Technical note on the Joint Research Centre report "*Updated estimation of the costs of quaternary wastewater treatment in the EU*"

February 2026

Executive Summary

Introduction

In December 2025, the European Commission published an updated JRC study on the costs of quaternary wastewater treatment under the UWWTD. The study does not address the core concerns raised by the European Parliament, the Council and affected sectors regarding the feasibility and proportionality of the Extended Producer Responsibility (EPR) scheme for medicines.

The Urban Wastewater Treatment Directive (UWWTD) introduces an extended producer responsibility (EPR) scheme on the pharmaceutical and cosmetics industries to finance at least 80% of the costs of quaternary treatment for the removal of chemical residues starting in 2029-2030. This Directive will require the application of EPR fees on the consumption of medicines and cosmetics placed on the EU market that are in scope. In the context of the Water Resilience Strategy, the European Parliament[1] required the Commission to conduct a new assessment of the UWWTD to assess:

- The claims from Member States and the Water industry that the European Commission and the JRC had underestimated the costs of quaternary treatment (and thus the costs of the EPR scheme) by 3-10 times; and
- The specific impact of the EPR scheme on the availability, accessibility and affordability of medicine as there is evidence that the adopted EPR scheme will undermine the economic viability of the supply of critical and essential generic medicines, based on high-volume, low-margin economic model, and which represent70% of EU prescription medicine supply in Europe.

Cost discrepancies and methodological assumptions

The updated study does not reconcile major cost discrepancies identified by Member States and stakeholders. It also relies on a revised assumption that only 35% of medium-sized wastewater treatment plants will require quaternary treatment, which mechanically lowers cost estimates without supporting evidence, sensitivity analysis or a clear justification based on the final text of the Directive. The JRC claims that the UWWTD only covers this limited number of wastewater plants (35%) but there

[1] European Parliament resolution of 7 May 2025 on the European Water Resilience Strategy (2024/2104(INI))

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is no evidence to justify this assumption, and it is not supported by the views of Member States and the responsible authorities for water treatment.

Missing analysis of EPR implementation and impacts

Affordability is assessed using aggregate pharmaceutical expenditure, which ignores product-level impacts in the high-volume, low-margin off-patent medicines market. The study does not analyse how EPR fees would be allocated in practice. Available modelling shows that several essential off-patent medicines would become economically unsustainable, creating a substantial risk of supply disruptions and shortages in critical therapy areas for public health including but not limited to cardiovascular (including diabetes), anti-infectives, anti-epileptics, pain, etc.

Scientific basis and lack of consultation

The updated study does not reassess the toxicological assumptions underpinning the EPR scheme, nor was it developed through structured consultation with affected sectors. The original feasibility study and impact study for the UWWTD claimed that medicines and cosmetics from human consumption amounted to 92% of the toxic load in urban wastewater. For medicines, this was based on an analysis of 4 medicines where, it was claimed, that a single cardiovascular medicine (Telmisartan) represented 41% of ***all*** the chemical residues and toxic load in wastewater, and where the 4 medicines were calculated to constitute 58% of the entire toxic load across all industrial sectors. This information was only revealed after the Directive was adopted and following multiple access to documents requests. However, the JRC has incorrectly attributed a toxicity rating (PNEC value) that was 90 000 times lower (meaning the anticipated pollution effect is 90 000 times higher) than the real (laboratory tested in aquatic animals) PNEC value of this medicine.[2]

Conclusions

Overall, the updated JRC study does not provide a sufficient or reliable evidence base to demonstrate the feasibility and proportionality of the EPR scheme under the UWWTD and severely underestimates the impact on essential off-patent medicines.

