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1. http://ec.europa.eu/growth/sectors/chemicals/legislation/index_en.htm

European Commission

Science for Environment Policy

New controls recommended to reduce environmental risks of human pharmaceuticals

Controls on pharmaceutical production in the EU should be changed to guard against the spread of antibiotic resistance, protect wildlife and improve transparency in the industry, a team of scientists from Sweden and the UK recommends. The scientists propose 10 changes to the environmental risk assessment (ERA) of pharmaceuticals.

Pharmaceuticals pose a range of risks to the environment. These include the spread of resistant bacteria by the release of antibiotics, the release of toxins into aquatic ecosystems, and the poisoning of wildlife through predation on livestock treated with pharmaceuticals.

EU companies have had to explore the risks to the environment posed by all new medicines they produce since 2006, according to guidelines produced by the European Medicines Agency. The authors of the study recommend that this should also extend to products approved before 2006.

Moreover, while the results of ERAs are used to identify possible risks associated with pharmaceuticals, they cannot be used to refuse market authorisation for human pharmaceuticals. The authors suggest this should change in order to give the assessments greater authority.

A recent study showed that 83% of ERAs performed during 2011–1012 were of unsatisfactory quality or incomplete. Furthermore, under the existing system, pharmaceutical companies are allowed to keep the location of production sites confidential, even though water bodies and soil beside such sites can become contaminated with high concentrations of active ingredients. The authors believe that making the location of such sites publicly available would help scientists and journalists link severe cases of environmental pollution to the relevant company and product, and result in better informed choices by consumers and the healthcare sector.

The authors are also in favour of making all ERA dossiers publicly available, as is already the case for the majority of data under the EU's legislation for industrial chemicals, REACH[1]. They argue that this move would lead to even greater transparency. As well as increasing transparency, the researchers recommend promotion of the REACH approach in other ways, including the use of a common ERA for each pharmaceutical ingredient, to prevent each company producing a separate assessment for the same compound.

Based on their review of the latest scientific understanding, the authors warn that the greatest risk to human health posed by pharmaceutical residues is the promotion of antibiotic resistant bacteria. Antibiotics can enter the environment via wastewater treatment plants and even a low concentration can cause harmless bacteria to pass resistance genes to pathogenic ones. While this risk is not currently addressed as part of an ERA, it could be achieved using existing data.

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European Commission

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New controls recommended to reduce environmental risks of human pharmaceuticals *(continued)*

Aquatic wildlife can be particularly vulnerable to the effects of pharmaceutical residues. A man-made form of oestrogen is known to impair reproduction in fish, for example, while frogs exposed to residues of the morning after pill can become sterile. The authors recommend focusing resources on the most vulnerable species and the most problematic substances, by incorporating toxicological and pharmacological data generated during the drug development process.

Finally, the authors acknowledge that the timetable for implementing each of their recommendations might differ depending on its complexity, controversy and how much time is needed to gain acceptance. In order to fulfil some of the recommendations, legislative changes to the European Directive for medicinal products for human use may be needed.

This study builds on previous research into the effects of pharmaceuticals in the environment and shows the important influence drugs can have on the environment. It also indicates how some of the risk assessment and regulatory solutions developed under environmental policy may be transplanted to the regulation of pharmaceuticals for greater efficacy as well as to reduce the adverse impacts of present and future pharmaceutical compounds on the environment.

Finally, it recommends modifications to the current legislation on human pharmaceuticals so as to better take into account risks and reduce adverse impacts on the environment. These recommendations are informed by existing European regulatory frameworks for chemicals, such as REACH.

Note: For a policy brief based on this research, see http://www.mistrapharma.se/outcomes/policy-brief-27166372

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