

11. Regulation of autonomous robots in health care

Klaus Heine, Professor of Law and Economics and European Policy

Evert Stamhuis, Professor of Law and Innovation

Introduction

This project combines a number of regulation issues regarding disruptive technology induced changes in a concrete societal sector. Health care is a sector where public interests are in the hands of public, private or hybrid actors, such as hospitals, doctors, health tech industry, health insurance and various state supervisory bodies. One immediate regulation issue comes to the forefront: Which jurisdictional level is best suited to regulate a health related activity? At the moment there is EU regulation (a.o. re medical devices), member state legislation (a.o. re market supervision), medical self-regulation and contract law (including liability law). Another obvious regulation issue is the plurality of interests of the various stakeholders, whereas the regulations aim to combine norms. There is the interest of the patient, the interest of the doctor, the interest of the hospital and the public policy interests, but also the interest of the insurance sector and of the health tech industry.

PhD project

The use of robots in health care for supporting nursing and medical treatment (such as surgery) is going on for a while and becomes incrementally embedded in the current regulation of routines and practices in hospitals as well as nursing homes. As a consequence of advancing technology robots develop into autonomous actors and create new legal challenges. The extra utility of the autonomous machine action might collide with the appreciations of patients and doctors and the incumbent framework of legal and ethical rules and principles. To meet those challenges may require far-reaching innovation of the law.

The overarching theme of the research is the analysis of regulation of disruptive innovation in a specific sector that comprises various levels of regulation and a plurality of actors: patients, doctors, hospitals, producers, insurers. The focus of the PhD is the deep analysis of current and future regulation of autonomous robots for treatment and nursing in health care.

Empirical research

The empirical component in this project is modest but no less important. In order to be able to answer the questions of regulation the research has to comprise a reliable inventory of the current medical practices with robotics in one specific subsector, yet to be chosen. How health care professionals perceive the human-machine interaction and what regulatory framework they would expect to assist them in balancing all the relevant interests might be included in a qualitative field study as a subproject.