[2] EU Pharmaceutical regulation requires marketing authorisation holders to conduct an Environmental Risk Assessment of medicines when applying for a marketing authorisation. This usually includes laboratory studies on the environmental impact of the medicines in water (aquatic animals). PNEC values as therefore widely accessible on the internet so there is no clear explanation why the JRC. For example, the Swedish website FASS provides such information: https://fass.se/
See also Medicines for Europe note on the list of substances found in urban wastewater, compiled by Bio Innovation Service for the Extended Producer Responsibility feasibility report informing the Urban Wastewater Treatment Directive Impact Assessment, 7 July 2025

Introduction

On 10 December 2025, the European Commission published its updated study of the estimated costs of quaternary wastewater treatment under the Urban Wastewater Treatment Directive (UWWTD)[3], prepared by the Joint Research Centre (JRC), and following the European Commission's commitment to conduct an updated study to its first impact assessment[4], in the Water Resilience Strategy[5].

Medicines for Europe, the European voice for generic, biosimilar, and value-added medicines, welcomed the European Commission's commitment to conduct an updated study. However, and despite the explicit requests from the European Parliament and Council for clarifications, corrections, and additional evidence, the European Commission and the Joint Research Centre have not addressed the core concerns raised regarding the feasibility, proportionality, and financial impacts of the Extended Producer Responsibility (EPR) scheme adopted under the UWWTD.

The updated JRC study replicates the shortcomings of the original Impact Assessment and continues to rely on key assumptions and datasets that were already contested during the legislative process, thus failing to deliver the evidence base required for informed and sustainable policymaking.

1. Lack of proper assessment and response to major cost discrepancies and methodological inconsistencies

In the updated JRC assessment, the authors have compared their identified costs with alternative estimates derived from recently published evidence by the Umweltbundesamt (UBA, Germany)[6], Envidan (Denmark)[7], and Politecnico di Milano (PoliMi, Italy)[8], and the already in place Swiss model, also considering an inflation rate of 30% since 2020.

However, the JRC has not addressed the major discrepancies in the foreseen impact of the EPR scheme on the pharmaceutical and cosmetic sectors identified by:

- **The Netherlands:** Estimates from the Dutch Government[9] point to annual costs in the Netherlands of €400 million, i.e., **six times** the Commission's projection of €65 million in the original impact assessment.
- **EurEau:** Estimates from the water industry[10] points out annual per capita costs at €8–€25, translating to EU-wide costs of up to **€11.3 billion annually**, instead of €1.2 billion annually as estimated by the European Commission in the original impact assessment.

[3] Updated estimation of the costs of quaternary wastewater treatment in the EU, Joint Research Centre, 2025
[4] Commission Staff Working Document, Impact Assessment, Accompanying the Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), 26 October 2022
[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, European Water Resilience Strategy, 4 June 2025
[6] Moving forwards: The European Commission's Proposal for a Recast Urban Wastewater Treatment Directive, Umweltbundesamt, April 2023
[7] New report on the choice of technology for the 4th treatment step, Evidan, 23 January 2025
[8] Micropollutants removal, residual risk, and costs for quaternary treatments in the framework of the Urban Wastewater Treatment Directive, Ianes et al., November 2024
[9] Letter from the Minister of Health, Welfare and Sport to the President of the House of Representatives of the States General, 12 December 2024
[10] Position paper on the Proposal for a Directive concerning urban wastewater treatment (recast), EurEau, February 2023

- **Comparisons of the costs in Switzerland:** Although the study does refer to the Swiss cost evaluation, it fails to underline that the model is financed by a low-cost contribution from water users.

They provided detailed and substantiated analyses demonstrating that the JRC's estimated costs of quaternary treatment and EPR scheme are unrealistically low.

While the JRC compares the Impact Assessment cost function with selected alternative models (including German and Danish estimates), it does not provide a systematic analysis and reconciliation of the divergent cost estimates reported across Member States. Yet, it concludes that '*the increase in the costs of quaternary treatment that we may quantify even at the upper end of the alternative cost models considered above would not substantially change the conclusions of the IA concerning the impacts of the recast UWWTD on the affordability of and accessibility to pharmaceuticals*'[11].

