

Press Release European Parliament report urges for reassessment Urban Wastewater Treatment Directive's impact on medicines

07 May 2025, Strasbourg

The European Union is actively engaged on a European Water Resilience Strategy. Our industry manages water resources through comprehensive risk assessments, optimised manufacturing processes and advanced treatment. This ensures that medicines are manufactured in line with strict quality standards, with minimal impact on the environment and water systems.

Environmental sustainability and continued patient access to medicines must be complimentary and waterrelated regulation must consider the essential nature of medicines and pharmaceutical manufacturing, as medicines are necessary for the functioning of society.

Unfortunately, this was not considered with the Urban Wastewater Treatment Directive (UWWTD), which introduced an unworkable extended producer responsibility (EPR) system with a disproportionate impact on generic medicines.

The feasibility study used for the impact assessment only examined the potential impact on 12 molecules out of thousands, ¹ clearly not representative of the pharmaceutical sector, and based on significantly underestimated water treatment costs. National cost estimates of the UWWTD are multiples of the Commission estimate of \pounds 1.18 billion, leading to EU-wide costs ranging between \pounds 5 and 11 billion per year.² The water sector also estimated the cost to be multiples of the Commission's estimate confirms this dramatic estimation.³

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:

¹ Feasibility of an EPR system for micro-pollutants, Bio Innovation Service (2022)

² Data are based on EU-wide projections of the <u>German Environment Agency</u> and <u>Dutch Government</u>.

³ EurEau in 2023 estimated quaternary treatment costs between €8 and €25 per capita per year, i.e. between €3.6 and 11.2 billion per year across the EU.



- **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%.

Medicines for Europe therefore welcomes the European Parliament Plenary's call for a new and comprehensive assessment of the impact of EPR on the availability and affordability of medicines. Medicines for Europe calls on the European Commission to pause the implementation of the EPR provisions in the UWWTD, and to conduct a thorough review of its impact on pharmaceuticals to safeguard patient access to medicines.

MEMO on UWWTD