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Master's Thesis

"Assessing the regulatory strategy of a novel biodegradable stent"

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Summary

The aim of this thesis is to provide a regulatory approval strategy with the particular focus on the regulatory issues, which include the adoption and implementation of the European Union recommendation for a definition of “nanomaterial” and assessing the safety and efficacy of a novel biodegradable stent, the BIOMAGSCAR (Biodegradable Magnetic Stent for Coronary Artery Luminal Regeneration) stent. The strategy can further be used for products with similar characteristics that are or will be in the pipeline for future development.

While reviewing the available literature on the stent platform, written in the viewpoint of the legal experts, the ethical experts and the medical experts, the different perspectives were unified. Risk assessment and risk management are not specifically tailored to evaluate the questions based on “nanoparticles”. The knowledge gap between the potential benefits and risks paves the way for more toxicological studies in order to understand the novel characteristics of “nanomaterials”.

A comprehensive overview of the European Union’s regulatory process, regarding the development of the regulatory structure on the approval of “nanomedicine” and the role played by the various organizations and bodies in the regulatory process, is offered. Regulatory problems, such as the lack of a universal definition of “nanomedicine”, unnecessary regulatory hype, as well as the inappropriateness of safety, quality and efficacy standards and methods to analyse the potential impact on environment and health, are identified. The uncertainties related to the definition and behaviour of “nanomaterials” and “nanotechnologies”, their multi-sectorial character, the lack of appropriate standards and testing procedures makes the regulation of “nanotechnology” products a challenging affair. Most of the attention is currently focused on regulatory causes and classification issues, thus on the ability to regulate and control the introduction and use of “nanomaterials” and nano-related products into the market.

Thereafter, it turns to the results and the practical impact of the definition and the regulatory requirements. After summarizing the current technical limitations, none of the currently available methods can determine for all kinds of potential “nanomaterials”, whether they fulfil the definition or not. The results are incorporated for developing the strategy for the novel stent, which concludes with closing considerations.

Through this, the problem of the information gap becomes less substantial and it forms the basis for the regulatory approval strategy and the objective for creating a consultation dossier and a preclinical dossier for the biodegradable magnetic stent under development.

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