The updated assessment also relies on a revised assumption that **only 35% of wastewater treatment plants between 10,000 and 150,000 population equivalents** would require quaternary treatment, compared to the 70% assumption used in the original impact assessment. [12] The study does not provide empirical evidence, sensitivity analysis, or Member State data to justify why 35% constitutes a realistic assumption in practice. **As a result, the 35% assumption reduces total cost estimates by artificially limiting the number of plants subject to quaternary treatment, without being supported by any evidence or analysis.**

This assumption is difficult to reconcile with the final text of the Directive. The risk-based trigger for applying quaternary treatment to small and mid-size plants remains unchanged compared to the original proposal, while the scope of sensitive areas has been expanded to include coastal, marine, and transitional waters. These elements would logically increase, rather than reduce, the number of plants potentially falling within scope of the Directive**.**

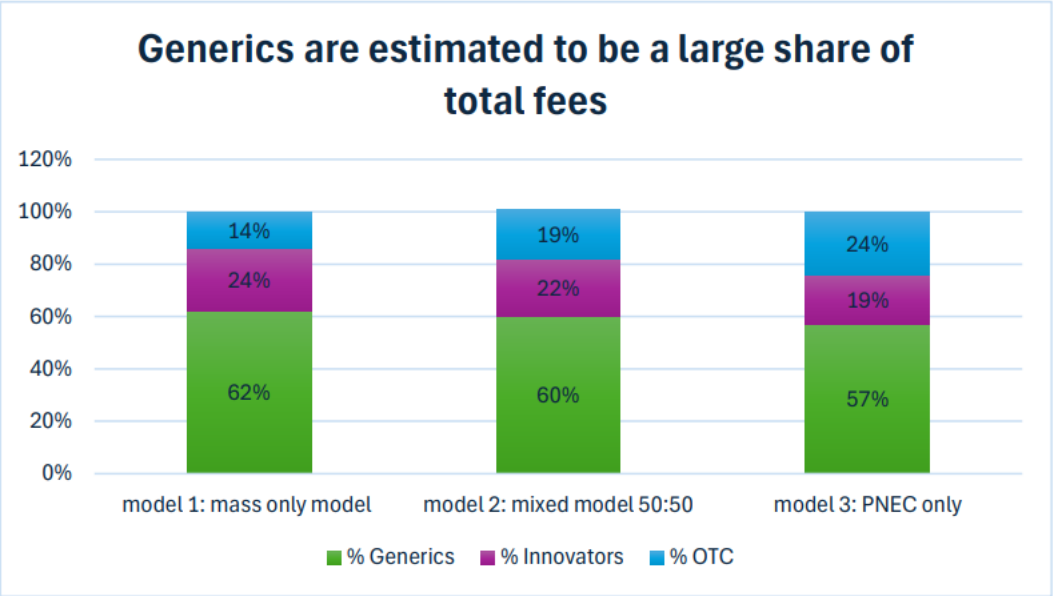
2. Missing analysis on the impact of the implementation of the EPR scheme and massive medicinal product-level consequences

The updated assessment relies on **aggregate pharmaceutical expenditure** to contextualise affordability impacts. This assumption is not appropriate for the pharmaceutical sector, where economic sustainability is determined at product level rather than at market-wide level. **High aggregate expenditure ignores the realities of the off-patent medicines market, which is characterised by regulated and capped prices, fixed reimbursement levels, and structurally low margins**. As a result, comparisons based on average expenditure massively understate the real economic impact of EPR obligations on individual medicinal products.

[11] Updated estimation of the costs of quaternary wastewater treatment in the EU, p. 25
[12] Updated estimation of the costs of quaternary wastewater treatment in the EU, p. 14

The legislation clearly stipulates that fees must be calculated based on the volume of products placed on the EU market and their hazardousness[13].
To assess the impact of the EPR scheme on the affordability and availability of critical and essential medicines, Medicines for Europe has modelled multiple fee scenarios using these parameters, and the European Commission's cost estimates from its original impact assessment, in order to distribute costs across molecules based on hazardousness, quantities, or a combination of both criteria.

