

Leading manufacturers appeal in proceedings against discriminatory wastewater fees on medicine before European Court of Justice

Brussels, 27 April 2026

Medicines for Europe members Adamed, Fresenius Kabi, InsudPharma, Polpharma, Sandoz, Stada, Zentiva, TEVA and Viartis will appeal before the European Court of Justice today regarding the admissibility of their annulment actions against what we consider discriminatory and legally flawed cost allocations under the Urban Wastewater Treatment Directive (UWWTD). This **appeal** is about seeking to ensure an outcome **preventing medicine shortages, ensuring health security and maintaining the manufacture of critical and essential medicines in Europe**.

The case regards the legal basis, design and impact of the so-called Extended Producer Responsibility (EPR) Scheme, which were not assessed by the first instance General Court. The General Court had only dealt with the admissibility of the actions and denied standing of the companies challenging the EPR scheme, without considering the negative impact of this scheme on fundamental rights, healthcare systems and the competence of the EU Member States. The EPR scheme underestimates the cost that will fall on medicines (up to €11 billion per year which is 10 times higher than the Commission's estimates) and overestimates the claimed toxicity levels caused by patient use (and excretion) of medicines. When using laboratory test data¹, as required by the European Medicines Agency for environmental risk assessment², the 4 molecules assessed by the Commission amount to less than 1% of the total chemical residues instead of the claimed 58%.

This legislation will have dramatic effects on public health and on manufacturers of medicines:

- The **epilepsy medicine** levetiracetam, which is **essential for children, could face fees of 322%**, making it uneconomic to supply patients in Europe, which would have dramatic public health consequences.
- **16 million EU patients** rely on **diabetes medicine** metformin, which could face **fees of 875%** making it uneconomic to supply the EU. Switching to alternative medicines would increase diabetes treatment costs significantly (for example, 25 times in Spain).
- **Critical antibiotics** like ciprofloxacin, which is essential for everyday infections and for security in case of a bio-terrorist attack, could face **EPR fees** equivalent to **1358%** of its value **rendering it uneconomic to produce for Europe**.

This law will not lead to 'greener' medicines as active ingredients usually cannot be modified without losing their effectiveness. In addition, any modification of medicines, if possible at all, would require billions of Euros of research and development costs as well as years of new clinical testing for patient safety and efficacy without any guarantee of success. In some cases, such as antibiotics, this would not only be prohibitively expensive, but could require higher dosing, therefore contributing to accelerating antimicrobial resistance which kills over 35,000 patients annually in the EU.

Crucially, solutions to protect affordable medicines cannot wait until implementation of the Directive or its review in 2033. **2029 EPR fees will be based on 2028 sales volumes, meaning companies must take imminent and irreversible decisions to continue production for Europe**. Without a solution, this risks precautionary withdrawals of medicines, reduced supply and increased unpredictability for health systems. Any correction during implementation will come too late to prevent significant harm to public health and our critical and essential

¹ See data available on the [NORMAN Ecotoxicology Database](#), a platform for systematic collection and evaluation of ecotoxicity studies for harmonised derivation of environmental quality standards.

² European Medicines Agency, [Guideline on the environmental risk assessment of medicinal products for human use](#) (2024)

medicines manufacturing. For this reason, the Medicines for Europe members seek legal protection before the European courts.

Speaking on the legal filings from our members, **Adrian van den Hoven – Medicines for Europe Director General** said: *“This appeal is about ensuring Europe does not put patients at risk through poorly designed legislation. We need laws to protect the environment, but this must be based on rigorous science, go hand in hand with preventing shortages for patients and protecting a strong healthcare system and industry. If no action is taken, our members will be forced to make irreversible decisions risking shortages of vital medicines and weakening Europe’s crisis preparedness. We urgently need to stop the implementation of the current system and find an evidence-based, economic policy that protects both patients and the environment.”*

Notes for editors

Resource hub:

- [Memo on Urban Wastewater Treatment Directive](#)
- [Ramboll study on Micropollutants in Urban Wastewater](#)
- [Note on Bio Innovation list of substances found in Urban Wastewater](#)

What is the UWWTD and the EPR scheme it creates?

- The *production* of pharmaceuticals has for many years been subject to strict wastewater treatment requirements. Manufacturing site effluents are already closely monitored and minimized by producers. In addition to that, the UWWTD shall now introduce an “extended producer responsibility” (EPR) on the *sale* of medicines and cosmetics, to pay for the late-stage (“quaternary”) treatment of urban wastewater which contains micropollutants from a large variety of sources, including to only some extent the excretion of residuals from medicines. In practice, generic medicine producers will need to collect levies on the sale of medicines to finance infrastructure investments and operational costs of the water industry. The levies apply to the sale of medicines because pharmaceutical residues in wastewater come from patient consumption. in accordance with strict emission laws. Hence, the EPR fees will be based on the volume of medicines consumed by patients in each member state.
- This levy is particularly problematic for the generic medicines industry, which supplies most of the essential medicines for patients. Member State cost estimates are 3 to 6 times higher than the Commission estimates. Based on [economic modelling](#)³ of the real impact of the UWWTD, the Directive will cause a tsunami of medicines shortages.
- Also, the UWWTD ignores the peculiar characteristics of the operating business model of the generic industry which fundamentally relies on the use of established active pharmaceutical ingredients (APIs) after loss of exclusivity in order to secure patient access to essential and life-saving medicines at affordable costs. This business model would be undermined if the generic industry was financially sanctioned for using such established APIs and was thus be forced to switch the operating business model into the new development of APIs – if possible at all – which would dramatically increase the costs for patients.
- Finally, the EPR scheme established by the UWWTD violates the 'polluter pays' principle as the producers of medicinal products would (i) have to bear the costs for the removal of micropollutants that they have not caused, whereas the producers of other products causing micropollutants would be exempted from bearing the costs for the removal of micropollutants that they have actually caused, and (ii) would have to bear a cost burden higher than the pollution actually linkable to their products.

³ [Assessing the Cost Burden of UWWTD Extended Producer Responsibility on Pharmaceuticals: Implications for the accessibility, availability and affordability of medicines.](#)

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.

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