Medical Writing by ELC

Environmental Risk Assessment (ERA)

When is it required?

1. All New Marketing Authorization Applications

Under Article 8(3) of Directive 2001/83/EC, an ERA is required for all new applications for a human medicinal product through a centralized, mutual recognition, decentralized, or national procedure.

An ERA is to be provided in Module 1.6 of the MA application; if the ERA is not included, then a justification should be provided.

2. Type II Variations and Extension Applications

For existing marketing authorizations, the environmental impact should be evaluated to check if there is a potential increase in the environmental exposure.

Phases of ERA

Phase I.

- Calculation of exposure estimates by comparing the proposed dosage against the default action limit
- If the limit is exceeded, a complete risk assessment of the active ingredient will be required (Phase II)

Phase II.

- Review of existing company and open literature data
- Initiate and monitor environmental fate and effects studies
- Advise on tiered testing
- Study protocol review and monitoring
- Peer review of draft study reports

**Note: Availability of data will differ for new and generic medicines*

How ELC can support your project

Our experts have extensive experience in assisting both proprietary and generic pharmaceutical companies in conducting ERAs in support of their marketing authorization applications. This includes both new and existing medicinal products.

Our ERA services include:

- Evaluating whether, for generic or well established pharmaceuticals, a complete ERA is actually required
- Support with management of scientific advise (if requested by the applicant from the CHMP)
- Preparation of Expert Report for submission in Module 1.6 of the dossier
- Post-submission support with authorities

ELC Group is a fully-fledged global regulatory partner, working with pharmaceutical stakeholders for over a decade. From the development stage through to the implementation of clinical trials, completion of product registration, and successful marketing of the product, ELC Group aligns itself as a strategic partner to help pharmaceutical companies achieve their goals.

Concept to Compliance

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