Pharmaceuticals:
Environmental Impact Assessments

The specialist environmental team at Enviresearch can help you perform the Environmental Risk Assessment (ERA) required for all applications for marketing approval for human medicinal products (HMPs), complying with Directive 2001/83/EC.

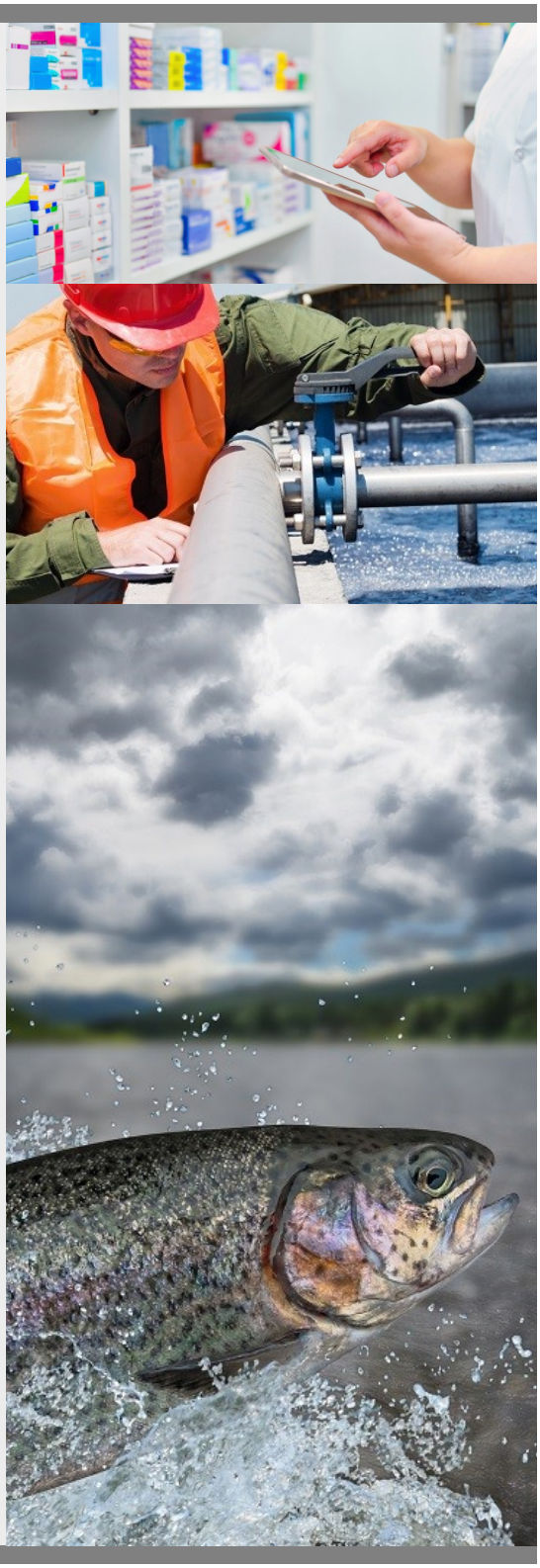
The current European Medicines Agency (EMA) guidelines for performing ERA for HMPs came into effect in 2006, with supporting details provided in a Question & Answer document (EMA, 2016). However, the EMA guidelines have recently undergone their first major revision since 2006 (EMA, 2018). The new guidelines are in the draft stage, and the public consultation period has closed.

As well as providing further technical details on assessment methods and a decision tree to help clarify when new ERA studies are required; the proposed revisions in the new EMA draft guidelines include the following notable changes;

- A new section on the requirements for addressing Endocrine Active Substances, resulting in a more tailored Phase II ERA with specific tests recommended for different mechanisms of action.
- The expensive & lengthy OECD test 308 on transformation in aquatic sediments is no longer necessarily required (except where triggered by PBT assessment). The test is replaced with mandatory sediment toxicity testing in Phase II.
- Soil assessments will now be triggered after consideration of PEC_{SW}, and not just the K_{oc} in sludge.

Enviresearch can guide you through the new requirements for your product; conduct the necessary data searches and the data gap analysis; perform the PBT assessment and the ERA with refinements where required.

For further information please contact Senior Risk Assessor, Louise Pope, Louise.Pope@enviresearch.com + 44 (0) 191 243 0687.



enviresearch

34 Grainger Park Road, Newcastle Upon Tyne, NE4 8RY

Phone: +44 (0) 191 243 0687, www.enviresearch.com