Environmental risk of veterinary medicines

Key measures for effective environmental risk assessment

A discussion paper on the Proposal for a Regulation of the European Parliament and of the Council on Veterinary Medicinal Products [COM (2014) 558 final]

Für Mensch & Umwelt

tukes
Turvallisuus- ja kemikaalivirasto

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1. Introduction

The German Federal Environment Agency (UBA) and the Finnish Safety and Chemicals Agency (Tukes) agree with the overall objective of the Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products – that is, to put in place an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector, while safeguarding public health, animal health, food safety and the environment, as well as with the five objectives set:

- increasing the availability of veterinary medicinal products;
- reducing the administrative burden;
- stimulating competitiveness and innovation;
- improving the functioning of the internal market; and
- addressing the public health threat of antimicrobial resistance.

We also strongly agree that these objectives shall be met "(...) while guaranteeing the highest level of public and animal health and environmental protection". [COM (2014) 558 final; para 5]

With this position paper, we express our concern that the current draft regulation does not include sufficient provisions to assure a high level of environmental protection. In particular, we underscore the need to address the following key measures for 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; and
(b) Ensuring the provision of publicly available environmental information.

These measures would make a significant contribution to safeguarding the environment and at the same minimize animal testing and save resources for both industry and society. Moreover, these measures would greatly facilitate the effective use of environmental data and would give stakeholders of the public health and environment sector access to environmental information on medicinal products.

2. Review programme for active pharmaceutical substances

Incomplete data on environmental risks

The environmental risk assessment (ERA) of new marketing authorizations of medicinal products was first introduced into the European legislation in the mid 1990s. However, a review programme for existing products already on the market was not foreseen at that time.

Under the current legislation, an ERA is mandatory for a new Marketing Authorization (MA) application for veterinary medicinal products. It moreover is required for generics as well as for major variations and for extension applications, should an increase in environmental exposure be expected.

However, there are still many products on the market for which no or only incomplete environmental risk assessments are available. This particularly applies to veterinary medicinal products which were authorized before the environmental risk assessment became mandatory. The existing post-marketing surveillance system (pharmacovigilance) is not able to compensate this data deficit due to methodologically irresolvable difficulties.

Environmental risk assessments for generic products: Partially inefficient and inconsistent

Under current regulations, an environmental risk assessment has to be carried out for each generic product to be authorized. Generic product applicants have to provide the necessary data, despite the fact that in many cases, an ERA is already carried out in the initial authorization of the reference product.

Therefore, authorizing generic products often involves re-evaluating the same molecules based on different studies whose results may differ. The existing system leads to duplication of data, redundant assessments, repeated animal testing and hence to an inefficient use of resources for both applicants and national competent authorities as well as to divergent decisions in the MA of similar products.

Monographs: Consolidating data for environmental risk assessment

Establishing a review programme and consolidating data on environmental fate and effects data on active pharmaceutical substances in a monograph system

would be an excellent instrument to address the issues explained above and to provide up-to-date data for the ERA of medicinal products.

The aim of monographs are:

- to collate existing date on fate and effects of active pharmaceutical substances,
- to generate high quality studies when information is missing,
- to evaluate studies and to agree on the endpoints to be used for ERAs of medicinal products.

Subsequent MA applications would be able to refer to the monograph containing environmental data on the corresponding active substance. Hence, monographs would facilitate resource and knowledge sharing, harmonization and consistency in decisions. Data collated in monographs would have to be protected by intellectual property rights with regard to the use of these data by other manufacturers. Also, the confidentiality of commercial or industrial information would have to be guaranteed. Furthermore it would have to be ensured, that the implementation of a monograph system would not have any impact on the availability of veterinary medicinal products.

Corresponding demands were raised during the public consultation on the veterinary review in 2009 and in the published report on Environmental risks of pharmaceuticals in the environment (BIO IS 2013) financed by the EU Commission.

To minimize pharmaceuticals in the environment the following recommendations are presented by the report:

- *"Developing a monograph system based on experience from REACH, biocides and plant protection products legislation" (1.1)*
- *"Testing the framework on pilot substances" (1.2)*
- *"Establishing a catching-up procedure to assess active substances (which would be more feasible if the MA procedure becomes active substance-based): Prioritisation of substances to assess; Results of assessment to feed the monograph system (e.g. short summaries of study reports and their assessments like for plant protection products)". (2.2)*

The current proposal for a regulation does not include the above recommendations.

3. Making relevant environmental information publicly available

There is an increasing demand for publicly available environmental data by different stakeholders such as water authorities, water boards, the public, etc. Pharmaceutical substances are biologically highly active substances and they are unintentionally, but regularly released in the environment. There is significant public concern about the occurrence of pharmaceutical substances e.g. in surface water but also in ground water. Environmental information plays a key role for risk management. A publicly available database containing validated data on the fate and effects of active pharmaceutical substances in the environment is therefore needed to make such information accessible to all relevant actors like water authorities and water board's.

This demand was also recognized by the BIO IS report (BIO IS 2013), which recommended:

- *"Requiring medicinal agencies to communicate ERA results and data to water authorities and other interested parties" (5.4)*
- *"Increasing availability of ERA data and results. Improving information provided in EPARs and national PARs [(European) Public Assessment Report]: Publication of ERA results and endpoints as a minimum standard;" (6.1)*
- *"Creating a dedicated centralized Internet database, which could stem from or constitute the monograph system" (6.2)*

The proposed regulation currently does not address the above recommendations. A dedicated centralized online database comprising validated environmental fate and effects data on active pharmaceutical substances would be an appropriate instrument to communicate environmental data and results of the environmental risk assessment to all relevant stakeholders as well as the interested public. Such a database would ensure that the increased demand for environmental information from different competent authorities, in relation with sectoral framework directives (e.g. water and ground water directives) is met. Such a database should preferably stem from a monograph system as described above. The data collated in monographs would need to be protected by intellectual property rights with regard to the use of these data by other manufacturers.

4. Summary

This discussion paper on the Proposal for a Regulation of the European Parliament and of the Council on veterinary medicinal products (EU COM (COM (2014) 558 final) expresses our concern that environmental issues are not adequately addressed in several aspects of the proposed Regulation. The precautionary principle according to the Lisbon Treaty has not been given enough consideration. This paper moreover outlines sustainable solutions to the issues raised. A monograph system with environmental data on active pharmaceutical substances would be a suitable system to guarantee a high level of public health and environmental protection. Based on the experience from other regulations, the establishment of monographs on active substances would result in efficient and consistent environmental risk assessments of veterinary medicinal products, in minimized administrative burden and costs, and reduced animal testing. We thus reiterate the need to establish a review programme on active pharmaceutical substances and to publish the results of such a review in monographs. This measure will greatly contribute to an effective use of environmental data and would give stakeholders responsible for public health and environmental protection access to environmental information needed for risk mitigation measures.

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Federal Environment Agency
P.O. Box 14 06
D-06844 Dessau-Roßlau
Tel: +49 340-2103-0
info@umweltbundesamt.de
Internet: www.umweltbundesamt.de

/umweltbundesamt.de
/umweltbundesamt

Finnish Safety and Chemicals Agency (Tukes)
P.O. Box 66 (Opastinsilta 12 B)
FI-00521 Helsinki, Finland
Internet: www.tukes.fi

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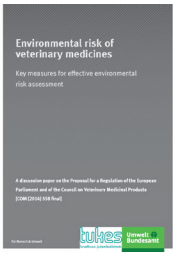

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