PAN Germany
Pestizid Aktions-Netzwerk e.V.

Recommendations for Enhanced Protection of the Environment from Adverse Effects of Veterinary Medicinal Products

Position Paper

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Veterinary Medicinal Products Pollute the Environment

It is widely known that fertiliser and pesticides used in agriculture can lead to environmental problems. But residues from veterinary medicinal products and their metabolites are also increasingly being detected in water bodies and soil. Veterinary medicinal products and medicated feedingstuffs used in animal farming enter the environment via the excrements of treated animals, manure, or slurry. Due to precipitation they can run off from soil to surface water or pass into ground water through the soil.[1,2]

Many veterinary medicinal products are water-soluble (hydrophilic) as well as persistent. In water bodies they effect the entire aquatic ecosystem: antibiotics inhibit the growth of plants and primary aquatic producers such as algae and cyanobacteria, antiparasitics affect invertebrates - small animals that do not develop a vertebral column like insects, worms and crabs -, and hormone residues in bodies of water have significant effects on the development and reproductive capacities of fish.[3]

But though alarming studies exist, a systematic documentation and publication of data on the amounts of products used is lacking, no systematic environmental monitoring for veterinary pharmaceuticals is in place, and there are still veterinary pharmaceuticals on the market that have never been tested for their environmental impacts. Knowledge on the extent and the impacts of the adverse environmental effects of veterinary medicinal products is alarmingly fragmentary. Moreover, there is a lack of risk management measures.

Revision of Legislation on Veterinary Medicinal Products - Opportunities for Enhanced Environmental Protection

On the European level, legislation on veterinary medicinal products is currently being revised. This includes the authorisation and supervision of medicinal products for veterinary use. It is expected that the Commission will present its draft in the second quarter of 2013.[4] The revision mainly aims at facilitating trade with veterinary medical products in the internal market and at improving market economic factors.[5] Users of veterinary medicinal products seek to secure the availability of products; producers have an interest in a simple and quick authorisation process. Proposals that suggest how the revised legislation on veterinary medicines might enhance environmental protection have played a minor role so far, according to PAN Germany.

The revision offers an opportunity for overcoming current deficits and securing improved protection of the environment from the adverse effects of veterinary medicinal products. To enhance the protection of natural resources from such adverse effects of veterinary medicinal products in the future, improvements in other areas of European regulation, for example in water protection or animal welfare, are needed.

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[1] Landesumweltamt Brandenburg (ed.) (2001): Tierarzneimittel in der Umwelt. Erhebung von Tierarzneimittelmengen im Land Brandenburg für den Zeitraum von Juli 1998 bis Juni 1999. Studien und Tagungsberichte, vol. 29. http://www.brandenburg.de/cms/media.php/2320/lua_bd29.pdf (download 12 June 2012)

[2] Bayerisches Landesamt für Umwelt (ed.) (2008): Austrag von Tierarzneimitteln aus Wirtschaftsdünger in Sickerwasser, Grundwasser und oberirdische Gewässer. Abschlussbericht. http://www.lfu.bayern.de/analytik_stoffe/tierarzneimittel_im_sickerwasser/doc/abschlussbericht.pdf (Download 12 June 2012)

[3] Maack, G. und Rönnefahrt, I. (2012): Toxische Wirkungen von Pharmaka – ein Problem für die Umwelt? In: 24. Kolloquium zur Abwasserwirtschaft: Hamburg 12/13 September 2012. pp. 57-58

[4] Information by the EU Commission on the revision process: http://ec.europa.eu/health/veterinary-use/pubcons_frame_index_en.htm (accessed 12 June 2012)

[5] Revision of Veterinary Pharmaceutical Legislation – Roadmap 2011.Online: http://ec.europa.eu/governance/impact/planned_ia/docs/2012_sanco_002_veterinary_pharmaceutical_legislation_en.pdf

Demands for Improved Protection of the Environment from the Adverse Effects of Veterinary Medical Products

The European Union has committed itself to the protection of its natural resources; environmental protection is anchored in the goals of the European Union Animal Health Strategy[6]. In PAN Germany's opinion, the implementation of the following demands can contribute to reduce the existing deficits and to achieving the umbrella goals of the European Union, such as sustainable use of natural resources, the protection of biodiversity and water, consumer protection, and the protection of human and animal health.

Incorporation of more environmental protection into the authorization process

- **Ban the use of veterinary pharmaceuticals without environmental risk assessment: introduce a review programme to evaluate the environmental effects of veterinary pharmaceuticals that have been approved without being tested for their environmental impacts.**
- **Introduce a regular environmental review of authorised veterinary pharmaceuticals based on the current state of scientific knowledge that must be conducted at intervals of ten to fifteen years.**

Background: Numerous veterinary medical products that are now in use were authorised before environmental impact assessment became an obligatory element of the authorisation process[7]. These products have never been tested for their environmental impacts. After a period of five years and following the submission of an appropriate application, authorised veterinary medical products – in contrast to pesticides or biocides – are generally admitted infinitely. Regular environmental review intervals secure an assessment based on the current state of scientific knowledge. The established pharmacovigilance system in its present design is not suitable for monitoring the environmental impact of veterinary pharmaceuticals.

