Save the Date: Workshop

An effective tool to strengthen the environmental safety of VMPs: Monograph system for active pharmaceutical substances

26 November 2014	Brussels, Belgium (Science 14 Atrium)

Background:

Recently, the EU Commission published the report on the *"Study of environmental risks of medicinal products"*. Herein, the establishment of a monograph system for active pharmaceutical substances has been proposed as one of the most promising legislative action to ensure the environmental safety of Veterinary Medicinal Products (VMPs) in use. This also applies to 'old' products which were already on the market before the requirement for an environmental risk assessment was introduced into the legislation. On 10 September 2014 the Commission adopted a proposal for a new Regulation of the European Parliament and of the Council on Veterinary Medicinal Products (VMPs). However, the establishment of a monograph system was not considered in this proposal.

The workshop aims to review the current state of the environmental risk assessment in the pre- and post-market control of VMPs and to discuss the opportunity for improvement by implementing a monograph system on active pharmaceutical substances (APIs). The concept of a monograph system and research results will be presented and discussed.

Workshop description

The one-day workshop (ca. 9 am -16 pm) will be hosted by the German Federal Environment Agency (UBA) and by the French Agency for Veterinary Medicinal Products / ANSES. It will start with introductory lectures, followed by discussions in working groups focused on more detailed aspects of the monograph system. Poster contributions from all participants are very welcome. To disseminate the obtained results the conclusions of the scientific discussion will be published in a workshop report.

Questions to be discussed are:

- What are the benefits and challenges of a monograph system?
- What information should be included in the monograph for an API?
- What are the proposed timelines and procedures?
- How does the monograph system interact with the authorization of products?
- What are the next steps to implement a monograph system into the legislative framework?

Who should attend:

Experts from science, industry, and ministries/regulatory agencies as well as policy stakeholders are welcome to discuss the benefits and challenges of a monograph system and to contribute proposals for the practical implementation.

Registration:

For registration please use the following e-mail: monograph-workshop@uba.de.
There is no registration fee.

For further information please contact:

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