaction benefits (e.g. transmission of learning processes and trust in the processes). Moreover, they would not enjoy the same authority as top-managers for whom it would be easier to instil change. Adherence to the network objectives from the home organisations would in these circumstances be more problematic, adaptation of internal work processes to requirements of collaborative projects more difficult to install, and uptake a bigger challenge to overcome.

4) Mixed management approach in HTA networks

No adequate distinction between process- and project management has been made in HTA networks. Policy entrepreneurs have played an important role in the setup of

networks by understanding the complexity of HTA and the need to establish a link to policymaking. Policy-entrepreneurs have been identified in the early cooperation projects (e.g. EUR-ASSESS), the EUnetHTA project as well as at the European level. Cooperation between the network- and the EU level has led to alignment of policy-objectives and securing political and financial support. Management of the first networks followed a logic of management by objectives, pursued via Subgroups or Working groups. Management of the EUnetHTA network became more complex, although the approach remained the same in the establishment of Work Packages pursuing the realisation of specific sub-objectives (e.g. development of tools, guidelines, Core Models, joint assessments). EUnetHTA has long been characterised to be a network of peers - HTA doers, scientists - and has been qualified in this research as a *network of scientists managed by scientists*. Till JA3, network coordination and the setup of a sustainable HTA network have been often considered as one objective. This has resulted in mixing two different management approaches needed to reach what should be considered as two distinct objectives. The first, the establishment of a sustainable HTA cooperation framework responding to process management. The second, coordinating a project supporting the establishment of a sustainable framework on HTA cooperation, responding to project management. Mixing two approaches has not been effective in terms of goal attainment regarding the creation of a sustainable framework and uptake. The establishment of the EU HTA Network has permitted to make this differentiation by separating policy orientation form technical and scientific HTA activities. The EU HTA Network pursuing the establishment of a sustainable framework for HTA coordination (process management) and EUnetHTA focusing on the tools enabling the framework to operate (project management).

Goal attainment of the HTA cooperation network has since the establishment of the EU HTA Network been divided between EU HTA network and EUnetHTA. To date, we cannot assess whether this will result in goal attainment of the establishment of a sustainable framework and uptake of joint work. The creation of the EU HTA Network resulted from the insertion of an article on HTA cooperation in the Cross-Border Health Care Directive. When drafting the article, confusion regarding the role of this network still existed, and EUnetHTA was often considered as the future sustainable network. The legal framework proposed by the Commission in its HTA Regulation should in principle allow for the establishment of a sustainable framework. However, the mandatory aspects regarding joint clinical assessments respond to a closed cooperation structure and stumble on resistance from Member States. A new legal framework could in principle have been designed in various ways and could have integrated mechanisms allowing for flexible approach in which various cooperation forms would be integrated including regional cooperation initiatives. To date, the Commission has opted for a rather classical approach in EU integration policies.

8.3. SUMMARY KEY FINDINGS

HTA cooperation in Europe has emanated from within the HTA arena, initially by the creation of informal networks, which could also be considered as epistemic communities. Through these networks, operating on the basis of soft governance steering mechanisms, diffusion of common values and understanding regarding HTA has taken place predominantly within the HTA arena. Salience for HTA cooperation has been found in the European Commission which has integrated this topic in EU high level expert networks turning HTA into a European policy issue. Although OMC has been envisaged at a certain stage to structure the cooperation efforts, European HTA cooperation has finally been developed by means of so-called Joint Actions, giving the European Commission the opportunity to develop from a funding institution in the early cooperation initiatives into a metagovernor of newly established European cooperation networks.

Soft governance has structured HTA cooperation within an EU framework by means of various forms of networking ranging from epistemic communities, high-level policy expert networks, to networks which could be qualified as governance networks. The development stages of the latter also refer to different governance steering mechanisms adopted in each, ranging from participant-governed networks (Early cooperation initiatives), to lead-organisation networks (EUnetHTA) to network-administrative organisations (EU HTA Network). Although convergence of tools, methodologies and practices has taken place, no harmonisation of this has been observed in the EU Member States. Indeed, integration of commonly developed tools and methodologies into national HTA practices has not been generalised and has not been done in a harmonised manner. Decisions to do so remained fully at the discretion of HTA agencies. Production of joint HTAs, has been realised to some extent, however, no generalised nor harmonised use of those in the national decision-making processes has taken place.

Explanatory reasons related to *governance* aspects of the cooperation initiatives to explain the above, and as identified in this research, have pointed to the following factors: the network composition (e.g. under representation of policymakers), stakeholder policy (informative rather than collaborative involvement, underrepresentation of stakeholders, stakeholder coordination policies), social interaction (e.g. network – ministries, network-network), and management approaches (e.g. project vs process management). These reasons complement elements identified in Commission and HTA networks' studies regarding lack of uptake and lack of effectiveness in establishing sustainable network mechanism. The latter would point to qualitative, legal, technical, organisational, financial and timeliness factors.

To overcome these barriers, the Commission has proposed to change the governance approach by submitting a Proposal for a Regulation on HTA cooperation, whereby an HTA coordination group would steer the overall work and sub-groups would deal with one of the four pillars of the proposal: Joint Clinical Assessments, Joint Scientific Consultations, Identifying emerging health technologies and voluntary cooperation in non-clinical domains. This mechanism would encompass mandatory elements of uptake related to joint clinical assessments of (some) medicines and medical devices. The choice for a Regulation has been motivated by an interpretation of the subsidiarity principle based on the fact that after more than 25 years of cooperation, no sustainable HTA cooperation framework has been established and diversity of HTA approach still exists in EU Member States despite the cooperation outputs created by the networks, such as common tools, methodologies and Core Models of joint assessments.

Whilst reasons for the lack of goal attainment - regarding the establishment of a sustainable HTA cooperation framework and in particular uptake of joint work - underpinning the Commission proposal for a Regulation, are often sought for in external network aspects, this research demonstrates that part of the explanation can be found in the governance aspects of the cooperation initiatives. As such, the lack of goals attainment of the cooperation initiatives in terms of uptake and the creation of a sustainable network, lays not necessarily in the *recourse to* soft governance but rather in the *manner* of implementing it. In order words, lack of effectiveness of some of the HTA goal attainment processes is not necessarily a result of the lack of effectiveness of soft governance as such. Hence, adapting the soft governance approaches of HTA cooperation could be a means to overcome the other barriers identified by the networks and the European Commission, and listed above, without having to resort to hard governance legislative means.

Soft governance through social interaction seems to have played an important role in uptake of joint work. There where this has been observed, learning processes, shared values and understandings, capacity-building and trust have been able to overcome barriers to national use of common HTA cooperation outputs. The level of (managerial) representation participating in the HTA networks, the size of the HTA agencies, and their country of origin play a role in the interaction and transmission of the results of HTA network and the national decision-making level.

Lack of active participation of the ministerial level as well as an inadequate stakeholder policy, based on informative rather than collaborative purposes has further contributed to the low level of uptake in the Member States. Moreover, in the case of HTA cooperation, process- and project management have for a long time been mixed, creating confusion as regard the networks' *raison d'être*: developing tools and methodologies to be used in a

future sustainable framework or becoming the sustainable network. Both objectives requiring a different management approach. The disentanglement of the objectives by creating the policy-orientated EU HTA Network alongside the EUnetHTA Joint Action was an attempt of the European Commission to resolve this problem. The Regulation proposal on HTA cooperation, a manner of creating the sustainable cooperation mechanism within the EU framework. To date, no success has been recorded in either way.

The area in which cooperation has led to positive results in terms of effectiveness of soft governance regards the synergies created between the European regulatory framework and HTA in the field of Joint Scientific Advice. Presenting a less complex area of cooperation (advice on (pre-marketing) evidence generation *versus* nine assessment domains for a full core-HTA), the inclusive participatory stakeholder approach, and the presence of a shadow of hierarchy have been positive factors contributing to effectiveness of soft governance cooperation mechanisms in this field. Evidence generation throughout the full life cycle of a technology becomes however of increasing importance in many EU Member States seeking to develop solid methodological approaches, capable to answer the upcoming challenges in this area. The cooperation initiated in European settings could offer a unique chance to develop a common framework and thereby avoid further fragmentation of methodologies underpinning HTA in the EU.

8.4.   POLICY RECOMMENDATIONS

The findings of this research could serve to inform policymaking in the field of HTA cooperation but also in other areas where recourse to soft governance is made.

Many studies have underscored the need for cooperation in HTA considering the important disparities that exist in this area in Europe and the benefits it would offer to the health systems. In our examination of the various HTA networks which have pursued this idea, we have highlighted the challenges to achieve this goal in such a complex area as HTA. Indeed, the complexity stems not only from technical and methodological issues but also from political and policy ones as HTA finds itself on the crossroad of science and policy and in the midst of two regulatory processes: European market authorisation and national pricing and reimbursement. Recent research related to evidence requirements throughout the life cycle of a health technology, further underscore the need to develop European standards, acceptable to all. The new and costly developments of health technologies and the need to further develop research in fields such as rare diseases, personalised medicines or even the use of artificial intelligence in health care will even more require strong cooperation between regulators and HTA agencies in the EU.

Cooperation does not necessarily involve loss of sovereignty or national competences but rather an exchange of experiences and best practices allowing for the establishment of new and improved standards available to all. Soft governance can be a mean to establish cooperation initiatives in a safe environment for national policymakers, provided the latter actively cooperate in the process.

This research has underscored how, in sensitive areas such as health policy which refer to exclusive competences of EU Member States, **soft governance processes should include hard policy-makers**. A successful example of the latter can be found in the Bologna process, structured on the basis of soft governance. The latter has led to the establishment of a European Higher Education Area uniting 48 countries in Europe building a common set of values and norm and leading to structural reforms such as adaptation of higher education system to make them more compatible and qualitative (e.g. adopting a common Bachelor – Master – PhD track) (Veiga and Amaral 2010; http://www.ehea.info/index.php).

Second, when establishing cooperation processes based on soft governance in sensitive policy areas, a clear **stakeholder policy should be defined in an early stage of the process**. We have underscored how stakeholder policy approaches are politically not neutral and will require social interaction processes to clarify position of all actors involved. No clear definition of the stakeholders' role and expected inputs may jeopardise implementation of collaboration outputs. Although in some cases, stakeholder policy could be restricted to informative purposes, an inclusive participatory stakeholder approach would instil adherence of the stakeholder group and/or allow manifestation of barriers that should be overcome to guarantee successful policy implementation. Moreover, horizontal stakeholder coordination should be encouraged for creative problem-solving approaches to occur.

Third, in highly sensitive areas such as health policy and HTA cooperation, **a European legislative framework should leave space for the development of flexible cooperation structures**. At present, in a Union of 27 Member States, where the European integration objective loses ground and an increasing number of countries are governed by anti-EU policymakers, Europe needs to become creative in the cooperation approaches it proposes. Whereas the Community method can still be effective in many areas, convergence of practices in sensitive policy areas should respect the political will of Member States in strengthening integration policies or not.

In the case of HTA cooperation, where consensus exists on the benefits of cooperation, a one-size fits all approach does not federate Member States. The various consultation processes have highlighted how a **flexible cooperation approach (including mandatory aspects of uptake) would appeal more to Member States**. Such an integration policy

has already been implemented in policy areas such as border control (e.g. Schengen agreements) and monetary integration (e.g. Eurozone). In HTA, a legislative framework offering flexibility to Member States could also offer the perspective of including intergovernmental cooperation initiatives (e.g. Visegrad + 2, Beneluxa) in a common EU cooperation framework in the long run. Should these continue to develop at their own pace, HTA agencies joining several of these initiatives would be exposed to potential overlap and conflicting interests. As these initiatives respond to different regulatory frameworks but could address similar issues, outcomes could again diverge. Integration on one level could lead to fragmentation on another level. Hence, in case of extensive membership overlap, coordination between regional organisations would become necessary.

Fourth, **additional evidence generation throughout the life cycle of a product is a new area** with potential for further development in the years to come. Cooperation in this area has already been initiated and builds further upon the synergies created between the HTA and European regulatory processes. However, this area comprises many methodological challenges to resolve and **early cooperation would therefore be highly recommended so as to streamline quality requirements as well as methodological and legal approaches, rather than letting disparities develop** in areas such as Real World Evidence and conditional reimbursements. A soft governance approach responding to some key-aspects of effectiveness in network governance should be observed.

Fifth, HTA is a highly specialised field requiring specific expertise often given in an academic environment and further developed within HTA agencies. Initial training given to future HTA scientists is enshrined in the domestic HTA approaches in terms of quality requirements and methodological implications of those. Although in the data collection of this research, attention has been given to the collection of potential cooperation in HTA education, no significant initiatives have been developed by the HTA networks in the field of academic cooperation. However, **if new collaborative approaches could be developed in HTA, transmission of those should also take place in the initial academic training of HTA scientists.**

Finally, HTA cooperation is based on policy and scientific coordination of activities taking place on multiple levels and with multiple actors. Synergies have been created in the HTA arena bringing about consensus on HTA tools, methodologies and practices between a certain amount of HTA agencies. This consensus is however not shared with all HTA actors in the HTA arena as disagreements still exists. Synergies between the European regulatory and HTA arena have also been developed and could serve as a basis for further work on evidence generation including issues such as Real-World Data and post-marketing additional evidence generation. However, to pursue the cooperation efforts and increase their

effectiveness in terms of goal attainment, synergies at other levels should be developed. In particular between the **HTA arena and Member States'** high-level policy-making level (e.g. Ministries of health, Ministries of social security). Moreover, the dual economic and public health profile of health technologies leads to contrasting and sometimes conflicting policy-making approaches towards HTA. For a consistent policy of HTA cooperation on a European level, **synergies between Directorate Generals of the European Commission** would be highly recommended.

8.5. RESEARCH CONTRIBUTIONS

This research has proceeded to a systematic examination of the European cooperation process in HTA from an EU governance perspective. It has identified factors impacting effectiveness of soft governance implemented in European HTA networks aiming to establish a sustainable HTA cooperation framework within the EU. As, to our knowledge, no other study has examined European HTA cooperation in the light of soft governance within the EU framework, the thesis has filled this research gap.

Moreover, analysing soft governance in HTA cooperation through the prism of network analysis has proven valuable in highlighting the practical impacts of this governance mode in the area. The research framework established by cross-checking different strands of academic research regarding network governance has permitted to identify the typology of the different HTA networks as well as factors favouring or hindering effectiveness of the networks operating through soft governance mechanisms. Amongst the factors included in the research framework and affecting goal attainment, social interaction has been identified as playing a particular role in the HTA networks. Moreover, It has underscored how effectiveness of soft governance does not only depend on the instruments used but also on the manner in which they are implemented.

Hence, the network analysis based on the research framework has provided insight in soft governance mechanisms that contribute (or not) to convergence of practices in the field of HTA cooperation and has underscored the circumstances in which this can (or not) occur. The conclusions drawn with regard to European HTA cooperation can also give insight in the effectiveness of soft governance in other policy fields falling under exclusive Member States' competences and in which some degree of convergence is sought. Moreover, networking is often used in the EU context and this research has given insight in how the Commission can develop and act as metagovernor in some cases. It also demonstrates how the EU can use soft governance as a strategic instrument to pursue hard regulation objectives.

Organising the data collected by using the five stages of the policy cycle, has operated positively and allowed to break up a complex process into smaller stages, easier to analyse and compare amongst each other. The policy cycle also made possible the systematic comparison of networks operating in different periods of time as well as the systematic comparison of policy developments between the EU level and the HTA arena. This analysis has highlighted how both levels mutually influenced each other in the elaboration of specific policy fields, such as, HTA and EU health policy, through networking at multiple levels

Finally, this thesis has given a unique outline of the history of HTA cooperation in Europe since it originated. It has highlighted its connectivity with EU health policy by giving a parallel description of the developments in both arenas and underscoring how they mutually influenced each other. This account furthermore illustrates the evolution of a new policy area in the EU and has outlines the development path of new legislative tools within an EU setting.

8.6.   RESEARCH LIMITATIONS & POTENTIAL NEW RESEARCH AVENUES

The limitations of this research reside first in the low number of respondents on a ministerial level. Although contacts have been made, the ongoing debate on the HTA Regulation proposal at time of the field work, made participation for ministerial representatives harder to accept. Although, information has been collected via HTA arena representatives having first-hand experience with the ministerial level, the low respondence rate of some key actors leads to the fact that some positions are not sufficiently reflected in the research. An example hereof is this issue of uptake, where positions have been expressed by the HTA arena and the European Commission. The opinions regarding uptake reflecting the ministerial level have not been integrated in this research. This limitation does however reflect the low involvement of this important policy actor in the overall cooperation process.

Exploring Governance of European HTA cooperation at a time where the European Commission decided to propose a Regulation on HTA cooperation made it more difficult to take the necessary distance of what became a hot topic in European health policy. Besides influencing the respondence rate of interviewees, the debate also influenced the content of the personal interviews. Whilst in some cases, respondents became very cautious in sharing their experiences – or even refused taking part in it - , in most cases the proposal led to a stronger positioning of actors in the field, eager to share their experiences, thoughts and opinions about the cooperation efforts.

By adopting a holistic approach of the network activities, some issues have not been looked at into more depth. The topic of uptake of Joint Scientific Advice could be cited as examples hereof and were initially considered as case-studies for the thesis. Ultimately the choice has been made to integrate these as activities of the networks, as both issues could be a thesis topic on a standalone basis and are subject for further research.

Finally, the thesis has restricted its focus on *European* cooperation initiatives and has not integrated in its analyses similar experiences taking place in other places worldwide. Convergence of HTA approaches in Canada could be cited as an example hereof. As each of these situations take place in particular policy environments, only partially comparable to the EU framework, we have decided to keep the focus exclusively on Europe. However, it would have been interesting to make a comparable analysis of similar initiatives elsewhere. This too, would be subject for further research.

Similarly, the research has not given attention to the impact of the cooperation efforts in countries where HTA is organised on a regional/local basis and having more than one agency participating in any of the networks. Further research as to how the European cooperation initiatives would impact national approaches to HTA could be of interest.

Finally, as mentioned under the policy recommendation, no specific attention has been given to academic collaboration on HTA. As outlined above, initial training of HTA doers is of high importance in the methodological approach one will take on HTA. Many issues identified as hurdles to convergence of HTA approach are related to methodological approaches on which quality qualifications are made and which prohibit some players to put their trust in collaborative HTA assessments. Further research in academic approaches and the link to domestic policymaking would thus be of outmost interest for European HTA cooperation.

8.7. CONCLUDING REMARKS

Soft governance applied in EU policy often triggers the question whether it serves European integration or on the contrary restrains it. The conclusions of this research indicate that no clear-cut answer can be given and arguments can be found to comfort both positions. What this thesis does display is that soft governance can be used as a strategic instrument to pursue either goal. In the case of HTA cooperation, the European Commission has used soft governance as an instrument to prepare the ground for the convergence of practices by means of hard regulation. Some EU Member States used soft governance to benefit from external expertise and resources while remaining in control of national policy-making

processes, refusing convergence at a European level. With the HTA Regulation proposal lay-
ing on the table, the denouement of the process is still open.

Soft governance in EU policy making is often implemented within a context of integration
struggles. The outcome will mostly depend on the way soft governance will be operation-
alised. The arsenal of soft governance instruments does indeed contain some powerful
instruments favouring integration strategies. If used to pursue the convergence of practices,
the challenge will lay in the choice and handling of those instruments. As they are 'soft', no
handbook or rule-set exists to guide the users. Impact of soft governance will largely depend
on interpersonal skills, social competences, governance, management and communication
abilities of the operators to translate expertise into policy. Presence of policy entrepreneurs is
paramount to create political salience for the issue, bringing about the convergence of the
politics and policy streams and rendering effective policy-making achievable.

The belief that soft and hard governance are mutually exclusive often implicitly underpins
the debate regarding the convergence capacity of soft governance. Dichotomy between soft
and hard governance is found in their implementation capacity, highlighting the compli-
ance challenges related to soft governance (e.g. Citi and Rhodes 2007). At first sight, the
case of European HTA cooperation would corroborate these assertions. Similarly, need for
a shadow of hierarchy to enhance effectiveness of soft governance - herewith signifying its
implementation limitations - (Héritier and Rhodes 2011) is also substantiated in our research.
The junction between the two modes will often only be found in soft governance being a
strategy to prepare hard regulation and subsequent harmonisation (e.g. Kröger 2009). In the
case of HTA cooperation this too seems indeed to be verified.

The network analysis we have made in the case of HTA cooperation points however to deeper
ties between the two governance modes and opens new reflexion paths as to the place of
soft governance in EU integration policies. The limitations of soft governance found in our
research emerge as a consequence of the *absence* of adequate soft governance implementa-
tion rather than inherent weaknesses of soft governance modes. Instead of opposing both
modes or considering one mainly as subordinated to another in terms of integration capacity,
the case of HTA cooperation displays how both governance approaches can – and maybe
should – be complementary in health policy and could be implemented side by side. Soft
governance creates integration capacity on the one hand by consensus building, essential for
hard regulation to be adopted. On the other hand, by offering flexibility and gradualism in
the convergence of policies, it potentially also allows for the development of more innovative
approaches of integration.

Soft and hard governance are also often synonyms for the division of competences between the EU and its Member States. Combining both governance approaches requires however that one steps away from the traditional disputes about competences division. Competence division stands at the core of EU integration processes and should retain a central place. Nevertheless, integration processes are not static and respond to political, economic, and societal challenges. Consequently, introducing elasticity in competences distribution would be highly recommended. Soft governance can create opportunities and provide frameworks whereby actors elaborate common policies in areas where a joint approach would serve common interests, while remaining in charge of their national policy.

To date, EU integration debates in health policy remain enshrined in Member States' refusal to converge part of their policies at an EU level. Keeping full responsibility for the organisation of their health systems is considered a question of national interests, comprising besides health care also financial and economic concerns. Regretfully, discussions consequently tend to be focused on legalistic competence issues rather than on health care interests of European citizens. Economic considerations often prevail over health care concerns. Health becomes the subject of national trade-offs between industry, payers and patients, health care providers often only participating on the margin.

At times where cross-border health threats reveal shortcomings of national responses, where research, development, production and marketing of health technologies are globalised, where all players seek to optimise their economic and financial interests, individual EU Member States' responses may however not be sufficient to address the issues at stake and secure the best interests of their citizens. New challenges may require new responses. Reassessing the scope of EU competences in health policy should therefore not be fully dismissed and new opportunities for collaboration should be envisaged within innovative frameworks. Legal certainty would facilitate the choice of governance approaches and instil transparency in governors' intentions. Flexibility coupled to commitment should be guiding the roadmap towards convergence in those areas where the interests of European citizens would be better served by enhanced European cooperation.

Soft governance is a powerful tool to support public policy dedicated to serve public interest. It presents many features allowing for the convergence of positions whilst preserving national interests. It should however be 'handled with care' so that it could express itself in all its dimensions and bring the public interest back into the debate. Governance networks can serve as a medium for interest mediation, shift actors' beliefs and values as well as their positioning. Consensus building and common policy development are feasible objectives, provided all stakeholders participate in the process. At a time where the EU integration process is under strain by multiple challenges, soft governance would deserve renewed at-

tention as it could provide the flexibility and gradualism needed in convergence strategies. This would require, however, that it be granted a different status and functionality within the EU governance modes, whereby it would be conceived as a real alternative to classic modes of integration rather than 'sub-ordinated' to them and essentially utilised to pave the way for such long established, but perhaps no longer uniformly applicable models.

ANNEXES

ANNEX 1 - LIST MEMBERS EUNETHTA

EUnetHTA Project[202]

EU Member States:

1. **Main Partner**

DACEHTA – Danish Centre for Evaluation and HTA, **Denmark**

Associated Partner (AP) & Collaborating Partners (CP)[203]

2. Ludwig Boltzman Institute of Health Technology Assessment, LBI@HTA (former ITA) (AP), **Austria**

3. Gesundheit Österreich GmbH, Austrian Health Institute (CP) , **Austria**

4. Hauptverband der Österreichischen Sozialversicherungsträger (CP), **Austria**

5. KCE - Belgian Health Care Knowledge Centre (AP), **Belgium**

6. Ministry of Health Cyprus (AP), **Cyprus**

7. CAST - Center for Anvendt Sundhedstjenesteforskning og Teknologivurdering, University of Southern Denmark, Center for Applied Research and Technology Assessment (AP), **Denmark**

8. DSI- Danish Institute for Health Services Research (AP), **Denmark**

9. HTA and Health Service Research, Center of Public Health (CP), **Denmark**

10. University of Tartu, Department of Public Health (AP), **Estonia**

11. FinOHTA - Finnish Office for HTA (AP), **Finland**

12. HAS - Haute Autorité de santé / French National Authority for Health (AP), **France**

13. CEDIT - Commitee for Evaluation and Diffusion of Innovative Technologies, Direction de la Politique Médicale (CEDIT) (CP), **France**

14. DAHTA@DIMDI- German Agency for HTA at the German Institute for Medical Documentation and Information (AP), **Germany**

15. University of Lübeck, Institute for Social Medicine (AP), **Germany**

16. Technische Universitaet Berlin (AP), **Germany**

17. University of Bremen, Interdisciplinary Centre for HTA (AP), **Germany**

18. German HTA Association (CP), **Germany**

19. IQWIG - Institute for Quality and Efficiency in Health Care (CP), **Germany**

---

202 Source: Lund Håheim L, Imaz I, Laubli M, Gasparetto T, GonzálezEnríquez J, Trofimovs I, Dahlgren H, Liberati A, Berti E, Mørland B. (2008). Report on the internal evaluation of European network for Health Technology Assessment – EUnetHTA: 48-51.

203 AP – Associated Partner, financially and technically contributing to the project, Member of the project's Steering Committee; CP- Collaborating Partner, advisory and scientific excellence role.