In all models, the results demonstrate a very substantial financial impact on off-patent medicines, which rely on a high-volume, low margins economic model.



These findings are supported by modelling of EPR fee scenarios conducted by IQVIA, based on the Directive fee parameters

The findings confirm that **across all scenarios, several essential or critical medicines would become economically unsustainable**, due to the EPR fees, posing an extremely high risk of shortages. The difference lies only in which products are most affected, and consequently, which patients will face the highest risk of shortages.

The updated JRC report does not analyse the implementation of fees, nor does it consider the resulting economic burden on individual medicines. This omission is critical, because fee design and allocation between the producers is the determinant of real economic impact for manufacturers.
In most EU Member States off-patent medicinal product prices cannot legally be increased, and pricing and reimbursement levels are fixed by national legislation. Off-patent medicines manufacturers are therefore unable to pass on additional costs arising from the EPR obligation to the market.

[13] As per Article 9(3)(c) (*Extended Producer Responsibility*) of the Directive, '*each producer's contribution, as referred to in point (b), is determined on the basis of the quantities and hazardousness in the urban wastewater of the substances contained in the products that are placed on the market*'.

The absence of this crucial analysis means that the updated assessment does not provide Member States with the necessary evidence to evaluate the feasibility or proportionality of the EPR scheme for the transposition and implementation of the UWWTD at national level.

From an economic and distributional perspective, it would be more reasonable to recover the estimated **€2.6–€3.2 per-capita costs claimed in the new JRC study** through water tariffs, where they would be effectively spread across society in proportion to actual use. This approach would reflect the collective nature of wastewater treatment services, as the first three levels of wastewater treatment are financed in this way, and avoid concentrating the financial burden on a limited number of essential medicines, whose prices are regulated and whose supply cannot absorb additional costs without risking shortages.

By contrast, even when using the Commission's original, lower quaternary treatment cost estimates from the Impact Assessment, EPR fees applied to essential medicines such as **metformin** would exceed current public health insurance expenditure for this product by up to **142% in the Netherlands** and **104% in Germany**.

3. Updated study's failure to reassess the toxicity, PNECs, and science-based evidence

By not reassessing the claim that pharmaceuticals contribute 66% of wastewater toxicity, the updated impact study also fails to revisit or improve the toxicological basis underpinning the original feasibility study, including the Predicted No-Effect Concentrations (PNECs) of pharmaceutical residues.

The entire foundation for the EPR scheme is based on inaccurate modelling used by the JRC, which relied on computer-generated models, instead of the laboratory tests required by the European Medicines Agency (EMA), a miscalculation leading to a significant overestimation. In fact, the top 4 medicines in the list used by the Commission were calculated to constitute 58% of the entire toxic load across all industrial sectors but based on the laboratory data that would be required by the EMA for the environmental risk assessments, they would be well below 1%[14,15]. It is unfathomable that the JRC would estimate the toxic load of pharmaceuticals without relying on the data from laboratory tests which is widely accessible, for instance in publicly available databases such as FASS[16] and on the Norman Ecotoxicology Database[17].

