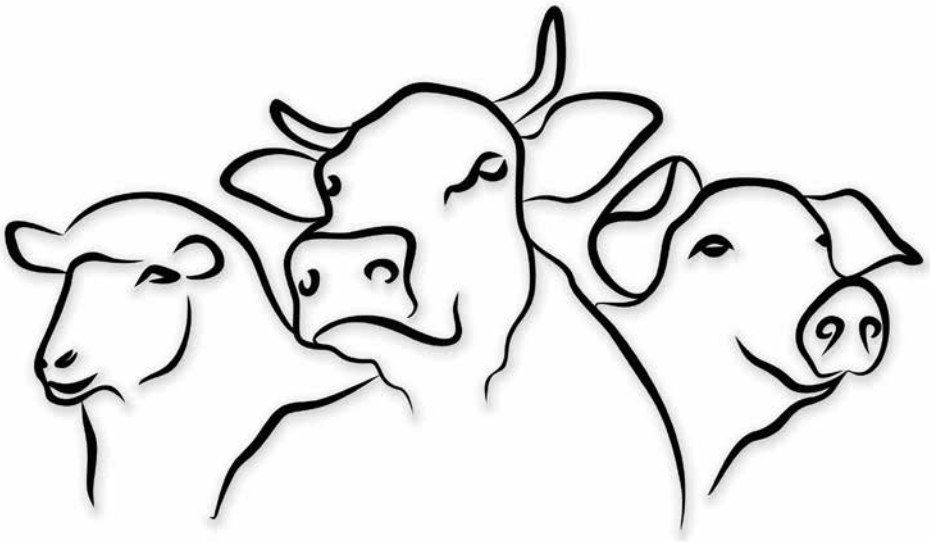
PAN Germany
Pestizid Aktions-Netzwerk e.V.

Ecological Impacts of Veterinary Pharmaceuticals: More Transparency – Better Protection of the Environment



Avoiding Environmental Pollution from Veterinary Pharmaceuticals

To reduce the contamination of air, soil, and bodies of water caused by veterinary medicinal products used in agriculture and livestock farming, effective measures must be taken throughout the entire life cycle of these products – from production and authorisation to application and disposal.

All stakeholders – whether they are farmers, veterinarians, consumers, or political decision makers – are called upon to contribute to reducing contamination of the environment caused by pharmaceutical residues and to improving protection of the environment and human health. Appropriate measures include establishing “clean” production plants, developing pharmaceuticals with reduced environmental impacts, assessing the environmental impacts of all veterinary pharmaceuticals more stringently, monitoring systematically their occurrence in the environment, converting animal husbandry practices to preserve animals’ health with a minimal use of antibiotics, and enforcing legal regulations to ensure implementation of all the measures outlined here.

In the context of the revision of veterinary medicinal products legislation that is currently underway, this background paper focuses on three measures that would contribute to making information on the occurrence of veterinary drugs in the environment and their eco-toxicological effects more widely available and enhance protection of the environment from contamination with veterinary pharmaceuticals.

Introduction of a monograph system for documenting relevant environmental data and making information on the environmental impact of veterinary pharmaceuticals more widely available

PAN Germany's position is that data on the substances used in veterinary medicinal products and on their environmental impacts should be compiled in substance-based monographs and made available to the general public in databases similar to existing databases on pesticides.

For more than ten years, risk assessment in the context of authorising veterinary medicinal products has generated information on pharmaceuticals, including data on the physio-chemical properties of their active ingredients and on their environmental effects. Data collected for approval purposes are initially private property that belongs to the pharmaceutical company applying for authorisation, which must submit information from relevant test series and other data. If two different companies apply for authorisation of products with the same active ingredient, these drugs undergo the mandatory environmental impact assessments that are part of the process separately; this means that, for example, the effects of the active ingredient on model organisms are examined twice. By documenting environmentally relevant data acquired in the context of authorisation procedures in a substance-based monograph and exchanging this data between companies that have been granted authorisation of different products with the same active ingredients, the number of repetitions of test series could be reduced. As a result, environmental impact assessments could be harmonised, diverging assessments of the same active ingredient avoided, and the reduction of repeated testing with animals would contribute to enhanced animal protection. Information on the environmental occurrence, fate, and effects of active substances found in comparable products could be exchanged and published in a harmonized format: the monograph. Data on a substance's physio-chemical properties, mode of action, degradation, possible environmental consequences, its metabolic paths, and rates at which it is excreted, and so on, additional information gained from environmental monitoring, as well as data from scientific publications could be compiled and serve as a basis for assessing environmental risks.