20. Public Health Genomics European Network (PHGEN), German Center for Public Health Genomics (DZPHG) (CP), **Germany**
21. HunHTA - Unit of Health Economics and Health Technology Assessment (AP), **Hungary**
22. HIQA - Health Information and Quality Authority (AP), **Ireland**
23. ASSR Regione Emilia-Romagna - Agenzia Sanitaria e Sociale Regione Emilia-Romagna (AP), **Italy**
24. Agenas.- Agenzia Nazionale per i Servizi Sanitari Regionali (CP from 2007), **Italy**
25. Università Cattolica del Sacro Cuore, Policlinico universitario "A. Gemelli", Health Technology Assessment Unit and Laboratory of Health Economics (Institute of Hygiene) (AP), **Italy**
26. Regione Veneto (AP), **Italy**
27. VSMTVA - Health Statistics and Medical Technology State Agency (AP), **Latvia**
28. Ministry of Health of the Republic of Lithuania (AP), **Lithuania**
29. Agency for HTA in Poland, AHTAPol (CP), **Poland**
30. CEESTAHC - Central and Eastern European Society for Technology Assessment in Health Care (CP), **Poland**
31. Institute of Molecular Medicine (CP), **Portugal**
32. National School of Public Health and Health Services Management (CP from 2007), **Romania**
33. Institute of Public Health of the Republic of Slovenia (AP), **Slovenia**
34. AETS - Agencia de Evaluación de Tecnologias Sanitarias (AP), **Spain**
35. AETSA - Andalusian Agency for Health Technology Assessment (AP), **Spain**
36. CAHTA - Catalan Agency for Health Technology Assessment and Research (AP), **Spain**
37. Galician Agency for Health Technology Assessment (AP), **Spain**
38. OSTEBA - Basque Office for Health Technology Assessment (AP), **Spain**
39. Servicio Canario de la Salud (AP), **Spain**
40. UETS - Unidad de Evaluación de Tecnologías Sanitarias, Agencia Laín Entralgo (AP), **Spain**
41. SBU - Swedish Council on Technology Assessment in Health Care (AP), **Sweden**
42. CVZ - College voor zorgverzekeringen (AP), **The Netherlands**
43. ZonMw (AP), **The Netherlands**
44. NCCHTA - National Coordinating Centre for HTA (AP), **The United Kingdom**
45. CRD - Centre for Reviews and Dissemination, University of York (CP), **The United Kingdom**
46. NICE - National Institute for Health and Clinical Excellence (CP from 2007), **The United Kingdom**

EEA Countries:

47. Directorate of Health (CP), **Iceland**

48. NOKC - Norwegian Knowledge Centre for the Health Services (AP), **Norway**

Other countries

49. SNHTA - Swiss Network for Health Technology Assessment (CP), **Switzerland**

50. Ministry of Health (CP), **Serbia**

51. MSAC - Medical Services Advisory Committee (CP), **Australia**

52. CADTH (former CCOHTA) - Canadian Agency for Drugs and Technologies in Health (CP), **Canada**

53. ICTAHC - Israeli Center for Technology Assessment in Health Care (CP), **Israel**

54. AHRQ - Agency for Healthcare Research and Quality, Center for Outcomes & Evidence (CP), **USA**

55. CMTP - Center for Medical Technology Policy (CP from 2007), **USA**

International organisations:

56. Cochrane Collaboration - The Cochrane Collaboration Secretariat (AP)

57. Council of Europe - Directorate General III - SOCIAL COHESION (CP)

58. European Observatory on Health Systems and Policies (CP)

59. EuroScan - European Information Network on New and Changing Health Technologies (CP)

60. G-I-N Executive - Guidelines International Network (CP)

61. HTAi - HTAi Secretariat (CP)

62. INAHTA - INAHTA Secretariat (CP)

63. OECD - Organisation for Economic Cooperation and Development (CP)

64. WHO - Health Evidence Network (HEN) (CP)

EUnetHTA Joint Action 1[204]

1. **Main Beneficiary:**
   Danish Health and Medicines Authority - DHMA

Associated Partners:

2. Agencja Oceny Technologii Medycznych - Agency for Health Technology Assessment in Poland, **Poland**

3. Agenzia Italiana del Farmaco (Italian Medicines Agency), **Italy**

4. Agenzia Nazionale Per i Servizi Sanitari Regionali, **Italy**

5. Belgian Health Care Knowledge Centre/Federaal Kenniscentrum voor de Gezond-heidszorg, **Belgium**

---

204 http://ec.europa.eu/chafea/projects/database.html?prjno=20092302

6. Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark, **Denmark**

7. College voor Zorgverzekeringen, **Netherlands**

8. Deutsches Institut für Medizinische Dokumentation und Information, **Germany**

9. Gesundheit Österreich GmbH / Bundesinstitut für Qualität im Gesundheitswesen, **Austria**

10. Hauptverband der Österreichischen Sozialversicherungsträger // Evidenzbasierte Wirtschaftliche Gesundheitsversorgung EWG (Evidence Based Economic Health Care), **Austria**

11. Haute Autorité de Santé, **France**

12. Health Information and Quality Authority, **Ireland**

13. Institute for Healthcare Quality Improvement and Hospital Engineering (until 30/04/2011), **Hungary**

14. Institute of Public Health of the Republic of Slovenia - NIPH, **Slovenia**

15. Instituto De Salud Carlos III, **Spain**

16. Ludwig Boltzmann Gesellschaft GmbH - Ludwig Boltzmann Institut für Health Technology Assessment, **Austria**

17. Medicines Pricing and Reimbursement Agency (until 31/10/2011), **Latvia**

18. Ministry of Health, the Elderly and Community Care - MHEC, **Malta**

19. Ministry of Health - MOH-CZ, **Czech Republic**

20. National Authority of Medicines and Health Products, **Portugal**

21. National Center of Public Health Protection, **Bulgaria**

22. National Institute for Health and Clinical Excellence, **United Kingdom**

23. National Institute for Health and Welfare, **Finland**

24. National Institute for Strategic Health Research (until 30/04/2011), **Hungary**

25. National School of Public Health, **Greece**

26. State Health Care Accreditation Agency, **Lithuania**

27. Stiftung für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Foundation for Quality and Efficiency in Health Care, **Germany**

28. Swedish Council on Technology Assessment in Health Care, **Sweden**

29. The Norwegian Knowledge Centre for the Health Services, **Norway**

30. University of Southampton (NIHR Evaluation, Trials and Studies Coordinating Centre), **United Kingdom**

31. University of Tartu, **Estonia**

32. Region Del Veneto, **Italy**

33. Ministry of Health and Social Policy, **Spain**

34. National Institute for Quality and Organizational development Health - GYEMSZI (from 01/05/2011), **Hungary**

35. National Health Service - NHS (from 01/11/2011), **Latvia**

EUnetHTA Joint Action 2[205]

1. **Main Beneficiary**:
   Danish Health and Medecines Authority, **Denmark**

Associated Partners:

2. Agencja Oceny Technologii Medycznych – AHTAPOL, **Poland**
3. Agencija Za Kvalitetu i Akreditaciju u Zdrastvu AQAHC, **Croatia**
4. Agenzia Nationale per Servizi Sanitari Regionale AGENAS, **Italy**
5. Agenzia Sanitaria e Sociale Regionale * Regione Emilia-Romagna - ASSR RER, **Italy**
6. Centre Fédéral d'Expertise des Soins de Santé – KCE, **Belgium**
7. College voor Zorgverzekeringen CVZ, **Netherlands**
8. Deutsches Institut für Medizinische Dokumentation und Information DIMDI, **Germany**
9. Lääkealan Turvallisuusja Kehittmämiskeskus FIMEA, **Finland**
10. Gesundheit Österreich GmbH – GÖG, **Austria**
11. Haute Autorité de Santé HAS, **France**
12. Health Information and Quality Authority HIQA, **Ireland**
13. Department of Health Technology Assessment - HSR/DHTA, **Denmark**
14. Inštitut Za Ekonomska Raziskovanja IER, **Slovenia**
15. Instituto de Salud Carlos III – ISCIII, **Spain**
16. Agenzia Italiana Farmaco – AIFA, **Italy**
17. Ludwig Boltzmann Gesellschaft GmbH LBGG, **Austria**
18. Hauptverband der Österreichischen Sozialversicherungsträger – HVB, **Austria**
19. Ministry for Health, the Elderly and Community Care – MHEC, **Malta**
20. Ministerstvo Zsravotnictví eské Republiky MZ, **Czech Republic**
21. Ministry of Health of Cyprus – MOH, **Cyprus**
22. Autoriadade Nacional do Medicamento e Produtos de Saude I.P. INFARMED, **Portugal**
23. National Center of Public Health and Analyses NCPHP, **Bulgaria**
24. National Institute for Health and Clinical Excellence – NICE, **United Kingdom**
25. Terveyden Ja Hyvinvoinnin Laitos THL, **Finland**
26. Gyógyszerészeti és Egészségügyi Minség és Szervezetfejlesztési Intézet GYEMSZI, **Hungary**
27. Inštitut Za Varovanje Zdravja – NIPH, **Slovenia**
28. National School of Public Health Special Research Account – NSPH, **Greece**
29. National School of Public Health, Management and Professional Development in Health Bucharest NSPHMPDHB, **Romania**
30. University of Southampton NETSCC, **United Kingdom**
31. Regione del Veneto REGVEN, **Italy**

---

205 https://webgate.ec.europa.eu/chafea_pdb/health/projects/20112301/summary

32. Nadácia ZRAK SLOVAHTA (until 13/05/2013), **Slovakia**
33. State Health Care Accreditation Agency under the Ministry of Health of Lithuania VASPVT, **Lithuania**
34. Stiftung für Qualität und Wirtschaftlichkeit im Gesundheitswesen IQWIG, **Germany**
35. Statens Beredning för Medicinsk Utvärdering SBU, **Sweden**
36. Nacionlais Veselbas Dienests – NHS, **Latvia**
37. Nasjonalt Kunnskapssenter for Helsetjenesten NOKC, **Norway**
38. Tartu Ülikool TARTU, **Estonia**
39. Ministry of Health of the Slovak Republic, **Slovakia**

EUnetHTA Joint Action 3[206]

1. **Main Beneficiary**
   ZIN - National Health Care Institute, **Netherlands**

Partner Organisations and Institutions

2. ACSS IP - Administração Central do Sistema de Saúde, I.P., **Portugal**
3. AEMPS - Agencia Española de Medicamentos y Productos Sanitarios, **Spain**
4. AETSA - Andalusian HTA Agency, **Spain**
5. AETS-ISCIII - The Instituto De Salud Carlos III, **Spain**
6. Agenas - National Agency for Regional Health Services, **Italy**
7. AIFA - Italian Medicines Agency, **Italy**
8. AOTMiT - Agency for Health Technology Assessment and Tariff System, **Poland**
9. AQuAS - Agency for Health Quality and Assessment of Catalonia, **Spain**
10. AVALIA FNS - Fundacion Profesor Novoa Santos, **Spain**
11. AVALIA-T - Galician Agency for HTA, **Spain**
12. AWTTC - All Wales Therapeutics and Toxicology Centre, **United Kingdom**
13. BIOEF - Basque Foundation for Health Innovation and Research, **Spain**
14. CHIF - Croatian Health Insurance Fund, **Croatia**
15. CIPH - Croatian Institute of Public Health, **Croatia**
16. CRUF/AOUIVR - Centro Regionale Unico sul Farmaca del Veneta, **Italy**
17. DEFACTUM (formerly CFK) – DEFACTUM, **Denmark**
18. DGFDM IT **-** Sede del Ministro – Ministero della salute, **Italy**
19. DGFPS MSPSI - Directorate General for Pharmacy and Health Care Products, **Spain**
20. DIMDI - German Institute for Medical Documentation and Information, **Germany**
21. DPA/MoH Malta - Directorate for Pharmaceutical Affairs, **Malta**
22. EKAPTY SA - National Evaluation Center of Quality and Technology in S.A.- EKAPTY, **Greece**

---

206 https://eunethta.eu/about-eunethta/eunethtanetwork/.

23. EKAPTY-NKUA - National and Kapodistrian University of Athens, **Greece**
24. EOF - National Organization for Medicines, **Greece**
25. EOPYY - National Organisation for Healthcare Provision, **Greece**
26. EUR - Erasmus Universiteit Rotterdam, **Netherlands**
27. FIMEA - Finnish Medicines Agency, **Finland**
28. FPS - Fundación Pública Andaluza Progreso y Salud, **Spain**
29. Funcanis - Fundación Canaria de Investigación Sanitaria, **Spain**
30. GBA - Gemeinsamer Bundesausschuss, **Germany**
31. GOG - Gesundheit Österreich GmbH/Geschäftsbereich, **Austria**
32. HAS - French National Authority for Health (Haute Autorité de Santé), **France**
33. Hdir - Norwegian Directorate of Health, **Norway**
34. HI - The Institute of Hygiene, **Lithuania**
35. HIQA - Health Information and Quality Authority, **Ireland**
36. HIS - Healthcare Improvement Scotland, **United Kingdom**
37. HVB - Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions), **Austria**
38. IFET - Institute of Pharmaceutical Research and Technology, **Greece**
39. INFARMED - National Authority of Medicines and Health Products, **Portugal**
40. IPH - Scientific Institute of Public Health, **Belgium**
41. IQWIG - Institute for Quality and Efficiency in Health Care, **Germany**
42. JAZMP - Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices, **Slovenia**
43. KCE - Belgian Health Care Knowledge Centre, **Belgium**
44. LBI-HTA - Ludwig Boltzmann Institute for Health Technology Assessment, **Austria**
45. MIZ - Ministry of Health of the Republic of Croatia, **Croatia**
46. MoH Cyprus - Ministry of Health of Cyprus, **Cyprus**
47. MoH Czech - Ministry of Health of the Czech Republic, **Czech Republic**
48. MoH Slovak Republic - Ministry of Health of the Slovak Republic, **Slovakia**
49. MoH Slovenia - Ministry of Health of the Republic of Slovenia, **Slovenia**
50. MoH Ukraine - HTA Department of SEC of Ministry of Health of Ukraine, **Ukraine**
51. MPA - Medical Products Agency, **Sweden**
52. NCPE - National Centre for Pharmacoeconomics, St. James Hospital, **Ireland**
53. NCPHA - National Center of Public Health and Analyses, Bulgaria
54. NICE - National Institute for Health and Care Excellence, **United Kingdom**
55. NIJZ - National institute of Public Health (NIJZ), **Slovenia**
56. NIPHB - Institutu National De Sanatate Publica (INSP), **Romania**
57. NIPHNO (formerly NOKC) - The Norwegian Institute of Public Health, **Norway**
58. NIPN - National Institute of Pharmacy and Nutrition, **Greece**
59. NOMA - Norwegian Medicines Agency, **Norway**

60. NSPHMPDB - National School of Public Health, Management and Professional Development, **Romania**
61. NVD - National Health Service, **Latvia**
62. OCSC - Onassis Cardiac Surgery Centre, **Greece**
63. Osteba - Basque Office for Health Technology Assessment- Ministry for Health, **Spain**
64. RER - Regione Emilia-Romagna, **Italy**
65. RIZIV-INAMI - Rijksinstituut voor Ziekte- en Invaliditeitsverzekering, **Belgium**
66. SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services, **Sweden**
67. SESCS - Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service, **Spain**
68. SNHTA - Swiss Network for HTA, **Switzerland**
69. SU - Health Services Management Training Center, **Greece**
70. SUKL - State Institute for Drug Control, **Czech Republic**
71. THL - National Institute for Health and Welfare, **Finland**
72. TLV - Dental and Pharmaceutical Benefits Agency, **Sweden**
73. UBB - Babes-bolayi University, Cluj School of Public Health, **Romania**
74. UCSC GEMELLI - University Hospital A. Gemelli, **Italy**
75. UMIT - University for Health Sciences, Medical Informatics and Technology, **Austria**
76. UniBA FOF - Comenius University in Bratislava, **Slovakia**
77. UTA - Institute of Family Medicine and Public Health, **Estonia**
78. UU - Utrecht University, **Netherlands**
79. UVTA/AOP - Unita di Valutazione Technology Assessment, **Italy**
80. VASPVT **-** State Health Care Accreditation Agency, **Lithuania**
81. Veneto/CRUF - Regione Del Veneto – Area Sanita E' Sociale, **Italy**

ANNEX 2 - LIST OF INTERVIEWS

Interview 1   Representative of EUnetHTA/ZIN, Zorginstituut Nederland, The Netherlands

Interview 2   Former Representative of EUR-ASSESS, HTA-Europe, ECHTA-ECHAI, The Netherlands/US

Interview 3   Former Representative of the European Commission, DG Sanco, Belgium

Interview 4   Representatives of EUnetHTA (project, JA1, JA2), Danish Health and Medicines Authority, Denmark

Interview 5   Former consultant European Commission, the Netherlands

Interview 6   Former Representative of CAHTA, Agency for Health Quality and Assessment of Catalonia, Spain

Interview 7   Representative of EUnetHTA (project, JA1, JA2), Denmark

Interview 8   Representatives of European Commission, DG Santé, Belgium

Interview 9   Representatives of European Commission DG Santé – HTA team, Belgium

Interview 10   Former Representative of EUR-ASSESS, HTA-Europe, ECHTA-ECHAI, The Netherlands/US

Interview 11   Representative of AAZ, Agency for Quality and Accreditation in Health Care and Social Welfare, Croatia

Interview 12   Representatives of Eurordis, France

Interview 13   Representative of AIM, International Association of Mutual Benefit Societies, Belgium

Interview 14   Representative of AQuAS, Agència de Qualitat i Avaluació Sanitàries de Catalunya, Spain

Interview 15   Representative of EUnetHTA (JA3), The Netherlands

Interview 16   Representative of Sanofi-Genzyme, The Netherlands

Interview 17   Representatives of the Dutch Ministry of Health- Ministerie van Volksgewondheid, Welzijn en Sport, The Netherlands

Interview 18   Representative of THL, Terveyden Ja Hyvinvoinnin Laitos – Finland

Interview 19   Representative of HIQA, Health Information and Quality Authority – Ireland

Interview 20   Former Representative of KCE, Belgian Health Care Knowledge Centre – Belgium

Interview 21   Representative of CPME, Standing Committee of European Doctors, Belgium

Interview 22   Representative of IQWiG, Stiftung für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Germany

Interview 23   Representative of Medtech Europe, Belgium

Interview 24   Representative of EFPIA, Belgium

Interview 25   Representative of UEMO, European Union of General Practitioners, Belgium

Interview 26   Representative of synergy group/AIFA, Agenzia Italiana Farmaco – Italy

Interview 27   Representative of NICE, National Institute for Health and Clinical Excellence – United Kingdom

Interview 28   Representative of HSMTC, , Health Services Management Training Center, Semmelweis University – Hungary

Interview 29   Representative of HAS, Haute Autorité de Santé - France

Interview 30   Representative of AOMiT, Agency for Health Technology Assessment and Tariff System, Poland

Written contribution 1   Representative of Ministry of Health of the Slovak Republic – Slovakia

Written contribution 2   Representative of LBI-HTA - Austria

REFERENCES

Abellán-Perpiñán, J-M. (2015). "Measuring QALYs for HTA and Health Policy Decision Making: Bridging the Gap Between Power and ACT" in J. E. del Llano-Señarís and C. Campillo-Artero (eds.) *Health Technology Assessment and Health Policy Today: A multifaceted View of their Unstable Crossroads* (Springer International Publishing, Switzerland), pp. 95-108.

Abel-Smth, B., J. Figueras, W. Holland M. McKEE and E. Mossialos (1995). *Choices in health policy: an agenda for the European Union* (Luxembourg: Office for Official Publication of the European Communities).

Abelson, J., F. Wagner, D. De Jean, S. Boesveld, F-P. Gauvin, S. Bean, R. Axler, S. Petersen, S. Baidoobonso, G. Pron, M. Giacomini and J. Lavis (2016). "Public and patient involvement in health technology assessment a framework for action", *International Journal of Technology Assessment in Health Care*, 32 (4): 256–264.

Abrishami, P., W. Oortwijn and B. Hofmann (2017). "Ethics in HTA: Examining the 'need for Expansion", *International journal of health policy and management*, 6 (10), pp. 551–553.

Acheson, D. (1988). *Public health in England. The report of the Committee of Inquiry into the Future Development of the Public Health Function* (London: HSMO).

Agranoff, R. and M. McGuire (2001). "Big Questions in Public Network Management Research", *Journal of Public Administration Research and Theory* 11 (3): 295-329.

Agranoff, R. (2007). *Managing within Networks: Adding Value to Public Organizations* (Washington DC: Georgetown University).

Agranoff, R. and M. McGuire (2003). *Collaborative Public Management: New Strategies for Local Governments* (Washington, DC: Georgetown University Press).

Akehurst, R., E. Abadie, N. Renaudin and F. Sarkozy (2017). "Variation in Health Technology Assessment and Reimbursement Processes in Europe", *Value in Health* 20: 67-76.

Allen, N., S. Walker, L. Liberti and S. Salek (2017). "Health Technology Assessment (HTA) Case Studies: Factors Influencing Divergent HTA Reimbursement Recommendations in Australia, Canada, England and Scotland", *Value in Health* 20: 320-28.

Altenstetter, C. (2003). "EU and Member State medical devices regulation", *International Journal of Technology Assessment in Health Care* 19 (1): 228-48.

Altenstetter, C. and G. Permanand (2007). "The EU regulation of medical devices and pharmaceuticals in comparative perspective", *Review of Policy Research* 24 (5): 385-405.

Anell, A. (2004). "Priority setting in pharmaceuticals", *European Journal of Health Economics* 5: 28-35.

Angelis, A. and P. Kanavos. (2016). "Value-Based Assessment of New Medical Technologies: Towards a Robust Methodological Framework for the Application of Multiple Criteria Decision Analysis in the Context of Health Technology Assessment", *PharmacoEconomics*, 34 (5): 435–446.

Angelis, A., A. Lange and P. Kanavos, P. (2018). "Using Health Technology Assessment to Assess the Value of New Medicines: Results of a Systematic Review and Expert Consultation Across Eight European Countries," *The European Journal of Health Economics: Health Economics in Prevention and Care*, 19 (1): 123–152.

Argyris, C. and D. Schön. (1996). *Organisational learning II: Theory, method and practice* (Reading, Mass: Addison Wesley).

Ataíde, J. and H. Granzow (2018). "Taking stock: European cross-border cooperation on medicines' value-assessment, and Pricing & Reimbursement negotiations". Available at: https://globalpricing. com/news/taking-stock-european-cross-border-cooperation-on-medicines-value-assessment-and-pricing-reimbursement-negotiations/. Last accessed: 21 October 2019

Atienza M., G. and L. Varela Lema (2008). "Needs and demands of policy-makers", in M. Garrido, F.B. Kristensen, C.P. Nielsen and R. Busse (2008). *Health Technology Assessment and Health Policy-making in Europe: Current Status, Challenges and Potential* (Copenhagen: European Observatory on Health Systems and Policies), pp. 137-160.

Aucoin, P. (1990). "Administrative Reform in Public Management: Paradigms, Principles, Paradoxes and Pendulums", *Governance* 3 (2): 115-137.

Bache, I. and George, S. (2006). *Politics in the European Union. 2nd ed*. (Oxford: Oxford University Press).

Baeten (2012). *Europeanization of national health systems. National impact and EU codification of the patient mobility case law*. Report in the context of the EPSU Project 'Europeanisation of health policies and health care systems and common challenges for the health care workforce – options for trade unions and the role of social dialogue to address them in the next decade', (ESO/EPSU). Available at: http://www.epsu.org/IMG/pdf/Baeten-Europeanisation-Healthcare-Systems_Patient-Mobility-26-09-12.pdf. Last accessed: 28 October 2013.

Banta, D. (2003) "The Development of Health Technology Assessment," *Health policy*, 63 (2): 121–132.

Banta, D. (2009). What is technology assessment?", *International Journal of Technology Assessment in Health Care* 25 (Suppl 1): 7-9.

Banta, D. and S. Perry (1997). "A history of ISTAHC: A personal perspective on its first 10 years", *International Journal of Technology Assessment in Health Care* 13: 430-453.

Banta, D. and United States. Congress - Office of Technology Assessment (1995) *Health care technology and its assessment in eight countries*. Washington, DC: Office of Technology Assessment, United States Congress. Available at: https://www.princeton.edu/~ota/disk1/1995/9562/9562.PD. Last accessed: 23 January 2018.

Banta, D. and W. Oortwijn (1999). *Health technology assessment in Europe: The challenge of coordination,* report for the European Commission, Directorate-General for Employment, Industrial Relations and Social Affairs (Luxembourg: Office for Official Publications of the European Communities).

Banta, D. and W. Oortwijn (2000). 'Introduction: health technology assessment and the European Union', *International Journal of Technology Assessment in Health Care* 16 (2): 299-302.

Banta, D. and W. Oortwijn (2000b). "Health technology assessment and health care in the European Union". *International Journal of Technology Assessment in Health Care* 16 (2): 626-635.

Banta, D. and W. Oortwijn (2009). "The Netherlands", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 143–47.

Banta, D., and E. Jonsson (2009). "History of HTA: Introduction", *International Journal of Technology Assessment in Health Care*, 25(S1): 1-6. doi:10.1017/S0266462309090321

Banta, D., E. Jonsson, and P. Childs (2009). "History of the international societies in health technology assessment: International Society for Technology Assessment in Health Care and Health Technology Assessment International", *International Journal of Technology Assessment in Health Care* 25 (Suppl 1): 19-23.

Banta, D., F.B. Kristensen, and E. Jonsson (2009). "A history of health technology assessment at the European level", *International Journal of Technology Assessment in Health Care* 25 (Suppl 1): 68-73.

Banta, D., L. Werkö, R. Cranovsky, A. Granados, C. Henshall, E. Jonsson, A. Liberati, Y. Matillon and T. Sheldon (1997). "Report from the EUR-ASSESS Project: Introduction to the EUR-ASSESS report", *International Journal of Technology Assessment in Health Care* 13 (2): 133-43.

Banta, D., W.J. Oortwijn, and W.T. Van Beekum (1995). *The Organisation of Health Care Technology Assessment in the Netherlands* (The Hague: Rathenau Institute).

Banta, D., L. Werkö, R. Cranovski et al. (1997). "Report from the EUR-ASSESS Project", *International Journal of Technology Assessment in Health Care* 13:133–40.

