



# Environmental Risk Assessment for the European Medicines Agency

Medicinal products used for the treatment of humans or animals may have an impact on the environment. This EU pharmaceutical legislation requires companies to submit an environmental risk assessment (ERA) as part of an assessment report required for the marketing authorisation application.

As a result of the EU pharmaceutical legislation, the European Medicines Agency (EMA) requires an Environmental Risk Assessment (ERA) for any human or veterinary product you want to market. The ERA will be part of the assessment report that needs to be submitted. An ERA is required for:

- All new marketing authorisation applications.
- Variations (type II).
- Line extensions (for medicinal products for human use if there is an increase in environmental exposure, e.g. a new indication may result in a significant increase in the extent of the use).

Royal Haskoning experts can assist you through all steps of your ERA obligations.

Chemicals Management is an advisory group within Royal Haskoning. This group consists of 25 experts, including toxicologists, chemists, industrial hygienists as well as Regulatory Affairs- and Information specialists. We are trained chemicals management consultants (e.g. industrial chemicals, cosmetics, biocides, pesticides, etc.) that assist companies in the implementation and management of ERA services. Our extensive experience within various industry branches and with authorities enable us to support you on every management level in organizing ERA services in relation to other chemicals management activities within your company.



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## **ERA (Environmental Risk Assessment)**

ERA consists of two phases. ERA phase 1 for veterinary products can be completed by answering questions in a decision tree. For medicinal products for human use, phase 1 is an exposure driven screening phase.

When phase 1 shows that no environmental risk is expected, phase 2 is generally not necessary and the ERA is completed at this point. For some veterinary products and for substances that may affect the reproduction of vertebrates or lower animals at concentrations lower than a threshold value, phase 2 is always required!

ERA phase 2 is a full risk assessment based on environmental fate and effect data using a tiered approach. In tier A, a basic data set on environmental fate and effects is used to calculate no-effect concentrations. In tier B, the assessment is further refined when considered necessary. Also selection and assignment of appropriate control measures (risk mitigation measure) are to be considered.

## **Royal Haskoning services on ERA**

Royal Haskoning experts can assist you with services on ERA phase 1 and phase 2. For phase 2, we can support you with the collection of all relevant data and conducting a data gap analysis. Royal Haskoning experts can conduct a complete phase 2 ERA according to tier A and/or tier B approach. We have experience with the calculation procedures and have contributed to the development of models that are used in these procedures. Royal Haskoning experts can also advise you concerning the selection of risk mitigation measures.

## **Royal Haskoning**

Royal Haskoning is a Dutch company employing 4,400 consultants, architects and engineers. Since 1881 we use our extensive network of knowledge, expertise and relations to deliver high quality support and solutions to you, our clients. Our headquarters are situated in the oldest city of the Netherlands, Nijmegen. In addition, we have regional offices in 20 countries in the world to support us.

The company is organized in expertise-based divisions, which consist of advisory groups. These groups all have their specific specialization. It is this diversity in expertise from which we derive our professional strength. We are specialists interacting to share and enhance our knowledge and experience for the benefit of our clients

## **Our worldwide offices**



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