The top 4 medicines on the list used by the Commission are incorrectly considered to be 58% of toxic load in wastewater but based on laboratory data they represent less than 1%[1]

The new EU Commission review on the impact to critical medicines of its Urban Wastewater Treatment Directive and Extended Producer Responsibility (EPR) scheme - asking the pharmaceutical and cosmetics industry to pay the majority of costs for water treatment to remove pollutants caused by the human consumption of medicine - must recognise that the original evidence base for the scheme is scientifically flawed and makes a series of wildly inaccurate claims.

July 2025

The Joint Research Centre (JRC) data, used in the feasibility study upon which the EPR scheme is based, vastly over-estimates the toxicity of medicines and underestimates the water treatment costs, threatening supply of critical medicines for millions of patients as they will be made commercially unviable.

A leading global environmental consultancy, Ramboll, found no evidence supporting the Commission's claim that pharmaceuticals make up 66% of wastewater micropollutants[2]. Their expert review of the evidence shows that sources of micropollutants are far more diverse than just medicines or cosmetics, including pesticides, biocides, veterinary drugs, food additives, industrial chemicals and personal care products. The data used by the Commission also does not account for the fact that pharmaceuticals are more studied and often over-represented in wastewater screening studies, leading to a bias.

This urges the immediate pause of the EPR scheme (introduced by the UWWTD in articles 9 and 10) while the Commission conducts new thorough impact studies.

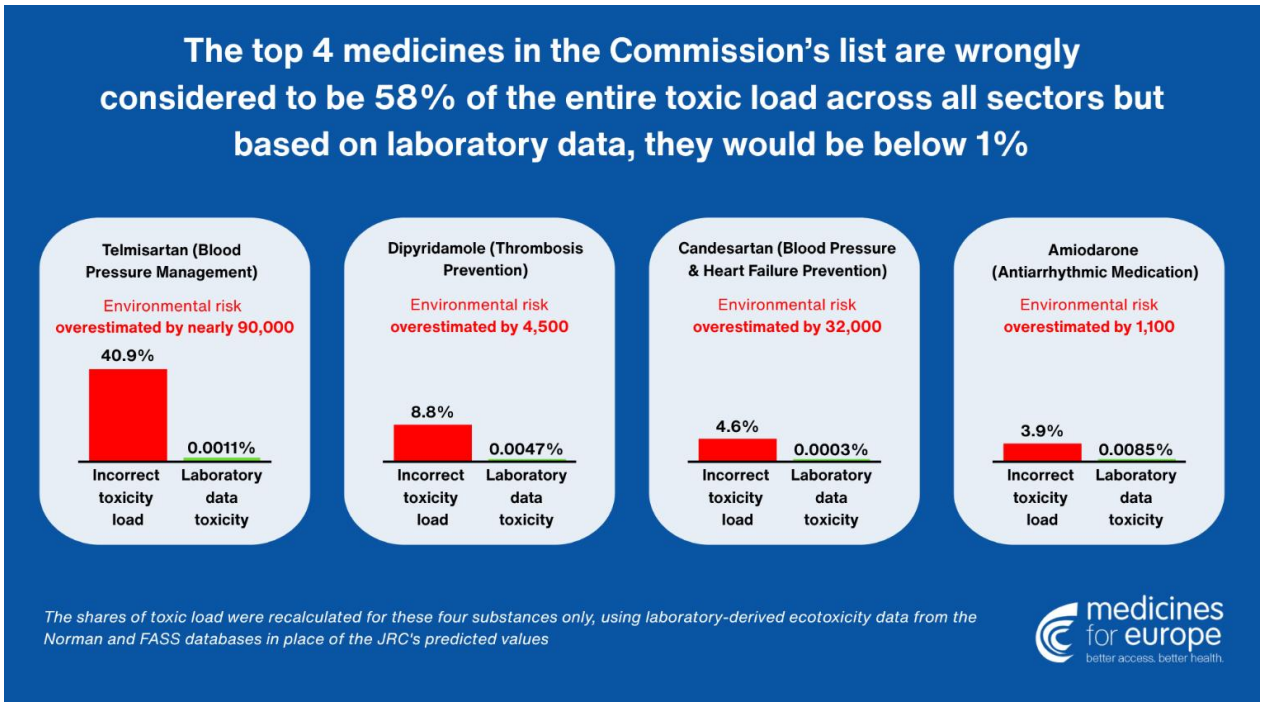
[1] The percentages of toxic load are based on corrected PNECs (lowest experimental PNECs in the Norman Ecotoxicology Database) for these four substances only. The relative toxic load shares for all substances in the list (~1,300 in total) would need to be reassessed using experimental PNEC data to provide a comprehensive recalculation.

[2] European Commission, Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), 26 October 2022, p. 57: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022SC0541

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

Vast over-estimation of toxicity and impact of medicines on wastewater

The entire foundation for the scheme - claiming that pharmaceuticals contribute 66% of wastewater toxicity - has recently been discovered to be 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%[3][4]. 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 on the FASS database[5] and on the Norman Ecotoxicology Database[6].



