Press Release

Medicines for Europe supports legal action against provisions in the Urban Wastewater Treatment Directive (UWWTD), which puts access to medicines at risk

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Medicines for Europe supports its members Accord, Adamed, Fresenius Kabi, Insud, Polpharma, Sandoz, STADA, Teva, Viatris and Zentiva who have filed a legal case with the Court of Justice of the European Union against the creation of an Extended Producer Responsibility (EPR) system in the Urban Wastewater Treatment Directive (UWWTD). The legal action seeks to avoid a discriminatory and disproportionate cost burden and thus to safeguard patient access to vital medicines.

The supply of medicines to millions of patients across the EU is under threat because the EPR system disproportionately affects the producers of generic medicines. It obliges them to finance the lion's share of the costs for removing residues from urban wastewater which come from various industrial or agricultural sources beyond medicines and cosmetics. The EPR system, which claims to incentivise the development of “greener” medicines, ignores the unique nature of pharmaceuticals, where redesigning the product is extremely complex and often unfeasible without compromising efficacy.

Generic medicines are the backbone of European healthcare systems and are essential to society, representing 70% of dispensed medicines and 90% of critical medicines while accounting for just 19% of pharmaceutical value. The generic medicines taken by millions of Europeans are at highest risk of being made commercially unviable by the new directive because companies cannot freely adjust prices – some as low as €0.50/box - to offset this levy. Our modelling shows the negative impact on the supply of widely used medicines taken by millions of patients across Europe. For example, due to EPR applied in the Netherlands:

- 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%.

Moreover, our modelling reveals a stark and deeply concerning imbalance: the burden of this scheme falls disproportionately on inexpensive generic medicines. Despite accounting for 19% of the total market cost, the generics industry is expected to incur a staggering up to 60% of the costs of the scheme. This lopsided distribution threatens the very foundation of a sector that plays a critical role in ensuring affordable and sustainable access to medicines. The Directive refers to an estimated water treatment cost of €1.18 billion annually, which would undermine the economic viability of many vital medicines. Yet, this is a dramatic underestimation of the true cost which could range between €5 billion and €11 billion per year, according to, e.g., the German government and statements by the European water industry. This massive cost would create a tsunami of generic medicine shortages, with catastrophic consequences on patient access to medicines and the sustainability of healthcare

systems in Europe.

The UWWTD fails on the principles of fairness and equitable allocation of burden by imposing the levy almost exclusively on the sales of medicines (and cosmetics) based on a highly untransparent and flawed impact assessment of the European Commission, and this, despite the huge variety of chemical residues found in urban waste water. This massive levy is a dead end for sustainable access to medicines and the real victims will be patients and deteriorating public health.

Speaking on the legal filings from our members, Adrian van den Hoven – Medicines for Europe Director General said *"We strongly support the legal filings against the discriminatory and disproportionate Extended Producer Responsibility system in the Urban Wastewater Treatment Directive. Access to healthcare is a fundamental right of European citizens. This unworkable and massive levy contradicts this fundamental right and jeopardises all efforts to improve access to medicines."*

Notes for editors

Relevant sources:

- European Medicines Agency, first version of the Union List of Critical Medicines, December 2023
- European Commission (2022), Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), p. 68
- German Environment Agency (2023), Moving forward: The European Commission's Proposal for a Recast Urban Wastewater Treatment Directive, p. 8
- EurEau (2023), Position Paper on the Proposal for a Directive concerning urban wastewater treatment (recast), p. p. 5, 2023
- Modelling estimates showing the cost impact of EPR are based on an economic model developed with the support of data from IQVIA.

What is the UWWTD and the EPR scheme it creates?

The UWWTD introduces an "extended producer responsibility" (EPR) on the sale of medicines and cosmetics, to pay for the late-stage ("quaternary") treatment of urban wastewater. In practice, generic medicine manufacturers 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 most pharmaceutical residues in wastewater result from patient consumption,1 rather than manufacturing sites, whose effluents are strictly monitored and minimised by manufacturers in accordance with strict emission laws. Hence, the EPR fees will be based on the volume of medicines dispensed to patients in each member state.

This levy is particularly problematic for the generic medicines industry, which supplies most of the essential and medicines for patients with serious illnesses. The UWWTD does not set a maximum EPR contribution which means that the total cost could be substantially higher than the costs estimated by the Commission (€1.18 billion/year from 2030-2045 and beyond). Member State cost estimates are 5 to 6 times higher than the Commission estimate. Based on our modelling of the real impact of the UWWTD, the Directive will cause a tsunami of medicines shortages.

[1] European Commission (2019), European Union Strategic Approach to Pharmaceuticals in the Environment, p. 2

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.