Joint Press Release of ERM Coalition and ZeroPM

Upcoming Pharma legislation must connect milestones of EPR in UWWTD with new CLP amendment

Karlsruhe, 13.04.2023: In the recast proposal of the EU Urban Wastewater Treatment Directive (UWWTD) published in October 2022 by the European Commission, an Extended Producer Responsibility (EPR) was proposed for medicinal products for human use and cosmetic products. These two product groups were chosen as they represent the main sources of micropollutants found in urban wastewater requiring additional (quaternary) treatment. The EPR system obligates producers (including importers) to cover monitoring and quaternary treatment costs if they place medicinal and cosmetic products on the national market which pollute urban wastewater with micropollutants above two tonnes per year. The financial contribution of each producer will be established based on the quantities and toxicity of micropollutants found in wastewaters.

On the 29th of March 2023, the European Commission postponed its proposal for the revision of the EU general pharmaceuticals legislation for the second time. However, the introduction of hazard classes for persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances into the Classification, Labelling and Packaging (CLP) Regulation, will go ahead. The steps forward made by the CLP Regulation, the UWWTD and its long-awaited EPR, can be further strengthened when the "pharmaceuticals in the environment" approach is properly implemented. By applying the polluter pays principle correctly, costs of environmental damage caused by pollution are covered by profits made from such pollution.

In its Special Report 12/2021, the European Court of Auditors made the importance of allocating costs to producers (and importers) to implement the polluter pays principle clear: "*By applying the Polluter Pays Principle (PPP), polluters are incentivised to avoid environmental damage.*" The question, however, becomes how can pollution be tackled at its source?

"*European Union legislation now needs coherence between the UWWTD, pharmaceutical legislation and the amended CLP Regulation: In extended Environmental Risk Assessments (ERAs) as part of the authorisation, PMT/vPvM criteria according to the CLP Regulation have to be included*", Prof. Dr. Matthias Maier, IAWR President points out. "*To protect the environment and human health we need a development towards 'safe and sustainable by design' chemicals and pharmaceuticals. Here, the ZeroPM approach can lead the way*."

ZeroPM co-coordinator Sarah Hale explains: "*ZeroPM will interlink prevention, prioritization and removal strategies to protect the environment and human health from persistent and mobile substances. Persistent and mobile substances do not break down over appreciable time scales and can travel long distances with water. This - in combination with the fact that they are difficult to remove using common water treatment technologies - means that advanced, and thus costly, treatment methods are required. There are many persistent and mobile substances that are used in medicinal products and cosmetics*."

Coherence in legislation is strongly needed to tackle the increasing trend of organofluorine-containing pharmaceuticals. Like PFAS, these chemicals contain the extremely strong carbon-fluorine bond that does not degrade naturally. The presence of a CF_3 group is considered to

improve the performance of the medication but can also lead to the formation of the persistent degradation products including the extremely persistent and ubiquitous trifluoroacetic acid (TFA). Rising TFA concentrations in the environment are already evident. Emma Schymanski, ZeroPM partner from the University of Luxembourg states that "*Of the 19,118 pharmaceuticals in PubChem, 1,801 are organofluorine, of which 800 are PFAS and 669 contain CF_3.*" ZeroPM co-coordinator Hans Peter Arp adds *"We call for a comprehensive alternatives assessment for these pharmaceuticals that are PFAS, and also a phase-out if their use is not critical for the functioning of society or where there is an acceptable, safer alternative available."*

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