EFPIA review of the European Commission approach to allocating toxic load to pharmaceuticals in urban wastewater



- We support the objectives of the Urban Wastewater Treatment Directive (UWWTD) to protect the environment and human health.
- Any regulatory measures aimed at tackling micropollution in the context of UWWTD must be proportionate, science-based and comply with Polluter Pays Principle.



The European Commission's assessment of pharmaceutical contribution to urban wastewater toxic load is based on insufficient data and is scientifically flawed.¹



Toxic Load²



Micropollutant concentration in urban wastewater



Predicted No-Effect Concentration (PNEC) - the limit below which a chemical is unlikely to harm the environment

Pharmaceutical contribution to the toxic load is overestimated – potentially up to 3 times – due to both overestimating the amount of pharmaceuticals in wastewater and the toxicity that pharmaceuticals have.³



The toxicity of pharmaceuticals was overestimated by using computer-simulated toxicity estimations while ignoring reliable measured data that was collected using rigorous ECHA/EMA protocols.



A lack of representative concentration data of micropollutants in urban wastewater hinders any valid assessment.⁴



Each micropollutant was assigned to a single sector, which is an over-simplistic and biased approach. Some micropollutants were falsely assigned to pharmaceutical sector.



Ignoring the impact of tertiary treatment, including potential biodegradability of micropollutants, inflates the overall toxic load of micropollutants.

Telmisartan (anti-hypertension medicine) is ~90,000 times less toxic than computer-simulated prediction.

There are data gaps for 40% of the analysed micropollutants. Such gaps were filled only for pharmaceuticals, thus inflating pharmaceutical toxic load compared to other micropollutants.

Some micropollutants (e.g. Chloroxylenol, benzethonium chloride) are attributed only to pharmaceuticals despite being used by various sectors.

This will also change the contribution of pharmaceuticals to the toxic load.

^{1.} Bio Innovation Service et al. (2022), "Feasibility of an EPR system for micro-pollutants."

[.] Based on the European Commission's approach, "toxic load" is the ratio between the concentration of a micropollutant in urban wastewater and its toxicity (Predicted No-Effect Concentration – PNEC).

s. RSA Study "Review of the European Commission approach to allocating toxic load to pharmaceuticals in urban wastewater" based on the analysis of datasets and approaches applied by the European Commission (Bio Innovation Service et al. (2022), Feasibility of an EPR system for micro-pollutant.

^{4.} As Highlighted in the research used for the EU Commission Feasibility study "Pistocchi et al. (2021), Treatment of micropollutants in wastewater: balancing effectiveness, costs and implications."

Estimates of "toxic load" are highly sensitive to data availability and quality, underscoring the importance of a thoughtful scientific approach for research integrity and informed decision-making.



Initial assessment (European Commission Feasibility Study)¹ Applying measured toxicity data for telmisartan (anti-hypertension medicine)

Further data refinement
(applying available measured toxicity
data and using estimates for all
projected micropollutants that don't
have measured concentrations)

To address the inconsistencies in the assessment of toxic load in the wastewater and ensure fair implementation of the UWWTD, EFPIA recommends:



Pause the implementation

of the two sector-specific Extended Producer Responsibility (EPR) provisions.



Implement a thorough and transparent reassessment

of the contribution to "toxic load" from various substances based on scientific and unbiased approaches.



Develop alternative solutions for EPR implementation that would be science-based, proportionate, comply with Polluter Pays Principle and that do not jeopardise patient access to medicines and security of supply.