Barrett, M. (2004). "Implementation Studies: Time for a Revival? Personal Reflections on 20 Years of Implementation Studies", *Public Administration* 82 (2): 249-62.

Barron, A., C. Klinger, S. Shah and J. Wright (2015). "A regulatory governance perspective on health technology assessment (HTA) in France: The contextual mediation of common functional pressures", *Health Policy* 119: 137–46.

Batista R. and N. Hodge (1995). "The development of Health Technology Assessment. An international Perspective", *International Journal of Technology Assessment in Health Care* 11 (2): 287-300.

Battista, R. (2006). "Expanding the scientific basis of health technology assessment: A research agenda for the next decade", *International Journal of Technology Assessment in Health Care* 22 (3): 275-282.

Battista, R. and M.J. Hodge (1999). "The evolving paradigm of health technology assessment: reflections for the Millennium". *Journal of the Canadian Medical Assocation* 160 (10): 1464-1467.

Battista, R. N., B. Côté, M. J.Hodge and D. Husereau (2009). "Health technology assessment in Canada", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 53–60.

Battista, R., J.M. Lance, P. Lehoux, and G. Regnier (1999). Health technology assessment and the regulation of medical devices and procedures in Quebec. Synergy, collusion, or collision? I*nternational Journal of Technology Assessment in Health Care* 15 (3): 593-601.

Baumgarten, F. and B. Jones (1991). "Agenda Dynamics and Policy Subsystems", *Journal of Politics* 53 (4): 1044-74.

Baumgartner F. and B. Jones (1993). *Agendas and Instability in American Politics* (Chicago and London: University of Chicago Press).

Baumgartner, F. and B. Jones (2005). *The Politics of attention. How Government prioritizes problems* (Chicago and London: University of Chicago Press).

Beal, D., R. Cohen, M. Burke, and C. McLendon (2003). "Cohesion and performance in groups: A meta-analytic clarification of construct relations", *Journal of Applied Psychology*, 88 (6), 989.

Beierle, T. C. and J. Cayford (2002). *Democracy in Practice: Public Participation in Environmental Decisions* (Washington, DC: Resources for the Future).

Benford, R. and D. Snow (2000). "Framing Processes and Social Movements: An Overview and Assessment", *Annual Review of Sociology* 26: 611-39.

Bennet, C. and M. Howlett (1992). "The Lessons of learning: reconciling theories of policy learning and policy change", *Policy Sciences* (25): 275-94.

Berg, M., T. van der Grinten, and N. Klazinga (2004). "Technology assessment, priority setting and appropriate care in Dutch health care", *International Journal of Technology Assessment in Health Care* 20(1): 35-43.

Bergmann, L., H. Enzmann, K. Broich, A. Hebborn, S. Marsoni, L. Goh, J. F. Smyth and H. Zwierzina (2014). "Actual developments in European regulatory and health technology assessment of new cancer drugs: what does this mean for oncology in Europe?", *Annals of Oncology* 25: 303–306.

Bermeo, N. (ed.) (2001). *Unemployment in the New Europe* (Cambridge/NewYork: Cambridge University Press).

Berntgen, M., A. Gourvil, M. Pavlovic, W. Goettsch, H-G. Eichler and F. B. Kristensen (2014). "Improving the Contribution of Regulatory Assessment Reports to Health Technology Assessments — A Collaboration between the European Medicines Agency and the European network for Health Technology Assessment", *Value in Health* 17: 634-41.

Bertinato L, Busse R, Fahy N, Legido-Quigley H, McKee M and W Palm (2005). *Cross-border health care in Europe* (Copenhagen: European Observatory on Health Systems and Policies, WHO).

Bevir, M. (2011). "Public Administration as Storytelling", *Public Administration* 89 (1): 183-195.

Bevir, M. and R. Rhodes (2007). "Decentred Theory Change and Network Governance", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan), pp. 77-93.

Bijlmakers L, D. Mueller, R. Kahveci, Y. Chen and GJ. van der Wilt GJ (2017) "Integrate-HTA: A Low- and Middle-Income Country Perspective", *International journal of technology assessment in health care*, 33 (5): 599–604.

Blume, S. (2009). "Assessing health technologies in a changing world", *International Journal of Technology Assessment in Health Care*, 25: Supplement 1: 276–280.

Böhm, K. and C. Landwehr (2013). "The Europeanization of Health Care Coverage Decisions: EU-Regulation, Policy Learning and Cooperation in Decision-Making", *Journal of European Integration* 36 (1): 17-35. Doi: 10.1080/07036337.2013.793679.

Bond, K. and L. Weeks (2017) "Using the Integrate-Hta Guidance: Experience from Cadth," *International journal of technology assessment in health care*, 33(5): 591–596.

Borgatti, S., C. Jones, and M. Everett (1998). "Network Measures of Social Capital." *Connections* 21 (2): 28–36.

Borowski, H.Z., J. Brehaut, and D. Hailey (2007). "Linking evidence from health technology assessments to policy and decision making: The Alberta Model", *International Journal of Technology Assessment in Health Care* 23(2): 155-61.

Borras, S. and K. Jacobsson (2004). "The open method of co-ordination and new governance patterns in the EU", *Journal of European Public Policy*, 11 (2): 185-208. Doi:10.1080/1350176042000194395

Börzel, T. and K. Heard-Lauréote (2009). "Networks in EU Multi-Level Governance: Concepts and Contributions", *Journal of Public Policy* (29): 135-152.

Börzel, T. (1998). "Organising Babylon. On the Different Conceptions of Policy Networks", *Public Administration* 76 (2): 253-73.

Börzel, T. (2002). "Pace-setting, foot-dragging and fence-sitting: member states responses to Europeanization", *Journal of Common Market Studies* 40, (2): 193–214.

Börzel, T. (2010). "Drawing Closer to Europe. New Modes of Governance and Accession", in A. Héritier and M. Rhodes (eds.) *Governance in the Shadow of Hierarchy* (Houndmills: Palgrave Macmillan), pp. 75-103

Börzel, T. and D. Panke (2007). "Network Governance: Effective and Legitimate?", in E. Sørenson and J. Torfing (eds.). *Theories of Democratic Network Governance* (Palgrave MacMillan: New York), pp. 153-68.

Bos, M. (2000). "Health technology assessment in the Netherlands", *International Journal of Technology Assessment in Health Care* 16 (2): 485-519.

Bowman-Busato, J. (2011). "Patient engagement in health technology assessment (HTA)", *Pharmaceuticals Policy and Law* 13: 193–201.

Bozeman, B. (ed.) (1993). *Public Management: The State of the Art* (San Francisco: Jossey-Bass).

Bozzini, E. 2008. "Multi-level governance and interest representation in the common agricultural policy", Paper presented at the CINEFOGO Conference on The Governance of the European Union: Theories, Practices and Myths, January 25–6, Brussels.

Bressers, H. (1998). "The Choice of Policy Instruments in Policy networks", in G. Peters and F. Van Nispen (eds.) (1998) *Public Policy Instruments: Evaluating the Tools of Public Administration* (New York: Edward Elgar), pp. 85-105.

Bressers, H. and P-J. Klok (1988). 'Fundamentals for a Theory of Policy Instruments', *International Journal of Social Economics* 15 (3-4): 22-41.

Breyer, S. (1979). "Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives, and Reform", *Harvard Law Review* 92 (3): 549-609.

Bridges, J. F.P. (2006). "Lean Systems Approaches to Health Technology Assessment A Patient-Focused Alternative to Cost-Effectiveness Analysis", *Pharmacoeconomics* 24 (2): 101-109.

Brixner, D., N. Maniadakis, Z. Kaló, S. J. Shen and K. Wijaya (2017). "Applying Multi-Criteria Decision Analysis (MCDA) Simple Scoring as an Evidence-based HTA Methodology for Evaluating Off-Patent Pharmaceuticals (OPPs) in Emerging Markets" *Value in Health Regional issues* 13 (C): 1-6.

Brooks, E. (2012). "Crossing borders: A critical review of the role of the European Court of Justice in EU health policy", *Health policy* 105: 33-37.

Bruijn, H. de, E. F. Ten Heuvelhof, and R. J. in't Veld (1998). *Process Management* (Schoonhoven: Academic Service).

Bruijn, H. de, G. R. Teisman, J. Edelenbos and W. Veeneman (eds.) (2004). *Multiple Land Use and the Management of Iowa State University* (Utrecht: Lemma).

Bulfone, L., S. Younie and R. Carter (2009). "Health Technology Assessment: Reflections from the Antipodes", *Value in Health* 12 (Supplement 2): 28-38.

Bultman, J. (2006). "Health Technology Assessment Health Technology Assessment and Quality of Care and Quality of Care What What's in it for the transition countries", Presentation at 9th European Health Forum European Health Forum Gastein 2006. Available at: http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/Presentations%20from%20Theme%20E.pdf. Last accessed: 10 August 2015.

Burt, R. (1992). *Structural holes: The social structure of competition* (Cambridge, MA: Harvard University Press).

Burt, R. (2000). "The Network Structure of Social Capital." In B. Staw, and I. Robert (eds.), *Research in Organizational Behavior* 22, (Sutton, Greenwich, CT: JAI Press), pp 345–423.

Busse, R. et al. (2002). "Best practice in undertaking and reporting health technology assessments", *International Journal of Technology Assessment in Health Care* 18 (2): 361-422.

Busse, R., J. Orvain, M. Garrido, et al. (2002). "Best practice in undertaking and reporting health technology assessments", *International Journal of Technology Assessment in Health Care* 18 (2): 361-422.

Carbonneil, C., F. Quentin, S. Lee-Robin, for the European network for Health Technology Assessment (EUnetHTA) (2009). "A common policy framework for evidence generation on promising health technologies", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 2): 56–67.

Carlsson, P. (2004). "Health technology assessment and priority setting for health policy in Sweden", *International Journal of Technology Assessment in Health Care* 14 (4): 687-94.

Carlsson, P., E. Jonsson, L. Werkö and D. Banta (2000). "Health technology assessment in Sweden", *International Journal of Technology Assessment in Health Care* 16 (2): 560-75.

Cavazza M. and Jommi C. (2012). "Stakeholders Involvement by Hta Organisations: Why Is so Different?", *Health policy* 105 (2-3): 236–45.

Chalkidou, K., J. Lord, A. Fisher and P. Littlejohns (2008). "Evidence-based decision making: When should we wait for more information?", *Health Affairs* 27: 1623–42.

Chalkidou, K., S. Tunis, R. Lopert, L. Rochaix, P. T. Sawicki, M. Nasser and B. Xerri (2009). "Comparative effectiveness research and evidence-based health policy: Experience from four countries", *Milbank Quarterly* 87(2): 339–367.

Chalmers, D., G. Davies and G. Monti (2010). *European Union Law* (Cambridge: Cambridge University Press).

Charles River Associates (2017). Report: *Assessing the wider benefits of the EU's proposal on strengthening cooperation on HTA.* Prepared for EFPIA. Available a*t:* https://www.efpia.eu/media/219813/cra-efpia-european-cooperation-on-hta-impact-assessment-final-report-july-2017-stc.pdf.   Last accessed: 9 July 2019.

Chevreul, K. and I. Durand-Zaleski (2009). "HTA in coverage and reimbursement decisions in France: Towards a new paradigm?", *Euro Observer* 11 (1): 5–6.

Chinitz D. (2004). "Health technology assessment in four countries: response from political science", *Journal of Technology Assessment in Health Care* 20 (1): 55-60.

Cicchetti, M., A., M. Iacopino, V. D'Amico and G. Sampietro-Colom (2015). "Organisational Models of Hospital Based Hta: Empirical Evidence from Adhophta European Project," *Value in Health*, 18 (7): 561-9.

Citi, M. and M. Rhodes (2007). "New Modes of Governance in the EU: Common Objectives Versus National Preferences", *European Governance Papers* EUROGOV ISSN 1813-8826 http://www.connex-network.org/eurogov/. Last accessed: 9 March 2020.

Cleemput, I. and P. Van Wilder (2009). "History of health technology assessment in Belgium", *International Journal of Technology Assessment in Health Care* 25 (Supplement 1): 82–87.

Clement, F., A. Harris, J.J. Li, K. Yong, K. M. Lee and B. J. Manns (2009). "Using Effectiveness and Cost-effectiveness to Make Drug Coverage Decisions. A Comparison of Britain, Australia, and Canada", *Journal of the American Medical Association*, 302 (13): 1437-43.

Cobb, R, J-K. Ross and M.Ross (1976). "Agenda Building as Comparative Political Process", *The American Political Science Review*, 70 (1): 126-38.

Cohen, M. J. March and J. Olson (1972). "A Garbage Can Model of Organizational Choice", *Administrative Science Quarterly* 17 (1): 1-25.

Cookson, R. and A. Maynard (2000). "Health technology assessment in Europe: Improving clarity and performance", *International Journal of Technology Assessment in Health Care* 16 (2): 639-50.

Cookson, R. and J. Hutton (2003). "Regulating the economic evaluation of pharmaceuticals and devices: A European perspective", *Health Policy* 63 (2): 167-78.

Council of the European Union (2000). 'The Ongoing Experience of the Open Method of Coordination' Presidency Note, 13, June 2000. Luxembourg: Office for Official Publications of the European Communities.

Council of the European Union (2002). 2440th Council meeting - HEALTH - Luxembourg, 26 June 2002. PRES/02/182. 26/06/2002.

Council of the European Union (2005). Meeting of the European Council 22 and 23 March 2005. Presidency Conclusions 7619/1/05 REV 1 CONCL 1. 23/03/2005.

Council of the European Union (2014). Council conclusions on innovation for the benefit of patients (2014/C 438/06).

Council of the European Union (2015). Council conclusions on Personalized medicine for patients (2015/C 421/03).

Council of the European Union (2016). Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (2016/C 269/06).

Council of the European Union (2018). Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU [doc. 5844/18 - COM(2018) 51 final] - Reasoned Opinion on the application of the Principles of Sub-

sidiarity and Proportionality. Available at: https://www.consilium.europa.eu/register/en/content/out?&typ=ENTRY&i=LD&DOC_ID=ST-7840-2018-COR-1. Last accessed: 29 September 2019.

Council of the European Union (2018a). Note from the General Secretariat of the Council to Council. Employment, Social Policy, Health and Consumer Affairs Council session on 14 June 2019. Regulation on health technology assessment and amending Directive 2011/24/EU. Interinstitutional file 2018/0018(COD). Brussels, 5 June 2019. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_9770_2019_INIT&from=EN. Last accessed: 30 September 2019.

Council of the European Union (2019). Employment, Social Policy, Health and Consumer Affairs Council session on 9 December 2019. Regulation on health technology assessment and amending Directive 2011/24/EU - Information from the Presidency on the state of play, Brussels, 29 November 2019, 14619/19. Available at: https://data.consilium.europa.eu/doc/document/ST-14619-2019-INIT/en/pdf. Last accessed 10 March 2020.

Covaleski, M.A. and M. W. Dinsmith (1988). "An Institutional Perspective on the Rise, Social Transformation and Fall of a University Budget Category", *Administrative Science Quarterly* 33 (4): 562-87.

CPMP - Committee for Proprietary Medicinal Products (1994). *Annual report 1993–1994* (Brussels: Committee for Proprietary Medicinal Products).

Cranovsky, R., Y. Matillon and D. Banta (1997). "EUR-ASSESS Project Subgroup Report on Coverage, *International Journal of Technology Assessment in Health Care* 13 (2): 287-332.

Culyer Anthony J. (2015). "Four Issues in Cost-effectiveness analysis and Health technology assessment: a view from the touch-line" in J. E. del Llano-Señarís and C. Campillo-Artero (eds.), *Health Technology Assessment and Health Policy Today: A multifaceted View of their Unstable Crossroads* (Switzerland: Springer International Publishing), pp. 77-94.

Cummings, J. N., & Cross, R. (2003). "Structural properties of work groups and their consequences for performance". *Social Networks*, 25 (3), 197–210.

Cyert, R. and March, J. (1992). *A Behavioural Theory of the Firm*, 2nd edition (Oxford: Blackwell).

Dally, A. (1998). "Thalidomide, was the Tragedy preventable?", *The Lancet* 351: 1197-99.

Davesne, A. et S. Guigner (2013). "La Communaut;e européenne de la santé (1952-1954). Une redécouverte intergouvernementaliste du projet fonctionnaliste de « pool blanc »", *Politique européenne* 41: 40- 63.

Davies, L., M. Drummond and P. Papanikoloau (1999). *Prioritising investments in health technology assessment : can we assess the potential value for money?* (University of York: Centre for Health Economics).

Davis, J. (2002). "The Governance of Urban Regeneration. A Critique of the "Governing without Government" Thesis", *Public Administration* 80 (2): 301-22.

De La Porte, C,, Ph. Pochet and G. Room (2001). "Social Benchmarking, policy making and new governance in the EU", *Journal of European Social Policy,* 11 (4): 291-307.

De la Porte, C. and Ph. Pochet (2002). "The European Employment Strategy: existing research and remaining questions", *Journal of European Social Policy* 14 (1): 71-78.

De Schutter,O., J. Lebesis and J. Patterson (eds.) (2001). *Governance in the European Union* (Luxembourg: Office for Official Publications of the European Communities).

De Sola-Morales, Oriol and Alicia Granados (2009*).* "Health technology assessment in Catalonia: An overview of past and future perspectives", *International Journal of Technology Assessment in Health Care* 25 (Supplement 1): 88–93.

Dean, M. (1991). *Governmentality: Power and rule in modern society* (London: Sage).

Dedeurwaerdere, T. (2005). "The contribution of network governance to sustainable development", *Les séminaires de l'Iddri* (13). Available at http://www.iddri.org/Evenements/Seminaires-reguliers/s13_dedeurwaerdere.pdf. Last accessed: 14 September 2016.

Del Llano-Señarís, J. E. (2015), "What Health Technology Assessment System Do we really Need? A Critical Review of the Current Situation of Health Technology Assessment in Five European Countries" in J. E. del Llano-Señarís and C. Campillo-Artero (eds.) *Health Technology Assessment and Health Policy Today: A multifaceted View of their Unstable Crossroads* (Switzerland: Springer International Publishing), pp. 109-30.

Del Llano-Señarís, J. E. and C. Campillo-Artero (2015). *Health Technology Assessment and health policy today: a multifaceted view of their unstable crossroads* (Switzerland : Springer International Publishing) DOI 10.1007/978-3-319-15004-8.

Den Exter, A., A. Santuari and T. Sokol, (2015). "One Year after the EU Patient Mobility Directive: A Three-Country Analysis", *European law review* 40(2): 279-93.

Di Maggio, P. and W. Powell (1991). "The Iron cage Revisited: Institutional Isomorphism and Collective Rationality in Organisation Fields", in W. Powell and P. Di Maggio (eds.) *The New Institutionalism Organisational analysis* (University of Chicago Press), pp. 63-82.

Diedrichs, U. (2008). „Policy Paper: New Modes of Governance and the Evolution of the EU System: A Theoretical Perspective", available at http://www.eu-newgov.org/database/DELIV/D01D96_NMG_and_the_Evolution_of_the_EU-System.pdf.

Diedrichs,U., W. Reiners and W. Wessels (2011). "Hidden Steps of EU Integration", in A. Héritier and M. Rhodes (eds.) *New Modes of Governance in Europe, Governing in the Shadow of Hierarchy* (Basingstoke: Palgrave Macmillan), pp.19-47.

Doern, G. (1981). *The Nature of Scientific and Technological Controversy in Federal Policy Formation* (Ottawa: Science Council of Canada).

Draborg, E. and C.K. Andersen. (2005). "What influences the choice of assessment methods in health technology assessments? Statistical analysis of international health technology assessments from 1989 to 2002". *International Journal of Technology Assessment in Health Care* 22 (2): 155-60.

Draborg, E., D. Gyrd-Hansen, P.B. Poulsen, and M. Horder (2005). "International comparisons of the definition and the practical application of health technology assessment", *International Journal of Technology Assessment in Health Care* 21: 89-95.

Dragborg, E. et al. (2005). "International comparison of the definition and the practical application of health technology assessment", *International Journal of Technology Assessment in Health Care* 21(1): 89-95.

Drucker, P. (1954). *The Practice of Management* (New York: Harper & Row).

Drummond, M. (2009). "More haste, less speed? The emerging practice of HTA in the United Kingdom", *Euro Observer*, 11 (1): 9–10.

Drummond, M. (2012). *Twenty Years of Using Economic Evaluations for Reimbursement Decisions. What Have We Achieved?* (York: University of York). Available at www.york.ac.uk/che/publications. Last accessed: 23 January 2018.

Drummond, M. (2015). "Health technology assessment and its Interface with regulation, Policy and Management", in J. del Llano-Señarís and C. Campillo-Artero (eds.), *Health Technology Assessment and Health Policy Today: A multifaceted View of their Unstable Crossroads* (Switzerland: Springer International Publishing), pp. 3-14.

Drummond, M. and C. Sorenson (2009). "Nasty or nice? A perspective on the use of health technology assessment in the United Kingdom", *Value in Health* 12 (Supplement S2): S8-S13.

Drummond, M. and M. Sculpher (2005). "Common methodological flaws in economic evaluations", *Medical Care* 43 (Supplement 7): 165-71.

Drummond, M., B. Jönsson, F. Rutten, T. Stargardt (2011). "Reimbursement of pharmaceuticals: Reference pricing versus health technology assessment", *The European Journal of Health Economics* 12 (3): 263- 71.

Drummond, M., J.S. Schwartz, B. Jonsson, B.R. Luce, P.J. Neumann, U. Siebert and S.D. Sullivan (2008). "Key principles for the improved conduct of health technology assessments for resource allocation decisions", *International Journal of Technology Assessment in Health Care* 24: 244–58.

Drummond, M., M. Sculpher, K. Claxton, and G. Stoddart ad G. Torrance (2015). *Methods for Economic Evaluations of Health Care Programmes, 4th ed.* (Oxford: Oxford University Press).

Drummond, M.F., A.Griffin, and R. Tarricone R. (2009). "Economic evaluation for devices and drugs. Same or different?", *Value in Health* 12 (4): 402-404.

Dunsire, A. (1995). "Administrative theory in the 1980s: A viewpoint", *Public Administration* 73(1): 17-40.

Duthi,K. and K.Bond (2011). "Improving ethics analysis in health technology assessment, *International Journal of Technology Assessment in Health Care*, 27 (1) :64–70.

EAHC - Executive Agency for Health and Consumers of the European Commission (2011). Health Information. Joint Action N° 20112301 under EU Health Programme 2008-2013. European network for HTA Joint Action 2 (EUnetHTA JA 2), Summary. Available at:http://ec.europa.eu/chafea/ projects/database/database_new.inc.data.20112301.pdf. Last accessed: 15 August 2017.

Eatwell, E. and A. Swierczyna (2019). "Emerging voluntary cooperation between European healthcare systems: Are we facing a new future?" *Medicine Access Point of Care*: 1 –8.

Eberlein, B. and D. Kerwer (2004). „New Governance in the European Union: A Theoretical Perspective", *Journal of Common Market Studies* 42 (1): 121-42.

ECHTA/ECAHI (2001). The ECHTA/ECAHI Project. Grant Agreement No. SI2.122594 (99CVF3-508). Available at: http://ec.europa.eu/health/ph_projects/1999/monitoring/fp_monitoring_1999_ frep_09_en.pdf.

Eddy, David (2009). "Health Technology Assessment and Evidence-Based Medicine: What Are We Talking About?", *Value in Health* 12 (Supplement 2): 6-7.

Edelenbos, J. Erik-Hans Klijn & Bram Steijn (2011). "Managers in Governance Networks: How to Reach Good Outcomes?", *International Public Management Journal*, 14 (4): 420-44.

Edelenbos, J., and E. Klijn (2009). "Project versus process management in public-private partnership: Relation between management style and outcomes", *International Public Management Journal*, 12 (3): 310-31. doi:10.1080/10967490903094350.

EFPIA (2018). EFPIA position on proposal for a Regulation of the European Parliament and the Council on Health Technology assessment and amending Directive 2011/24/EU. Available at: https://www. efpia.eu/media/361850/efpia-position-paper-on-the-commission-proposal-for-a-regulation-on-hta.pdf. Last accessed: 8 October 2019.

EHMA (2009). 'EU briefing: The impact of the Treaty of Lisbon on EU health law', *EHMA Occasional papers* (European Health Management Association). Downloaded from www.ehma.org. Last accessed: 26 November 2016.

EHMA (2011). "EU Briefing: A Brave new world. EU adopts cross-border care Directive", *EHMA Occasional papers* (European Health Management Association). Downloaded from www.ehma.org. Last accessed: 19 April 2013.

Eichler, H.G., B. Bloechl-Daum, E. Abadie, D. Barnett, F. Konig, and S. Pearson (2010). "Relative efficacy of drugs: An emerging issue between regulatory agencies and third-party payers", *Nature Reviews* 10: 277-91.

Ellig, J. and D. Lavoie (1995). "The Principle-Agent Relationship in Organisations", in P. Foss (ed.), *Economic Approaches to Organisations and Institutions: An Introduction* (Aldershot: Darmouth).

EMA (2016). *European Medicines Agency, About Us*. 29 June 2016, EMA/338312/2016. Available at: www.ema.europa.eu. Last accessed: 6 April 2017.

EMA (2017). Press release: EMA and EUnetHTA step up interaction to align data requirements. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/07/news_detail_002771.jsp&mid=WC0b01ac058004d5c1. Last accessed: 7 September 2017.

Endo, K. (1994). "The Principle of Subsidiarity: From Johannes Althusius to Jacques Delors", *Hokkaido Law Review,* 44 (6): 552-653.

Etzioni, A. (1967). "Mixed-Scanning: A "Third" Approach to Decision-Making", *Public Administration Review* 27(5): 385-92.

EUnetHTA (2007). EUnetHTA contribution to the EU Consultation regarding Community action on health services. Copenhagen, January 29, 2007. Available at: https://ec.europa.eu/health/archive/ph_overview/co_operation/mobility/docs/health_services_co56.pdf. Last accessed: 29 August 2017.

EUnetHTA (2008a*).* Internal evaluation of European network for Health Technology Assessment. Available at www.eunethta.net. Last accessed: 23 June 2017.

