Fachbereich
Angewandte Naturwissenschaften
Studiengang: Regulatory Affairs M.Sc.

TECHNISCHE HOCHSCHULE LÜBECK

Master-Abschlussarbeit

Thema: Regulatory Strategies for launching a Dual-Use Product under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2012/528 (BPR)

Zusammenfassung:

In the European Union chemical disinfectants which can be used on medical devices as well as other surfaces can be marketed as so-called Dual-Use products, if certain requirements are met. Since depending on the area of application and the respective intended purpose of a product, a chemical disinfectant can fall under the scope of the Medical Device Regulation (MDR) or the Biocidal Product Regulation (BPR), a Dual-Use Product has to adhere to both regulations simultaneously.

A regulatory strategy has to be formed early on in the developing stages of a Dual-Use Product to ensure regulatory compliance as well as economic feasibility. Throughout the course of the product's lifecycle the regulatory strategy has to be adapted several times. A regulatory strategy has to be considered an iterative process. The aim of this thesis is to illustrate which aspects of the regulatory strategy have to be considered to create maximum synergies between the provisions posed by the MDR and BPR.

As the BPR allows for different pathways to gain marketability for a biocidal product, the choice of an authorisation type is a crucial part of the regulatory strategy. The medical device component of the Dual-Use Product gains unionwide marketability at the end of the conformity assessment procedure. Therefore, the biocidal product should be authorised by means of a unionwide authorisation or a simplified authorisation, if the formulation of the chemical disinfectant is eligible for the latter. Due to the different setups of the MDR and BPR the manufacturer of a Dual-Use Product can create synergies by identifying content overlaps in the requirements in the medical device's technical documentation and the biocidal product dossier. Additionally, the execution of the medical device's conformity assessment procedure should be timed with regard to the processing times of the BPR authorisations to achieve marketability at the same point in time. The microbiological testing according to European standards is a significant aspect in the regulatory strategy as on the one hand there are different standards for efficacy claims in the medical and non-medical area of application, while on the other hand testing according to

standards can be used as a basis for the clinical evaluation of the medical device side of the Dual-Use Product.

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