

European Parliament report on the Urban Wastewater Treatment directive acknowledges the critical importance of patient access to medicine

Brussels, 20 September 2023

The European Parliament ENVI Committee voted today to ensure that the Extended Producer Responsibility (EPR) system, envisaged in the Urban Wastewater Treatment Directive, does not jeopardise the affordability, accessibility and availability of generic medicines, which account for around 70% of prescriptions.

This is an important improvement to the proposal, which significantly underestimated the impact of wastewater treatment fees/taxes on generic medicines which are sold at minimal prices set by national government regulation.

The original proposal posed a real risk to the continued manufacture of these products, since generic medicines have low margins due to years of cost-containment pricing and procurement policies.

While the ENVI Committee report fell short of including producer turnover to determine fair fees, as recommended in the Commission's <u>feasibility study</u> for a fairer cost-allocation among sectors with varying economic capacity, it has nonetheless introduced improvements such as:

- National public co-financing of up to 20% for the upgrade of urban wastewater treatment plants.
- Dialogue among stakeholders involved in EPR implementation to ensure an efficient process and prevent unintended consequences for medicines availability.
- Possibility for Member States to add other sectors in their EPR schemes and to envisage additional reimbursement of the difference of costs caused by the Directive for access to essential medicines.
- A more risk-based and pragmatic approach to the scope of quaternary treatment.

Following the adoption of the report in plenary, we urge the Council to include the necessary safeguards to ensure availability of medicines that patients rely on daily, including consideration of the producer's turnover or the sales value of the affected products.

Adrian van den Hoven, Director General at Medicines for Europe, said "While we strongly disagree with the introduction of extended producer responsibility fees primarily targeting human medicines that are essential for public health to remove micropollutants from all industrial sectors and a disproportionate proposal underpinned



by limited and piecemeal scientific evidence, the European Parliament ENVI Committees' efforts to protect patient access to medicines is a positive first step. We now call on the Council to make the EPR systems fairer for lower cost generic medicines and to prevent shortages of essential generic medicines across Europe."

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 Twitter @medicinesforEU.