EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Human Medicinal Products (CHMP)

Concept paper on the revision of the 'Guideline on the environmental risk assessment of medicinal products for human use' (EMEA/CHMP/SWP/4447/00 corr 2)

Agreed by Safety Working Party	April 2016
Adoption by CHMP for release for consultation	28 April 2016
Start of public consultation	4 May 2016
End of consultation (deadline for comments)	31 October 2016

The proposed guideline will replace guideline on the environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/447/00 corr 2).

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

Keywords	***Environmental, Guideline, Medicinal products, Human***

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1. Introduction

In 2006, the 'Guideline on Environmental Risk Assessment of Medicinal Products for Human Use' (EMEA/CHMP/SWP/4447/00) was published. The purpose of the guideline is to describe the assessment of potential environmental risks of human medicinal products including considerations for risk mitigation measures to limit their impact on the environment. Minor, editorial, changes have been included at later stages in the current version (EMEA/CHMP/SWP/4447/00 Corr 2). A Questions and Answer document (EMA/CHMP/SWP/44609/2010) to the Guideline was released in 2011, and has been updated recently.

2. Problem statement

The Guideline on Environmental Risk Assessment (ERA) of Medicinal Products for Human Use has now been available for 10 years. The implementation of some aspects of the current guideline is not straightforward. These issues have been addressed in the Q&A, however within the limits of such a document which is aimed at clarifying an existing guideline. Also, based on the experience that has been gained with the current guideline, a review of its adequacy in assessing the potential environmental risks of human medicinal products (HMP) is warranted. In addition, it would be beneficial to update the guideline taking into account scientific developments and changes in relevant guidance documents under other legislative frameworks.

3. Discussion (on the problem statement)

In accordance with Article 8(3) of Directive 2001/83/EC, as amended, a new marketing authorization application shall be accompanied by the evaluation of the potential environmental risks posed by the medicinal product. For some types of applications or products the guideline indicates that the ERA may consist only of a justification where the applicant should explain the reasons why a risk to the environment is not expected. However the assessment of such justifications is often an area of debate due to the lack of guidance for applicants on what constitutes an adequate justification. This is a recurrent issue in particular for known active substances and/or generics, where data protection rules do not allow cross reference without consent from the originators. These issues will be addressed in the revised guideline, within the frame of the current legislation.

Improvement and facilitation of the ERAs for human medicinal products could be achieved by systems of data sharing and/or by periodic updates of the ERA. This would however require legislative changes and/or activities of the pharmaceutical industry and can therefore not be handled within revision of the guideline.

For the revision of the guideline, the following aspects will be addressed:

1. Review of the tiered approach strategy and triggers for further assessment and additional studies. This includes a review of the use of consumption data.
2. Review of the groups of medicinal products for which data are not currently required due to the nature of their constituents and clarification of the scientific conditions for such approaches.
3. Review of possibilities for better utilisation of data in the public domain to make a scientifically sound assessment of the environmental risk, with a special interest to avoid unnecessary repetition of animal studies (e.g. fish).

4. Review of whether the approaches for substances with specific properties (e.g. PBT substances, endocrine disruptors, mixtures, substances highly toxic to specific taxonomic groups) are still adequate.

5. Review of the applicability of the current test strategies to pharmaceuticals, considering their known pharmacodynamic and pharmacokinetic properties.

6. Update of test systems recommended in the current guideline based on new scientific information and if possible, their validity for specific types of medicinal products.

7. Consideration for recommendations of additional test systems/assays including areas not, or poorly, addressed in the present guideline.

8. Review of possible options for risk mitigation measures, including discussion on how to monitor the potential impact of pharmaceuticals in the environment.

4. Recommendation

The Safety Working Party (SWP) of the CHMP recommends the revision of the 'Guideline on the environmental risk assessment of medicinal products for human use' (EMEA/CHMP/SWP/4447/00 corr1). The revision of the guideline will be based on a scientific review and evaluation of the performance of the present guideline in relation to the new scientific information.

5. Proposed timetable

It is anticipated that a draft of the revised guideline will be available 18 months after the CHMP adoption of this concept paper. The draft guideline will be released for a 6-month public consultation.

6. Resource requirements for preparation

The preparation of this guideline will involve the Safety Working Party of the CHMP and in particular a multidisciplinary drafting group composed of SWP members and specialised ERA assessors from EU National medicines agencies and environmental agencies.

7. Impact assessment (anticipated)

The revised guideline is anticipated to provide harmonised ERA requirements and testing up-to-date with current scientific knowledge, as well as an ERA stepwise approach optimised to the use of human medicines.

8. Interested parties

Pharmaceutical industry developing HMPs, consultants, EU national competent authorities and other regulatory agencies. Research Organisations and Societies for environmental toxicology and chemistry.

9. References

Guideline on the environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/4447/00 corr 2).

87 Questions and answers on 'Guideline on the environmental risk assessment of medicinal products for
88 human use (EMA/CHMP/SWP/44609/2010).