Press Release

Urban Wastewater Treatment Directive risks undoing Europe's efforts to improve the availability, affordability and accessibility of medicines

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The generic, biosimilar and value-added pharmaceutical sector represented by Medicines for Europe is seriously concerned about the impact of the Urban Wastewater Treatment Directive (UWWTD), which, if implemented in the current form without adjusting the systemic framework the industry is operating in,could lead to the disappearance of essential and critical medicines.

Our sector is engaged in making aquatic environments cleaner and safer. Our companies closely monitor, manage and minimise effluents in discharge waters at manufacturing sites. Pharmaceutical residues are mainly present in European waters due to human consumption and subsequent excretion by patients, as acknowledged by the Commission itself. [1]

The UWWTD Extended Producer Responsibility (EPR) system presents an unprecedented challenge. Only the pharmaceutical and cosmetics sectors will have to finance the upgrades of wastewater treatment plants across Europe to introduce the quaternary treatment required to remove persistent substances from all sectors, as well as the operational costs.

Generic medicines are the backbone of European healthcare systems, representing 7 out of 10 dispensed medicines and 9 out 10 of critical medicines while accounting for just 19% of the market value. They are particularly vulnerable to the UWWTD EPR system, due to their high volumes, narrow margins and strictly capped prices.

The Commission's estimate of EPR costs of €1.2 billion annually [2] would already make several essential generic medicines economically unviable. A cost increase of even one cent per pill could have devastating effects on products sold for just a few cents per pill, such as antibiotic or diabetes medicines.

Even the Commission's feasibility study for the proposal, which fundamentally misunderstood the realities of the pharmaceutical industry, highlighted that the EPR could lead to additional costs of up to 45% for paracetamol and up to 48% for metformin.[3]

[1] European Commission Communication "European Union Strategic Approach to Pharmaceuticals in the Environment", March 2019, p.2, available here

[2] European Commission Staff Working Document, Impact Assessment, October 2022, p. 57, available here

[3] Bio Innovation Service et al., "Feasibility of an EPR system for micro-pollutants", March 2022, p. 145, available here

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

Paracetamol, an analgesic and antipyretic medicine used for the treatment of painful and febrile conditions, is included in the Union list of critical medicines, whose supply is considered a priority in the EU to avoid serious harm to patients and the functioning of healthcare systems. [4]

Metformin is the most common prescribed oral medication for patients with Type 2 diabetes. It helps regulate blood sugar levels and is critical in preventing complications such as heart disease, kidney damage, and nerve problems. Its affordability and widespread availability are crucial for millions of patients across Europe. Without metformin, many patients would face the risk of uncontrolled diabetes or be forced to rely on more expensive and less accessible alternatives.

This situation becomes even more alarming when considering official cost projections from Germany,[5] which applied on an EU-level would lead to annual costs of over €5 billion, with the European water industry projecting an even higher annual cost of over €11 billion[6].

Those costs would create an existential threat to Europe's generic pharmaceutical industry, leading to severe supply disruptions, compromising patient access to affordable essential and critical medicines and undermining Europe's efforts to improve its open strategic autonomy in the context of the Critical Medicines Alliance.

As we approach the adoption of the legislation, we urge Member States to carefully assess the Directive's impact on the availability, affordability and accessibility of medicines, before moving forward with the current proposal.

Adrian van den Hoven, Medicines for Europe Director General, stated: *"The European Union is working hard to improve patient access to affordable medicines and reduce shortages with a strengthened supply of generic medicines. However, by endorsing the proposed UWWTD EPR system, the EU risks undoing these efforts. While we remain engaged in environmental sustainability, the financial burden imposed by this system exceeds the capacity of our sector. It is not too late for Member States to assess the impact of the EPR on medicines before adopting the legislation. Recent legislative examples show the importance of including feasible provisions in the text from the start, rather than having to delay implementation or make immediate revisions. If the UWWTD is approved in its current form, we call on the European Commission and on the Member States to ensure that the EPR system does not endanger the availability of essential and critical medicines, and on the European Parliament, that already expressed concerns on the impact on medicines during the legislative discussions, to closely monitor this process."*

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

[4] The Union list of critical medicines is available here

[5] German Environment Agency, Scientific Opinion Paper "Moving forward: The European Commission's Proposal for a Recast Urban Wastewater Treatment Directive", April 2023, p. 7-8, available here

[6] EurEau, Position Paper on the Proposal for a Directive concerning urban wastewater treatment (recast), February 2023, p. 5, available here

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.