Press release

Environment omnibus and impact study fail to address huge flaws in Urban waste water treatment directive

12 December, Brussels, Belgium

The European Commission has failed to address the major flaws in the EU urban waste water treatment directive (UWWTD), missing the opportunity of simplification in the Environment omnibus and omitting any meaningful assessment of the impact on medicines in the updated impact study, which just focuses on an update of water treatment costs based on inflation and on a limited number of alternative cost models.

This lack of action, which ignores the commitment taken by the Commission in the Water Resilience Strategy to assess the potential impact on the concerned sector, further extends the risk to patient access to essential medicines, which will be disproportionately impacted by this directive. For example, the UWWTD would impose an excess on the current healthcare expenditure the diabetes medicine metformin up to 875% in the Netherlands and up to 445% in Germany.

The case for revising the UWWTD is compelling. The current directive, which targets only two sectors to pay the water bill, will have a disproportionate impact on low cost generic medicines, putting their availability at risk. This risk was not fully assessed in the original directive, and the sector not adequately consulted. The cost projections of the directive have also been shown to be massively under-estimated, with country level and water industry cost calculations exceeding the Commission's estimates by multiple times. Inexplicably, these cost calculations have not been assessed in the updated impact study.

The directive is built on the incorrect assumption that the affected sectors can easily pass on the costs of the EPR scheme to consumers - or in the case of medicines, to patients, to fund this water treatment scheme. This assumption completely ignores the reality for off-patent medicine manufacturers, who face strict price regulation in Europe[1], and operate with very small product margins. In many cases, the costs of these medicines are being driven down by payers and health procurers, despite increases in the cost of production. A recent study showed that the top 10 essential antibiotics have seen prices fall by 10% since 2020, while the industrial producer costs increased by 31.6%, labor costs by 25.7%, and energy prices by +88% (gas) and +62% (electricity)[i].

[1] In over 80% of countries, generic medicine prices cannot be increased according to our latest analysis of generic medicine markets in the EU. https://www.medicinesforeurope.com/wp-content/uploads/2025/11/GENERIC-MEDICINES-MARKET-REVIEW-2025-Key-findings.pdf

The updated impact study fails to acknowledge that the EPR fees will fall disproportionately on high volume, low cost medicines – with fees expected to exceed the sales value of those essential or critical medicines for cardiovascular, epilepsy, pain and anti-infective treatment. The suggestion that manufacturers can "pass on" these costs to patients completely ignores the regulatory realities of Europe's off patent medicines market for these vital medicines.

Moreover, the updated impact study fails to correct the major data flaws from the first impact assessment. The entire foundation for the EPR scheme - claiming that pharmaceuticals contribute 66% of wastewater toxicity – is based on totally inaccurate modelling used by the Joint Research Centre. Instead of using the laboratory test data required by the European Medicines Agency (EMA), the JRC relied on computer-generated models, leading to massive overestimations. According to the Commission's data, the top 4 medicines alone supposedly represent 58% of the entire toxic load across all industrial sectors. Yet, based on actual EMA-standard laboratory data, their contribution would be well below 1%. It is unfathomable that an updated impact study ignores such a glaring error – one that led to toxicity overestimations by as much as 90,000 times, as is the case for blood pressure medicine, telmisartan[ii]. By failing to correct or even acknowledge these inaccuracies, the updated impact study misleads policymakers and the public alike, leaving the proposed EPR scheme without a credible scientific foundation.

Medicines for Europe reiterates its call for action to pause the implementation of the UWWTD, to correctly analyse the major flaws in this legislation and to protect the supply of essential and critical medicines for European patients.

Annex - What is the EU Urban Waste Water treatment Directive (UWWTD) and why is it a problem?
The UWWTD introduces an "extended producer responsibility" (EPR) scheme targeting the pharmaceutical and cosmetics industries, forcing them to pay for the late-stage ("quaternary") treatment bill on behalf of water companies. Pharmaceutical residues in waste water mainly result from patient consumption, rather than from emissions in manufacturing sites which are already strictly monitored and minimised by the industry. Despite this, EPR fees will be based on the volume of medicines sold or dispensed in each member state. This design hits the generic medicines industry hardest - the very sector which supplies the majority of essential medicines prescribed by doctors to patients with serious illnesses. While the Directive sets out how EPR costs will be calculated, it does not set a maximum total EPR contribution. This creates huge uncertainty for companies that need to know if their production lines will be economically viable after 2028. Based on our modelling of the real impact, the Directive will cause a tsunami of medicines shortages.

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.

[i] https://www.medicinesforeurope.com/wp-content/uploads/2025/09/Securing-access-improving-lives-Report-Sept-2025.pdf

[ii] www.medicinesforeurope.com/wp-content/uploads/2025/07/UWWTD-MEMO-updated-state-of-play-July-2025.pdf