EUnetHTA (2008b). The HTA Core Model. HTA Core Model for Diagnostic Technologies v 1.0r. Developed by Work Package 4, December 2008. Available at: www.eunethta.eu. Last accessed 8 August 2017.

EUnetHTA (2009). EUnetHTA Project. Overview of Results 2006-2008, EUnetHTA Secretariat, March 28, 2009. Available at: www.eunethta.eu. Last accessed: 7 August 2017.

EUnetHTA (2009a). EUnetHTA Collaboration Organisational Structure 2009 – 2012. Governance Guiding Principles. September 29, 2009. Available at: www.eunethta.eu. Last accessed: 8 August 2017.

EUnetHTA (2010). EUnetHTA Collaboration key activities and achievements in 2009. Available at: www.eunethta.eu. Last accessed: 8 August 2017.

EUnetHTA (2010a). EUnetHTA Joint Action 2010-2012, Stakeholder Involvement Policy, October 2010. Available at: www.eunethta.eu. Last accessed: 8 August 2017.

EUnetHTA (2011a). EUnetHTA Adaptation Toolkit: Version 5, October 2011. Available at: www.eunethta.eu. Last accessed: 29 August 2017.

EUnetHTA (2011b). EUnetHTA. Interim Technical Report WP 1 – Appendices. Year 2011. Available at: www.eunethta.eu. Last accessed: 29 August 2017.

EUnetHTA (2012). Consortium Agreement for EUnetHTA Joint Action 2, 2012-2015. Version 2.2 20130523. Available at: www.eunethta.eu. Last accessed: 29 August 2017.

EUnetHTA (2012a). EUnetHTA Business Model report, Version 1.2 – May 24, 2012. Produced by: EUnetHTA Secretariat, DHMA, Danish Health and Medicines Authority. Supported by: Board of Innovation. Available at: www.eunethta.eu. Last accessed: 31 August 2017.

EUnetHTA (2013). EUnetHTA Joint Action European Network for Health Technology Assessment. Final Technical Report, May 2013. Available at: www.eunethta.eu. Last accessed: 29 August 2017.

EUnetHTA (2013a). EUnetHTA Joint Action 2 on HTA 2012-2015, 3-year Work Plan, May 2013. Available at: www.eunethta.eu. Last accessed: 31 August 2017.

EUnetHTA (2013b): EUnetHTA Joint Action. Internal evaluation report. January 2013. Available at: http://www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/Internal%20Evalua-

tion%20Report%20of%20the%20EUnetHTA%20JA%20from%20WP3.pdf. Last accessed: 12 September 2017.

EUnetHTA (2014). Recommendations on the implementation of a sustainable European cooperation on HTA – FINAL. Available at: www.eunethta.eu. Last accessed: 4 September 2017.

EUnetHTA (2015). EUnetHTA Joint Action 2. Summary Report Plenary Assembly 28-29, May 2015, Copenhagen Denmark. Available at: http://www.eunethta.eu/. Last accessed: 26 March 2017.

EUnetHTA (2015a). Joint Action on HTA 2012-2015. Procedure Manual for rapid REAs of pharmaceuticals, December 2015. Available at: http://www.eunethta.eu/outputs/procedure-manual-strand-rapid-relative-effectiveness-assessment-pharmaceuticals. Last accessed: 7 September 2017.

EUnetHTA (2015b). Joint Action on HTA 2012-2015. Consolidated Procedure for Early Dialogues (Drug and Non-Drug), December 2015; Available at: http://www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20early%20dialogue%20consolidated%20procedure_%20November%202015.pdf. Last accessed: 7 September 2017.

EUnetHTA (2015c). Joint Action on HTA 2012-2015. Methodological Standards and Procedures (MSP) for Full core HTA content development. Developed by Work Package 4, 30 November 2015. Available at: www.eunethta.eu. Last accessed: 6 September 2017.

EUnetHTA (2016). EUnetHTA JA2 Final Technical Report – Executive Summary. Available at www.eunethta.eu. Last accessed: 4 September 2017.

EUnetHTA (2016a). Joint Action on HTA 2012-2015. HTA Core Model Version 3.0. for the full assessment of Diagnostic Technologies, Medical and Surgical Interventions, Pharmaceuticals and Screening Technologies Developed by Work Package 8 – Maintenance of HTA Core Model® infrastructure to support shared production and sharing of HTA information, 25 January 2016. Available at. www.eunethta.eu. Last accessed: 6 September 2017.

EUnetHTA (2018). EUnetHTA Assembly and Forum. Available at: www.eunethta.eu. Last accessed: 18 August 2019.

EUnetHTA (2018a). Horizon Scanning, Topic Identification, Selection and Prioritisation for European cooperation on HTA - Draft recommendations. Developed by Work Package 4. Joint production of Health Technology Assessments WP4, 29.06.2018. Available at: https://www.eunethta.eu/wp-content/uploads/2018/07/180629-Horizon-scanning-recommendations_draft-5_forconsultation.pdf. Last accessed: 20 August 2019.

EUnetHTA (2019). EUnetHTA WP7. Implementation Report May 2019. Available at :https://www.eunethta.eu/wp-content/uploads/2019/06/Implementation-Report-May-2019-FINAL.pdf. Last accessed: 11 September 2019.

EUnetHTA (2019a). EUnetHTA WP7. Implementation Report November 2019. Available at: https://eunethta.eu/national-implementation/implementation-reports. Last accessed: 14 March 2020.

European Commission (1985). A White Paper, completing the Internal Market. COM (85) 310final, Brussels 14 June 1985. Available at: http://europa.eu/documents/comm/white_papers/pdf/com1985_0310_f_en.pdf. Last accessed: 12 April 2017.

European Commission (1993). White Paper: Growth, Competitiveness and Employment – *The challenges and ways forward into the 21st century*, Bull. E.C., Suppl. 6/93 (Luxembourg: Office for Official Publications of the European Communities).

European Commission (1994). European Social Policy – a way forward for the Union, COM (94) 333. Available at: http://aei.pitt.edu/1118/1/social_policy_white_paper_COM_94_333_A.pdf. Last accessed: 6 April 2017.

European Commission (1998). Draft Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the development of public health policy in the European Community.14/04/1998.

European Commission (1998a). Communication on the development of public health policy in the European Community, COM(98) 230final, Brussels, 15 April 1998.

European Commission (1999b). Communication from the Commission: A Concerted Strategy for Modernising Social Protection, COM(1999) 347 final, Brussels, 14.07.1999.

European Commission (2000). Communication on Health Strategy of the European Community- COM(2000) 285final, 16 May 2000.

European Commission (2000a). Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions. Strategic Objectives 2000-2005: Shaping the New Europe, COM(2000) 154final, Brussels, 9 February 2000.

European Commission (2000b). "2000-2005 Shaping the New Europe", Speech of Romano Prodi, President of the European Commission before the European Parliament 15 February 2000 - Speech/00/41.available at: http://europa.eu/rapid/press-release_SPEECH-00-41_en.htm. Last accessed: 24 May 2015.

European Commission (2001). European Governance: A White Paper. Brussels, 25.7.2001 COM(2001) 428final.

European Commission (2001a). The Internal Market and Health Services. Report of the High Level Committee on health, 17.12.2001. Available at: http://ec.europa.eu/health/archive/ph_ overview/documents/key06_en.pdf, Last accessed: 12 July 2016.

European Commission (2001b). Summary White Paper on governance. Available at: http://eur-lex. europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:l10109&from=EN. Last accessed: 10 September 2016.

European Commission (2001c). Global Competitiveness in pharmaceuticals, a European Perspective. Report prepared by A. Gambardella, L. Orsenigo and F. Pammolli for the Enterprise Directorate-General of the European Commission (Luxembourg: Office for Official Publications of the European Communities).

European Commission (2001d). Memo 01/262. Brussels, 18 July 2001. Reform of EU pharmaceutical legislation. Available at: https://ec.europa.eu/health/documents/eudralex/vol-1_en. Last accessed: 14 June 2019.

European Commission (2001e): The Internal Market and Health Services Report of the High Level Committee on Health, European Commission Health and Consumer Protection Directorate-General. Directorate G - Public Health, 17.12.2001. Available at: http://ec.europa.eu/health/archive/ ph_overview/documents/key06_en.pdf. Last accessed: 13 March 2017.

European Commission (2002). *European Governance. Preparatory Work for the White Paper* (Luxembourg: Office for Official Publications of the European Communities).

European Commission (2002a). High Level Group on innovation and provision of medicines in the European Union: recommendations for action. G10 Medicines Report. Available at: http://ec.europa. eu/health/ph_overview/Documents/key08_en.pdf. Last accessed: 7 April 2017.

European Commission (2003). Communication from the Commission to the Council, The European Parliament, the Economic and Social Committee and the Committee of the regions. *Strengthening the social dimension of the Lisbon strategy: Streamlining open coordination in the field of social protection*, COM(2003) 261final, Brussels, 27.5.2003.

European Commission (2003a). High level process of reflection on patient mobility and healthcare developments in the European Union; Meeting of the high level process of reflection on patient

mobility and healthcare developments in the EU, 3 February 2003 – minutes of the meeting, HLPR/2003/2/REV1. Available at: http://ec.europa.eu. Last accessed: 1 May 2016.

European Commission (2003b). Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and he Committee of Regions. A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action, COM(2003) 383 final, Brussels, 1.7.2003.

European Commission (2004a). Communication from the Commission: Follow-up to the High Level Reflection Process on patient mobility and healthcare developments in the European Union. COM(2004)301 final, Brussels, 20.04.2004.

European Commission (2004b). First meeting of the High Level Group on Health Services and Medical Care, 1 July 2004. HLG/2004/9. Brussels, 6 July 2004. Available at: http://ec.europa.eu. Last accessed: 12 March 2017.

European Commission (2004c). Second meeting of the High Level Group on Health Services and Medical Care, 22 September 2004. HLG/2004/16. Brussels, 5 October 2004. Available at: http://ec.europa.eu. Last accessed: 12 March 2017.

European Commission (2004d). *Enabling Good Health For All, A reflection process for a new EU health strategy*. Communication of David Byrne Commissioner for Health and Consumer Protection. Available at http://ec.europa.eu/health/ph_overview/Documents/pub_good_health_en.pdf. Last accessed: 11 August 2016.

European Commission (2004e). High Level Group on Medical Services and Health Care, HLG/2004/7 REV1, Brussels, 1 July 2004. Available at: http://ec.europa.eu. Last accessed: 4 April 2017.

European Commission (2004f). High Level Group on Health Services and Medical Care. Report from the High Level Group to the Employment, Social Affairs, Health and Consumer Protection Council on 6-7 December 2004. Executive Summary, HLG/2004/21 FINAL. Brussels, 30 November 2004. Available at: ec.europa.eu. Last accessed: 12 March 2017.

European Commission (2004g). Correspondence between the Director of the Directorate C – Public health and Risk Assessment – of DG Sanco and the Chairman of the board of INAHTA, 12.07.2004. Personal documentation INAHTA Chairman.

European Commission (2004h). Third meeting of the High Level Group on Medical Services and Health Care, Brussels, 18 October 2004, HLG/2004/19 REV1. Available at: ec.europa.eu. Last accessed: 12 March 2017.

European Commission (2004i). Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions. Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the "open method of coordination". Brussels, 20.4.2004, COM(2004) 304final. Available at: http://ec.europa.eu/employment_social/soc-prot/healthcare/com_04_304_en.pdf. Last accessed: 6 April 2017.

European Commission (2004j). Proposal for a Directive of the European Parliament and of the Council on services in the Internal Market. COM(2004) 2 final/3, Brussels, 5.3.2004.

European Commission (2005). Communication from the Commission to the Council, The European Parliament, the European Economic and Social Committee and the Committee of Regions. Working together, working better: A new framework for the open coordination of social protection and inclusion policies in the European Union. COM(2005) 706final, Brussels, 22.12.2005.

European Commission (2005a). Community action in the field of public health (2003-2008) - Work plan 2005. Available at: https://ec.europa.eu/health/ph_programme/howtoapply/proposal_docs/workplan2005_en.pdf. Last accessed: 12 June 2017.

European Commission (2006). Meeting of the High Level Group on Health Services and Medical Care, 7 June 2006. HLG/2006/6 Brussels, 16 June 2006.

European Commission (2006a). Amended proposal for a Directive of the European Parliament and of the Council on services in the Internal Market 2004/0001 (COD), COM(2006) 160, Brussels, 4 April 2006.

European Commission (2006b) Press release 'Patient mobility: Commission to launch public consultation on EU framework for health services. IP/06/1150 05/09/2006.

European Commission (2006b). Minutes. Pharmaceutical Forum 3rd Meeting of the Working Group on Relative Effectiveness, 11 October 2006, Brussels. Available at. Last accessed: 20 April 2020.

European Commission (2007). Flash Eurobarometer Series #210, Cross-border health services in the EU, Analytical report, conducted by The Gallup Organisation, Hungary upon the request of the European Commission, the Health and Consumer Protection Directorate-General (DG SANCO), 2007.

European Commission (2007a). *Joint Report on Social Protection and Social Inclusion* 2007 (Luxembourg: Office for Official Publications of the European Communities).

European Commission (2008): DG Enterprise and Industry, DG Health and Consumers. High Level Pharmaceutical Forum 2005-2008. Conclusions and Recommendations (Brussels: European Communities).

European Commission (2008a). Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. COM(2008) 414 final, Brussels, 2.7.2008.

European Commission (2008b). Commission communication on the Renewed Social Agenda: Opportunities, access and solidarity in 21st century Europe, COM(2008) 412final. Brussels, 2 July 2008.

European Commission (2008c). Commission Staff Working Document. Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Impact assessment. COM(2008) 414final, Brussels, 2.7.2008. Available at http://ec.europa.eu/health/archive/ph_overview/co_operation/healthcare/docs/impact_assessment_en.pdf. Last accessed: 27 March 2017.

European Commission (2008d): Joint report on social protection and inclusion. Directorate-General for Employment, Social Affairs and Equal Opportunities. Document drawn up on the basis of SEC(2008) 91 final and COM(2008) 42 final (Luxembourg: Office for Official Publications of the European Communities).

European Commission (2008e). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. "A renewed commitment to social Europe: Reinforcing the Open Method of Coordination for Social Protection and Social Inclusion". COM(2008) 418final, Brussels, 2.7.2008. Available at: http://aei.pitt.edu/45905/1/com2008_0418.pdf. Last accessed: 6 April 2017.

European Commission (2008f). Pharma Forum Working Group on Relative Effectiveness. Core principles on relative effectiveness. Ref. Ares(2014)3848986 - 19/11/2014. Available at: http://ec.europa.eu/DocsRoom/documents?locale=en&tags=Working%20Group%20on%20Relative%20EffectivenessLast accessed: 5 June 2019.

European Commission (2008g). Pharma Forum Working Group on Relative Effectiveness. Data availability to conduct on relative effectiveness assessments. Ref. Ares(2014)3849045 - 19/11/2014. http://ec.europa.eu/DocsRoom/documents?locale=en&tags=Working%20Group%20on%20Relative%20EffectivenessLast accessed: 5 June 2019.

European Commission (2008h). Pharma Forum Working Group on Relative Effectiveness. Development of networking and collaboration. Ref. Ares(2014)3849073 - 19/11/2014. http://ec.europa.eu/DocsRoom/documents?locale=en&tags=Working%20Group%20on%20Relative%20EffectivenessLast accessed: 5 June 2019.

European Commission (2009a). Health and Consumers Directorate-General. Public Health and Risk Assessment. Health Strategy and Health Systems, SANCO.C5/jboe D(2009). Final minutes. Brussels, 20 February 2009. Available at: https://www.eunethta.eu/wp-content/uploads/2018/01/Summary-of-the-discussions-February-20-2009.pdf. Last accessed: 19 March 2020.

European Commission (2009b). Health and Consumers Directorate-General. Public Health and Risk Assessment. Health Strategy and Health Systems, SANCO.C5/NPD (2009). AGENDA – 2nd Meeting of the National HTA appointed bodies for the setting up of a Joint Action between the Commission and the Member States, Brussels, 15 April 2009. Available at: http://ec.europa.eu/health/archive/ph_systems/docs/ev20090415_mi_en.pdf. Last accessed: 17 August 2017.

European Commission (2010). *Joint Report on Social Protection and Social Inclusion 2010 (*Luxembourg: Publications Office of the European Union).

European Commission (2013a). Health and Consumers Directorate-general. Health systems and products. e-Health and Health Technology Assessment. Adopted minutes first HTA Network meeting. Brussels, 16 October 2013. Available at/ https://ec.europa.eu/health//sites/health/files/technology_assessment/docs/ev_20131016_mi_en.pdf. Last accessed: 19 August 2017.

European Commission (2013b). Health and Consumers Directorate-general. Health systems and products. e-Health and Health Technology Assessment. Multiannual Work Programme 2014-2015 adopted at the 1st HTA Network meeting, 16 October 2013. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/hta_network_wp2014_15_en.pdf. Last accessed: 13 September 2017.

European Commission (2014). Impact of information on patients' choice within the context of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Final Report. August 2014. Available at: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/cbhc_information_patientschoice_en.pdf. Last accessed: 27 March 2017.

European Commission (2014a). Health and Consumers Directorate-general. Health systems and products. e-Health and Health Technology Assessment. Adopted minutes second HTA Network meeting. Brussels, 7 April 2014. Available at: https://ec.europa.eu/health//sites/health/files/technology_assessment/docs/ev_20140407_mi_en.pdf. Last accessed: 22 August 2017.

European Commission (2014b). Health and Consumers Directorate-general. Health systems and products. e-Health and Health Technology Assessment. Approved minutes of the third HTA Network meeting. 29 October 2014. Available at: https://ec.europa.eu/health/technology_assessment/events/ev_20141029_en. Last accessed: 18 September 2017.

European Commission (2014c). European Health Technology Network. Strategy for EU cooperation on Health Technology Assessment. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf. Last accessed: 18 September 2017.

European Commission (2015). Ex-post Evaluation of the Health Programme (2008-2013) - Final report. Available at file:///C:/Users/magal/Downloads/EW0115342ENN.en.pdf. Last accessed: 19 March 2020.

European Commission (2015a). Health and Consumers Directorate-general. Health systems and products. e-Health and Health Technology Assessment. Approved minutes of the fourth HTA Network

meeting. 23 March 2015. Available at: https://ec.europa.eu/health/technology_assessment/ events/ev_20150323_en. Last accessed: 18 September 2017.

European Commission (2015b). Health and Consumers Directorate-general. Health systems and prod-ucts. e-Health and Health Technology Assessment. Approved minutes of the fifth HTA Network meeting. 29 October 2015. Available at: https://ec.europa.eu/health/technology_assessment/ events/ev_20151029_en. Last accessed: 18 September 2017.

European Commission (2015c). Health and Consumers Directorate-general. Health systems and prod-ucts. e-Health and Health Technology Assessment. HTA Network reflection paper on "reuse of joint work in national HTA activities". Adopted by the Network, April 2015. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/reuse_jointwork_na-tional_hta_activities_en.pdf. Last accessed: 13 September 2017.

European Commission (2015d). Ex-post Evaluation of the Health Programme (2008-2013). Directorate-General for Health and Food Safety, Health Programme. Available at: https://ec.europa.eu/health/ sites/health/files/programme/docs/ex-post_ev-hp-2008-13_final-report.pdf. Last accessed: 12 October 2019.

European Commission (2016). Inception Impact Assessment. Strengthening of the EU cooperation on Health Technology Assessment (HTA). 14/09/2016. Available at: http://ec.europa.eu/smart-regu-lation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf. Last accessed: 6 September 2017.

European Commission (2016a). Health and Consumers Directorate-general. Health systems and prod-ucts. e-Health and Health Technology Assessment. HTA Reflection paper on "synergies between regulators and HTA issues on pharmaceuticals", adopted by the HTA Network, 10 November 2016. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ ev_20161110_co06_en.pdf. Last accessed: 13 September 2017.

European Commission (2016b). Rules of procedure of the health Technology Network adopted by the HTA Network on 10 November 2016. Available at: https://ec.europa.eu/health/sites/health/files/ technology_assessment/docs/ev_20161110_co03_en.pdf. Last accessed: 29 August 2017.

European Commission (2016c). *Questionnaire for administrations, associations and other organisations,* published and available from 21/10.2016 till 20/01/2017 on the https://ec.europa.eu/health/ technology_assessment/consultations/cooperation_hta_fr.

European Commission (2016d). Approved Minutes of the 7th HTA Network Meeting, 10 November 2016. Ref. Ares(2017)645359 - 06/02/2017. Available at: https://ec.europa.eu/health/sites/health/files/ technology_assessment/docs/ev_20161110_mi_en.pdf. Last accessed: 14 March 2020.

European Commission (2017). DG SANTE B4 – Medical products: safety, quality, innovation. Results of the online public consultation. 29 March 2017. Available at: https://ec.europa.eu/health/ sites/health/files/technology_assessment/docs/ev_20170329_co01_en.pdf. Last accessed: 12 September 2017.

European Commission (2017a). *Study on impact analysis of policy options for strengthened EU coopera-tion on Health Technology Assessment (HTA) Final. Available at:* https://ec.europa.eu/health/sites/ health/files/technology_assessment/docs/2018_ia_policyoptions_en.pdf. Last accessed: 9 July 2019.

European Commission (2017b). *Mapping of HTA methodologies in EU and Norway.* Available at: https:// ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_mapping_methodolo-gies_en.pdf. Last accessed: 9 July 2019.

European Commission (2017c). Mapping of HTA national organisations, programmes and processes in EU and Norway. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_mapping_npc_en.pdf. Last accessed: 9 July 2019.

European Commission (2017d). Directorate General for Health and Food Safety. *Strengthening of the EU cooperation on Health Technology Assessment (HTA). Online public consultation report.* Ref. Ares(2017)2455149 - 15/05/2017. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/20161020_frep_en.pdf . Last accessed: 9 July 2019.

European Commission (2017e). *Study on impact analysis of Policy Options for strengthened EU cooperation on Health Technology Assessment (HTA) Annexes. Available at:* https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_ia_policyoptions_en.pdf. Last accessed: 9 July 2019.

European Commission (2018). Proposal for a regulation of the European Parliament and of the Council on health technology and amending Directive 2011/24/EU. Brussels 31.01.2018 COM(2018) 51 final.

European Commission (2018a). Commission Staff Working Document - Impact Assessment. Strengthening of the EU Cooperation on Health Technology Assessment (HTA), Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. COM(2018) 51 final - SWD(2018) 42 final. Available at : https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_ia_final_en.pdf. Last accessed: 19 March 2020.

European Communities (1999). *Health technology assessment in Europe: The challenge of coordination* (Luxembourg: Office for Official Publications of the European Communities).

European Parliament (2005). European Parliament report on patient mobility and healthcare developments in the European Union (2004/2148(INI)), A6-0129/2005. 29 April 2005. Available at: http://www.europarl.europa.eu. Last accessed: 4 April 2017.

European Parliament (2007a). European Parliament Resolution on Community action on the provision of cross-border healthcare. B6-0098/2007. 15 March 2007.

European Parliament (2007b). Résolution du Parlement européen sur l'impact et les conséquences de l'exclusion des services de santé de la Directive relative aux services dans le marché intérieur. A6-0173/2007 / P6_TA-PROV(2007)0201. 23.05.2007.

European Parliament (2009). Explanatory Statement. Report on the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. A6-0233/2009. (COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)). 3 April 2009.

European Parliament (2010). The Lisbon Strategy 2000 – 2010. An analysis and evaluation of the methods used and results achieved. Final Report. Directorate General for Internal Policies policy Department A: economic and scientific policy employment and social affairs. (Brussels, European Parliament). Available at: http://www.europarl.europa.eu/document/activities/cont/201107/2011 0718ATT24270/20110718ATT24270EN.pdf. Last accessed: 20 November 2016.

European Parliament (2011). Procedure file 2008/0142(COD). Patients' rights in cross-border healthcare. Available at http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?id= 566163. Last accessed: 27 March 2017.

European Parliament (2015). European Parliament resolution on the Commission Work Programme for 2016 (2015/2729(RSP)).

European Parliament (2016). EU Options for Improving Access to Medicines Brussels, 14 July 2016. PE 587.304. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2016/587304/IPOL_STU(2016)587304_EN.pdf. Last accessed: 13 March 2020.

European Parliament (2017). European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI). Available at: http://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.pdf. Last accessed: 28 September 2019.

European Parliament (2017a). Report on EU options for improving access to medicines (2016/2057(INI)). Committee on the Environment, Public Health and Food Safety. 14.02.2017. Available at: http://www.europarl.europa.eu/doceo/document/A-8-2017-0040_EN.pdf. Last accessed: 1 October 2019.

European Parliament (2018). Amendments adopted by the European Parliament on 3 October 2018 on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018)0051 – C8-0024/2018 – 2018/0018(COD))1. Available at: http://www.europarl.europa.eu/doceo/document/TA-8-2018-0369_EN.html. Last accessed: 28 September 2019.

EURORDIS (2008). Understanding Health Technology Assessment (HTA). Patient guide published by Health Equality Europe. Available at http://img.eurordis.org/newsletter/pdf/nov-2010/58-1%20HEE%20Guide%20To%20HTA%20for%20Patients%20English.pdf. Last accessed: 11 August 2013.

Facey, K. (2011). "Patient involvement in HTA: What added value?", *Pharmaceuticals Policy and Law* 13 (3-4): 245-251.

Facey, K., A. Boivin, J. Gracia, H.P. Hansen, A. L. Scalzo, J. Mossman, and A. Single (2010). "Patients' perspectives in health technology assessment: A route to robust evidence and fair deliberation", *International Journal of Technology Assessment in Health Care* 26 (3): 334-340.

Favaretti, C., A. Cicchetti, G. Guarrera, M. Marchetti and W. Ricciardi (2009). "Health technology assessment in Italy", *International Journal of Technology Assessment in Health Care*, 25 (Supplement): 127–133.

