



What is the Urban Waste Water Treatment Directive (UWWTD)

The objective of Directive 91/271/EEC is to protect the environment from being adversely affected by insufficiently treated urban wastewater discharges. Established in 1991, the Directive aims to safeguard public health and the environment by mandating wastewater collection and treatment in urban areasⁱ.

What is Urban Wastewater? It can be formed by different mixtures of domestic wastewater, urban runoff and non-domestic wastewater from other origins. Domestic wastewater refers to wastewater from residential settlements and services originating predominantly from human metabolism and household activities. Wastewater from institutions such as offices, schools, kitchens with food preparation which originates predominantly from the human metabolism qualifies as domestic wastewater.ⁱⁱ

The revised Directive: In November 2024, the European Parliament adopted the revised Urban Wastewater Treatment Directive, which introduces extended producer responsibility (EPR) obligations. A 2019 evaluation by the European Commission identified emerging pollution sources, including micropollutants from pharmaceuticals, cosmetics, and microplastics, which the revised Directive seeks to mitigate. Member States must implement the new UWWTD by July 31, 2027 and must apply the new EPR obligations to in-scope companies by December 31, 2028.ⁱⁱⁱ

What is the proposed new treatment of Urban Wastewater? The Directive requires that for urban wastewater plants treating urban wastewater, Member States must progressively introduce an additional treatment, known as quaternary or fourth purification stage treatment, for the purpose of removing micropollutants such as pharmaceutical residues, pesticides or microplastics, which are not fully captured by the conventional biological or chemical treatment stages.^{iv} Pharmaceutical residue from domestic waste refers to excrement from the human metabolism of medicines.

The impact of the EPR: According to an EU Commission feasibility study 92 % of the micropollutants found in wastewater are caused by pharmaceuticals and cosmetics (industry challenges the basis for this, see below details). As a consequence, the UWWTD imposes important new Extended Producer Responsibility ("EPR") obligations that will have a significant financial and administrative impact on companies marketing human medicines and cosmetic products in the EU as at least 80% of the costs of achieving the fourth purification stage are to be borne almost exclusively by these two sectors.

What is the pharmaceutical industry view on treating wastewater?

The pharmaceutical industry is taking action independently of the Directive to mitigate water pollution and is committed to paying its fair share of the cost of treating wastewater.

- Companies are working hard on individual initiatives to address all impact of medicines and their impact on the environment.
- Industry already treats water from manufacturing processes.
- Over the past 15 years industry has also worked to reduce micro-pollutants from medicines and from the disposal of medicines.



- However, through the use of everyday medicines – from cancer medicines to paracetamol - pollutants do enter the European wastewater – either by excretion and to a limited extent incorrect disposal of expired medicines – some of which is unavoidable.

What is industry's view on the UWWTD?

Industry remains committed to the implementation of the Directive in a fair, predictable, proportionate and non-discriminatory way. However, the arbitrary decision to select only the pharmaceutical and cosmetic industries to pay for the clean-up of micropollutants of all other sectors in Europe is unfair and won't work.

The UWWTD runs counter to three key principles of EU Treaties:

- Industry supports the **polluter pays principle** whereby all producers responsible for pollution should be held accountable and bear the costs of pollution that they have caused. Yet:
 - The Directive ignores the contribution to the micropollution of urban wastewaters of sectors other than pharmaceuticals and cosmetics.
 - Companies will pay more than the costs of treatments to remove micropollutants from their products.
 - Extended Producer Responsibility (EPR) of the Directive obligations are not in line with other EPR schemes.^v
- Industry believe the EPR is in violation of the **Principle of Proportionality**
 - The EPR obligation is not an appropriate measure to achieve substitution to greener products. Rather these financial obligations will impose an excessive burden on individual producers (and on the pharma sector as a whole).
- The Directive singles out two sectors for EPR obligations without considering the contribution of others which violates the **Principles of Non-Discrimination**.

These concerns have been echoed by 17 Member States who released political statements with the approval of the UWWTD many of whom called on the on the EU Commission to carry out an urgent impact assessment on the Directive focusing on the impact on medicines.

Will the UWWTD impact patients?

Depending on the financial contribution that will be required from the pharmaceutical sector, availability of some medicinal products may no longer be viable.

- According to water operators, the costs to be incurred by the pharmaceutical and cosmetics sectors, as indicated by the EU Commission, may be underestimated by up to ten times.
- Therefore, the affordability and accessibility of medicines in Europe could be impacted as the EU Commission will only assess the impact of the UWWTD in 2033.
- Studies identify that 5 % of critical medicines will be impacted.
- This directive is not focusing on manufacturing pollution. However, stricter requirements could drive manufacturing outside the Europe and risk the EU's ability to provide security of supply of medicines, forcing us to be dependent on foreign supply chains.



Legal Challenges to the UWWTD:

1. **Poland submitted a direct action for annulment** of Article 9(1) of the UWWTD to the Court of Justice of the European Union. In their pleas of law they:
 - i) allege breach of the ‘polluter pays’ principle set out in Article 191(2) TFEU and of the principle of equal treatment (prohibition of discrimination); and
 - ii) allege breach of the principle of proportionality set out in Article 5(4) TEU, in conjunction with Article 296 and Article 191(3) TFEU, by establishing measures which incur costs that are disproportionate to the attainment of the objectives pursued.
2. **EFPIA** filed an application before the General Court of the European Union to challenge the extended producer responsibility obligations of the UWWTD on 7th March 2025. The industry is challenging the Directive to seek greater clarity on how the decision to include only two sectors to bear responsibility for Europe’s urban wastewater quaternary treatment aligns with the EU’s own polluter-pays principle.
3. **Cosmetics Europe** filed an action with the EU General Court to seek clarity on UWWTD provisions on Extended Producer Responsibility on 10th March 2025. Cosmetics Europe’s claims that their analysis of the contribution of the cosmetics sector to urban wastewater pollution, based on the JRC study, is around 1%, with a range of other sectors involved.
4. On 10th March 2025 **ten generic companies** filed a legal case with the Court of Justice of the European Union against the creation of an Extended Producer Responsibility (EPR) system in the Urban Wastewater Treatment Directive (UWWTD). The legal action seeks to avoid a discriminatory and disproportionate cost burden and thus to safeguard patient access to vital medicines.

What is the ask of industry in relation to the UWWTD?

We are not seeking to block the Directive as we support its ambition. Industry’s concerns with the Directive are not a case of not wanting to bear the cost, but for those costs to be appropriately apportioned and proportionate to those creating pollution through micropollutants.

Therefore, industry is asking that:

- Under the Polluter Pays Principle, other sectors be required to take responsibility for their own pollution.
- For a legislation that works for Europe, ensuring clean wastewater while incentivising all sectors to play their part.
- For further research to be conducted to understand each sector’s contribution; however, industry will work on the implementation of the Directive until this becomes clear.

ⁱ <https://www.environet.ie/news/new-urban-wastewater-treatment-directive>

ⁱⁱ [https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739370/EPRS_BRI\(2023\)739370_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739370/EPRS_BRI(2023)739370_EN.pdf)

ⁱⁱⁱ <https://www.environet.ie/news/new-urban-wastewater-treatment-directive>

^{iv} <https://www.almawatech.com/en/news/the-new-eu-urban-wastewater-directive-impact-on-industry-and-wastewater-treatment/>

^v Other EPR schemes batteries, waste electronics, packaging require producers to take responsibility for the waste resulting from their own products. In addition, under those EPR regimes, the waste of the products is essentially the same as the products marketed.