No authorisation for substances that are especially hazardous to the environment

- **Establish a process to define criteria for active ingredients in veterinary medicinal products that are especially hazardous to the environment.**
- **Establish a process that denies authorisation of such products in the future.**

Background: In other spheres of regulation - e.g. on pesticides and biocides - the need for stricter regulation of especially hazardous substances has been recognized because an effective protection of human health and of the environment can only be secured by excluding their approval and, in consequence, their use. Such exclusion criteria for the authorisation of veterinary pharmaceuticals are missing to date. Substances are regarded as especially hazardous to the environment when they are persistent, bio-accumulative, and toxic (PBT substances) or when they are very persistent and very bio-accumulative (vPvB substances).

[6] A New Animal Health Strategy for the European Union (2007-2013) "Prevention is better than cure". Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee of the regions COM 539 (2007) final.http://ec.europa.eu/food/animal/diseases/strategy/animal_health_strategy_en.pdf

[7] PAN Germany (2012): Veterinary medicinal products and protection of the environment. Online: http://www.pan-germany.org/download/tierarzneimittel/tierarznei-EN-130207-web.pdf

Increasing transparency: Recording and publishing data on the use of veterinary medicinal products

- **Publish data on amounts of products marketed (for domestic use and export), on amounts used as well as on controls regarding the use of and the trade with veterinary medicinal products**
- **Oblige member states to set up control programmes for veterinary pharmaceuticals and publish annual reports on these programmes. These reports should include Information regarding the control process (frequencies, time, etc.), the extent of the controls and detected violations**
- **Include medicated feedingstuffs in the control program.**

  Background: Information on the amount of veterinary medical products used in the member states is incomplete or missing altogether. For the public as well as for experts, access to data on the use of veterinary medical products (use patterns, amounts used, active substances) and on their toxicological risk potential is very limited. Transparency is the basis for effective monitoring to assess the environmental impact of veterinary medicines and for effective risk management. The German pesticide control programme might serve here as a model.[8]

Introduction of environmental monitoring – identifying pollution from veterinary medical products

- **Introduce obligatory environmental monitoring for veterinary medical products (water bodies, aquatic ecosystems, soil, sediments).**
- **Publish monitoring data in a data base. The data must be freely accessible for further evaluation and use.**
- **Ensure that monitoring data must be taken into account in the pharmacovigilance system.**

  Background: Although assessment during the authorisation process is intended to evaluate the efficacy and potential risks of veterinary medical products, knowledge of the actual environmental effects of a specific product at the time it is authorised is incomplete. It is not until the products are in actual use, which leads to their release into the environment, that knowledge about possible adverse effects (such as interactions with other substances) and processes (e.g. accumulation) becomes more comprehensive. Observing authorised products through monitoring and linking monitoring results to the authorisation process are therefore of great importance for long-term evaluation of a veterinary medical product. Although pharmacovigilance has been established as a system for identifying and evaluating undesirable effects of veterinary medical products, this system is inadequate for identifying environmental impacts. Even the Periodic Safety Update Reports, which manufacturers of such products must submit at regular intervals to document that authorised veterinary medical products are harmless, are only required to encompass investigation of environmental aspects if a “reasonable suspicion” of such impacts has been determined. From the perspective of precautionary environmental protection, there is a need for improvement here. Moreover, monitoring must be conducted by independent experts.

[8] Information of the Federal Office of Consumer Protection and Food Safety on the German Plant Protection Control Program (Pflanzenschutz-Kontrollprogramm). http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/06_Pflanzenschutzkontrollprogramm/psm_Pflanzenschutzkontrollprogramm_node.html

Closing gaps in assessment of environmental impacts of pollution

- **Include the environmental assessment of veterinary medical products in digestate in assessment procedures.**

  Background: Residues of veterinary medical products can also be identified in digestate from biogas plants. So far, such digestates are not subject to environmental assessment, and there is a lack of knowledge about possible environmental impacts of digestates that contain residues.

Promoting environmentally-sustainable alternatives – substitution of veterinary medical products of high environmental concern

- **Specify procedures for substituting especially hazardous substances.**
- **Deny authorisation if environmentally-sustainable alternatives (products/processes) exist.**
- **Establish obligatory plans for phasing-out and substituting environmentally-hazardous products within defined, short-term timeframes.**

  Background: Whether environmentally-sustainable alternatives are available for especially environmentally hazardous substances (substances of high environmental concern) must be raised during the authorisation process. Implementation of the substitution principle depends to a large extent on the availability of alternative active substances and alternative processes. In order to guarantee significant progress in implementing the substitution principle, alternative products and processes must be promoted.

