

(English version)

**Question for written answer E-002108/25
to the Commission
Christine Anderson (ESN)
(26 May 2025)**

Subject: Impact of the Urban Wastewater Treatment Directive on the availability and affordability of essential medicines

The revised ⁽¹⁾ Urban Wastewater Treatment Directive ⁽²⁾ (UWWTD) may significantly increase production costs for essential, low-cost medicines such as Metformin, a key treatment for type two diabetes used by nearly three million patients in Germany ⁽³⁾.

Estimates suggest that pharmaceutical and cosmetic companies are required to cover at least 80% of the costs (Article 9) of additional treatment to remove micropollutants in order to comply with the directive. This could lead to a cost increase of up to 445% for Metformin production. Manufacturers warn that this would make the continued EU-based production of such medicines unviable, risking market withdrawals, medicine shortages and greater dependence on non-EU imports.

1. Can the Commission confirm whether the estimate of up to a 445% cost increase for Metformin is accurate, and whether it anticipates similar effects across other Member States and medicines, particularly for low-margin generics?
2. How does the Commission reconcile the provisions of the UWWTD, specifically the mandatory cost allocation under Article 9(4), with the objectives of the proposed Critical Medicines Act, which aims to strengthen EU production and supply security for essential pharmaceuticals?
3. Given the risk to medicine affordability and availability, does the Commission consider a targeted revision or exemption within the UWWTD necessary in order to safeguard public health and pharmaceutical resilience?

Submitted: 26.5.2025

**Answer given by Ms Roswall on behalf of the European Commission
(30 July 2025)**

The Commission conducted a timely impact assessment ⁽¹⁾ to accompany its 2022 proposal for a revised Directive on Urban Wastewater Treatment (UWWTD) ⁽²⁾.

It draws notably on a feasibility study ⁽³⁾ which analysed the impact of extended producer responsibility (EPR) on the price of pharmaceuticals, including on metformin. It concluded that the cost of the EPR is expected to have a marginal overall impact ⁽⁴⁾ on the pharmaceutical sector in the EU.

The revised Directive notes that, based on available data, the potential increase of costs of products or the potential reduction of the profit margins of the industries placing products on the EU market due to the EPR application would neither endanger the affordability nor the availability of those products on the EU market ⁽⁵⁾.

As announced in the European Water Resilience Strategy ⁽⁶⁾, adopted on 4 June 2025, the Commission will, in the context of the implementation of the EPR, conduct an updated study of its costs and its potential impacts on concerned sectors. This update will focus on the cost of quaternary treatment and does not constitute a new impact assessment.

Should there be concerns over potential effects on specific products at national level, the industry, under the control of Member States, can propose safeguards in the way the contributions are calculated ⁽⁷⁾. Exemptions are possible for products placed on the EU market under certain conditions ⁽⁸⁾.

¹ COM(2022)0541.

² Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment, OJ L, 2024/3019, 12.12.2024, ELI: <http://data.europa.eu/eli/dir/2024/3019/oj>.

³ Der Spiegel, <https://www.spiegel.de/wirtschaft/diabetes-medikament-metformin-droht-das-aus-hohe-kosten-durch-eu-abwasserrichtlinie-a-25ab387e-8ef2-43c7-a9e0-7714d850aeb3>.

⁽¹⁾ Impact assessment accompanying the proposal for a directive concerning urban wastewater treatment (recast), 2022: https://environment.ec.europa.eu/publications/proposal-revised-urban-wastewater-treatment-directive_en..

⁽²⁾ Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment (recast), OJ L, 2024/3019, 12.12.2024.

⁽³⁾ Feasibility of an EPR system for micro-pollutants: <https://op.europa.eu/en/publication-detail/-/publication/14249cbc-5f1c-11ed-92ed-01aa75ed71a1/language-en>.

⁽⁴⁾ Ibid.

⁽⁵⁾ Recital 21 of Directive (EU) 2024/3019. As regards the proposed Critical Medicines Act, it aims to support manufacturing and improve the availability of critical medicines in the EU, without prejudice to the applicable EU environmental rules, https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/critical-medicines-act_en.

⁽⁶⁾ https://commission.europa.eu/topics/environment/water-resilience-strategy_en..

⁽⁷⁾ Recital 21, Articles 9 and 10 of Directive (EU) 2024/3019.

⁽⁸⁾ Article 9.2 of Directive (EU) 2024/3019.

A full evaluation ⁽⁹⁾ of the directive is planned by 2033.

⁽⁹⁾ Article 30 of Directive (EU) 2024/3019.