Legislative Action at the Beginning of the Life Cycle of Pharmaceuticals

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The Situation

Up to 2011 192 active pharmaceutical ingredients had been detected in the aquatic environment in Germany, 131 of them in surface waters, 55 in groundwater, 23 in drinking water.
35 active components have been analysed in surface waters, 13 agents in groundwater in a maximum concentration of more than one microgram per litre (1).

The Problem

There are only sufficient data from 70 ingredients detected in surface waters which allow an evaluation of the effects on biotic communities. 28 pharmaceutical ingredients have been identified in a concentration that may cause detrimental effects in the aquatic ecosystem (1).
All problematic residues in the aquatic environment are due to pharmaceuticals that have passed the authorization process before 2006.

Necessary Legislative Action

1. All pharmaceuticals on the market have to pass an environmental audit.
2. All published and unpublished informations on environmental effects of pharmaceutical residues have to be collected and evaluated by a neutral agency.
3. The environmental compatiblity of pharmaceuticals must become an effective criterion in the authorization procedure (2) with the following consequences.
4. A new pharmaceutical is not allowed to enter the market if there is already another product with the same therapeutic utility which is less detrimental for the aquatic environment.
5. All pharmaceuticals on the market have to be substituted if a new product with the same therapeutic utility shows a better aquatic compatibility in the authorization process.
6. Environmentally optimized pharmaceuticals should be favoured in the patenting process.

References

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(2) Kern, Katharina: Rechtliche Regulierung der Umweltrisiken von Human- und Tierarzneimitteln, Berlin 2010

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