EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on assessing the toxicological risk to humans and the environment of veterinary pharmaceuticals in groundwater

Agreed by ERAWP and SWP	January 2013
Adopted by CVMP for release for consultation	11 April 2013
Start of public consultation	19 April 2013
End of consultation (deadline for comments)	30 June 2013

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

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1. Introduction

Residues of veterinary medicinal products may gain access to groundwater systems. The CVMP guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/418282/2005-Rev.1) indicates that if the predicted concentration of residues of a veterinary medicinal product in groundwater exceeds a trigger value, the applicant should provide a risk assessment to demonstrate that this concentration does not represent an unacceptable risk. However, existing guidance provides no further information on how this risk assessment should be performed.

This intended guideline should provide further technical support to the implementation of the VICH guidelines GL6 and GL38 on the environmental risk assessment (ERA) of veterinary medicinal products (VMPs).

2. Problem statement

The CVMP guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/418282/2005-Rev.1) outlines a two step process for the risk assessment of residues of veterinary medicinal products in groundwater. In the first step, the predicted concentration in groundwater is compared to a trigger value of 0.1 µg/l. If the predicted concentration in groundwater is below this value, the risk is considered negligible and no further assessment is needed. If the predicted concentration in groundwater exceeds 0.1 µg/l, the applicant should provide a risk assessment to demonstrate that exceeding the trigger value for groundwater is not indicative of an unacceptable risk. The current absence of guidance on how such a risk assessment should be performed represents a difficulty for both applicants and assessors.

3. Discussion

There is a need for guidance on the methodology to use when performing the groundwater risk assessment. The methodology should consider both the risk for human health resulting from residues of veterinary medicinal products in groundwater, and the risk to the environment.

In its groundwater risk assessment the CVMP should follow Directives 80/86/EEC on the protection of groundwater against pollution caused by certain dangerous substances, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration, Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD) and the Directive 98/83/EC on the quality of water intended for human consumption.

4. Recommendation

The Committee recommends the development of a guideline outlining the methodology to perform a risk assessment for both human health and the environment in cases where the concentration of residues of veterinary medicinal products in groundwater is estimated to be above the trigger value of 0.1 µg/l.

This guidance should be applied to new substances to be used in veterinary medicine for food producing species and for existing products in cases where the presence of residues in groundwater has been found or calculated to exceed the trigger value.

5. Proposed timetable

To be released for consultation during Q1 2013.

April 2013 – release of concept paper for consultation

June 2013 – deadline for receipt of comments

March 2014 – SWP and ERAWP to endorse draft guideline for publication

July 2014 – CVMP to adopt draft guideline for publication

January 2015 – deadline for receipt of comments

July 2015 – SWP and ERAWP endorse final guideline for publication

September 2015 – CVMP adopts final guideline for publication

6. Resource requirements for preparation

The ERAWP and the SWP would jointly develop the guideline. A Rapporteur from each working party will be nominated. Adequate time for discussions at both working parties will be required. The EMA secretariat will coordinate the consultation and communication between the working parties as well as the public consultation. Time at plenary CVMP will be required to discuss and adopt the various drafts of the guideline.

7. Impact assessment (anticipated)

The guideline would be beneficial for both industry and regulators as it would promote the use of a consistent and scientifically justifiable approach.

The number of substances for which residues above the trigger value can be expected is minimal. In those cases where a risk for man is identified a portion of the ADI might need to be reserved to take into account consumer exposure to residues in the ground water.

8. Interested parties

Pharmaceutical industry, enviromentalists and regulatory bodies, environmental agencies.

9. References to literature, guidelines, etc.

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Longley, G., 1981: The Edwards aquifer: earth's most diverse groundwater ecosystem? – Int. J. Speleol. 11: 105–122.

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Steube, C., S. Richter and C. Griebler, 2008: First attempts towards an integrative concept for the ecological assessment of groundwater ecosystems. – Hydrogeol. J. 17: 23-25.

Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances

Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration

Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy (the EU Water Framework Directive)

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption