Press release

Medicines for Europe intervenes in legal challenge against Urban Wastewater Treatment Directive's EPR scheme

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Medicines for Europe has formally applied to intervene in the legal cases filed by its members before the General Court of the European Union against the establishment of an Extended Producer Responsibility (EPR) scheme under the recast of the Urban Wastewater Treatment Directive (UWWTD) adopted in November 2024.

The EPR scheme imposes a discriminatory and disproportionate cost burden on the generic pharmaceutical industry, which would threaten patient access to critical and essential medicines.

The generic industry supplies 70% of medicines dispensed and 90% of critical medicines in the EU(1), while representing only 19% of the market value. The essential role of the sector for patient access, healthcare sustainability and security of supply, as well as its low and strictly regulated prices, contrasts with the staggering high share of the costs of the EPR system to be burdened on this industry (it is estimated that up to 60% of the multi-billion investment and operational costs may have to be borne by the generic sector).

Moreover, now that the European Commission has finally published the list of substances used in its impact assessment, after several requests for access to documents (2), it is evident that the estimated attribution of 66% of the toxic load to pharmaceuticals, which underlies the one-sided cost allocation, is based on completely flawed data. The list includes significant inaccuracies and assumptions in substance concentrations and, more worryingly, toxicity values derived from computer-generated predictive models rather than laboratory ecotoxicity data. The latter is the standard method, required by both the European Medicines Agency (EMA), which does not even accept computer-generated predictive models, and the European Chemicals Agency (ECHA).

For example, Telmisartan, a widely used medicine for treating high blood pressure and cardiovascular conditions, was deemed the most toxic substance in the study (41% of the total toxic load of all residues in the water) due to an assigned predicted no-effect concentration (PNEC)(3) nearly 90,000 times lower than the value supported by publicly available laboratory ecotoxicological studies. Similar major errors, with discrepancies of several orders of magnitude, were made for the other pharmaceutical substances at the top of the list(4).

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In addition to the serious flaws in the scientific basis of the data with the science behind the data, the Commission has also substantially underestimated the impact of the costs of the EPR scheme on medicines used by millions of patients in Europe every day.

For example, projections based on the costs estimated by the Netherlands (more than six times higher than the Commission's forecasts) show that due to EPR:

- Metformin, a medicine used by up to 50% of patients with diabetes, faces increases in the cost of treatment by up to 875%
- Amoxicillin, a first-line antibiotic medicine, would see costs rise by up to 368%
- Levetiracetam, a widely used epilepsy medicine, faces increases of up to 321%

Adrian van den Hoven, Medicines for Europe's Director General, commented "*Medicines for Europe aims to intervene in support of the legal challenge of the EPR system in the Urban Wastewater Treatment Directive. This is a discriminatory and disproportionate levy that is completely unworkable, and threatens patient access as well as security of supply of medicine. In addition, the data shared by the Commission confirms that the proposal was based on widely incorrect calculations of the impact of medicine consumption on urban waste water.*"

References

1. European Medicines Agency, Union list of critical medicines, December 2024.
2. Electronic Access to Commission Documents (EASE), disclosure in April 2025.
3. The Predicted No-Effect Concentration (PNEC) value is the concentration of a substance below which no adverse effects on the environment (in this case the aquatic ecosystem) is expected. The lower the PNEC value, the higher the ecotoxicity.
4. Medicines for Europe note on Bio Innovation list of substances found in urban wastewater, July 2025. The note is informed by an expert technical review conducted by Ramboll.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on LinkedIn and X @medicinesforEU.