Science-Policy Event:
Environmental risks of veterinary medicinal products

Brussels, 4th March 2015

Introduction to the panel discussion:
Summary of main arguments raised in the presentations

1. Legal Provisions for Environmental Risk Assessment

Legal requirements for environmental risk assessment for veterinary medicines exist since 1992.

Directive 2001/82/EC as amended by Directive 2004/28/EC

- → Data requirements regarding environmental risk assessment for all new marketing authorization applications
- → ERA is part of risk/benefit balance of VMPs

Proposal for a Regulation on Veterinary medicinal products: COM (2014) 558 final

Key question: Is the legislation able to entirely ensure the **environmental safety** of veterinary medicinal products?

2. EU activities on Pharmaceuticals in the Environment

In the last couple of years the European commission has funded resp. is still funding several R&D projects on pharmaceuticals in the environment, as e.g. the following projects: Eravmis, Rempharmawater, ERAPharm, Poseidon, Neptune, Pharmas, CytoThreat, Pills. These projects proved the risks resulting from the regular occurrence of active pharmaceutical substances in the environment. There are various examples of active pharmaceutical substances, which cause harmful effects even at very low concentrations as they are found in the environment. Furthermore, measures which may lead to a reduction of environmental pollution by pharmaceuticals were investigated and necessary improvements of the EU legislation were identified.

EEA Report on Pharmaceuticals in the Environment (2010)

Technical Report on Pharmaceuticals in the environment

→ European Environment Agency (EEA) acknowledges pharmaceuticals as emerging environmental problem

Key finding of an EEA workshop:

"… need to look at impacts across the whole life cycle of pharmaceuticals."

EU Report on Environmental Risks of medicinal products (2013)

2010: New Pharmacovigilance Legislation:

Respective recitals call upon the Commission, *"to produce a report on the scale of the problem, along with an assessment of whether amendments to Union legislation on medicinal products or other relevant Union legislation are required".*

2013: EU-Report on Environmental Risks of medicinal products:

→ EU Commission acknowledges that environmental pollution with pharmaceuticals is an emerging problem.

3. Experiences with the current legislation

Existing (‚legacy') products: Veterinary medicinal products which have been approved before the requirement for an ERA was introduced into the legislation

→ A review program of these ‚legacy' products (substances) was/is not envisaged.

The environmental risk assessment is partially inefficient and inconsistent: The existing system leads to duplication of data, redundant assessments, repeated animal testing and hence to an inefficient use of resources as well as to divergent decisions in the marketing authorization of similar products.

Key messages: Environmental information is only available for about 30% of the active substances used in veterinary medicinal products.
Improvements of the existing system are necessary.

4. Review program on active pharmaceutical substances

Aim: to consolidate and to evaluate data on active pharmaceutical substances necessary for an environmental risk assessment

Consolidation of data in **Monographs on active pharmaceutical substances!**

→ provide up-to-date data for the environmental risk assessment of medicinal products

→ facilitate resource and knowledge sharing, harmonization and consistency in decisions

5. Availability of environmental data on pharmaceuticals

Current situation:

→ Lack of public information

→ Outcome of ERA of a medicinal product is only partly and not systematically published in product based databases.

Data on environmental fate and ecotoxicological effects are the essential base for any kind of **identification and management of risks** and should be adequately available. Data are of interest for e.g. water authorities.

→ Dedicated centralized online database is necessary!

→ Database should stem from monographs on active substances

6. Key measures to ensure the environmental safety of VMPs

(a) Putting in place a review program on active pharmaceutical substances for environmental data, with the intention to establish a monograph system;

(b) Ensuring publicly available environmental information;

(c) Ensuring the protection of the aquatic environment from rededicated veterinary medicines

(d) Limiting initial marketing authorisations

(e) Post-marketing surveillance with new pharmacovigilance criteria

7. Conclusions

The current draft regulation does not include sufficient provisions to assure a high level of environmental protection. The recommendations provided e.g. in the EU-Report on Environmental Risks of medicinal products (2013) were not considered.

There is a need to address additional key measures for effective environmental risk assessment as base for risk management

→ to facilitate the effective use of environmental data

→ to give stakeholders assess to environmental information

→ to safeguard the environment.