



European Medicines Agency
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PRESS RELEASE

EMA Conference on Environmental Risk Assessment for Human and Veterinary Medicinal Products 27-28 October 2005

The European Medicines Agency held a conference with interested parties on 27-28 October to discuss the current state and future developments in the area of environmental risk assessment for human and veterinary medicinal products.

Medicinal products used for the treatment of humans or animals may have an impact on the environment. The new EU pharmaceutical legislation requires companies to submit an environmental risk assessment as part of a marketing authorisation application.

More than 130 participants from the Agency's Committee for Medicinal Products for Human Use (CHMP) and Committee for Medicinal Products for Veterinary Use (CVMP), the Committees' Working Parties, national competent authorities, the European Commission, academia, dedicated interest groups and industry met in four sessions to review and discuss key issues on:

- Exposure of the environment to veterinary and human medicinal products
- Regulatory aspects of environmental risk assessment for medicines
- Risk management and mitigation measures
- Future developments and impact.

The following provides an overview of each session:

Session I: Exposure of the environment to veterinary and human medicinal products

The subject of pharmaceuticals in the environment has become more important to regulators and industry as a consequence of the widespread detection of pharmaceuticals in environmental samples. Exposure-modelling and results of monitoring studies were discussed, and data gaps required for modelling and priority-setting were flagged. The environmental concentrations observed are unlikely to exert acute ecotoxicological effects. However, there is a need to obtain more data on the chronic ecotoxicological effects of human pharmaceuticals before potential risks can be ruled out. Different models currently used in EMEA and VICH guidelines, comparisons with actual exposure data, and proposals for improvements to exposure-modelling, that should be representative throughout Europe, were presented and discussed.

Session II: Environmental risk assessment and the regulatory aspects for pharmaceuticals

For human and veterinary medicinal products, the legal requirements of the new legislation for an environmental risk assessment (ERA) have been clarified. ERA applies to all new applications, to variations (Type II) and to line extensions. In relation to renewals for veterinary medicinal products, the consideration of the risks to the environment is required as part of the risk-benefit re-evaluation. However, the potential impact on the environment is not part of the assessment of the risk-benefit

balance of a human medicine. If appropriate, measures, to limit the impact on the environment shall be envisaged on a case-by-case basis.

A new technical guidance document on environmental impact assessment of veterinary medicines, supplementing the current VICH guidelines with technical details, is currently being prepared and should be sent out for consultation soon.

Following public consultation, there are no major concerns from industry on the current technical content of the draft ERA guideline on human medicinal products. Key discussion points were whether the predicted environmental concentration (PEC) estimation be based on default values or actual data, and the possibility of introducing more flexibility and science-driven testing strategy. Depending on the number of changes that are necessary, the finalisation of the guideline could be possible in early 2006.

Session III: Risk management/mitigation - Too much or not enough?

The speakers addressed the perspective of the national competent authorities on risk management/mitigation. A comparison was made between the risk management/mitigation possibilities for veterinary and human medicinal products. Intensive discussion on the acceptability of labelling as an effective mitigation measure took place. Discussions on the appropriate way of addressing the ecotoxicity assessment for veterinary and human medicinal products that are already authorised took place, and the meeting was informed that the German Authorities have launched a research project addressing this with respect to veterinary medicinal products, involving other EU Member State authorities.

Session IV: Future Developments/Impacts

ERAPharm is a promising project, funded by the European Commission, intended to improve both the environmental hazard and exposure-assessment for pharmaceuticals. The project will finish in September 2007. In addition, the Water Framework Directive under preparation by the European Commission was discussed, which shall merge different pieces of legislation addressing chemicals in the aquatic environment in the near future. A prioritisation list was developed for chemicals of concern, and, in the near future, pharmaceuticals might also be included.

Organisational matters

Conference proceedings will be made available on the website.

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This press release, together with other information on the work of the EMEA, can be found on the EMEA website at www.emea.eu.int.

Media enquiries only to:

Monika Benstetter

Tel. (44-20) 74 18 84 27, E-mail: <mailto:press@emea.eu.int>