[3] **Telmisartan** (blood pressure management): wrongly assigned **41% of the total toxic load**, the highest share of any substance across all sectors, based on an alleged maximum concentration threshold tolerable for the water ecosystem (PNEC, Predicted No-Effect Concentration) almost **90,000 times stricter** than laboratory data available in scientific literature. // **Dipyridamole** (thrombosis prevention): attributed **8.8%**, based on a threshold **4,500 times stricter**.// **Candesartan** (blood pressure management and heart failure prevention): assigned **4.6%**, threshold **32,000 times stricter**.// **Amiodarone** (antiarrhythmic medication): assigned **3.9%**, threshold **200–1,000 times stricter**.

[4] The percentages of toxic load are based on corrected PNECs (lowest experimental PNECs in the Norman Ecotoxicology Database) for these four substances only. The relative toxic load shares for all substances in the list (~1,300 in total) would need to be reassessed using experimental PNEC data to provide a comprehensive recalculation.

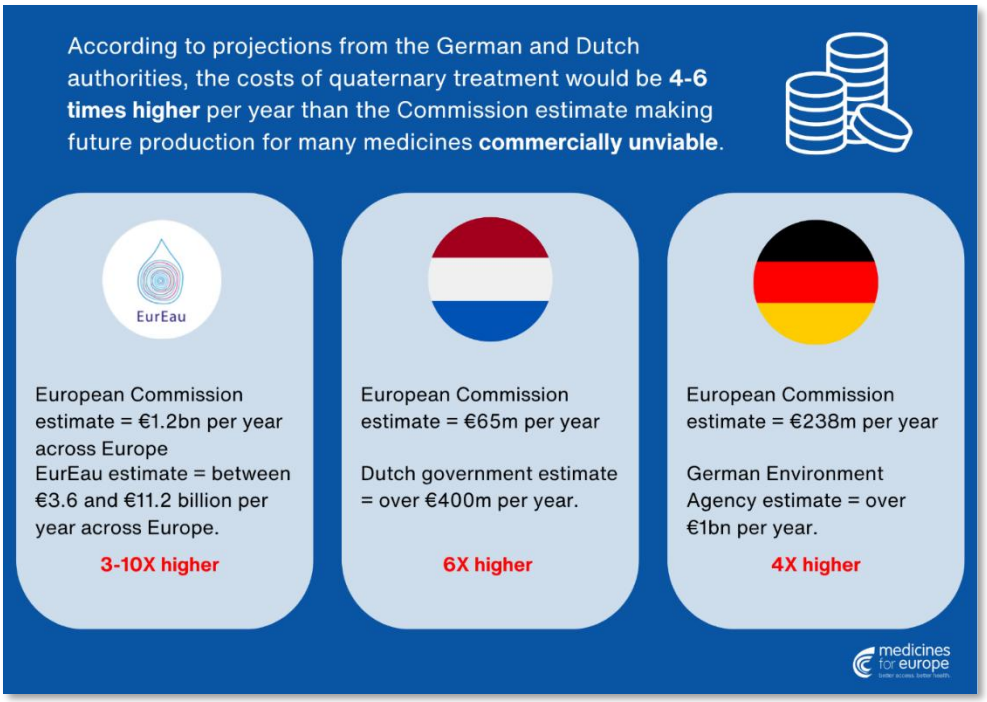
[5] Since 2005, Sweden has a unique environmental classification system for pharmaceutical substances. It is a self-declaration system where each pharmaceutical company is responsible for their own environmental information, which is published on the open web-based portal www.Fass.se. Prior to publication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

[6] 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.

Vast underestimation of the cost of treating wastewater, rendering many essential and critical medicines economically unviable

Detailed projections also show that generic medicines, which account for just 19% of pharmaceutical expenditure, would shoulder around 60% of the total EPR costs, making many essential medicines economically unviable and risking widespread shortages. The EPR will operate like a tax on the volume of medicines sold, with dramatic consequences on generic medicines supply.

Germany [7] and the Netherlands [8] project the quaternary treatment costs to be 4 to 6 times higher than the Commission's €1.2bn per year estimate [9] while the water industry estimates are up to 10 times higher [10]. As the generics industry has strictly regulated pricing and cannot pass on costs, this will make many medicines economically unviable.



