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Joint press mailing of Tukes and UBA

UBA and Tukes concerned about the environmental impacts of veterinary medicines

Joint press mailing on the lunch debate:
Environmental risk of veterinary medicines,
4 March 2014

Für Mensch & Umwelt

tukes
Turvallisuus- ja kemikaalivirasto

Umwelt Bundesamt

The Finnish Safety and Chemicals Agency (Tukes) and the German Federal Environment Agency, Umweltbundesamt (UBA), are concerned about the environmental risks of veterinary medicines. In their opinion, a proposal adopted in September by the European Commission – for a new Regulation on Veterinary Medicinal Products – does not include sufficient provisions to ensure a high level of environmental protection. Both public authorities are stressing out the aim of a new legislation to guarantee successfully a high level of environmental protection. There are additional key measures as e. g. a review program on environmental data of active pharmaceutical substances and the public availability of these data necessary to ensure the environmental safety of veterinary medicines. UBA and Tukes expressed their concerns to representatives of the European Parliament and Commission, NGOs, competent authorities and researchers at an event in Brussels on Wednesday.

In many European countries, consumption of veterinary medicinal products is high, particularly in intensive livestock production. Many of the veterinary pharmaceuticals used are released into the environment via manure or even directly from animals on pastures. Maria Krautzberger, the president of the German Federal Environment Agency: "Pharmaceutical substances are biologically highly active substances that are unintentionally, but regularly, released in the environment. Hence, there is a significant public concern regarding the occurrence of pharmaceutical substances in the environment." Examples of the harmful impacts of such substances include the near extinction of vultures in India in the 1990s due to the use of the anti-inflammatory diclofenac and the loss of biodiversity and reduction in dung degradation on pastures due to the use of parasiticides and their effect on dung fauna organisms. Adverse environmental effects of antibiotics include, for example, the growth inhibition of plants and algae. As an alarming consequence of the increasing use of antibiotics in animal and human medicine an increasing development of resistant pathogenic bacteria has been observed.

"New veterinary medicinal products have to undergo a detailed environmental risk assessment since 2004. However, currently there are still about two third of active substances on the market for which no or only incomplete environmental risk assessments are available. A lot of these substances have been monitored in soil, surface water and even ground water", said Krautzberger. However, a comprehensive review program of existing veterinary medicines has not been foreseen by the EU-Commission so far. The current EU regulations and the respective Finnish and German national legislation require that all pharmaceutical products administered to animals are safe for the animal itself, the person administering the product, and the environment. Preconditions for obtaining marketing authorisation for veterinary medicines include an assessment of the product's environmental impacts, performed by the applicant or obtained from a third party.

Regardless of the legislation in force, no environmental risk assessment has been conducted for many veterinary pharmaceutical products marketed in Europe today, because these products were authorised before the regulations and instructions requiring an environmental impact assessment of veterinary medicines entered into force in the mid-2000s. Tukes and UBA are of the view that an environmental risk assessment should be mandatory, even for products that came onto market before a detailed environmental risk assessment was required. In addition, Tukes and the UBA consider it vital that the environmental impact assessment of veterinary medicines involve a thorough review program of active substances, using the same methods as those used in the case of most other chemicals. This would make a more unified approval procedure possible for products containing such substances. "Having veterinary pharmaceuticals assessed based on their active substance, rather than by product, would reduce the amount of animal testing involved and save resources amongst both the industry and the authorities. It would also enhance the quality and visibility of assessment and environmental protection," comments Esa Nikunen.

Environmental Information play a key role for risk management. Hence, there is a high demand for publicly available environmental data by different stakeholders such as water authorities. A publicly available database on environmental data on active pharmaceutical substances would give stakeholders responsible for public health and the environment access to environmental information needed for risk management measures. The event, arranged by UBA

and accompanied by Tukes in Brussels on Wednesday, was attended by more than 80 participants, including 19 representatives of the European Parliament and eleven members of the European Comission. “The views of Tukes and UBA received positive feedback and the event likely had a positive effect on the future development of the new Regulation on Veterinary Medicinal Products,” says Esa Nikunen, Director, Chemical Products Surveillance, Tukes.

At the request of the Finnish Medicines Agency Fimea, Tukes is responsible for the environmental risk assessment of veterinary medicines in Finland. Tukes also has broad expertise in the environmental risk assessment of other chemicals. Fimea is responsible for the marketing authorisation of veterinary medicines in Finland. In Germany, the UBA is responsible for the environmental risk assessment within the framework of national and centralised marketing authorisation procedures. The competent authority, the Office of Consumer Protection and Food Safety (BVL) decides on obligations to protect the environment in agreement with the UBA.

3. Further information

- Position paper – Environmental risk of veterinary medicines: http://www.umweltbundesamt.de/en/publikationen/environmental-risk-of-veterinary-medicines
- Press release 12/2014: “Veterinary drugs – a new problem for groundwater?”: http://www.umweltbundesamt.de/en/press/pressinformation/veterinary-drugs-a-new-problem-for-groundwater

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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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