ENVIRONMENTAL RISK ASSESSMENT (ERA) OF MEDICINAL PRODUCTS FOR HUMAN USE

The updated guideline on the environmental risk assessment (ERA) of medicinal products for human use - Revision 1 (EMEA/CHMP/SWP/4447/00 Rev. 1 - Corr.) came into effect 1st September 2024, bringing a more holistic and rigorous approach to the environmental risk assessment of medicinal products. The revised guideline better aligns with other EU ERA regulatory frameworks, for example those applicable to chemicals (REACH), biocides, and veterinary. The ERA promotes a two tiered approach, emphasizes assessing multiple endpoints (e.g., growth, reproduction, survival) rather than relying on one single endpoint and uses a broad range of concentrations to capture effects at lower levels. The adoption of a dose-response curve (specifically, the EC10 value) instead of the earlier binary "effect/no effect" approach, enhances the sensitivity and statistical power, and allows for better risk assessment to be conducted and one that is more aligned to REACH, biocides, and pesticide approaches.

OVERVIEW OF OUR SERVICES

- Preparation of EMA compliant with EMEA/CHMP guidelines.
- Literature review on endpoints of significance to ERA to find new information on ecotoxicity of active substances.
- Evaluation of the relevance and reliability of ecotoxicity and eco-fate data using CRED criteria.
- Assessment of intrinsic properties of substances such as PBT and endocrine-disruption.
- Development of ecotoxicology and ecological fate testing strategies.
- Securing contract research organizations and monitoring of study performance.
- Liaison with competent authorities, responding to comments and questions during registration process.

ToxMinds
THINKING AHEAD IN TOXICOLOGY

ToxMinds has over a decade of experience in helping clients navigate the pharmaceutical, biocide, and REACH regulations and has in-depth expertise in environmental risk assessment across these frameworks. We can help you to proactively manage the potential environmental risks arising from pharmaceuticals in the environment, ensuring that they are adequately studied, and suitable precautions are taken in case specific risks are found.

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