Filtenborg, M., S. Gänzle and E. Johansson (2002). "An Alternative Theoretical Approach to EU Foreign Policy 'Network Governance' and the Case of the Northern Dimension Initiative", *Cooperation and Conflict: Journal of the Nordic International Studies Association* 37 (4): 387–407.

Fischer, K., T. Heisser and T. Stargardt (2016). "Health benefit assessment of pharmaceuticals: An international comparison of decisions from Germany, England, Scotland and Australia", *Health Policy* 120: 1115–22.

Flanagan, K., E. Uyarra, and M. Laranja (2011). "Reconceptualising the 'Policy Mix 'for Innovation." *Research Policy* 40 (5): 702–13.

Fleurette, F., and D. Banta (2000). "Health technology assessment in France", *International Journal of Technology Assessment in Health Care* 16 (2): 400-11.

Foucault, M. (1991). "Governmentality", in G. Burchell, C. Gordon and P. Miller (eds.), *The Foucault effect* (Hertfordshire: Harvester Weatsheaf), pp. 87-104.

Frances, J. (1991) "Introduction" in G. Thompson et al. (eds), *Markets Hierarchies and Networks: The Co-ordination of Social Life* (London, Sage).

Francis, J. (1993). *The Politics of Regulation: A comparative Perspective* (Oxford: Blackwell).

Friend, J., J. Power, and C. Yewlett (1974). *Public Planning: The Inter-corporate Dimension* (London: Tavistock Publications).

Frønsdal, K., F. Pichler, L. Mardhani-Bayne, C. Henshall, J-A. Røttingen, B. Mørland and M. Klemp (2012). "Interaction initiatives between regulatory, health technology assessment and coverage bodies and industry", *International Journal of Technology Assessment in Health Care*, 28 (4): 374–81.

Fuchs, S., B. Olberg, D. Panteli, M. Perleth and R. Busse (2017). "HTA of medical devices: Challenges and ideas for the future from a European perspective", *Health Policy* 121: 215–29.

Gage, R. and M. Mandell (eds.) (1990). *Strategies for Managing Intergovernmental Policies and Networks* (New York: Praeger).

Gagnon, M.-P., M. Desmartis, J. Gagnon, M. St-Pierre, F-P. Gauvin, M/ Rhainds, D. Lepage-Savary, M. Coulombe, M. Dipankui, M. Tantchou and F. Légaré (2014) "Introducing the Patient's Perspective in Hospital Health Technology Assessment (HTA): The Views of HTA Producers, Hospital Managers and Patients", *Health Expectations*, 17 (6): 888–900.

Garattini, L., D. Cornago and P. De Compadri (2007). "Pricing and reimbursement of in-patent drugs in seven European countries: A comparative analysis", *Health Policy* 82: 330–39.

Garrido, M. and R. Busse (2005). *Health Technology Assessment: An Introduction on Objectives, Role of Evidence, and Structure in Europe* (Brussels: European Observatory on Health Systems and Policies).

Garrido, M. Kristensen, F. Nielsen, C. Busse, R. (eds.) (2008). *Health Technology Assessment and Health Policy-Making in Europe. Current Status, Challenges and Potential* (Kopenhagen: World Health Organisation on behalf of European Observatory on Health Systems and Policies).

Garrido, M. Zenter and R. Busse (2008). "Health systems, health policy and health technology assessment" in M. Garrido, F.B. Kristensen, C.P. Nielsen and R. Busse (2008). *Health Technology Assessment and Health Policy-making in Europe: Current Status, Challenges and Potential* (Copenhagen: European Observatory on Health Systems and Policies), pp. 53-78.

Garrido, M., F. B. Kristensen, C. Nielsen and R. Busse (eds.) (2008). *Health Technology Assessment and Health Policy-making in Europe*, *Current Status, Challenges and Potentials* (Copenhagen: WHO Regional Office for Europe).

Gauvin, F., J. Abelson, M. Giacomini, J. Eyles, and J. Lavis (2010). "It all depends": Conceptualizing public involvement in the context of health technology assessment agencies. *Social Science and Medicine* 70 (10): 1518-1526.

Gerhardus, A. (2006). "The role of HTA in German health care. Do we need impact objectives?", *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 49 (3): 233–240.

Gerhardus, A. and C.-M. Dintsios, (2005) "The Impact of HTA Reports on Health Policy: A Systematic Review," *GMS health technology assessment* 1: 2 November 2005.

Gerston, L. (1997). *Public Policy Making: Process and Principles* (Armonk NY: M.E. Sharpe).

Gillespie, F. and M. Cerbo (2014). "Collaborative Models for the joint production of core health technology assessments: negative and positive aspects for the joint work of different agencies", *International Journal of Technology Assessment in Health Care*, 30 (5): 536–43.

Goetschy, J. (1999). "The European Employment Strategy (EES) Genesis and Development", *Industrial Relations Journal* 5 (2): 117-37.

Goldsmith, S., and W. D. Eggers (2004). *Governing by Network: The New Shape of the Public Sector* (Washington DC: Brookings Institute).

Goodman, C. (Ed.) (1988). *Medical Technology Assessment Directory. A Pilot Reference to Organisations, Assessments, and Information Resources.* Council on Health Care Technology Institute of Medicine (Washington: National Academy Press).

Gorry, Ph., M. Montalban and A. Smith (2015). "The EU's government of pharmaceuticals" in A. Smith and B. Jullien (eds.), *The EU's government of industries: markets, institutions and politics*

(Abingdon, Oxon: Routledge/Routledge studies on government and the European Union, 2), pp.115-38.

Gray, A. and B. Jenkins. 1995. "From Public Administration to Public Management: Reassessing a Revolution?", *Public Administration* 73 (Spring), 75-99.

Greer, S. (2006). "Uninvited Europeanization: neofunctionalism and the EU in health policy", *Journal of European Public Policy* 13 (1): 134-52.

Greer, S. (2009). *The Politics of European Union Health Policy* (Philadelphia: Open University Press).

Greer, S., N. Fahy, H. Elliott, M. Wismar, H. Jarman, W. Palm (2014). *Everything you always wanted to know about European Union health policies but were afraid to ask* (Copenhagen: WHO Regional Office for Europe).

Grubert, Neil (2018). "A landmark for international collaboration on HTA and pharmaceutical pricing", published on *LinkedIn*, 17 May 2018. Available at: https://www.linkedin.com/pulse/landmark-international-collaboration-hta-pricing-neil-grubert. Last accessed: 6 October 2019.

Guegan, E., and A. Cook (2014). "Success factors for international HTA projects: Evaluating EUnetHTA joint action as an exemplar", *International Journal of Technology Assessment in Health Care, 30* (5), 544-51. doi:10.1017/S0266462314000580

Guigner, S. (2007). 'L'européanisation cognitive de la santé: entre imposition et persuasion', In O. Baisnée and R. Pasquier (eds.), *L'Europe telle qu'elle se fait. Européanisation et sociétés politiques nationales* (Paris: CNRS Editions), pp: 263-81.

Gulacsi, L., V. Brodszky, M. Pentek, S. Varga, G. Vas, I. Boncz (2009). "History of health technology assessment in Hungary", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 120–26.

Haas, E. (1958). *The uniting of Europe: Political, Social and Economic Forces 1950-1957* (Standford University Press).

Haas E.B. (1990). *When Knowledge is Power: Three Models of Change in International Organizations* (Berkeley/Los Angeles/London: University of California Press,).

Haas P.M. (2004), "When does power listen to truth? A constructivist approach to the policy process", *Journal of European Public Policy* 11 (4): 569-592. doi: 10.1080/1350176042000248034.

Haas P.M. and E.B. Haas. (2002), "Pragmatic constructivism and the study of international institution", *Millennium: Journal of International Studies:* 573-601.

Haas, P. (1990) "Obtaining International Environmental Protection through Epistemic Consensus", *Journal of International Studies* 19 (3): 347–363.

Håheim, L., I. Imaz , M. Laubli, T. Gasparetto, J. González Enríquez, I. Trofimovs, H. Dahlgren, A. Liberati, E. Berti E, B. Mørland (2008). Report on the internal evaluation of European network for Health Technology Assessment – EUnetHTA. 2008, *International Journal of Technology Assessment in Health Care*, 25 (Supplement 2): 99-106.

Hailey D. (2007). "Health technology assessment in Canada: Diversity and evolution", *Medical Journal Australia* 187: 286-88.

Hailey, D. (2009). "Development of the International Network of Agencies for Health Technology Assessment", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 24–27.

Hailey, D. (2009b). "The history of health technology assessment in Australia", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 61–67.

Hall, P. (1993). "Policy Paradigms, Social Learning, and the State: The Case of Economic Policymaking in Britain", *Comparative Politics*, 25 (3): 275-96.

Hall, T. E. and L. J. O'Toole, (2004). "Shaping Formal Networks Through the Regulatory Process", *Administration and Society* 36 :186-207.

Halmesmäki E, I. Pasternack and R. Roine (2016). "Hospital-Based Health Technology Assessment (HTA) in Finland: A Case Study on Collaboration between Hospitals and the National HTA Unit", *Health research policy and systems,* 14: 25.

Hancher, L. (1992). "Competition and the European Pharmaceutical Market", *Antitrust Bulletin* 1992/ summer: 387-428.

Hancher, L. (2010). "The EU Pharmaceutical market: parameters and pathways" in E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds.) *Health systems governance in Europe: The Role of European Union Law and Policy* (New York: Cambridge University Press).

Hansen, H. (2007). "Patients aspects in HTA", in F.B. Kristensen, and H. Sigmunds (eds.), *Health Technology Assesment handbook 2nd edition* (Copenhagen: Danish Centre for Health technology Assessment, National Board of Health).

Hansen, H. and A. Lee (2011). "Patient aspects and involvement in HTA: An academic Perspective", *Pharmaceuticals Policy and Law* 13: 123–28.

Hargrove, E. (1975). *The Missing Link: The Study of the Implementation of Social Policy* (Washington: Urban Institute).

Harousseau, J., M. Pavlovic, H. Mouas and F. Meyer (2015). "Shaping European Early Dialogues: The Seed Project", *Value in Health* 18 (7): A562.

Harris, A.H., M. Buxton, B. O'Brien, F. Rutten, and M. Drummond (2001). "Using economic evidence in reimbursement decisions for health technologies: Experience of 4 countries". *Expert Rev Pharmacoeconomics Outcome Res* 1: 7-12.

Hatzopoulos, V. (2010). "Public procurement and state aid in national health care systems" in Mossialos, E., G. Permanand, R. Baeten and T. Hervey (Eds.), *Health Systems Governance in Europe. The Role of European Union Law and Policy* (Cambridge/New York: Cambridge University Press), pp. 379-418.

Healy, P. and M. Pugatch (2009). *Theory versus Practice: Discussing the Governance of Health Technology Assessment Systems* (Stockholm Network). Available at http://www.stockholm-network.org/ Conferences-and-Programmes/Health-and-Welfare/HTA. Last accessed: 20 January 2018.

Heclo, H. (1974). *Modern Social Politics in Britain and Sweden: From Relief to Income Maintenance* (New Haven: Yale University Press).

Heclo, H. (1978). "Issue Networks and the Executive Establishment", in A. King (ed.) *The New American Political System* (Washington DC: American Enterprise Institute), pp 87-124.

Henschke, C., L. Sundmacher and R. Busse (2013). "Structural changes in the German pharmaceutical market: Price setting mechanisms based on the early benefit evaluation", *Health Policy* 109: 263–69.

Henshall, C. and T. Schuller, On behalf of the HTAi Policy Forum (2013). "Health Technology Assessment, value-based decision making and innovation", *International Journal of Technology Assessment in Health Care*, 29 (3): 1-7.

Henshall, C., L. Mardani-Bayne, K.B. Frønsdal, and M. Klemp (2011). "Interactions between health technology assessment, coverage, and regulatory processes: Emerging issues, goal, and opportunities", *International Journal of Technology Assessment in Health Care* 27 (3): 253-60.

Henshall, C., L. Sansom, H. Eichler, A. Lehmgruber, C. Longson, B. O'Rourke, and S. Tunis (2013). "Understanding the role and evidence expectations of health technology assessment and coverage/ payer bodies. What are they looking for, and how and why does this differ from what regulators require?" *Therapeutic Innovation & Regulatory Science* 48(3):341-46.

Henshall, C., W. Oortwijn, A. Stevens, A. Granados and D. Banta (1997). "Priority Setting for Health Technology Assessment", *International Journal of Technology Assessment in Health Care* 13 (2):144-65.

Héritier, A and D. Lehmkuhl (2011). "Governing in the Shadow of Hierarchy: New Modes of Governance in Regulation", in A. Héritier and M. Rhodes (eds.), *New Modes of Governance in Europe, Governing in the Shadow of Hierarchy* (London: Palgrave Macmillan), pp. 48- 74.

Héritier, A. and M. Rhodes (eds.) (2011). *New Modes of Governance in Europe. Governing in the Shadow of Hierarchy* (Basingstoke: Palgrave, McMillan).

Héritier, A. (2003). "New Modes of Governance in Europe: Increasing Political Capacity and Policy Effectiveness?", in T. Börzel and R. Cichowski (eds.), *The State of the European Union* (Oxford: Oxford University Press), pp. 105-27.

Héritier, A. (2006). NEWGOV, 2nd Annual Activity Report covering the period month from 13-24 September-2005-August 2006 (public version, November 2006), European University Institute, available at http://cadmus.eui.eu/handle/1814/8184. Last accessed: 20 April 2020.

Héritier, A. and D. Lehmkuhl (2011). "Governing in the Shadow of Hierarchy. New Modes of Governance in Regulation", in A. Héritier and M. Rhodes (eds.) (2011). *New Modes of Governance in Europe. Governing in the Shadow of Hierarchy* (Basingstoke: Palgrave, McMillan), pp. 48-74.

Héritier, A. and D. Lehmkuhl (2011a). "New Modes of Governance and Democratic Accountability", *Government and Opposition* 46 (1): 126-44.

Héritier, A. and M. Rhodes (eds.) (2011). *New Modes of Governance in Europe, Governing in the Shadow of Hierarchy* (Basingstoke: Palgrave Macmillan).

Hermesse J., H. Lewalle and W. Palm (1997) "Patient mobility within the European Union", *European Journal of Public Health*, 7(3): 4–10.

Hertting, N. (2007). "Mechanisms of Governance Network Formation – a Contextual Rational Perspective, in E. Sørensen and J. Torfing (eds.), *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan), pp. 43-60.

Hervey, T. and B. Vanbercke (2010). "Health care and the EU: the law and policy patchwork" in E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds.), *Health systems governance in Europe. The Role of European Union Law and Policy* (Cambridge: Cambridge University Press), pp.84-133.

Hivon, M., P. Lehoux, J.L. Denis, and S. Tailliez (2005). "Use of health technology assessment in decision making: Coresponsibility of users and producers?", *International Journal of Technology Assessment in Health Care* 21(2): 268-75.

Hix, S. (1998). "The study of the European union II: The 'new governance' agenda and its rival", *Journal of European Public Policy*, 5 (1): 38-65. doi:10.1080/13501768880000031.

Hix, S. (2005). The Political System of the European Union (2nd ed) (Basingstoke: Palgrave Macmillan).

Hjern B. and Porter, D.O. (1981) "Implementation Structures: A New Unit for Administrative Analysis", *Organisational Studies* 3: 211-37.

Hjern, B. and D. Porter (1993). "Implementation Structures. A New Unit of Administrative Analysis", in M. Hill (ed.) *The Policy Process: A Reader* (London: Harvester Wheatsheaf), pp. 248–65.

Hjern, B. and D. Porter (1993). "Implementation Structures: A New Unit of Administrative Analysis", *Hill* 1993.

Hood, C. (1986). *The Tools of Government* (Chatham House: Chatham, NJ).

Hood, C. (1991). "A Public Management for all seasons?", *Public Administration* 69 (1): 3-19.

Hooghe, L. (ed) (1996). *Cohesion policy and European integration. Building multi-level governance* (Oxford: Clarendon Press).

Houÿez, F., Y. Le Cam, F. Bignami, F. Macchia and F. Faurisson (2011). "Health Technology Assessment and patients' rights: Assess versus access?", *Pharmaceuticals Policy and Law 13,* 3 (4): 169-76.

Howlett, M. (2000). "Managing the "hollow state": Procedural policy instruments and modern governance", *Canadian Public Administration*, 43 (4); 412-31. doi:10.1111/j.1754-7121.2000.tb01152.x

Howlett, M. (2007). "Analyzing Multi-Actor, Multi-Round public Policy Decision-Making Processes in Government: Findings from Five Canadian Cases", *Canadian Journal of Political Science* 40 (3): 659-84.

Howlett, M. (2018). "Policy instruments and policy design choices, Selecting Substantive and Procedural Tools in Public Policymaking", in M. Howlett and I. Mukherjee (eds.) *Handbook of Policy Design* (Milton:Routledge), pp. 77-86.

Howlett, M., M. Ramesh and A. Perl (2009). *Studying Public Policy. Policy Cycles and Policy Subsystems* (3rd edition) (Oxford: Oxford University Press).

Howse, R., R. Prichard and M. Trebilcock (1990). "Smaller or Smarter Government?", *University of Toronto Journal* 40: 498-541.

HTAN (2014). *EU Health Technology Assessment Network. Strategy for EU Cooperation on Health Technology Assessment*. Available at: http://ec.europa.eu/health//sites/health/files/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf. Last accessed: 6 April 2017.

HTAN (2016). *HTA Network. Multiannual Work Programme 2016-2020*, available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf. Last accessed: 6 April 2017.

Huang, K. and K. Provan (2007). "Structural Embeddedness and Organizational Social Outcomes in a Centrally Governed Mental Health Service Network", *Public Management Review*, 9 (2): 169–89.

Huic, M., A. Nachtnebel, I. Zechmeister, I. Pasternak and C. Wild (2013). "Collaboration in health technology assessment (EUNETHTA Joint Action,2010–2012): Four case studies", *International Journal of Technology Assessment in Health Care*, 29 (3): 323–30.

Huppé, G., Creech, H., and Knoblauch, D. (2012). "The Frontiers of Networked Governance", *International Institute for Sustainable Development*, report February 2012. Available at: https://www.iisd.org/pdf/2012/frontiers_networked_gov.pdf. Last accessed: 10 April 2020.

Hutton, J., P. Trueman, and K. Facey (2008). "Harmonization of evidence requirements for health technology assessment in reimbursement decision making", *International Journal of Technology Assessment in Health Care* 24(4): 511-17.

Idema, T. and Daniel R. Kelemen (2006). "New modes of governance, the Open Method of Co-ordination and other fashionable red herring", *Perspectives on European Politics and Society* 7 (1): 108-123. Doi: 10.1080/15705850600839637

INAHTA (2001). International Network of Agencies for Health Technology Assessment. *A checklist for health technology assessment reports* (Stockholm). Available at http://www.inahta.org/HTA/Checklist/ Last accessed: 29 July 2015.

INAHTA (2004). Personal correspondence between the Chairman of the Board of INAHTA and the Director of the Health and Consumer Protection, Public health and Risk Assessment Directorate of the European Commission.

INAHTA (2007). International Network of Agencies for Health Technology Assessment. *About HTA*. http://www.inahta.org. Last accessed: 29 July 2015.

Jachtenfuchs, M. and B. Kohler-Koch (1999). "The transformation of European Governance", paper presented at the ESCA – Sixth Biennial International Conference, Pittburg, USA 2-5 June 1995. To

be published in the *Transformation of Governance in the European Union*, B. Kohler-Koch and R. Eising (eds.) (Routledge 1999).

Jeffery, C. (2000). "Sub-national mobilization and European integration: does it make any difference?", *Journal of Common Market Studies* 38 (1): 1–23.

Jefferys, D. and K. Jones (1995). "EMEA and the new pharmaceutical procedures for Europe", *European Journal of Clinical Pharmacology* 47:471-76.

Jelfs, E. and R. Baeten (2012). *Simulation on the EU Cross-Border Care Directive*, Brussels, 24 November 2011, Final Report. Available at http://www.ose.be/files/publication/2012/CrossBorderHealthcareSimulation_FinalRep_09052012.pdf. Last accessed: 30 March 2017.

Jessop, B. (1998). The rise of governance and the risks of failure: The case of economic development", *International Social Science Journal* 50 (155): 29-45.

Jessop, B. (2002). *The Future of the Capitalist State* (Cambridge: Polity Press).

Jessop, B. (2003). "Governance and Metagovernance: On Reflexivity, Requisite Variety, and Requisite Irony", in H. Bang (ed.) *Governance as Social and Political Communication* (Manchester: Manchester University Press), pp. 200-21.

Jonsson E., D. Banta, C. Henshall et al. (2002). "European collaboration for health technology assessment: developing an assessment network", *International Journal of Technology Assessment in Health Care* 18:213–55.

Jonsson, E. (2002). "Development of health technology assessment in Europe", *International Journal of Technology Assessment in Health Care* 18: 171-83.

Jonsson, E. (2009). "History of health technology assessment in Sweden", *International Journal of Technology Assessment in Health Care,* 25 (Supplement 1): 42-52.

Jonsson, E., D. Banta and T. Scherstén (2001). "Health technology assessment and screening in Sweden", *International Journal of Technology Assessment in Health Care* 17(3): 380-88.

Jordan, A. (1990). "Policy Community Realism versus "New Institutionalism" Ambiguity", *Political Studies* 38: 470-84.

Jordan, A. (1999). "Editorial introduction: the construction of a multilevel environmental governance system. Environment and Planning C", *Government and Policy* 17 (1): 1–17.

Jordan, G. and K. Schubert (1992). "A Preliminary Ordering of Policy Network Labels", *European Journal of Political Research* 21 (1–2): 7–27.

Judge, D. and D. Earnshaw (2002). "The European Parliament and the Commission Crisis: a New Assertiveness?", *Governance,* 15 (3): 345-74.

Kanavos, P. and O. Efthymiadou (2017). "VP78 - Cross-Country Variation in Health Technology Assessment Preferences: An International Survey," *International Journal of Technology Assessment in Health Care*, 33, pp. 185- 86.

Kanavos, P., A. Ferrario, G. Tafuri and P. Siviero (2017). "Managing Risk and Uncertainty in Health Technology Introduction: The Role of Managed Entry Agreements", *Global Policy* 8 (Supplement 2): 84-91.

Kanavos, P., E. Nicod, S. Van den Aardweg and S. Pomedli (2010) "The Impact of Health Technology Assessments: An International Comparison" *Euro Observer* 12(4): 1–6.

Kassim, H. (1994). "Policy networks, Networks and the European Union Policy Making: a Skeptical View", *West European Politics* 17 (4): 15-27.

Keast, R., M. Mandell and K. Brown (2006). "Mixing state, market and network governance modes: the role of government in "crowed" policy domains", *International Journal of Organization Theory and Behaviour*, 9 (1): 27-50.

Kenis, P. and L. Oerlemans (2008). 'The Social Network Perspective: Understanding the Structure of Cooperation', in S. Cropper, M. Ebers, C. Huxham and P. Ring (eds), *The Oxford Handbook of Inter-organizational Relations* (Oxford: Oxford University Press), pp. 289–312.

Kickert, W. and E-H Klijn and J. Koppenjan (eds.) (1997). *Managing Complex Networks: Strategies for the Public Sector* (London: Sage).

Kidholm K., A.M. Ølholm, M. Birk-Olsen, A. Cicchetti, B. Fure, E. Halmesmäki, R. Kahveci, R. A. Kiivet, J.B. Wasserfallen, C. Wild and L. Sampietro-Colom (2015). "Hospital Managers' Need for Information in Decision-Making-- An Interview Study in Nine European Countries," *Health policy* 119(11): 1424–32.

Kingdon, J. (1995). *Agendas, alternatives, and public policies*. (Boston: Little, Brown and Company).

Kingdon, J. (2003). *Agendas, alternatives, and public policies* (2nd Ed.). (New York: Longman).

Kirisits, A. and W.K. Redekop (2013). "The economic evaluation of medical devices", *Applied Health Economics and Health Policy* 11(1): 15-26.

Kleijnen, S. (2016). *Harmonizing relative effectiveness assessments of medicines in Europe*, PhD Thesis. Available at: https://dspace.library.uu.nl/bitstream/1874/331048/1/kleijnen.pdf. Last accessed: 25 January 2018.

Kleijnen, S., E. George, S. Goulden, A. d'Andon, P. Vitré, B. Osinska, R. Rdzany, S. Thirstrup, B. Corbacho, B. Nagy, H. Leufkens, A. de Boer, W. Goettsch (2012). "Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions", *Value in Health* 15: 954-60.

Kleijnen, S., W. Toenders, F. de Groot, M. Huic, E. George, B. Wieseler, M. Pavlovic, A. Bucsics, P. D. Siviero, M. van der Graaff, R. Rdzany, F. B. Kristensen, W. and Goettsch (2015). "European Collaboration on Relative Effectiveness Assessments: What Is Needed to Be Successful?", *Health policy*, 119(5): 569–576.

Klemp, M., Katrine B. Frønsdal and Karen Facey (2011). "What principles should govern the use of managed entry agreements?", *International Journal of Technology Assessment in Health Care* 27 (1): 77–83.

Klijn E-H., B. Steijn, and J. Edelenbos (2010). "The Impact of Network management on outcomes in Governance Networks, *Public Administration* 88 (4): 1063–82.

Klijn, E-H. (2001). "Rules as Institutional Context for Decision-Making in Networks: The Approach to Postwar Housing Districts in Two Cities", *Administration and Society* 33 (2): 133-64.

Klijn, E-H. (2008). Governance and Governance networks in Europe, An Assessment of Ten Years of Research on the Theme", *Public Management Review* 10 (4): 506-25

Klijn, E-H. and J. Edelenbos (2007). "Meta-governance as Network Management", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance*, (Houndmills, Basingstoke: Palgrave Macmillan), pp. 199-214.

Klijn, E-H. and J. Koppenjan (2000). "Public Management and Policy Networks: Foundations of a Network Approach to Governance", *Public Management an International Journal of Research and Theory* 2 (2): 135–58.

Klijn E-H. and J. Koppenjan (2004). *Managing Uncertainties in Networks: A Network Approach to Problem-Solving and Decision-Making* (London, Routledge).