Severe threat to supply of critical medicines for millions of patients: risk of tsunami of medicine shortages

While the impact on different medicines will vary, the threat to patients and therapy areas is severe[11]. Dutch cost projections (over six times higher than the Commission's) suggest the EPR could increase the

[7] UBA, Moving forward: The European Commission's Proposal for a Recast Urban Wastewater Treatment Directive – Scientific Opinion Paper, April 2023, pp. 7 – 8,: https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2023-06-28_sciopap_recast-urban-wastewater-treatment-directive_bf.pdf

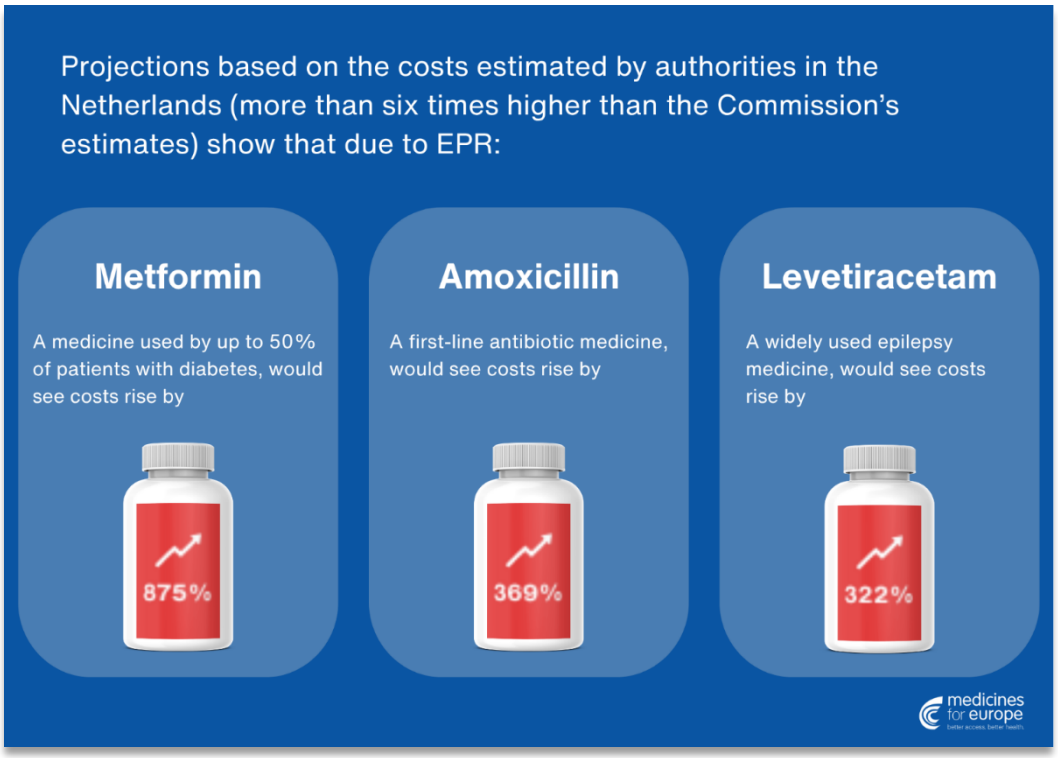
[8] Tweede Kamer der Staten-Generaal, vergaderjaar 2024–2025, 29 477, nr. 918, December 2024, p. 21: kst-29477-918.pdf

[9] European Commission, Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast), 26 October 2022, p. 57: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022SC0541

[10] EurEau estimated in 2023 that the implementation of quaternary treatment would cost between €8 and €25 per capita annually. This would correspond to total annual costs of between €3.6 and €11.2 billion across the EU. EurEau, Position Paper on the Proposal for a Directive concerning urbanwastewater treatment (recast), February 2023, p. 5: file.

[11] Medicines for Europe Memo "The Urban Waste Water Treatment Directive (UWWTD)must be simplified via the EU omnibus or essential medicines will no longer be available for patients in Europe", February 2025 Case-for-UWWTD-in-the-simplification-omnibus-03192025.pdf and Ramboll study on Micropollutants on Urban Wastewater.

cost spikes of **metformin** (used by half of diabetes patients) **by 875%**, **by 369% for amoxicillin** (a first line antibiotic medicine) **and by 322% for levetiracetam** (a widely used epilepsy medicine). Even under the Commission's lower estimate, costs would rise drastically.



URGENT CALL FOR ACTION: essential to urgently pause the EPR scheme to protect patient access to critical medicine

This uncertainty over costs and economic viability leaves medicine manufacturers unable to plan manufacturing, putting the future supply of critical medicines at risk. Therefore, due to these significant flaws and inaccuracies, Medicines for Europe calls for:

1. an **immediate pause of the EPR scheme** (Articles 9 and 10 of the Directive) via the upcoming environmental omnibus that should be **co-led by Environment, Industry and Health Commissioners** to avoid the negative consequences on future supply of critical medicines for millions of patients across the EU.
2. a **thorough and transparent new impact study**, that should be led by the Health, Environment, Industrial and Crisis Preparedness departments of the Commission, as well as the relevant stakeholders (e.g. industry), on the actual toxic load in light of the JRC data flaws, the real costs of quaternary treatment and on the impact on the access, availability and affordability of medicines.
3. a **revision of the EPR provisions** to ensure **a science-based** and **proportionate alternative** for funding quaternary treatment that does not harm patient and supply security.