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SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine

Agreed by ERA	25 June 2010
Adoption by CVMP for release for consultation	15 July 2010
End of consultation (deadline for comments)	1 September 2010

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

Keywords	*Persistent, bioaccumulative, toxic, PBT, vPvB*

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1. Introduction

Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (PBT/vPvB) are combinations of intrinsic properties which give substances the potential to accumulate in remote environments which is difficult to reverse as cessation of emission will not immediately result in a reduction in chemical concentration due to long half life. The target compartment and species at risk cannot be predicted due to the long-term presence in the environment, secondary poisoning and extreme toxicity. Consequently, for PBT(vPvB) substances a “safe” concentration in the environment cannot be established with a sufficient reliability. The PBT/vPvB assessment is particularly developed to consider the unacceptable high uncertainty in predicting reliable exposure and/or effect concentrations hampering quantitative risk assessment.

In the regulation of plant protection products and biocides the marketing authorisation of substances can be refused when they possess PBT or vPvB intrinsic properties.

The OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic on the Marine Environment[1] aims to prevent pollution by continuously reducing discharges, emissions and losses of hazardous substances (identified by specific PBT criteria). Within the legislation of industrial chemicals (REACH)[2] the registrant is obliged to perform a PBT/vPvB assessment for chemicals produced or imported of more than 10 tonnes. For those chemicals identified as PBT or vPvB an emission and risk characterisation is required in which all emissions throughout the lifecycle of the substance are characterised and risk management measures and operational conditions are implemented or recommended (to down stream users) to minimise exposure of humans and the environment. A Member State national competent authority or the European Chemical Agency (ECHA) can identify a PBT or vPvB substance as a ‘substance of very high concern’ for inclusion in Annex XIV[2] for which an authorisation is required.

2. Problem statement

The CVMP TGD[3] already indicates that veterinary medicinal products can be screened for PBT/vPvB properties using established criteria but does not provide detailed guidance on how the PBT assessment should be performed. As a consequence, for both the applicant and the regulatory bodies it might not be sufficiently clear how the PBT/vPvB criteria should be used and what testing strategy should be followed in the light of the test requirements of the VICH guidelines.

3. Discussion

Guidance is needed addressing the following topics:

- Criteria for identification of potential PBT/vPvB

- Assessment strategy

- Management strategy for veterinary medicinal products identified as PBT/vPvB (including compartments of concern)

[1] http://www.ospar.org/
[2] http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm
[3] Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38

4. Recommendation

The Committee recommends to prepare a guideline for the PBT assessment of veterinary medicinal products addressing the topics stipulated in section 3.

5. Proposed timetable

Consultation concept paper July-September 2010.

Draft guidance for consultation to be published by beginning of 2011.

6. Resource requirements for preparation

The Environmental Risk Assessment Working Party to prepare the guideline.

7. Impact assessment (anticipated)

Impact assessment for regulatory authorities, industry and other interested parties

The guideline will clarify the procedure of the PBT assessment for veterinary medicinal products.

For industry and other interested parties, the impact of the guideline will be limited as only a few number of substances used in veterinary medicinal products are expected to be PBT/VPvB candidates.

8. Interested parties

Pharmaceutical industry, enviromentalists and regulatory bodies.

9. References to literature, guidelines, etc.

- Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38 (http://www.ema.europa.eu/pdfs/vet/era/41828205enfin.pdf)
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals AgencyPesticides 1107/2009
- Stockholm Convention on persistant organic pollutants (POPs) (http://chm.pops.int/Home/tabid/36/language/en-US/Default.aspx)