Klijn, E-H. and J. Koppenjan (2016). *Governance Networks in the Public Sector*, (New York, Routledge).

Klijn, E-H., J. Edelenbos and B. Steijn (2010). "Trust in governance networks; its impacts on outcomes", *Administration and Society* 42 (2): 193-221.

Knill, C. and A. Lenschow (2003). "Modes of Regulation in the Governance of the European Union: Towards a Comprehensive Framework", *European Integration Online Papers (EioP),* 7 (1). Available at: http://eiop.or.at/eiop/pdf/2003-001.pdf. Last accessed: 20 October 2015.

Kohler-Koch, B. and B. Rittberger (2006). "The 'Governance Turn' in EU Studies", *Journal of Common Market Studies* 44 (s1): 27–49

Koliba, C. (ed.) (2011). *Governance networks in public administration and public policy* (Boca Raton, CBC Press).

Kooiman, J. (2003). *Governing as Governance* (London: Sage).

Kooiman, J. (ed.) (1993). *Modern Governance: New Government-Society Interactions* (London: Sage).

Koppenjan, J. and E. Klijn (2004). *Managing uncertainty in networks: A network approach to problem solving and decision making* (New York: Routledge).

Kristensen, F. B. (2006). EUnetHTA and health policy-making in Europe, *Eurohealth* 12 (1): 36-38.

Kristensen, F.B. (2009). "Health technology assessment in Europe", *Scandinavian Journal of Public Health*, 37: 335–39

Kristensen, F.B. (2012). "Development of European HTA: from Vision to EUnetHTA", *Michael* 9: 147–56.

Kristensen, F.B., K. Lampe, C. Wild, M. Cerbo, W. Goettsch, L. Becla (2017). "The HTA Core Models—10 Years of Developing an International Framework to Share Multidimensional Value Assessment", *Value in Health* 20: 244-50.

Kristensen, F.B., K. Lampe, D.L. Chase, et al. (2009a). "Practical tools and methods for health technology assessment in Europe: Structures, methodologies, and tools developed by the European Network for Health Technology Assessment, EUnetHTA", *International Journal for Technology Assessment in Health Care* 25(Supplement 2): 1-8.

Kristensen, F.B., M. Makel S. Neikter, N. Rehnqvist, L. Haheim, B. Mørland, R. Milne, C. Nielsen, R. Busse (2009). "European network for Health Technology Assessment, EUnetHTA: Planning, development, and implementation of a sustainable European network for Health Technology Assessment", *International Journal of Technology Assessment in Health Care* 25: Supplement 2 (2009b): 107–16.

Kristensen, F. B., M. Hørder and P. Poulsen (Eds.) (2001). *Health Technology Assessment Handbook* (1st ed.), (Copenhagen: Danish Institute for Health Technology Assessment).

Kröger, S. (2009). "The Open Method of Coordination: Underconceptualistion, overdetermination, de-politicisation and beyond", *European Integration online Papers (EIoP)*, Special Issue 1, vol. 13. Art 5; Available at: http://eiop.or.at/eiop/texte/2009-005a.htm.

Lampe, K. and P. Schnell-Inderst (2017) "Integrate-HTA: The Perspective of EUnetHTA," *International Journal of Technology Assessment in Health Care*, 33(5): 605–8.

Lampe, K., M. Mäkelä, M. Garrido and H.Anttila (2009). "The HTA Core Model: A novel method for producing and reporting health technology assessments", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 2): 9–20.

Lampe,K. F. B. Kristensen, M. Mäkelä, I. Norderhaug, A. Ravina, M. Garrido, K. Frønsdal (2008b). General Design, EUnetHTA WP4 - HTA Core Model for diagnostic technologies - Version 1.0r 31 Dec 2008. Available at www.eunethta.eu. Last accessed: 7 August 2017.

Lamping, W. (2005). "European integration and health policy. A peculiar relationship" in M. Steffen (ed.), *Health Governance in Europe. Issues, challenges and theories* (London and New York: Routledge), pp.18-48.

Lauslahti, K., R. Roine, V. Semberg, M. Kekomaki, M. Konttinen, and P. Karp (2000). "Health technology assessment in Finland", *International Journal of Technology Assessment in Health Care* 16(2): 382-99.

Le Galès, P. and C. Lequesne. 2002. *Regions in Europe* (London: Routledge).

Lehoux, P. and B. Williams-Jones (2007). "Mapping the integration of social and ethical issues in health technology assessment", *International Journal of Technology Assessment in Health Care* 23(1): 9-16.

Lehoux, P., J-L. Denis, S. Tailliez, and M. Hivon (2005). "Dissemination of Health Technology Assessments: Identifying the Visions Guiding an Evolving Policy Innovation in Canada", *Journal of Health Politics, Policy and Law* 30 (4): 603-41.

Liberati A., T. Sheldon, D. Banta (1997). "EUR-ASSESS Project Subgroup Report on Methodology", *International Journal of Technology Assessment in Health Care* 13 (2):186-219.

Lipsky, M. (1980). *Street-Level Bureaucracy: Dilemmas of the Individual in Public Services* (New York: Russel Sage Foundation).

Longworth, L., J. Youn, L. Bojke, S. Palmer, S. Griffin, E. Spackman, and K. Claxton (2013). "When does NICE recommend the use of health technologies within a programme of evidence development? A systematic review of NICE guidance", *Pharmacoeconomics* 31(2): 137-49.

Luce, B. and R. Singer Cohen (2009). "Health technology assessment in the United States", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 33–41.

Lysdahl K.B., W. Oortwijn, G-J. van der Wilt, P. Refolo, D. Sacchini, K. Mozygemba, A. Gerhardus, L. Brereton and B. Hofmann (2016). "Ethical analysis in HTA of complex health interventions". *BMJ Medical Ethics* 17:16.

Majone, G. (1988). "Policy analysis and public deliberation", in R.Reich (Ed.) *Die power of public ideas* (Cambridge, MA: Harvard University Press): pp. 157-178.

Makady A., R. ten Ham R., A. de Boer.,J.L. Hillege, O. Klungel, W. Goettsch (2016). "Policies for Use of Real-World Data in Health Technology Assessment: A Comparative Study of 6 HTA Agencies", *Value in Health* 19: A347-A766.

Mäkelä, M.and R. Roine (2009). "Health technology assessment in Finland", *International Journal of Technology Assessment in Health Care* 25 (Supplement 1): 102–7.

Mandell, M. P. (ed.) (2001). *Getting Results Through Collaboration: Networks and Network Structures for Public Policy and Management* (Westport, CT: Quorum Books).

March, D. and Rhodes, R.A.W. (eds.) (1992). *Policy Networks in British Government* (Oxford: Oxford University Press/Clarendon Press).

March, J. and J. Olson (1995). *Democratic Governance* (New York: The Free Press).

Marinoni, G. (2012). "Blurring the Boundaries Between Regulatory and HTA Agencies: A Risk-Benefit Analysis". *IHS Markit.* Available at: https://ihsmarkit.com/research-analysis/blurring-the-boundaries-between-regulatory-and-hta-agencies-a-risk-benefit-analysis.html. Last accessed: 25 January 2018.

Marks, G. (1993). "Structural policy and Multi-level governance in the EC", in A. Cafrany and G. Rosenthal (eds.), *The State of the European Community, vol. 2 The Maastricht Treaty and beyond* (Boulder, CO: Lynne Rienner), pp. 391-410.

Marks, G., L. Hooghe, and K. Blank (1996). "European integration from the 1980s: state-centric v. multilevel governance", *Journal of Common Market Studies* 34 (3): 341–78.

Marsh, K., M. IJzerman, P. Thokala, R. Baltussen, M. Boysen, Z. Kaló, T. Lönngren, F. Mussen, S. Peacock, J. Watkins, N. Devlin (2016). "Multiple Criteria Decision Analysis for Health Care Decision. Making—Emerging Good Practices: Report 2 of the ISPOR MCDA.". *Value in Health* 19: 125-37.

Marsh, K., M. Sculpher, J. Caro and T. Tervonen (2017). "The Use of MCDA in HTA: Great Potential, but More Effort Needed", *Value in health, the journal of the International Society for Pharmacoeconomics and Outcomes Research* 20 (9): 394-97.

Matland, R. (1995). "Synthesizing the Implementation Literature: The Ambiguity-Conflict Model of Policy Implementation", *Journal of Public Administration Research and Theory* 5 (2): 145-74.

May, P. (1992). "Policy Learning and Failure", *Journal of Public Policy*, 12 (4): 331-354.

Mayntz, R. (1993) "Modernization and the Logic of Interorganizational Networks", *Knowledge and Policy*, 6: 3-16.

Mayntz, R. (1998). "New Challenges in Governance Theory", *Jean Monnet Chair Paper Series* 50 (Florence: Robert Schuman Centre at the European University Institute).

Mc Elvily,B. ,V. Peronne and A. Zaheer (2003). "Trust as an organizing principle", *Organization Science* 14: 91-103.

McDaid D. (2003). "Co-ordinating health technology assessment in Canada: A European perspective", *Health Policy* 63: 205-13.

McKee, M. and E. Mossialos (2006). "Health Policy and European Law: Closing the Gaps", *Public Health* 120: 16-22

MedTech Europe (2015). "The European Medical Technology Industry in Figures 2015". Available at: www.medtecheurope.org. Last accessed 13 March 2020.

Meier, K. and L. O'Toole (2001). "Modelling Public Management: Empirical Analysis of the Management-Performance Nexus", *Public Administration Review* 9 (4): 503-27.

Meneu, R. (2015). "The wisdom tooth of Health technology assessment" in J. E. del Llano-Señarís and C. Campillo-Artero (eds.) *Health Technology Assessment and Health Policy Today: A multifaceted View of their Unstable Crossroads* (Switzerland: Springer International Publishing), pp. 37-50.

Menon, D. and L.A. Topfer (2000). "Health technology assessment in Canada. A decade in review", *International Journal of Technology Assessment in Health Care* 16(3): 896-902.

Menon, D. and T. Stafinski (2009). "Health Technology Assessment in Canada: 20Years Strong?", *Value in Health* 12 (Supplement 2): 14-19.

Meredith, J. R. and S. J. Mantel (2000). *Project Management: A Managerial Approach* (4th ed.) (New York: Wiley).

Milewa, T. (2006). "Health technology adoption and the politics of governance in the UK", *Social Science and Medicine* 63: 3102–12.

Milward H. and K. Provan (1998). "Principles for Controlling Agents: The Political Economy of Network Structure", *Journal of Public Administration Research and Theory*, 8 (2): 203-21.

Milward,H. and K. Provan (2000). "Governing the Hollow State, *Journal of Public Administration Research and Theory* 10 (2) 359-79.

Mintrom, M. and S. Vergari (1996); "Advocacy Coalitions, Policy Entrepreneurs, and Policy Change", *Policy Studies Journal* 24 (3): 420-34

Mintz, A. and N. Geva (1997). "The Poliheuristic Theory of Foreign Policy Decision-Making", in N. Geva and A. Mintz (eds.), *Decision-Making in war and Peace: The Cognitive-Rational Debate* (Boulder, Lynne Rienner), pp. 81-102.

Mitnick, B. (1980). *The Political Economy of Regulation: Creating, Designing and Removing Regulatory Forms* (New York: Columbia University Press).

Moharra, M. N. Kubesch, M. Estrada, A. Parad, M. Cortes and M. Espallagues on behalf of the Work Package 8, EUnetHTA Project 2008 (2008). Survey report on HTA organisations. Catalan Agency for Health Technology Assessment and Research (CAHTA), EUnetHTA project, Barcelona, Spain.

Moran, P. (2005). "Structural vs. relational embeddedness: Social capital and managerial performance", *Strategic Management Journal*, 26 (12): 1129-51.

Moravcsik, A. and F. Schimmelfennig (2009). "Liberal Intergovernmentalism" in A. Wiener and Th. Diez (eds.), *European Integration Theory* (Oxford: Oxford University Press), pp. 67-87.

Moret-Hartman, M., G-J. van der Wilt and J. Grin (2007). "Health technology assessment and ill-structured problems: A case study concerning the drug Mebeverine", *International Journal of Technology Assessment in Health Care*, 23 (3): 316–23.

Mørland, B. (2009). "The history of health technology assessment in Norway", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 148–55.

Mossialios E., G. Permanand, R. Baeten and T. Hervey (eds.) (2010). *Health systems governance in Europe: the Role of European Union Law and Policy* (New York: Cambridge University Press).

Mossialos, E. and J. Lear (2012). "Balancing economic freedom against social policy principles: EC competition law and national health systems", *Health Policy*. 106(2):127-37. Doi: 10.1016/j.healthpol.2012.03.008.

Mossialos, E., G. Permanand, R. Baeten and T. Hervey (Eds.) (2010). *Health Systems Governance in Europe. The Role of European Union Law and Policy* (Cambridge/New York: Cambridge University Press).

Mugyenzi , J. (2015). "EU External Governance: Regionalizing Multilevel Networks of Governance", *Journal of European Integration*, 37 (3): 353-70.

Nachtnebel, A., J. Mayer, J. Erdös, K. Lampe, S. Kleijnen, P. Schnell-Inderst, and C. Wild (2015). "HTA goes Europe: European collaboration on joint assessment and methodological issues becomes reality", *Zeitschrift für Evidenz Fortbildung und Qualität im Gesundheitswesen* 109: 291—99.

Nasser, M. and P. Sawicki (2009). *Institute for Quality and Efficiency in Health Care: Germany* (New York: The Commonwealth Fund).

Nickless, J. (2001). "A guarantee of similar standards of medical treatment across the EU: were the European Court of Justice decisions in Kohll and Decker rights?", *Eurohealth* 7 (1): 16-18.

Nicod, E. and P. Kanavos (2012). "Commonalities and differences in HTA outcomes: A comparative analysis of five countries and implications for coverage decisions". *Health Policy* 108 (2-3): 167-77.

Nicod, E. and P. Kanavos, P. (2016) "Developing an Evidence-Based Methodological Framework to Systematically Compare HTA Coverage Decisions: A Mixed Methods Study," *Health Policy*, 120 (1): 35–45.

Nicod, E., L. Annemans, A. Bucsics, A. Lee, S. Upadhyaya and K. Facey (2017) "HTA Programme Response to the Challenges of Dealing with Orphan Medicinal Products: Process Evaluation in Selected European Countries", *Health policy* 123 (2):140-151. Doi: 10.1016/j.healthpol.2017.03.009.

Nielsen, C. P., A. Sarriá Santamera, and H. Vondeling, (2008). "Policy processes and health technology assessment", in M. V. Garrido, F. B. Kristensen, C.P. Nielsen, and R. Busse (Eds.), *Health Technology Assessment and Health Policy Making in Europe* (Bodmin, Comwall: World Health Organization. European Observatory Studies), pp. 19-30.

Nielsen, C.P., S. Wadmann Lauritsen, F.B.Kristensen, M-L Bistrup, A. Cecchetti and E.Turk (2009). "Involving stakeholders and developing a policy for stakeholder involvement in the European network for Health Technology Assessment, EUnetHTA", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 2): 84–91.

Nielsen, J. (2008). HTA's future in Europe - Conference. Opening speech by Mr Jakob Axel Nielsen, Minister for Health and Prevention, Denmark. 20 November 2008Available on ww.eunethta.eu. Last accessed: 8 January 2017.

Nielsen, K. and O. Pedersen (1988). "The negotiated economy: ideal and history", *Scandinavian Political Studies*, 11 (2), 79-101.

Nugent, N. (2010). *The Government and politics of the European Union* (Basingstoke: Palgrave Macmillan).

Nys, H. and T. Goffin (2011). "Mapping national practices and strategies relating to patients' rights" in M. Wismar, W. Palm, J. Figueras, K. Ernst and E. van Ginneken (eds.), *Cross-Border Health Care in the European Union* (Copenhagen: WHO Regional Office for Europe), pp. 159-216.

O'Toole, L. (1997). "Treating Networks Seriously: Practical Research-Based Agendas", *Public Administration Review*, 57 (1): 45-52.

O'Toole, L. (2007). "Governing Outputs and Outcomes of Governance Networks", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan): pp. 215-229.

Obradovic D. and J. Alonso Vizcaino (2007). "Good Governance Requirements Concerning the Participation of Interest Groups in EU Consultations", in D. Obradovic and H. Pleines (eds.), *The Capacity of Central and Eastern European Interest Groups to Participate in EU Governance* (Stuttgart: Ibidem Publishers), pp. 67-108.

Odiorne, G. (1974). "Management by objectives and the phenomenon of goals displacement", *Human Resource Management* 13.1 (2).

O'Donnell J.C, Pham S.V, Pashos C.L, Miller D.W and Smith M.D (2009) "Health Technology Assessment: Lessons Learned from Around the World - an Overview," *Value in Health*, 12(Suppl. 2): 5.

OECD (2005). *The OECD Health Project: Health Technologies and Decision Making* (Paris: OECD publishing).

Office of Technology Assessment (1974). Annual Report to the Congress by the Office of Technology Assessment: March 15, 1974. (Washington, D. C.: U.S. Congress, Office of Technology Assessment). Last accessed: 8 June 2016.

Office of Technology Assessment (1976). Development of Medical Technology: Opportunities for Assessment (Washington, D. C.: U.S. Congress, Office of Technology Assessment, August 1976). Available at https://www.princeton.edu/~ota/disk3/1976/7617/7617.PDF. Last accessed: 8 June 2016.

Office of Technology Assessment (1978). Assessing the Efficacy and Safety of Medical Technologies (Washington, D. C.: U.S. Congress, Office of Technology Assessment, September 1978). Available at https://www.princeton.edu/~ota/disk3/1978/7805/7805.PDF. Last accessed: 8 June 2016.

Office of Technology Assessment (1980a). The Implications of Cost-Effectiveness Analysis of Medical Technology (Washington, D. C.: U.S. Congress, Office of Technology Assessment, August 1980). Available at https://www.princeton.edu/~ota/disk3/1980/8011/8011.PDF. Last accessed: June 2016.

Office of Technology Assessment (1980b). The Implications of Cost-Effectiveness Analysis of Medical Technology: Methodological Issues and Literature Review. (Washington, D. C.: U.S. Congress, Office of Technology Assessment, August 1980). Available at: https://www.princeton.edu/~ota/disk3/1980/8013/8013.PDF. Last accessed: 8 June 2016.

Olberg, B., S. Fuchs, D. Panteli, M. Perleth and R. Busse (2017). "Scientific Evidence in Health Technology Assessment Reports: An In-Depth Analysis of European Assessments on High-Risk Medical Devices", *Value in Health* 20: 1420-26.

Oliver, A., E. Mossialos, and R. Robinson (2004). "Health technology assessment and its influence on health-care priority setting". *International Journal of Technology Assessment in Health Care* 20(1): 1–10.

Oortwijn, W., P. Broos, H. Vondeling, D. Banta and L. Todorova (2013). "Mapping of Health Technology Assessment in Selected Countries", *International Journal of Technology Assessment in Health Care*, 29 (4): 424–34.

Oortwijn, W.J. (2000). *First things first: priority setting for health technology assessment*, PhD Thesis, Vrije Universiteit Amsterdam.

Organisation for Economic Co-operation and Development (2010) *Value for money in health spending* (Paris: Organisation for Economic Co-operation and Development).

Orvain, J., B. Xerri, and Y. Matillon (2004). "Overview of health technology assessment in France", *International Journal of Technology Assessment in Health Care* 20(1): 25-34.

Osborne, D. and T. Gaebler (1992). *Reinventing Government* (New York: Penguin Press).

O'Rourke B, W. Oortwijn and T. Schuller, the International Joint Task Group (2020). "The new definition of health technology assessment: A milestone in international collaboration", *International Journal of Technology Assessment in Health Care* 1–4. https://doi.org/10.1017/ S0266462320000215

O'Toole, L. (1990). "Theoretical developments in public administration: Implications for the study of federalism", *Governance*, 3 (4): 394-415. doi:10.1111/j.1468-0491.1990.tb00129.x

Palm W., J. Nickless, H. Lewalle and A. Coheur (2000). "Implications of recent jurisprudence on the coordination of health care protection systems". General report produced for the Directorate General for Employment and Social Affairs of the European Commission (Brussels: Association Internationale de la Mutualité (AIM)). Available at : http://ec.europa.eu/employment_social/soc-prot/disable/synt_en.pdf. Last accessed: 30 March 2017.

Palm W. and I. Glinos (2010). "Enabling Patient Mobility in the EU: between free movement and coordination" in E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds.), *Health systems governance in Europe: the Role of European Union Law and Policy* (New York: Cambridge University Press), pp. 509-60.

Palm, W. and R. Baeten (2011). "The quality and safety paradox in the patients' rights Directive", *European Journal of Public Health* 21 (3): 272-74.

Palmer, S. and P. Smith (2000). "Incorporating option values into the economic evaluation of health care technologies", *Journal of Health Economics* 19: 755-766.

Paris, V. and A. Colbert (2017). "Innovation, access and value in pharmaceuticals" in *New Health Technologies: Managing Access, Value and Sustainability* (Paris: OECD Publishing), pp: 81-113.

Pasternack, I., H. Anttila, M. Mäkelä, T. Ikonen, P. Räsänen, K. Lampe (2009). "Testing the HTA Core Model: Experiences from two pilot projects", *International Journal of Technology Assessment in Health Care* 25 (Supplement 2): 21–27.

Paterson, B. (2001). *Meta-study of qualitative health research. A practical guide to meta-analysis and meta-synthesis* (London: Sage publications).

Peeters,M., M. McKee and S. Merkur (2010). "EU law and health professionals", in E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds.), *Health systems governance in Europe. The Role of European Union Law and Policy* (Cambridge: Cambridge University Press), pp. 589-634.

Perleth, M., B. Gibis and B. Gohlen (2009). "A short history of health technology assessment in Germany", *International Journal of Technology Assessment in Health Care* 25(S1): 112–19.

Permanand, G. (2006). 'EU pharmaceutical regulation: the politics of policy-making', *European Policy Research Unit series* (Manchester: Manchester University Press).

Permanand, G. and Altenstetter, C. (2004). 'The politics of the EU pharmaceutical industry' in Mossialos, E. and Mrazek, M. and Walley, T. (eds.) *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*. (Open University Press, Maidenhead), pp. 38-54.

Permanand, G. and E. Mossialos (2005). "The Europeanization of regulatory policy in the EU pharmaceutical sector", in M. Steffen (ed.) (2005) *Health Governance in Europe. Issues Challenges and Theories* (New York: Routledge), pp. 49-80.

Permanand, G. and E. Mossialos (2005b). "Constitutional asymmetry and pharmaceutical policy-making", *European Union Journal of European Public Policy*, 12 (4): 687-709

Perry, S., E. Gardner, and M. Thamer (1997). "The status of health technology assessment worldwide: Results of an international survey", *International Journal of Technology Assessment in Health Care* 13(1): 81-98.

Peters, B. (2007). "Virtuous and Vicious Circles in Democratic Network Governance", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan), pp. 61-76.

Peters, G. (2002). "The Politics of Tool Choice" in L. Salamon (2002), *The Tools of Government: A guide to New Governance* (New York: Oxford University Press), pp. 552-64.

Petersen, J. (1995). "Decision-Making in the European Union: Towards a Framework for Analysis", *Journal of European Public Policy* 2(1): 69-93.

Phillips, Z., L. Bojke, M. Sculpher, K. Claxton, and S. Golder (2006). "Good practice guidelines for decision-analytic modelling in health technology assessment: A review and consolidation of quality assessment", *Pharmacoeconomics* 24(4): 355-371.

Pierre, J. and B. Peters (2000). *Governance, Politics and the State* (Houndmills, MacMillan Press Ltd/New York, St Martins Press).

Pollitt, C. (2001) "Clarifying convergence: striking similarities and durable differences in management reform", *Public Management Review* 3 (4): 1–22.

Porzsolt, F., H. Kajnar, A. Awa, M. Fässler and B. Herzberger (2005). "Validity of original studies in health technology assessment reports: Significance of standardized assessment and reporting", *International Journal of Technology Assessment in Health Care*, 21(3): 410–413.

Powell, W. W. (1991). "Neither Market nor Hierarchy: Network Forms of Organisation, in in G. Thompson *et al*. (eds), *Markets Hierarchies and Networks: The Co-ordination of Social Life* (London, Sage), pp. 265-76.

Powell, W., and P. Di Maggio (1991). *The new institutionalism in organizational analysis* (Chicago: University of Chicago Press).

Pressman, J. and A. Wildavsky (1984). *Implementation: How Great Expectations Are Dashed in Oakland* (3rd ed.) (Berkeley: University of California Press).

Princen, S. (2009). *Agenda setting in the European Union* (Basingstoke and New York: Palgrave Macmillan).

Princen, S. (2011). "Agenda setting", in E. Versluis, M. van Keulen and P. Stephenson (eds), *Analyzing the European Union policy process* (Basingstoke: Palgrave Macmillan), pp. 107-31.

Prosser, T. (2010). "EU competition law and public services" in Mossialos, E., G. Permanand, R. Baeten and T. Hervey (Eds.) (2010). *Health Systems Governance in Europe. The Role of European Union Law and Policy*. (Cambridge/New York: Cambridge University Press), pp. 315-36.

Provan, K. and Kenis, P (2008). "Modes of Network Governance: Structure, Management, and Effectiveness", *Journal of Public Administration Research and Theory*, 18 (2): 229-52.

Punyaratabandhu, S. (2004). "Commitment to good governance, development and poverty reduction: methodological issues in the evaluation of progress at the national and local levels", CDP Background Paper No. 4. Available at: https://www.un.org/en/development/desa/policy/cdp/cdp_background_papers/bp2004_4.pdf, Last accessed: 9 March 2020.

Quah, E. and K. C. Tan (2002). *Siting Environmentally Unwanted Facilities* (Cheltenham, UK: Edward Elgar).

Quentin, F., C. Carbonneil, C. Moty-Monnereau, E. Berti, W. Goettsch and S. Lee-Robin, for the European network for Health Technology Assessment (EUnetHTA) (2009). "Web-based toolkit to facilitate

European collaboration on evidence generation on promising health technologies", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 2): 68–74.

Raftery, J. (2011). "Research, Innovation and health technology assessment", in K. Walsh and J. Smith, *Healthcare Management* (Maidenhead: Open university Press), pp.80-95.

Randall, E. (2000). *The European Union and Health Policy* (Basingstoke: Macmillan).

Randall, E. (2000a). "European Union Health Policy with and without Design: Serendipity, Tradegy and the Future of EU Health Policy", *Policy Studies* 21 (2): 133-64.

Randall, E. (2000b). *The European Union and Health Policy* (Basingstoke: Macmillan).

Regent, Sabrina (2002), The Open Method of Co-ordination: A Supranational form of Governance? ILO Working Paper No. DP137/2002. Available at SSRN: https://ssrn.com/abstract=334902. Last accessed 7 April 2017.

Rhodes, R.A.W. (ed.) (1990). *Transforming British Government* (London: MacMillan).

Rhodes, R.A.W. (1994). "The hollowing out of the state: the changing nature of the public service in Britain", *The Political Quarterly* 64 (2): 138-51.

Rhodes, R. A.W. (1996). "The New Governance: Governing without Government", *Political Studies*, 44 (4): 652-67.

Rhodes, R.A.W (1997). *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability* (Buckingham: Open University Press).

Rhodes, R.A.W. (2012). "Waves of governance", in D. Levi-Faur (ed.), *The Oxford handbook of governance* (Oxford: Oxford University Press).

Richardson, Henry S. (2016). "Intelligence and transparency in Health Technology Assessment", *International Journal of Technology Assessment in Health Care*, 32 (1/2): 3–9.

Robinson, S. (2011). "Financing healthcare: funding systems and healthcare costs" in K. Walsh and J. Smith (eds.), *Healthcare Management* (Maidenhead: Open University Press), pp. 37-64.

Rochefort, D. and R. Cobb (eds.) (1994). *The Politics of Problem Definition. Shaping the Policy Agenda* (Lawrence, KS: University Press of Kansas).

Rogers, D. L. and D. A. Whetten (eds.) (1982). *Interorganizational Coordination: Theory, Research and Implementation* (Ames: Iowa State University Press).

Rose, N. and P. Miller (1992). "Political Power beyond the State: Problematics of government", *British Journal of Sociology* 43 (2): 172-205.

Rosenau, J.N. (1992). "Governance, order and change in world politics" in J.N. Rosenau and E-O Czempiel (eds.), *Governance without Government: Order and Change in World Politics* (Cambridge, Cambridge University Press).

Rottingen, J.A., A. Gerhardus and M. V. Garrido (2008). "Future Challenges for HTA in Europe" in M. V. Garrido, F. B. Kristensen, C. Nielsen and R. Busse (eds.), *Health Technology Assessment and Health Policy-Making in Europe. Current Status, Challenges and Potential* (Kopenhagen: World Health Organisation on behalf of European Observatory on Health Systems and Policies), pp. 161-181.

Rummel, P, K. Hawlik, and C. Wild (2016). Health Technology Assessments on Medical Devices in Europe. Final Report.LBI-HTA Rapid Assessment Nr. 12; (Vienna: Ludwig Boltzmann Institute for Health Technology Assessment).

Sabatier, P and C. Weible (2007). "The advocacy coalition Framework" in P. Sabatier *Theories of the policy process* (Colorado: Westview press), pp. 189- 220.

Sabatier, P. and H. Jenkins Smith (1988). "An Advocacy Coalition model of Policy Change and the Role of Policy Orientated Learning Therein", *Policy Sciences* 21: 21-168.

Sabatier, P. (1988). "An Advocacy Coalition Model of Policy Change and the Role of Policy-Oriented Learning Therein", *Policy Sciences* 21: 129–68.

Sabatier, P. (1993). "Top down and Bottom Up Approaches to Implementation Research", in M. Hill (ed.), *The Policy Process: A Reader* (New York: Harvester, Wheatsheaf), pp. 266-96.

Sabatier, P. and H. Jenkins-Smith (1999). "The Advocacy Coalition Framework: An Assessment.", in P. Sabatier (ed.) *Theories of the Policy Process*, (Boulder: Westview Press), pp. 117–168.

Sabatier, P. and H. Jenkins-Smith (eds.) (1993). *Policy Change and Learning: An Advocacy Coalition Approach* (Boulder: Westview Press).

Sabel, C. and J.Zeitlin (2008). Learning from Difference: The New Architecture of Experimentalist Governance in the European Union. *European Law Journal* 14 (3): 271-327.

Sacchini D., A. Virdis, P. Refolo, M. Pennacchini and I. de Paula (2009). "Health Technology Assessment (HTA): Ethical Aspects," *Medicine, health care, and philosophy*, 12(4): 453–7.

Saltman R. (2004). "Social health insurance in perspective: the challenge of sustaining stability" in R. Saltman, R. Busse and J. Figueras (eds.), *Social Health Insurance Systems in Western Europe* (Maidenhead: Open University Press), pp. 3-20

Saltman,R., R. Busse and J. Figueras (eds.) (2004). *Social Health Insurance Systems in Western Europe* (Maidenhead: Open University Press).

Sampietro-Colom, L. and Adopting Hospital Based Health Technology Assessment (2015). *The ad-HopHTA handbook: a handbook of hospital-based health technology assessment: information and knowledge for decision-making on managing technology at hospital level through the use of hospital-based health technology assessment*. (Barcelona: Adopting Hospital Based Health Technology Assessment).

Sanders J. (2002). "Challenges, choices and Canada", *International Journal of Technology Assessment in Health Care*,18:199-202.

Sandström, A. and L. Carlsson (2008). "The Performance of Policy Networks: The Relation between Network Structure and Network Performance", *The Policy Studies Journal* 36 (4), pp. 497-524.

Santiso, C. (2001). "Good Governance and Aid Effectiveness: The World Bank and Conditionality", *The Georgetown Public Policy Review* 7: 1-22.

Saurugger, S. (2009). 'Gouvernances", in S. Saurugger (ed.) *Theories et Concepts de l'intégration européenne* (Paris: Les Presses de Sciences Po), pp. 227-54.

Sauter, W. (2008). The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU. TILEC DP 2008-034. Downloaded from http://papers.ssrn.com/sol3/ papers. cfm?abstract_id=1277110. Last accessed: 27 April 2013.

Schaap, L. (2007). "Closure and Governance", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan), pp. 111-132.

Schandler, M. (2007). *Health Technology Assessments by the National Institute for Health and Clinical Excellence, A Qualitative Study* (Springer: New York).

Scharpf F. W. (1993). „Versuch über die Demokratie im verhandelnden Staat", in R. Czada and M.G. Schmidt (eds.), *Verhandlungsdemokratie, Interessenvermittlung, Regierbarkeit. Festschrift für Gerhard Lehmbruch*. (Opladen: Westdeutscher Verlag), pp. 25-50.

Scharpf, F. (2002). "The European Social Model: Coping with the Challenges of Diversity", *Journal of Common Market Studies* 40 (4): 645-70.

Scharpf, F. W. (1978). "Interorganizational Policy Studies: Issues, Concepts and Perspectives." in K. I. Hanf and F. W. Scharpf (eds.), *Interorganisational Policy Making: Limits to Coordination and Central Control* (London: Sage), pp: 345–370.

Scharpf, F. W. (1994). "Games Real Actors Could Play: Positive and Negative Coordination in Embedded Negotiations", *Journal of Theoretical Politics* 6 (1): 27-53.

Schattschneider, E. (1960). *The Semi-Sovereign People. A realist's View of Democracy in America* (New York: Holt, Rinehart and Winston).

Schmidt, V. (2006). "Procedural Democracy in the EU: The Europeanization of National and Sectoral Policy-Making Processes", *Journal of European Public Policy* 13 (5): 670-91.

Schmidt, V. and C. Radaelli (2004). "Policy Change and Discourse in Europe: Conceptual and Methodological Issues', *West European Politics* 27 (2): 183-210.

Scholz, J. (1991). "Cooperative Regulatory Enforcement and the Politics of Administrative Effectiveness", *American Political Science Review* 85 (1): 115-36.

Schön D. and M. Rhein, (1995). *Frame reflection: Towards the Resolution of Intractable Policy Controversies* (New York: Basic Books).

Schout A. and A. Jordan (2003). "Coordinated European governance: self-organising or centrally steered?", CSERGE working paper, EDM 03-14. The Centre for Social and Economic Research on the Global Environment. Available at: https://www.academia.edu/7562980/Coordinated_European_Governance_Self-organizing_or_Centrally_Steered. Last accessed: 9 March 2020.

Schubert, F. (2002). "Health Technology Assessment, The Pharmaceutical Industry Perspective," *International Journal of Technology Assessment in Health Care*, 18 (2): 184–191.

Schwarzer R. and U. Siebert (2009). "Methods, Procedures, and Contextual Characteristics of Health Technology Assessment and Health Policy Decision Making: Comparison of Health Technology Assessment Agencies in Germany, United Kingdom, France, and Sweden", *International Journal of Technology Assessment in Health Care*, 25 (3): 305–14.

Scott, J. and D. Trubek (2002). "Mind the Gap: Law and New Approaches to Governance in the European Union", *European Law Journal* 8 (1): 1-18.

SEED (Shaping European Early Dialogues for health technologies): http://www.earlydialogues.eu/has/#

Seychell M. and B. Hackbart. (2013). "The EU health strategy – investing in health". *Public Health Reviews* 35: 1-26.

Shah, S., M. Birchall, A. Barron, C. Klinger (2014). "A regulatory governance perspective in Health Technology Assessment (HTA) in Sweden", *Health Policy* 116: 27–36.

Shan, S. and M. Carter (2019). "European Medicines Agency-Health Technology Assessment Parallel Consultation Platform: An Industry Perspective", *Clinical Pharmacology & Therapeutics* 105 (4) :822-25.

Shaw, C. (2008). "Between Political Rocks and Economic Hard Places: Developments in EU Research Policy", *NEWGOV policy brief* 14 (2007-2008).

Sherlock, K., E. Kirk and A. Reeves (2004). "Just the Usual Suspects? Partnerships and Environmental Regulation', Environment and Planning C", *Government and Policy* 22 (5): 651–66.

Siebert, M., L.C. Clauss, M. Carlisle et al. (2002). "Health technology assessment for medical devices in Europe: What must be considered", *International Journal of Technology Assessment in Health Care* 18(3): 733-40.

Sigmund, H. and F.B. Kristensen. (2002). "Does health technology assessment benefit health services and politics? The experiences of an established HTA institution: the Danish Centre for Evaluation and HTA", *European Journal of Health Economics* 3(1): 54-58.

Sigmund, H. and F.B. Kristensen (2009). "Health technology assessment in Denmark: Strategy, implementation, and developments", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 94–101.

Sivalal, S. (2009). "History of health technology assessment: A commentary", *International Journal of Technology Assessment in Health Care*, 25: Supplement 1: 285–87.

Smith, J. (1991). *The idea brokers: Think tanks and the rise of the new policy elite* (New York: The Free Press).

Smith, M. (1999). *The Core Executive in Britain* (London: MacMillan).

Sørenson, E. (2007). "Local Politicians and Administrators as Meta Governors" in M. Marcussen and J. Torfing (eds.), *Democratic Network Governance in Europe* (Cheltenham: Edward Elgar), pp. 89-108.

Sørensen, E. and J. Torfing (eds.) (2007). *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan).

Sørensen, E. and J. Torfing (2007a). "An Introduction", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan), pp. 1-21.

Sørensen, E. and J.Torfing (2009). "Making Governance Networks Effective and Democratic Through Metagovernance", *Public Administration* 87 (2): 234-258.

Sørenson, C. and K. Chalkidou (2012). "Reflections on the evolution of health technology assessment in Europe", *Health Economics, Policy and Law* 7 (1): 25-45.

Sørenson, C. (2009), The role of HTA in coverage and pricing decisions: A cross-country comparison, *Euro Observer* 11 (1): 1-4.

Sørenson, C. (2010). *Use of Comparative Effectiveness Research in Drug Coverage and Pricing Decisions: A Six-Country Comparison* (New York: The Commonwealth Fund).

Sørenson, C. and P. Kanavos (2011). "Medical technology procurement in Europe: A cross-country comparison of current practice and policy", *Health Policy*,100 (1): 43-50.

Sørenson, C., M. Drummond, and P. Kanavos (2008*). Ensuring Value for Money in Health Care: The Role of HTA in the European Union* (Copenhagen: European Observatory on Health Systems and Policies).

Sørenson, C., M. Drummond, P. Kanavos, and A. McGuire (2008). *National Institute for Health and Clinical Excellence (NICE): How Does It Work and What Are the Implications for the US?* (Reston, VA: National Pharmaceutical Council).

Sørenson, C., P. Kanavos, and M. Karamalis (2009). "HTA in central and eastern Europe: Current status, challenges and opportunities". *Journal of Medical Device Regulation* 6(1): 34-45.

Sørenson, C., R. Tarricone, M. Siebert, and M. Drummond (2011a). "Applying health economics for policy decision making: Do devices differ from drugs?", *Europace* 13(suppl 2): ii54-ii58.

Steffen, M. (ed.) (2005). *Health Governance in Europe: Issues challenges and theories* (London: Routledge).

Stevens, A. and R. Milne (2004). "Health technology assessment in England and Wales", *International Journal of Technology Assessment in Health Care* 20 (1): 11-24

Stevens, A., R. Milne, and A. Burls (2003). Health technology assessment: History and demand. *Journal of Public Health Medicine* 25(2): 98-101.

Stoker, G. (1994). *Local Governance in Britain* (Glasgow: University of Stratclyde).

Stoker, G. (2000). *The New Politics of British Local Governance* (London: MacMillan).

Sullivan, S., D. Watkins, B. Sweet, S. Ramsey (2009). "Health Technology Assessment in Health-Care Decisions in the United States", *Value in Health* 12 (Supplement 2): 39-44.

Tafuri, G, M. Pagnini, J. Moseley, M. Massari, F. Petavy,A. Behring, A. Catalan, E. Gajraj, N. Hedberg, M. Obach, L. Osipenko, P. Russo, M. Van De Casteele, E.M. Zebedin, G. Rasi, S. Vamvakas (2016). "How aligned are the perspectives of EU regulators and HTA bodies? A comparative analysis of regulatory-HTA parallel scientific advice", *British Journal of Clinical Pharmacology* 82 (4); 965-73

Tantchou Dipankui, M., M-P. Gagnon, M. Desmartis, F. Légaré, F. Piron, J. Gagnon, M. Rhiands and M. Coulombe (2015). « Evaluation of patient involvement in a Health Technology Assessment », *International Journal of Technology Assessment in Health Care*, 31 (3): 166–170.

Tapestry Networks (2012). Pilots of multi 6 JUNE 2012 -stakeholder consultations in drug development. European Healthcare Innovation Leadership Network. Final Report. Available at: https://www.tapestrynetworks.com/sites/default/files/publication_pdf/Pilots-of-multi-stakeholder-consultations-in-drug-development-6-June-2012.pdf. Last accessed: 30 August 2019.

Taylor, R.S. and C.P. Iglesias (2009). "Assessing the clinical and cost-effectiveness of medical devices and drugs: Are they that different?", *Value in Health* 12 (4): 404-406.

Tekleab, A. Quigley, N., & Tesluk, P. (2009). "A longitudinal study of team conflict, conflict management, cohesion, and team effectiveness", *Group & Organization Management*, 34 (2): 170–205.

Ten Have, A. Oortwijn, W., Broos, P. Nelissen, E. (2013). European Cooperation on Health Technology Assessment. Economic and governance analysis of the establishment of a permanent secretariat. Final report. Available at: https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/study_ecorys_european_cooperation_hta_en.pdf. Last accessed: 12 September 2017.

Thatcher, M. (2010). Report: Governance structures and health technology assessment agencies: a comparative approach. Department of Government London School of Economics and Political Science, London, UK. July 2010. Available at: http://eprints.lse.ac.uk/29471/. Last accessed: 29 July 2013.

Tholoniat, L. (2010). "The Career of the Open Method of Coordination: Lessons from a 'Soft' EU Instrument", *West European Politics* (33) (1): 93-117.

Thomas, H. (2001). "Towards a New Higher Education Law in Lithuania: Reflection on the Process of Policy Formulation", Higher Education Policy 14 (3): 213-23

Timmermans, A. (2001). 'Arenas as Institutional Sites for Policymaking: Patterns and Effects in Comparative Perspective', *Journal of Comparative Policy Analysis* 3: 311-37.

Torfing, J. and E. Sørensen (2014). "The European debate on governance networks: Towards a new and viable paradigm?", *Policy and Society* 33 (4): 329-44.

Triantafillou, P. (2007). "Governing the Formation and Mobilization of Governance Networks", in E. Sørensen and J. Torfing (eds.) *Theories of Democratic Network Governance* (Houndmills, Basingstoke: Palgrave Macmillan), pp. 183-98.

Trubek J. and D. Mosher (2003). "Alternative Approaches to Governance in the EU: EU Social Policy and the European Employment Strategy", *Journal of Common Market Studies* 41 (1): 63–88.

Trubek, D. and L. Trubek (2005). "Hard and Soft Law in the Construction of Social Europe: The Role of the Open Method of Co-ordination", *European Law Journal*, 11 (3): 343–64.

Tsebelis G. (1990). *Nested Games* (Berkeley, University of California Press).

US Congress (1972). The Technology Assessment Act of 1972 October 1972, Public Law 92-484 92d Congress, H.R. 10243 October 13, 1972. Available at https://www.princeton.edu/~ota/disk3/1972/9604/9604.PDF. Last accessed. 8 June 2016.

Van de Wetering, E., J. Van Exel and W. Brouwer (2017). "The Challenge of Conditional Reimbursement: Stopping Reimbursement Can Be More Difficult Than Not Starting in the First Place!", *Value in Health* 20 (1): 118-25.

Van der Wilt, GJ, A. Gerhardus and W. Oortwijn (2017). "Toward integration in the context of health technology assessment: The need for evaluative frameworks", *International Journal of Technology Assessment in Health Care* 33 (5): 586-590. doi: 10.1017/S0266462317004354

Van Kersbergen, K. and B. Verbeek (1994). "The Politics of Subsidiarity in the European Union", *Journal of Common Market Studies* 32 (2), pp. 215-36

Velluti, S. (2010). *New Governance and the European Employment Strategy* (London: Routledge).

Versluis, E., M. van Keulen et P. Stephenson (2011). *Analysing the European Union Policy Process* (London: Palgrave Macmillan).

Vollaard, H., H. van de Bovenkamp and D. Martinsen (2016). "The making of a European healthcare union: a federalist perspective", *Journal of European Public Policy* 23 (2): 157-176. doi: 10.1080/13501763.2015.1034160

Voss,J-P., R. Kemp and D. Baukencht (2006). 'Reflexive governance: A view on an emerging path' in J-P. Voss, D. Baukencht and R. Kemp (eds.) *Reflexive governance for sustainable development* (Cheltenham: Edward Elgar), pp. 419-437.

Wahlster P., L. Brereton, J. Burns, B. Hofmann, K. Mozygemba, W. Oortwijn, L. Pfadenhauer, S. Polus, E. Rehfuess, I. Schilling, G-J. van der Wilt and A. Gerhardus (2017). "An Integrated Perspective on the Assessment of Technologies: Integrate-HTA", *International journal of technology assessment in health care*, 33 (5): 544–51.

Wallace, H. (2010). "An institutional Anatomy and Five Policy Modes", in H. Wallace, M. Pollack and A. Young (Eds.) *Policy-Making in the European Union*, sixth edition (Oxford: Oxford University Press), pp. 69-104.

Wallace, H., M. Pollack and A. Young (Eds.) (2010). *Policy-Making in the European Union*, sixth edition. (Oxford: Oxford University Press).

Wang, T., N. McAuslane, L. Liberti, H. Leufkens, A. Hövels (2017). "Building Synergy between Regulatory and HTA Agencies beyond Processes and Procedures—Can We Effectively Align the Evidentiary Requirements? A Survey of Stakeholder Perceptions", *Value for Health* 20 (10): 707-14. doi: 10.1016/j.jval.2017.11.003.

Weatherly, H., M. Drummond, K. Claxton, R. Cookson, B. Ferguson, C. Godfrey, N. Rice, M. Sculpher, A. Sowden (2009). "Methods for assessing the cost-effectiveness of public health interventions: Key challenges and recommendations", *Health Policy* 93: 85–92.

Weible, C and P. Sabatier, H. Jenkins-Smith, D. Nohrstedt, A. Henry, P. de Leon (2011). "A Quarter Century of the Advocacy Coalition Framework: An Introduction to the Special Issue", *The Policy Studies Journal* 39 (3): 349-60.

Weill C., and D. Banta (2009). "Development of health technology assessment in France", *International Journal of Technology Assessment in Health Care* 25 (Suppl 1): 108-11.

Weiss, C.H. (1980). "Knowledge Creep and Decision Accretion", *Knowledge: Creation, Diffusion Utilization* 1 (3): 381-404.

Wild, C. (2006) "Health Technology Assessment", *Der Anaesthesist*, 55 (5): 568–77.

Wild, C. (2009). "Austria: History of health technology assessment during the past 20 years", *International Journal of Technology Assessment in Health Care*, 25 (Supplement 1): 74–81.

Wiliamson, O. (1985). *The economic institutions of capitalism* (New York: The Free Press).

Wismar, M., W. Palm, J. Figueras, K. Ernst and E. van Ginneken (eds.) (2011). *Cross-border health care in the European Union. Mapping and analysing practices and policies* (Copenhagen: WHO regional Office for Europe).

Wismar, M., C. Maier, I. Glinos, J. Bremmer, G. Dussault and J. Figueras (eds.) (2011), *Health Professional Mobility and Health Systems. Evidence from 17 European countries* (Copenhagen: WHO Regional Office for Europe).

Woodford G., M. Huic and C. Teljeur (2014). "EUnetHTA: Further Steps towards European cooperation on Health Technology Assessment", *International Journal of Technology Assessment in Health Care*, 30 (5): 475–77.

Woolf, S. H. and C. Henshall (2000). "Health technology assessment in the United Kingdom. *International Journal of Technology Assessment in Health Care*" 16 (2): 591-625.

World Health Organisation - WHO: http://www.who.int/healthsystems/topics/stewardship/en/, Last accessed: 23 October 2015.

Zafonte, M. and P. Sabatier (1998). "Shared Beliefs and Imposed Interdependencies as Determinants of Ally Networks in Overlapping Subsystems", Journal of Theoretical Politics 10 (4): 473–505.

Treaties

Treaty of Amsterdam. Treaty on the European Union (Consolidated version of 1997) and Treaty establishing the European Community (Consolidated version of 1997). Official Journal C340, 10 November 1997

Treaty of Maastricht. Treaty on the European Union. Official Journal C 191, 29 July 1992.

Official Journal of the European Communities/Union

OJEC - Official Journal of the European Communities (1965). Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. Official Journal of the European Communities L22,09.02.65: 369.

OJEC - Official Journal of the European Communities (1975). Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products. Official Journal of the European Communities L147, 09.06.75: 1.

OJEC - Official Journal of the European Communities (1975). Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products. Official Journal of the European Communities L147, 09.06.75: 13.

OJEC - Official Journal of the European Communities (1986). Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology. Official Journal of the European Communities L15, 17.01.87: 38.

OJEC - Official Journal of the European Communities (1988). Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems. Official Journal of the European Communities L40, 11.02.89: 8.

OJEC - Official Journal of the European Communities (1992). Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use. OJ L 113, 30.4.1992.

OJEC - Official Journal of the European Communities (1992a). Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use, OJ L 113, 30.4.1992.

OJEC - Official Journal of the European Communities (1992b). Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets OJ L 113, 30.4.1992.

OJEC - Official Journal of the European Communities (1992c). Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use. OJ L 113 / 13, 30.04.1992

OJEC - Official Journal of the European Communities (1992d). Council Regulation 1786/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182, 2.7.1992.

OJEC - Official Journal of the European Communities (1996). Resolution 96/C 136/04 of 23 April 1996, designed to implement the outlines of an industrial policy in the pharmaceutical sector in the European Union. Official Journal of the European Communities C136, 08.05.1996.

OJEC - Official Journal of the European Communities (1997). Council Regulation (EC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, self-employed persons and to members of their families moving within the Community. Consolidated version – OJ No L28 of 30.1.1997.

OJEC - Official Journal of the European Communities (2000). Charter of Fundamental Rights of the European Union (2000/C 364/01). Official Journal of the European Communities 18.12.2000.

OJEC (2004a). Treaty establishing a Constitution for Europe, 16 December 2004 (C series, No 310).

OJEC. - Official Journal of the European Communities (1983). Directive 83/570/EEC amending 65/65/EEC. Official Journal of the European Communities L332, 28.11.83: 1.

OJEU - Official Journal of the European Union (2002). Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), L 271, 9.10.2002.

OJEU - Official Journal of the European Union (2003). Community Action in the field of public health (2003 to 2008). Work Plan 2003. 2003/C 62/06. OJ. 15.03.2003.

OJEU - Official Journal of the European Union (2004). Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. L166. 30.04.2004.

OJEU - Official Journal of the European Union (2005). Commission Call for Proposals 2005. Programme of Community action in the field of public health (2003-2008) (2005/C 11/10). Official Journal of the European Union. 15.01.2005.

OJEU - Official Journal of the European Union (2008). Treaty of Lisbon. Treaty on the Functioning of the European Union (Consolidated version of 2008) and Treaty on European Union (Consolidated version 2008). Official Journal of the European Union C 115/47, 9 May 2008.

OJEU - Official Journal of the European Union (2011). Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border health care. 9 March 2011. L88/45, 4.4.2011.

OJEU - Official Journal of the European Union (2013). Commission Implementing decision of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment (2013/329/EU). 27.06.2013

OJEU - Official Journal of the European Union (2017a). Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance). L. 117, 5.5.2017.

OJEU - Official Journal of the European Union (2017b). Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance). L 117, 5.5.2017.

