

The European Union cannot jeopardise patient access to generic medicines through the Urban Wastewater Treatment Directive

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Medicines for Europe is deeply concerned about the Extended Producer Responsibility (EPR) system in the Urban Wastewater Treatment Directive under discussion in trilogue negotiations, which:

- **Creates a “free rider” effect, forcing only human medicines and, to a lesser extent, cosmetic manufacturers to finance quaternary treatment to remove micropollutants originating from all industrial sectors**
- **Massively underestimates quaternary treatment costs to be financed by the industry.** According to the German Environmental Agency, the annual cost estimates in Germany alone are between € 885 and 1025 million, which are only slightly below the costs estimated by the Commission of €1213 million for the entire EU.¹ As Germany represents less than 20% of the total EU population, this implies an actual cost for the whole EU of €4.425-5.125 billion. This is only a fraction of the EU-wide impact.
- **Does not consider the complexity or potential impossibility of replacing pharmaceuticals with “greener alternatives”.**
- **Determines EPR fees based on volumes and hazardousness, without considering adjustment factors such as turnover or sales,** as recommended in the Commission feasibility study.

Generic medicines cover 7/10 prescriptions in Europe while accounting for just 29% of pharmaceutical expenditure. In Germany, Pro Generika estimates that the net sales value of prescription generic medicines in the pharmacy sector is €2 billion². If applied on a volume basis (assuming a 70% share and based on the German government estimates), the EPR scheme would cost 30% of the net value of the entire generic market. This is unsustainable for a sector that already has low margins, due to cost-containment pricing and procurement policies, with no possibility to increase government regulated prices.

When the European Union is working to improve the accessibility, affordability, availability of medicines through the pharmaceutical legislation review and initiatives to address shortages, it is extremely worrisome to see a proposal that could have a devastating impact for the sustainability of several products under EU shortage monitoring such as paracetamol.³ The Commission feasibility study for the Urban Wastewater Treatment

¹ German Environment Agency scientific opinion paper (2023) “[Moving forward: The European Commission’s proposal for a Recast Urban Wastewater Treatment Directive](#)”, p. 7-8

² <https://www.progenerika.de/publikationen/generika-in-zahlen/>

³ Together with EMA, the Commission continues to closely monitor the situation as it evolves, keeping day-to-day contact with the relevant companies and other stakeholders to detect early any unexpected shortfall of supplies of certain key

Directive recognised that the price impact of the EPR fee could be up to 45% for paracetamol⁴, and this calculation is based on a dramatic underestimation of the real wastewater treatment costs, as shown by the German government's cost estimates above.

Moreover, the EPR scheme will be profoundly unfair for generic medicine manufacturers. Tamoxifen, an important cancer medicine, on the [Union list of critical medicines](#) recently published by the European Medicines Agency, and which has been in short supply in Germany because of its low price, is sold by generic medicine manufacturers for less than €3/month (€8.80/3 months)⁵. Tamoxifen manufacturers will have to pay the EPR fees. Meanwhile, the highest priced orphan drugs in Europe, which sell for around €20000-30000/month⁶, will not contribute to the EPR fees because of their low volumes. As many expensive drugs will not have to pay the EPR fees, this will further increase the cost burden on low priced generic medicines that are the backbone of public health.

We therefore call on the European Parliament and the Council of the European Union to:

- **Agree to the safeguards introduced by the Parliament for a more balanced EPR system:**
 - **National public co-financing of 20%** for the upgrade of urban wastewater treatment plants.
 - **EPR schemes implementation** at national level to account for the **risks for medicines**
 - **Possibility for Member States to add other sectors** in their EPR schemes and **reimburse the difference of costs** caused by the Directive to preserve access to essential medicines.

- **Introduce targeted measures to protect essential generic medicines, such as:**
 - **Including the sales value of products and not only the volumes when modulating the fees**, in line with the recommendations of the Commission feasibility study which has already highlighted this problem.
 - **Granting Member States the possibility to opt-out of the EPR system** when necessary to safeguard the availability of critical products.

Adrian van den Hoven, Director General at Medicines for Europe, commented *“The Commission has presented the EPR fees in the Urban Waste Water Directive as some sort of Robin Hood tax on the “rich pharmaceutical industry”. In reality, the EPR tax, whose cost has been grossly underestimated according to the German government, will fall mainly on affordable generic medicines that are already in short supply. The most expensive and profitable drugs will contribute almost nothing and other industrial sectors responsible for micro-pollutants will pay nothing at all. This is really concerning also for patients, who rely on essential medicines to manage their conditions and already face challenges with shortages. This certainly will not improve that. We urgently call on the Council and Parliament to protect the supply of affordable generic medicines”.*

antibiotics, and to monitor the continued supply of other medicines commonly used in the autumn/winter season such as cough syrups, ibuprofen and paracetamol. https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf

⁴ Bio Innovation Service et al. (2022), [Feasibility of an EPR system for micro-pollutants](#), p. 100

⁵ <https://www.apotheke-adhoc.de/nachrichten/detail/markt/pro-generika-zu-tamoxifen-fuer-880-euro-geht-es-nicht-hoher-regulatorische-anforderungen/>

⁶ <https://www.politico.eu/article/belgium-netherlands-team-up-to-take-on-pharma-over-prices/>

Medicines for Europe

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