Title

**Continuous innovation in the drug life cycle**

PhD

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**Start of research** 2011  
**Status** Doctorate 2016

Background

Innovation may continue upon the approval of a new drug, for example through the licensing of new therapeutic indications or dosage forms, which is also known as post-innovation innovation. The development of new therapeutic indications for existing drugs, could allow for a quicker and cheaper drug development by the utilisation of existing knowledge. In the present project, special interest has been paid to the performance of the drug regulatory system and innovation in the period after the approval of the first generic product version of a drug: the post-generic phase. That occasion may significantly affect the intellectual property prospects of a drug and may limit the opportunities to make a return on investments for further innovations.

Objective

To provide insight in the performance of the drug regulatory system for medicines in the post-innovation phase, including the post-generic phase, of their life cycle from both a regulatory and a legal perspective.

Regulatory impact

The research project showed that in the European Union’s Decentralised Procedure and the Mutual Recognition procedure licensing failure occurred in about 1 out of 10 licensing procedures and due to a wide variety of both a drug quality and clinical nature related reasons. Increased knowledge of companies and regulators has reduced the frequency of late-stage failure of marketing applications via both procedures. Subsequently, it was found that extensions of the indication of already licensed medicinal products were mainly authorised a few years before approval of the first generic product version and ceased thereafter. On the contrary old drugs were still licensed as new medicinal products approved for new therapeutic indications or other innovations. The presence of window of opportunity seems to be of great importance for the viability of the business case for such drug development. A legal-analysis reflected on the need for prior market approval as a general rule of the EU legislation on medicinal products. The overall knowledge gained through the individual studies suggests that the drug regulatory system is under pressure. Regulatory reform is needed to enhance post-innovation innovation and use every drug to its full potential.
Academic collaboration
Utrecht Institute of Pharmaceutical Sciences
Utrecht University

Research track
Development & innovation

Research group
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Keywords
drug repositioning, drug rediscovery, marketing authorisation, drug development, off-label use, pharmacy preparations

Achievements


