Press release

European Commission risks repeating past mistakes in Urban Wastewater Treatment Directive cost study

Brussels: 15 October 2025

As the European Commission prepares to publish a long-awaited study on the costs associated with implementing quarternary-level treatment upgrades under the Urban Wastewater Treatment Directive (UWWTD), Europe's pharmaceutical industries say that lessons have not been learned and the same mistakes are set to be repeated.

The industries, represented by AESGP, EFPIA and Medicines for Europe, have not been consulted on a study that aims to assess the impact on the concerned sectors. This incomprehensible omission increases our deep concern about the Commission's approach, which disregards repeated calls and recommendations from the European Parliament and the Council of the European Union to ensure a comprehensive and transparent assessment, not just an updated study.

The concerns focus on several key points. A study limited to updating costs, correcting for inflation rates, does not constitute a proper sector assessment. It would fail to assess the broader consequences for the impacted sectors and their products. Moreover, the study seems to be conducted by the same body that carried out the original, flawed assessment, thus questioning its independence.

The Directive – which was adopted in 2024 – was based on considerable errors regarding toxic load allocation and underestimations regarding the implementation costs. This has resulted in unfairly singling out only two sectors and the companies involved facing significantly higher costs than originally forecast, impacting on both the competitiveness and sustainability of these sectors.

Concerns have also been publicly raised by Member States. France and Germany have called for the directive to be revised, and Italy has asked for a pause in implementation, while Poland has taken legal action against the Directive in the Court of Justice of the European Union.

The pharmaceutical sector urgently asks the European Commission to:

- **Pause the implementation of the EPR scheme for quaternary treatment in the UWWTD**
- **Consult the concerned industries in a transparent manner**
- **Conduct proper impact assessments on toxic load and implementation costs**
- **Take all necessary measures to preserve patient access and supply of medicines and uphold a decision-making process that is based on reliable and transparent scientific evidence.**

Ends

Accompanying background for journalists

BACKGROUND

The UWWTD introduces an Extended Producer Responsibility (EPR) scheme solely targeting the pharmaceutical and cosmetics industries. Under this system, these sectors will be required to pay for the late-stage ("quaternary") treatment bill on behalf of water companies. It is important to note that pharmaceutical residues in wastewater mainly result from patient use, rather than from manufacturing processes. Effluents from production sites are strictly monitored and minimised by pharmaceutical companies in compliance with existing environmental standards. The medicines that are widely prescribed and dispensed across Europe for millions of patients will be disproportionately impacted by the new fees introduced under this scheme.

FLAWED ASSESSMENT ALSO ON THE TOXIC LOAD CALCULATION

Leading environmental consultancies[i] have confirmed that the Feasibility Study[ii] that supports the Impact Assessment[iii] for the UWWTD was based on flawed assumptions from Joint Research Centre (JRC) data. These assumptions led to the claim that medicine residues represent 66% of the pollution in urban waste water – a conclusion that directly underpins the design of the EPR scheme.

An independent analysis by RSA[iv], based on the Feasibility Study data only disclosed after a Freedom of Information request, exposed a number of serious methodological issues, including:

1. **Selective use of data**, excluding significant contributors from other sectors.
2. **Disproportionate data availability**, relying heavily on datasets where pharmaceutical and cosmetics substances were overrepresented.
3. **Inflated toxic load calculations**, extrapolated from market sales data rather than measured environmental concentrations
4. Use of **poor-quality Predicted No Effect Concentrations (PNECs)**, significantly overestimating the toxicity of several pharmaceuticals compared to the laboratory test PNECs requested by the EMA, thereby introducing significant uncertainty into risk estimates.
5. **Overestimation of wastewater concentrations**, with extrapolations that did not reflect actual measured values.
6. **Over-simplistic assignment of responsibility**, concentrating the burden exclusively on two sectors while dismissing the role of diffuse and other point sources.
7. Failed to take into account the positive **impact of existing advanced tertiary wastewater treatment**, which already removes a substantial share of micropollutants, including pharmaceuticals.

In addition, **neither the pharmaceutical or cosmetics sector were among the consulted stakeholders ahead of the first impact assessment**, despite being the sectors targeted by the Directive – this lack of engagement undermines the transparency and credibility of the process.