Introduction of a monitoring system to collect data on the occurrence of (veterinary) pharmaceuticals in the environment

Information about the fate and effects of veterinary pharmaceuticals in the environment is to date inadequate. This is partly because data on the occurrence of veterinary medical products in the environment is not collected systematically and partly because eco-toxicological data collected in the context of authorisation procedures is not made available to the public, and the information acquired is not shared. Nevertheless, an appreciable volume of data on the environmental occurrence and behaviour of (veterinary) pharmaceuticals in the environment has been collected and published in recent years. To date, EU member states are not obliged to monitor pharmaceutical residues in bodies of water. However, individual and sometimes regional studies indicate that medicinal products have been found almost everywhere in surface waters in Europe and beyond. According to data from Germany's Federal Environmental Agency, more than 150 different active pharmaceutical ingredients alone have been detected in surface waters, sediments, ground water, and soil in

Germany. Many of these substances have a high potential for causing harm to fish and small aquatic organisms. Such active ingredients have been detected in surface waters at concentrations of 0.1 to 1 microgram per litre – and sometimes even higher. Long-term tests with fish, daphnia, and algae have shown that these concentrations can affect aquatic organisms. Antibiotics can inhibit the growth of plants, algae, and cyanobacteria; antiparasitics harm insects, worms, and crustaceans. Even very low concentrations of residues of endocrine-active drugs interfere with fish reproduction and can harm amphibians. And these effects do not yet take into account possible aggravated effects due to the combined action of various contaminants. Among the active pharmaceutical substances detected in concentrations above 0.1 µg/l in Germany's surface waters, there are four antibiotics used in veterinary medicine: sulfadimidine, sulfamethoxazole, erythromycin, and trimethoprim. In soil, veterinary pharmaceuticals bind to soil particles, where their germicidal, antifungal, and antiparasitic properties affect soil organisms and can have considerable negative impacts on beneficial organisms and ecosystem functions. Veterinary drugs such as sulfonamides and tetracyclines have also been detected in ground water. Even if the concentrations detected so far are low and the number of findings has been small, ground water should remain free of contamination. Contamination of veterinary pharmaceuticals in ground water is an alarming finding – not only with respect to our drinking water supplies.

PAN calls for the introduction of mandatory and coordinated monitoring of the occurrence of pharmaceuticals in soil and bodies of water. In keeping with the precautionary principle, PAN calls for applying the existing limit for active substances from pesticides and biocides in ground water of 0.1 micrograms per litre (µg/l) for a single substance and 0.5 micrograms per litre (µg/l) for the total of all such substances to pharmaceuticals, as well.

Revision of the pharmacovigilance system for veterinary pharmaceuticals to ensure monitoring of their environmental effects

Before a drug is placed on the market, it undergoes a mandatory authorisation procedure, during which its efficacy and tolerance are investigated and possible environmental risks are evaluated in an environmental impact assessment. But even if undesirable impacts are assessed in this process, monitoring a medicinal product after it has been authorised and been placed on the market is especially important, since this is the only way to observe a product in everyday use and ascertain whether it has any previously undetected (side) effects. Therefore, all pharmaceuticals are subject to statutory safety monitoring, called pharmacovigilance, by the doctors and veterinarians who prescribe them. This involves observing and reporting on the risks and side effects of drugs used in humans or animals. Unlike pharmacovigilance procedures for human pharmaceuticals, this monitoring of veterinary drugs includes possible negative effects on the environment. However, there is a discrepancy between the legal obligation to report on environmental risks in the context of monitoring a drug after it has been authorised (Directive 2001/82/EC as amended in 2004) and the current possibilities for fulfilling this obligation. The pharmacovigilance system is product-related, but contamination of the environment generally cannot be attributed to a single product. To ensure monitoring of negative impacts on the environment, at the very least the occurrence of active substances from veterinary products that have been shown to be environmentally hazardous should be checked in specific environmental matrixes. Also problematic is the fact that veterinarians are not trained to identify possible harm to organisms in soil and water. In view of current knowledge already gathered in the lab and in the field about existing contamination of soil and

PAN considers the current pharmacovigilance system to be unsuitable for monitoring possible negative impacts of veterinary pharmaceuticals on the environment. According to PAN Germany, the system must be revised or other systems of environmental monitoring have to be established.

bodies of water and about the effects of drug residues on non-target organisms and ecosystem's functioning, it is absolutely imperative that the occurrence and negative effects of veterinary pharmaceuticals in nature are systematically monitored after authorisation. Identifying the key contexts in which contamination and ecological damage occur would mean that appropriate measures to counter contamination and protect the environment could be implemented. Special attention must be paid to active ingredients and co-formulants regarded as especially hazardous to the environment, such as so-called PBT substances, which are persistent, bioaccumulative, and toxic and also accumulate in organisms; vPvB substances, which are very persistent and very bioaccumulative; and hormonally active substances, known as endocrine disrupters (EDs).

More information on the pharmacovigilance system for veterinary medicinal products

- Rönnefahrt, I., German Federal Environment Agency (2013): Experiences with environmental risk assessment in the authorization procedure of veterinary medicinal products. International Workshop on Eco-Pharmacovigilance of Veterinary Medicinal Products, Berlin, 4-5 December 2013. Online at https://www.umweltbundesamt.de/sites/default/files/medien/378/dokumente/roennefahrt_vortrag_veroeffentlichung_2.pdf
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More information from PAN Germany on this issue

- PAN Germany (2013): Recommendations for Enhanced Protection of the Environment from Adverse Effects of Veterinary Medicinal Products. Position Paper. Online at http://www.pan-germany.org/download/veterinary_pharmaceuticals/Enhanced_Protection_of_Environment_from_Veterinary_Medicinal_Products.pdf
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- PAN Germany: Information available (background papers, position papers, flyers, films, etc.). Online at http://www.pan-germany.org/deu/projekte/tierarzneimittel.html (German) and http://www.pan-germany.org/gbr/project_work/veterinary_pharmaceuticals.html (English).

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