Umwelt Bundesamt

Science-Policy-Event

Environmental risk of veterinary medicines

Key measures for an effective environmental risk assessment

New proposal for the regulation on veterinary medicinal products – state-of-the-art

The EU Commission recently adopted proposals on veterinary medicinal products in July 2014.
The proposed Regulation [COM (2014) 558 final] will repeal and replace the outdated Directive 2001/82/EC as amended. In parallel, a proposal for a regulation [COM (2014) 557 final] has been adopted amending Regulation (EC) 726/2004, that lays down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Other EU institutions, including the Council and the European Parliament consider the Commissions' proposals and adopt their positions in due course, in accordance with the co-decision procedure. While the Council has discussed the proposal on veterinary medicinal products since October 2014, the Committee (ENVI) of the European Parliament will start on 18 March 2015.

General aim of the proposed regulation

The proposal on veterinary medicinal products aims at making more medicines available in the EU, strengthening the EU market and treating and preventing diseases in animals. With its proposal, the EU Commission intends to tailor legislation of veterinary medicines to the needs of the veterinary sector whilst continuing to ensure a high level of public and animal health and a safe environment.

Veterinary pharmaceuticals in the environment

The need for an improved environmental protection has been raised during the public consultation on the veterinary review in 2009. The fact that most old veterinary medicines have still not been properly assessed for their environmental risk was pointed out by a variety of stakeholders. In addition, the report on "Environmental risks of pharmaceuticals in the environment" (BIOIS 2013), financed by the EU Commission, suggests a list of possible solutions and measurements that should be addressed in

due course in order to minimize these risks. Among others, a catching-up procedure to assess active substances and an increased availability of environmental data for the general public, have been addressed. In addition, the report highlights that veterinary medicines are extensively used in farming for therapeutic and metaphylactic purposes.
The consumption of both, veterinary and human medicines, significantly leads to the emission of medicinal products into the environment. Excretions of humans and animals are the major known contamination pathway. In consequence, veterinary medicines, such as antibiotics, have frequently been reported in literature for soil, surface and even ground water.

Impacts of veterinary pharmaceuticals on the environment have also been reported: e.g. the near extinction of vultures in India in the 1990s due to the use of the anti-inflammatory diclofenac; the finding of antibiotic-resistant pathogens in soils and surface-waters from human and animal sources; the loss of biodiversity and reduction in dung degradation on pastures due to the use of parasiticides and their effect on dung fauna organisms.

Impacts of the proposed regulation to the environment

The proposal for the regulation on veterinary medicinal products lacks sufficient provisions to assure a high level of environmental protection. It is to note, that environmental issues that have been raised during the public consultation and within the EU financed report on environmental risks of pharmaceuticals, have not been addressed in the draft regulation. In particular the following key measures were identified in order to ensure an effective environmental risk assessment:

(a) Putting in place a review program on active pharmaceutical substances for environmental data, with the intention to establish a monograph system;
(b) Ensuring the provision of publicly available environmental information;
(c) Ensuring the protection of the aquatic environment from rededicated veterinary medicines
(d) Limiting initial marketing authorisations

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