Hazard and risk assessment of human pharmaceuticals in the environment

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Low levels of many active human pharmaceutical ingredients (APIs) are detected in the aquatic environment. The dominant pathway for these residues is the administration to patients and excretion of their residues or the breakdown products entering sewage treatment systems and, after incomplete elimination, the surface waters. Environmental risks of new medicinal products are currently assessed based on a regulatory guideline on a standardized assessment scheme (EMEA, 2006) , in order to fulfill the requirements for market approval. The present testing scheme, however, is not designed to take into account specific properties of pharmaceutical substances in environmental organisms and is typically conducted when a medicinal product is close to an application for market approval. Scientifically based information on potential environmental properties, however, may be required during the early development process of an API, in order to be prepared for specific environmental concerns and consequently, to design substance specific environmental testing strategies. Very little information yet is available on a systematic approach to investigate the responses of environmental organisms to substances with specific properties such as physico-chemical behavior, pharmacological mode-of-actions and (mammalian) toxicity. Thus, model approaches could support predictions of the potential environmental risks of un-tested APIs during early development or on the market. This could help to focus experimental research on ecotoxicological effects on specifically sensitive organisms, life-stages and specific test designs for critical endpoints (intelligent testing).