EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Environmental risk-assessment of medicines

An agency of the European Union

Assessment of the environmental impact of medicinal products is a legal obligation, and must be performed to evaluate and limit potential adverse effects of medicines on the environment.

When is an environmental risk-assessment performed?

The environmental risk-assessment (ERA) of medicinal products is to be performed by companies during the development of new medicines.

The results are submitted to the European Medicines Agency for evaluation in conjunction with the scientific data on quality, safety and efficacy required to support the request for marketing authorisation of medicinal products intended for human or veterinary use via the centralised procedure.

How is an ERA performed?

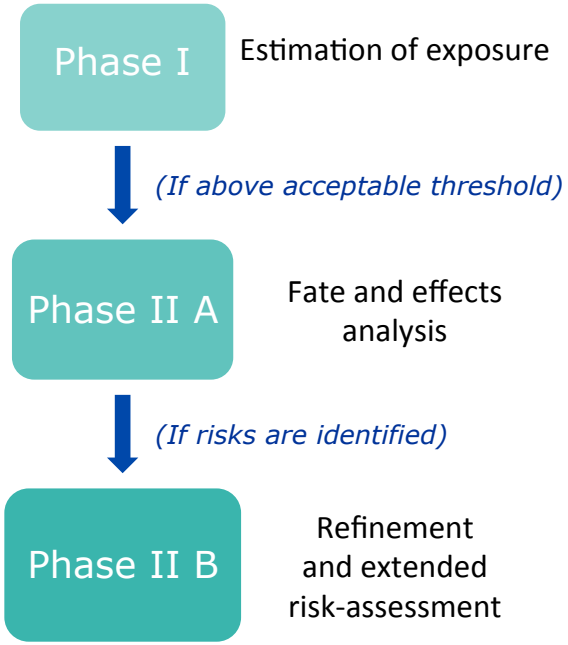
An ERA is performed in a stepwise approach, which starts with an initial screening phase (Phase I), aimed at identifying the environmental exposure of pharmaceuticals based on their potential for bioaccumulation and persistence in the environment.

If, following this preliminary assessment, significant environmental exposure is anticipated, or if specific risks are identified due to compound-specific characteristics, a number of studies should be performed (Phase II).

The Phase II tests identify the fate of medicinal products in the environment and their potential effects on representative organisms (e.g. fish or daphnids, for the aquatic environment).

For this purpose, the results of various widely accepted test methodologies (laid down mainly by the Organisation for Economic Co-operation and Development, OECD) form the basis of the risk-assessment process, which may be further extended on a case-by-case basis, depending on the outcome of the assessment.

ERA phases



What are the outcomes of the ERA?

The outcome of an ERA will serve as the basis for:

- minimising the amount of medicinal product released into the environment by appropriate measures;
- identification of specific risk-minimisation activities to be taken by the user of the medicine;
- appropriate labelling, to facilitate the correct disposal of the medicinal product by patients/ healthcare professionals (e.g. ensure that the medicine is disposed of in special containers or returned to a pharmacy).

Further information

- Directive 2001/82/EC — Community code relating to veterinary medicinal products.
- Directive 2001/83/EC — Community code relating to medicinal products for human use.
- Guideline on the ERA of medicinal products for human use (EMEA/CHMP/SWP/4447/00).
- Environmental impact assessment (EIAS) for veterinary medicinal products — Phase I & II (CVMP/VICH/592/1998 - CVMP/VICH/790/2003).

Environmental risk-assessment

Environmental risk-assessment of medicinal products for human and veterinary use is the process through which the European Medicines Agency ensures that the potential effects of pharmaceuticals on the environment are studied and adequate precautions taken in case specific risks are identified.

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Further information

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