



Fraunhofer Center for
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ENVIRONMENTAL RISK ASSESSMENT OF VETERINARY MEDICINAL PRODUCTS: A FEASIBILITY STUDY FOR AN ACTIVE SUBSTANCE-BASED SYSTEM IN THE EU

Background

Residues of veterinary medicines often enter the environment without being filtered in agriculture and private animal husbandry. Contaminated waters and soils can harm humans, animals and plants.

However, the current environmental risk assessment for marketing authorization of veterinary medicinal products is product-based, which is associated with data gaps on environmental safety and disadvantages, e.g. multiple assessments of the same active ingredient.

Project description

The project will include the feasibility study required by Regulation 2019/6 of the European Union (EU) on behalf of the European Commission.

The organizational, legal and financial aspects of an active substance-based system will be analyzed in comparison with the product-based system. The overall aim is to develop a proposal for an active substance-based system.

Methodical implementation

Guided by literature, the legal, organizational and financial aspects of different review systems are analyzed. Exploratory interviews are used to gather the perspectives of different stakeholders within the EU. Data gaps identified from the literature are filled through a quantitative survey.

The collected information will then be synthesized and processed and submitted to the European Commission.

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Project tasks

The health economics team of Fraunhofer Center for International Management and Knowledge Economy IMW is responsible for the analysis of the financial aspects in this project. Costs and benefits for various stakeholders are examined in comparison to the existing system. Information is generated by Fraunhofer IMW by means of a systematic literature research, an online questionnaire as well as interviews which are subsequently analyzed and processed. With the results of this analysis, Fraunhofer IMW contributes to political decision support on a European level.

Project partners



Client:



European Commission,
Directorate-General Health
and Food Safety (SANTE)

Project duration:

9/21/20–9/20/21