THE NEW COST ASSESSMENT

The new cost study is not an official impact assessment: According to the Commission, an updated study is being conducted building on the impact assessment numbers relating to the costs of upgrading wastewater treatment plants to quaternary level (micropollutant removal)[v]. This study, which had already been corroborated by Commission officials in UWWTD Expert Group meetings, merely updates figures for inflation and does not constitute an Impact Assessment.

The **European Parliament Resolution on the European Water Resilience Strategy** "notes the existence of differing figures and assessments regarding the impact this would have on the pharmaceutical sector and, consequently, on the availability and affordability of medicines, and therefore calls on the Commission to conduct a new and comprehensive assessment of the impact on this sector" [P.52][vi].
In recognising the extent of the uncertainties and consequences of this directive on medicines, in the June 2025 **Water Resilience Strategy** the Commission committed to conduct a new assessment to review the costs of EPR and the impact on the concerned sectors. However, only the cosmetic and pharmaceutical industries are in the scope of this legislation, despite a Ramboll report showing that many other sectors largely contribute to waste water micropollutants[vii].

Available national cost analyses by Member States of the impact of this directive show that the Commission underestimated the true costs of the EPR scheme by between 300 and 600%, so that the costs could go from €1.18 billion to over €7 billion per year[viii].

The same lack of transparency towards the concerned sectors is being repeated in the new study. **To date, no contact has been made with the relevant European industry associations to provide further data**, even though the study is reportedly at its final stage. This fails to address concerns raised, not only by the pharmaceutical and cosmetics industries, but also by the European Parliament and an increasing number of EU Member States.

Furthermore, the updated impact assessment is being led by the same institution responsible for the previous cost analysis and focuses only on revising the cost estimates of quaternary treatment upgrades and correcting for inflation rates. We believe this leaves the independence of the process in question, given that the same institution previously produced contested calculations, which significantly underestimated costs and overestimated toxicity loads.

This approach risks reinforcing perceptions of a pre-determined agenda rather than producing an objective, evidence-based assessment.

THE IMPACT ON THE SECTORS AND EUROPEAN CITIZENS

The Commission services have not clarified whether the analysis will also address the **impact on patient access to medicines, security of supply, and the competitiveness of the affected industries**, despite the commitment in the **Water Resilience Strategy** to reassess the impact on the concerned sectors.

1. The **disproportionate financial burden** placed on pharmaceuticals through EPR would drive costs beyond the limits of market sustainability.
2. In practice, this could mean that **some products face shortages or withdrawal from the market**. Soaring costs passed on to products would unduly impact consumers, patients, and public health systems.
3. Instead of strengthening water protection in a fair and effective manner, such an outcome would **undermine access to essential products** and **create additional pressure on already strained healthcare budgets**.

REFERENCES

[i] https://www.medicinesforeurope.com/wp-content/uploads/2025/07/Medicines-for-Europe-note-on-Bio-Innovation-list-of-substances-found-in-urban-wastewater_July2025.pdf

[ii] https://circabc.europa.eu/ui/group/1c566741-ee2f-41e7-a915-7bd88bae7c03/library/1f2054a9-8a9b-4ea0-b32a-a063a4991e66/details?download=true

[iii] https://environment.ec.europa.eu/system/files/2022-10/Impact%20assessment%20accompanying%20the%20proposal.pdf

[iv] https://www.efpia.eu/media/d3gd5agc/rsa-efp001-002-review-of-commission-approach-to-allocating-toxic-load-to-pharmaceuticals-3-june-2025.pdf

[v] https://www.europarl.europa.eu/doceo/document/E-10-2025-002988-ASW_EN.html#ref2

[vi] https://www.europarl.europa.eu/doceo/document/TA-10-2025-0091_EN.html

[vii] www.medicinesforeurope.com/wp-content/uploads/2025/05/Ramboll-Report_Micropollutants-in-Urban-Wastewater.pdf

[viii] Estimations of cost per country are available for Germany, Netherlands, EurEau all show drastic under-estimations of cost by the European Commission.