Implementation of more preventive activities with measures that promote animal health and welfare in animal husbandry

- **Promote husbandry practices that foster animal health.**
- **Promote conversion to husbandry that fosters animal welfare.**
- **Fund research on animal health and welfare in husbandry.**
- **Fund research on environmentally-sustainable veterinary products and drug delivery forms.**

  Background: Use of veterinary medical products depends on the husbandry form, fattening period, feed, level of specialisation of individual farms, and other factors. Strategies to reduce the use of veterinary medical products must thus also include “prophylactic” strategies that take effect outside the realm of regulations on veterinary medical products. What is needed are integrated concepts that foster animal health and that include the research for more environmentally-sustainable pharmaceuticals.

Enhanced protection of water bodies from pollution from veterinary medical products – Establish coherence with provisions on water regulation

- **Establish threshold values for veterinary medical products in surface and ground water and monitor compliance.**
- **Add problematic veterinary medical products to the lists of priority substances (Water Framework Directive).**

  Background: Water and aquatic ecosystems are especially endangered by pollution from veterinary medical products. On the EU level no binding threshold values currently exist for active pharmaceutical substances in surface and ground water.

Reduction of antibiotic use and prevention of antibiotic resistance

- **Publish annual data on antibiotic sales and use by the EU member states.**
- **Introduce specific controls and transparent, prompt reporting on the use of antibiotics within the framework of a veterinary medical products control programme (s. ↑).**
- **Prohibit the use of important antibiotics for human health care in livestock farming**
- **Establish a binding timeframe for implementing a ban on the prophylactic use of antibiotics.**
- **Define goals for reducing the amounts of antibiotics used in livestock farming**
- **Improve information on resistant pathogens in livestock animals and their meat by introducing a monitoring system in the member states.**
- **Incorporate the problem of antibiotics resistance into environmental assessment during the authorisation process for veterinary medical products.**

  Background: Treatment of serious bacterial diseases is becoming a global problem because a growing number of bacterial strains are resistant to commonly-used antibiotics. Use patterns, duration of use, and the amounts of antibiotics applied influence the development of resistant pathogens. The widespread, intensive use of antibiotics in livestock farming has increased the risk that resistant strains will develop. The European Food Safety Authority (EFSA) has identified the reduction of antibiotic use as an important priority. The use of third and fourth generation antibiotics in livestock farming are viewed as especially problematic, since these are important "reserve antibiotics" for human health care. Publication of data on the application of antibiotics (product categories, dosage, duration of use, and animal species) is necessary in order to ascertain whether the measures implemented are effective, reduction goals are being met, and risk management strategies must be adapted.

Improved information for the public and for product users

- **Introduce provisions that oblige member states create public spaces (e.g. on the internet) in which the public and main user groups (livestock owners, veterinaries, farming advisers, etc.) are informed about preventive measures and environmentally-sustainable alternative processes.**
- **Introduce compulsory training programmes for professional livestock owners that take environmental aspects into account as well as regular review of the level of competence of these individuals.**
- **Ensure that individuals who do business with or use veterinary medical products receive comprehensive advice on preventive environmental and health measures and that their activities are monitored.**
- **Ensure that veterinaries and livestock owners have access to advisers who are not associated with the veterinary medical products industry.**

  Background: To date, little is known about the environmental risks of use of veterinary medical products. Environmental issues play no role in the choice of treatment regimes, and there is a significant lack of knowledge about possible environmental effects of pollution through veterinary medical products. Veterinaries and livestock owners should not only be knowledgeable about how a product is to be used; they should also be well-informed about avoiding environmental pollution with veterinary medical products. To this end, steps must be taken to secure that independent advice is available for veterinaries and livestock owners from appropriate advisory institutions.

More about these issues

PAN Germany (2012): Veterinary medicinal products and protection of the environment. Authorisation and use of veterinary medicinal products in the EU - Legal framework and demands for enhancing the protection of the environment from adverse effects of veterinary medical products. Online at http://www.pan-germany.org/download/tierarzneimittel/tierarznei-EN-130207-web.pdf

Umweltbundesamt (2011): Workshop Monitoring Arzneimittel. Ergebnisse des UBA-Workshops: Monitoring von Arzneimitteln in der Umwelt – Notwendigkeit, Erfahrungen, und Perspektiven für die Arzneimittelzulassung am 14./15.09.2011. Available online in German at https://www.umweltbundesamt.de/chemikalien/arzneimittel/workshop_monitoring_arzneimittel.htm

German Federal Office of Consumer Protection and Food Safety (BVL) on authorisation of veterinary medical products. Online at http://www.bvl.bund.de/DE/05_Tierarzneimittel/tam_node.html

European Commission Directorate General Health & Consumers. Online information on the revision of the legal framework for veterinary medicinal products is available at http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

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