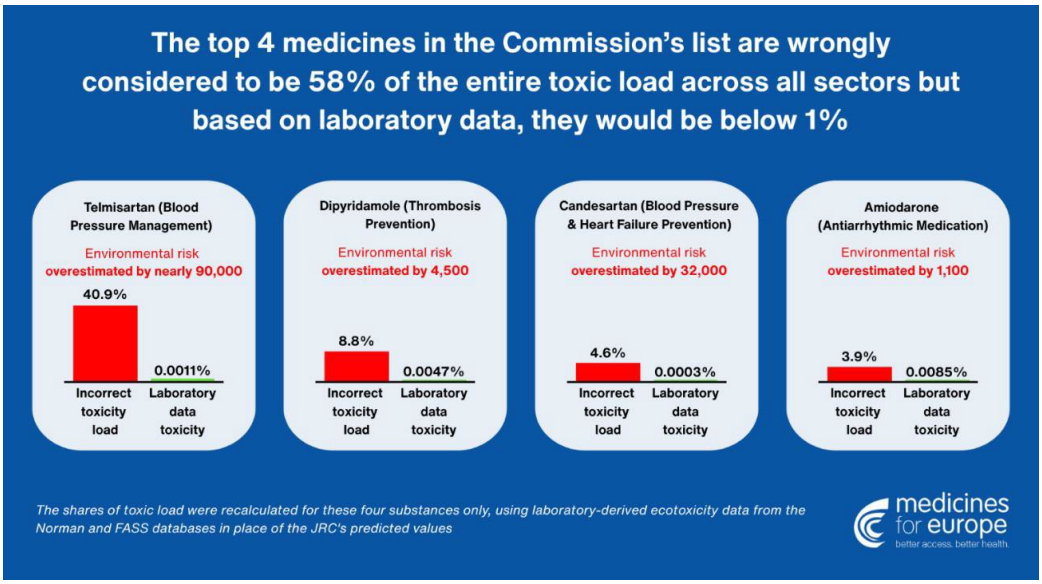
[14] Medicines for Europe note on the list of substances found in urban wastewater, compiled by Bio Innovation Service for the Extended Producer Responsibility feasibility report informing the Urban Wastewater Treatment Directive Impact Assessment, 7 July 2025

[15] The percentages of toxic load are based on corrected PNECs (lowest experimental PNECs in the Norman Ecotoxicology Database), applied to the JRC's reported estimated concentrations in wastewater, for these four substances only. The relative toxic load shares for all substances in the list (1,294 in total) would need to be reassessed using experimental PNEC data to provide a comprehensive recalculation.

[16] Since 2005, Sweden has a unique environmental classification system for pharmaceutical substances. It is a self-declaration system where each pharmaceutical company is responsible for their own environmental information, which is published on the open web-based portal https://www.fass.se/LIF/startpage. Prior to publication the environmental risk assessments are reviewed by IVL Swedish Environmental Research Institute (IVL) as an independent, external part.

[17] The NORMAN network started its activities in September 2005 with the financial support of the European Commission. In 2009, the NORMAN network became a permanent self-sustaining network of reference laboratories, research centres and related organisations for the monitoring and biomonitoring of emerging environmental substances. The NORMAN Ecotoxicology Database is a platform for systematic collection and evaluation of ecotoxicity studies for harmonised derivation of environmental quality standards.

No new analysis or refinement has been provided, and the scientific rationale for targeting broad categories of medicinal substances remains unsupported by a transparent and validated methodology.



4. The JRC's failure to consult the affected sectors to understand the impact of the EPR scheme under the UWWTD

The process through which the updated assessment was developed by the JRC lacked consultation with the pharmaceutical and cosmetic sectors, which will be directly affected by the proposed EPR scheme. Despite repeated requests, the European Commission and the JRC did not engage in consultation with industry representatives on this study, which prevented the correction of known inaccuracies and the inclusion of relevant operational and market data. As a result, the updated study replicates the flaws of the first impact assessment rather than providing a substantive methodological and scientific improvement.

Taken together, these shortcomings demonstrate that the updated JRC study does not address the questions or concerns set out by the European Parliament, the Council, and the pharmaceutical and cosmetic industries. It does not correct methodological inconsistencies, does not assess the actual operation of fee structures, does not examine the impacts on individual medicinal products, and does not revise the underlying toxicological assumptions. Nor has it been developed through standard consultative practice.

Without a fundamental revision, the evidence base remains inadequate for implementing the EPR scheme and its related requirements of the UWWTD. If applied in its current form, the proposed framework will impose disproportionate and unrecoverable costs on essential medicines, leading to shortages and undermining the resilience of Europe's medicine supply.