SUMMARY

Since its onset, Health Technology Assessment in Europe is characterised by the presence of multiple HTA bodies operating in different domestic health policy-systems based on divergent underlying values and decision-making processes. To address these diversities, promote efficiency and enhance input of HTA in national regulatory processes, HTA bodies have sought to cooperate and reach some form of convergence of assessment practices. The start of these cooperation initiatives would coincide with the launch of an EU public health policy. Gradually both processes would come together and mutually reinforce each other. Since 1994, several European HTA networks have been created seeking to establish a sustainable framework for HTA cooperation in Europe. In 2018, the European Commission has proposed a Regulation on HTA cooperation which adoption process is, to date, ongoing.

In this thesis HTA cooperation has been examined in relation to EU governance. EU competences in the field of HTA are restricted to support-lending and coordination policies. The research project has therefore examined the role of *soft governance* in structuring HTA cooperation within the framework of the European Union. Yet, as HTA aims to give input in domestic regulatory processes, it needs to respond to (hard) regulatory policy requirements. The question thus arises to what extent cooperation and convergence of practices on a European level can be structured through soft governance. This question is the overarching research question of the thesis. Various national HTA regulations may indeed hinder the establishment and implementation of new common European HTA agreements. To delimit the scope of this research question, three sub-research questions have been formulated, focussing each on the role of soft governance in a specific area of HTA cooperation: 1) convergence and harmonisation of HTA tools, methodologies and practices; 2) uptake of joint work; and 3) synergies between the HTA arena and the EU regulatory processes of pharmaceuticals.

The conjunction between EU health policy and HTA cooperation is situated in networks. European HTA cooperation has mainly taken place through networking. Networks, by their intrinsic characteristics, offer favourable conditions for the implementation of soft governance modes and instruments. Moreover, networking responds to the new governance approach of the EU adopted at the turn of the millennium. The role of soft governance in European HTA cooperation has therefore been examined through the prism of network analysis. The research has been structured according to qualitative research methods (e.g. semi-structured personal interviews with key-actors in the field, academic and grey literature, personal observations in international conferences) and based on a research framework constructed according to the concepts of governance networks, network governance, and metagovernance.

The thesis is composed of three parts. Part A establishes the theoretical and research framework. Finding itself at the intersection of two different academic fields – EU governance and health policy – the research topic first needs to be contextualised. Therefore, the thesis first addresses how HTA originated and how HTA cooperation relates to national and European regulatory processes (e.g. market authorisation and pricing and reimbursement decisions) and places it within the wider EU health policy and governance architecture. Attention is given here to the allocation of competencies, the subsidiarity principle and the implementation of soft governance through the so-called New Modes of Governance (NMG) developed since 2001 in the EU governance architecture. As networking is one of the approaches used by the EU to implement NMG, this part further develops how networks relate to national and European governance and policy-making approaches and can be considered as an adequate forum to implement soft governance. This part concludes with the setup of a research framework established by using input from different academic schools (e.g. political science, policy analysis, and organisational studies) and intended to examine the role of soft governance in European HTA cooperation by means of network analysis.

Part B outlines the findings of the empirical research on European HTA cooperation. It is structured according to three distinct development stages of HTA cooperation in Europe. The first period is situated from 1992 to 2001 and relates to establishment of the initial cooperation networks such as EUR-ASSESS, HTA-Europe and ECHTA/ECHAI. The data underscores how the onset of European HTA cooperation corresponded to the launch of an EU public health policy and how both processes became interconnected. Moreover, the role of policy entrepreneurs from the two arenas has been of prime importance for the further development of the cooperation initiatives. The second stage of HTA cooperation runs from 2001 to 2006 and highlights how three different EU policy streams have affected HTA cooperation: the EU health policy stream providing the institutional framework of HTA cooperation; the EU social policy stream, providing soft governance instruments in HTA cooperation; and the EU pharmaceutical policy stream, providing key content to HTA cooperation. The third development stage covers the period since 2006 and outlines how several networks have sought to setup a sustainable structure for HTA cooperation in Europe. Although concrete outputs have been produced supporting cooperation initiatives, the main objective pursued by the networks has, to date, not been reached. The European Commission has proposed a Regulation on HTA Cooperation to this end. Other initiatives have furthermore been developed to address this challenge by establishing regional (intergovernmental) cooperation frameworks.

Part C examines the empirical findings by applying network analysis based on the research framework developed in Part A. It highlights how the various cooperation networks can be considered as governance networks, responding however to different governance modes and network characteristics. Moreover, it examines effectiveness of network governance in

establishing a sustainable framework for HTA cooperation in Europe and highlights domains in which soft governance has had a positive impact on cooperation objectives as well as explanatory factors hereof. Finally, it underscores how the European Commission can be considered as metagovernor in European HTA cooperation networks. The final chapter addresses the research questions and presents the overall research conclusions.

The research has brought to the fore that HTA cooperation has been co-constructed by the HTA arena and the European Commission mainly through soft governance means. Domains in which a positive impact of soft governance on the cooperation processes have been found were related to the goal setting process of European HTA networks; the development of HTA cooperation tools, methodologies, and joint assessments. In some countries, uptake of common HTA tools and methodologies has been observed. Use of network outputs has also been identified in regional (intergovernmental) cooperation networks. Finally, soft governance has had a positive impact on the establishment of synergies between EUnetHTA and the EMA.

Factors favouring convergence were related to network structure (homogeneity and closeness) as well as governance modes (the more centralised, the more convergence). Social interaction would support learning-processes, shared values and understanding, trust and goal consensus, essential in the development of joint work. The role of policy entrepreneurs from both the HTA and the EU arena in steering the cooperation initiatives also has had a positive impact on convergence. Finally, the presence of a shadow of hierarchy as well as the active support of the European Commission as metagovernor, further supported convergence of practices, using soft governance also as a mean to prepare the ground for hard regulation.

Absence of positive impact of soft governance has been found in the lack of establishment of a sustainable European framework for HTA cooperation as well as the absence of *systematic* uptake of joint work in the EU Member States. Explanatory factors hereof were related to the network composition (e.g. under representation of policymakers), stakeholder policy (informative rather than collaborative involvement, underrepresentation of stakeholders, stakeholder coordination policies), low social interaction between some actors (e.g. network – ministries, network-network), and mixed management approaches (e.g. project vs process management). These factors complement elements identified in previous studies related to uptake and (in)effectiveness of establishing a sustainable network mechanism.

The conclusions of this thesis bring to the fore that soft governance by offering flexibility and gradualism can be a powerful instrument to instil convergence in policy areas of limited EU competences. Lack of effectiveness of soft governance has been attributed in this research to the manner in which soft governance instruments have been implemented rather than inherent weaknesses of soft governance itself. The findings of this thesis may be relevant

for cooperation initiatives in other health policy fields (e.g. additional evidence generation, rare diseases, personalised medicines or the use of artificial intelligence in health care). Policy recommendations point to the importance of active participation of (hard) policy-makers when seeking convergence in areas referring to exclusive competences of EU Member States. Moreover, a clear transparent stakeholder policy should be defined early and be based on an inclusive participatory stakeholder approach. Finally, European legislative frameworks should allow the development of flexible cooperation structures.

This thesis invites to reconsider the role of soft governance in EU integration policies. Instead of being essentially utilised as a means to pave the way for hard legislation, it could be granted a different status and functionality within the EU governance modes and conceived as a real alternative to classic modes of integration rather than 'sub-ordinated' to them.

SAMENVATTING

Sinds het begin wordt Health Technology Assessment in Europa gekenmerkt door de aanwezigheid van vele HTA-instanties in verschillende nationale gezondheidssystemen gebaseerd op uiteenlopende onderliggende waarden en besluitvormingsprocessen. Om deze diversiteit aan te pakken, de efficiëntie te bevorderen en de inbreng van HTA in nationale regelgevingsprocessen te vergroten, hebben HTA-instanties getracht samen te werken en een vorm van convergentie van assessmentpraktijken te bereiken. De start van deze samenwerkingsinitiatieven viel samen met de lancering van een EU-volksgezondheidsbeleid. Geleidelijk komen beide processen samen en gaan elkaar versterken. Sinds het begin van de samenwerkingsinitiatieven zijn er verschillende Europese HTA-netwerken opgericht met het doel een duurzaam kader voor HTA-samenwerking in Europa tot stand te brengen. In 2018 heeft de Europese Commissie een verordening over samenwerking op het gebied van HTA voorgesteld, het proces is tot op heden nog in gang.

Dit onderzoek heeft HTA-samenwerking bestudeerd in relatie tot EU-governance. De bevoegdheden van de EU op het gebied van HTA zijn beperkt tot ondersteunings- en coördinatiebeleid. In dit onderzoek is daarom gekeken naar de rol van *soft governance*[207] bij het structureren van HTA-samenwerking binnen het kader van de Europese Unie. Aangezien HTA ernaar streeft input te leveren in binnenlandse regelgevingsprocessen, moet het echter voldoen aan eisen die harde besluitvormingen met zich mee brengen. De vraag rijst dus in hoeverre samenwerking en convergentie van praktijken op Europees niveau kan worden gestructureerd door middel van soft governance. Deze vraag fungeert als overkoepelende onderzoeksvraag. Onderlinge verschillen in nationale HTA-regelgevingen kunnen namelijk de totstandkoming en uitvoering van nieuwe gemeenschappelijke Europese HTA-overeenkomsten belemmeren. Om het bereik van deze onderzoeksvraag af te bakenen, zijn er drie deelonderzoeksvragen geformuleerd, die elk gericht zijn op de rol van soft governance in een specifiek gebied van HTA-samenwerking: 1) convergentie en harmonisatie van HTA-instrumenten, methodologieën en praktijken; 2) 'uptake' van gezamenlijk werk; en 3) synergieën tussen de HTA-arena en de EU-regelgevingsprocessen voor farmaceutische producten.

De samenhang tussen het EU-gezondheidsbeleid en de HTA-samenwerking bevindt zich in netwerken. Europese HTA-samenwerking heeft voornamelijk plaatsgevonden via netwerken. Netwerken bieden door hun intrinsieke kenmerken een gunstig kader voor de implementatie

---

207 In deze Nederlandse vertaling van de samenvatting gebruiken we het Engelstalig begrip 'soft governance' (letterlijk vertaald een 'zachte wijze van besturen') aangezien de Nederlandse vertaling van governance ('besturen') de betekenis niet geheel dekt en soft governance als zodanig in het Nederlands een gangbaar begrip is.

van 'soft governance' modaliteiten en instrumenten. Netwerken maakt ook deel uit van de nieuwe Europese bestuursaanpak die rond de millenniumwisseling is aangenomen. De rol van soft governance in de Europese HTA-samenwerking is daarom onderzocht via het prisma van netwerkanalyse. Het onderzoek is gestructureerd volgens kwalitatieve onderzoeksmethoden (bv. semigestructureerde persoonlijke interviews met sleutelfiguren uit het veld, academische en grijze literatuur, persoonlijke observaties tijdens internationale conferenties) en gebaseerd op een onderzoekskader dat is opgesteld volgens drie hoofdconcepten: bestuursnetwerken (governance networks), netwerk governance en metagovernance.

Het proefschrift bestaat uit drie delen. Deel A legt het theoretische en onderzoekskader vast. Aangezien het onderzoek zich op het snijvlak van twee verschillende wetenschapsgebieden bevindt - gezondheidsbeleid en EU governance – is het nodig om het onderzoeksonderwerp in de context te plaatsen. Het proefschrift gaat daarom eerst in op hoe HTA-samenwerking tot stand is gekomen en hoe het zich verhoudt tot nationale en Europese regelgevingsprocessen (bijv. marktautorisatie en prijs- en vergoedingsbesluiten) en plaatst deze binnen de bredere EU-architectuur voor gezondheidsbeleid en governance. Hierbij wordt aandacht besteed aan de competentieverdeling tussen de EU en de lidstaten, het subsidiariteitsbeginsel en de implementatie van soft governance via de zogenaamde New Modes of Governance (NMG), ontwikkeld sinds 2001 in de EU governance architectuur. Aangezien netwerken een van de benaderingen is die de EU gebruikt om NMG te implementeren, wordt in dit deel ook ingegaan op de manier waarop netwerken zich verhouden tot nationale en Europese vormen van beleid en hoe netwerken kunnen worden beschouwd als geschikt forum om soft governance te implementeren. Dit deel wordt afgesloten met de opzet van een onderzoekskader ontwikkeld met behulp van input uit verschillende academische scholen (bijv. politicologie, beleidsanalyse en organisatiestudies). Dit framework zal worden gebruikt om de rol van soft governance in de Europese HTA-samenwerking door middel van netwerkanalyse te onderzoeken.

Deel B schetst de bevindingen van het empirisch onderzoek naar Europese HTA-samenwerking. Het is gestructureerd volgens drie verschillende ontwikkelingsfasen van HTA-samenwerking in Europa. De eerste periode ligt tussen 1992 en 2001 en heeft betrekking op de oprichting van de eerste samenwerkingsnetwerken zoals EUR-ASSESS, HTA-Europe en ECHTA/ECHAI. De bevindingen benadrukken hoe het begin van de Europese HTA-samenwerking overeenkwam met de lancering van een EU-volksgezondheidsbeleid en hoe beide processen met elkaar verweven raken. Het belang van 'policy entrepreneurs' uit de twee arena's voor de verdere ontwikkeling van de samenwerkingsinitiatieven wordt hier ook zichtbaar. De tweede fase van HTA-samenwerking loopt van 2001 tot 2006 en laat zien hoe drie verschillende Europese beleidsstromen de HTA-samenwerking hebben beïnvloed: de EU-beleidsstroom op gezondheidsgebied die het institutionele kader voor HTA-samenwerking plaatst; de EU

sociale beleidsstroom, die soft governance-instrumenten introduceert in HTA-samenwerking; en de EU farmaceutische beleidsstroom, die essentiële inhoud biedt voor HTA-samenwerking. De derde ontwikkelingsfase beslaat de periode sinds 2006 en schetst hoe verschillende netwerken hebben getracht een duurzame structuur voor HTA-samenwerking in Europa op te zetten. Alhoewel er concrete resultaten zijn geboekt ter ondersteuning van samenwerkingsinitiatieven, is de belangrijkste doelstelling van de netwerken tot dusver niet bereikt. De Europese Commissie heeft daartoe een verordening inzake HTA-samenwerking voorgesteld. Daarnaast zijn er ook andere initiatieven ontwikkeld om deze uitdaging aan te gaan zoals bijvoorbeeld regionale (intergouvernementele) samenwerkingskaders.

Deel C onderzoekt de empirische bevindingen door netwerkanalyse toe te passen op basis van het onderzoekskader dat is ontwikkeld in deel A. In dit deel wordt benadrukt hoe de verschillende samenwerkingsnetwerken kunnen worden beschouwd als bestuursnetwerken (governance networks) en hoe ze zich van elkaar onderscheiden in netwerkkenmerken en bestuursmodaliteiten. Verder wordt ook de doeltreffendheid van netwerkgovernance onderzocht ten aanzien van het tot stand brengen van een duurzaam kader voor HTA-samenwerking in Europa en worden domeinen belicht waarop soft governance een positieve invloed heeft gehad op de samenwerkingsdoelstellingen en de verklarende factoren hiervan. Ten slotte wordt in dit deel ook onderstreept hoe de Europese Commissie kan worden beschouwd als 'metagovernor'[208] in Europese HTA-samenwerkingsnetwerken. Het laatste hoofdstuk beantwoordt de onderzoeksvragen en presenteert de algemene conclusies van het onderzoek.

Het onderzoek heeft uitgewezen dat de HTA-arena en de Europese Commissie gezamenlijk de HTA-samenwerking tot stand hebben gebracht, voornamelijk door middel van soft governance. Domeinen waarin een positieve impact van soft governance op de samenwerkingsprocessen is gevonden, houden verband met het doelbepalingsproces van Europese HTA-netwerken; de ontwikkeling van HTA-samenwerkingsinstrumenten, methodologieën en gezamenlijke assessments. In sommige landen zijn gemeenschappelijke HTA-instrumenten en HTA-methodologieën in nationale praktijken opgenomen. Het gebruik van netwerkoutputs is ook vastgesteld in regionale (intergouvernementele) samenwerkingsnetwerken. Ten slotte heeft soft governance een positieve invloed gehad op de totstandbrenging van synergieën tussen EUnetHTA en de EMA.

Factoren die convergentie bevorderen, hebben betrekking op de netwerkstructuur (homogeniteit en nabijheid) en de bestuursmodaliteiten (hoe meer gecentraliseerd, hoe meer convergentie). Sociale interactie heeft invloed gehad op leerprocessen, het tot stand brengen

---

208   Letterlijke vertaling: 'metabestuurder'

van gezamenlijke normen en waarden, vertrouwen en consensus op het te bereiken doel, essentieel bij de ontwikkeling van gezamenlijk werk. De rol van beleidsondernemers ('policy entrepreneurs') uit zowel de HTA als de EU-arena bij het aansturen van de samenwerkingsinitiatieven heeft ook een positieve invloed gehad op de convergentie. Ten slotte heeft de aanwezigheid van een 'shadow of hierarchy' en de actieve steun van de Europese Commissie als 'metagovernor', de convergentie van praktijken verder ondersteund, waarbij soft governance ook als middel werd gebruikt om de basis te leggen voor harde regelgeving.

Er is geen positief effect van soft governance vastgesteld in het opzetten van een duurzaam Europees kader voor HTA-samenwerking, noch in een systematische 'uptake' van netwerkproducten in de EU-lidstaten. Verklarende factoren hiervan zijn gerelateerd aan de netwerksamenstelling (bijv. onder vertegenwoordiging van nationale beleidsmakers), stakeholderbeleid (informatieve in plaats van collaboratieve betrokkenheid, ondervertegenwoordiging van stakeholders, stakeholdercoördinatiebeleid), gebrek aan sociale interactie tussen bepaalde actoren (bv. netwerk - ministeries, netwerk-netwerk) en management benaderingen (bijv. project- versus procesmanagement). Deze factoren vullen elementen aan die in eerdere studies zijn geïdentificeerd met betrekking tot uptake en (on) effectiviteit van het opzetten van een duurzaam Europees HTA samenwerkingskader.

Uit het onderzoek komt naar voren dat soft governance, door flexibiliteit en geleidelijkheid te bieden, een effectief middel kan zijn om convergentie te bewerkstelligen op beleidsterreinen waar de EU beperkte bevoegdheden heeft. Gebrek aan effectiviteit van soft governance wordt in het kader van dit proefschrift toegeschreven aan de manier waarop soft governance-instrumenten zijn geïmplementeerd en niet aan inherente zwakheden van soft governance zelf. De bevindingen van dit proefschrift kunnen relevant zijn voor samenwerkingsinitiatieven op andere gebieden van het gezondheidsbeleid (bijv. 'additional evidence generation', zeldzame ziekten, 'personalised medicines' of het gebruik van kunstmatige intelligentie in de gezondheidszorg). Beleidsaanbevelingen wijzen op het belang van actieve deelname van (harde) beleidsmakers bij het zoeken naar convergentie op gebieden die verwijzen naar exclusieve bevoegdheden van EU-lidstaten. Bovendien moet een duidelijk transparant stakeholderbeleid vroegtijdig worden gedefinieerd en gebaseerd zijn op een inclusieve participatieve benadering van stakeholders. Ten slotte moeten Europese wetgevingskaders de ontwikkeling van flexibele samenwerkingsstructuren mogelijk maken.

In de conclusie van dit proefschrift wordt voorgesteld de rol van soft governance in het EU-integratiebeleid te heroverwegen. In plaats van in wezen te worden gebruikt als middel om de weg vrij te maken voor harde wetgeving, zou het een andere status en functionaliteit kunnen krijgen binnen de EU governance modaliteiten en zou het kunnen worden beschouwd als een goed alternatief voor klassieke integratiemethoden.

ACKNOWLEDGEMENTS

When I first addressed myself to Roland Bal, the head of the health care governance department of the Erasmus School of Health Policy & Management, and proposed the topic of the present PhD research, he suggested Bert Boer to act as my supervisor. This could not have been a better choice as Bert has completely transcended my expectations in accompanying me through all research stages and associated mindsets one encounters on a PhD journey. His clear guidance, sense for pragmatism and refined scholarly advice based on sound academic judgement, professional experience and personal values have been paramount in helping me to accomplish this endeavour. Thank you so much, Bert, for your presence, your precious advice and your encouragements, especially when, due to some difficult family circumstances, I had to put this research on a hold. If it would not have been for you, I would probably not have found the mental strength to pick up the work again and bring it to its final stage. Thank you, Roland, for having proposed this perfect match and for your understanding of the extra time I needed to finish the project.

My deep gratitude goes to my second supervisor Robert Harmsen for whom I already developed a great respect during my Masters' programme in European Governance at the University of Luxembourg. Without Robert's suggestion and encouragements to pursue my Masters' thesis findings into a doctoral research, I would not have started this journey. Robert, as always, your remarks were spot on. Your thorough mastery of European governance made your analyses and advice extremely precious and allowed me to fine-tune the research findings and finalise the work. I keep a very good memory of our meetings in the premises of the university where it all started.

Special thanks go to the many persons who have helped me understanding the developments in the field of European HTA cooperation. Unfortunately, I will not be able to mention all those who assisted me in this research project, but I do want to express my profound gratitude to a few of them who have played a particular role herein.

Thank you, David Banta, for the time you have given me on several occasions to share what became your life experience and help me to better understand the origins as well as the ins and outs of the whole cooperation initiatives. I will never forget our extremely interesting conversations which were not restricted to the topic of HTA. I believe, one should never disregard the knowledge and wisdom acquired by those that preceded us in anything we undertake, and you are the perfect example hereof. Thank you for your wise words and analyses. I hope people will never forget the courage and energy it took to have initiated HTA years ago! Europe owes you a great deal!

At this occasion I also would like to warmly thank all the representatives of the European Commission. Special thanks to Bernie Merkel who has been willing to share so many important insights about HTA cooperation and EU health policy in general, precious information that could not have been accessed, as such, elsewhere. Thank you Andrzej Rys, Flora Giorgio, Jérôme Boehm and all the members of the HTA team of the European Commission for the time you have given me to explain and outline important aspects of HTA cooperation in Europe and the role of the Commission herein.

I also want to express my gratitude to EUnetHTA representatives have shared their experiences with me and without whom this whole doctoral research project could not have taken place. Special thanks in this regard go to Finn Kristensen, whose personal investment has been crucial for the whole EUnetHTA undertaking. Thank you, Finn, for the time you have given me and the information you have shared permitting me to better grasp the various technical, political and policy aspects of the cooperation initiatives. Your input has been highly valuable in this thesis. Thank you also, Julia Chamova, for your remarks and insights regarding not only EUnetHTA but also the stages that preceded it and in which you played an important role. Thank you, Wim Goettsch, for your insights and guidance to define the initial direction of the field work and for letting me attend some conferences of EUnetHTA which has helped me a lot to better understand the various positions of stakeholders and key actors in HTA cooperation. This gratitude also extends to Marcus Guardian. Thank you for having taken the time to clarify important aspects of the work of EUnetHTA and the latest developments regarding the HTA Regulation proposal. Last but not least, I wish to thank all EUnetHTA members and stakeholders who have accepted to take part in the interviews. Your input has been incommensurable as it represents the core of the fieldwork of this thesis.

Having carried out this research for an important part in Luxembourg, I wish to thank all those who have hosted me during my numerous trips to Rotterdam. I will not be able to list all of my friends who have opened their doors to me but I do want to express a special word of gratitude to Rob and Astrid, Wendy and Marian who were always ready to host me even when I arrived late at night and on a short notice! Thank you for your incredible hospitality that has deepened a long-lasting friendship and has allowed me to reconnect with my homeland, left so many years ago.

A profound feeling of gratefulness goes to my parents who have been an incredible support at some crucial moments in my life and have allowed me to bounce back when facing moments of hardship. Their example of staying focused on the essence of life and the desire to push the boundaries of our own knowledge and capabilities remains an enormous source of inspiration. My mom always worried about the impact her disease had on my work, but the

wisdom she emanated during her last journey was a life lesson I would never have wanted to miss.

Thank you, Emmanuelle, for having been there exactly on the right time, remote but then so close as only a sister can be. I wish we did not live miles apart…

Finally, I owe my greatest debt of gratitude to Carlo, my husband, and Sarah, Lara and Noémie, my daughters, for their endless support and patience when my time and attention had to be shared with this work as well as with many other persons that requested my assistance during these few years. You are the centre of my life and this thesis is dedicated to you.

CURRICULUM VITAE

Magali Aurélie Nanda Elisabeth BOERS

Personal information

Born: August 25th, 1971 in Tilburg, The Netherlands
Nationalities: French, Luxembourgish, Croatian
Languages: French (mother tongue), Dutch (mother tongue), English, German, Luxembourgish, Croatian

Education

2015 – present   **Doctoral researcher**
                      Erasmus University Rotterdam, Erasmus School of Health Policy and Management (NL)
2011 – 2014   **Master in European Governance**
                      University of Luxembourg (L)
2004 – 2005   **Diploma Sales Management & Marketing**
                      Cambridge International College (UK)
1992 – 1996   **Master in International Relations & French Language and Literature**
                      University of Utrecht (NL)
1994 – 1995   **Certificate in Political Science**
                      Institut d'Etudes Politiques, Strasbourg (F)
1990 – 1991   **Propadeuse Diploma French Language and Literature**
                      University of Leiden (NL)

Work Experience

09/2009 – 09/2011 **Senior project manager,** *Quest Market Research*, Luxembourg
02/2009 – 08/2009 **Medical sales representative,** *Hospilux*, Luxembourg
02/2007 – 01/2009 **Product manager**, *Laboratoires Boehringer Ingelheim*, France
02/2005 – 01/2007 **Business analyst**, *Laboratoires Boehringer Ingelheim*, France
09/2001 – 05/2003 **Programme director**, *Europe House Zagreb*, Croatia
01/2001 – 08/2001 **Diplomatic mission**, *Croatian Embassy*, Belgium
10/1998 – 06/2000 **Project manager & Fundraising officer**, *Europe House Zagreb*, Croatia
01/1996 – 08/1997 **Coordinator of the Centre Européen d'Aide à la Vie Associative**, *Académie Européenne du Nord de l'Europe*, France