

**Question for oral answer O-000013/2026**

**to the Commission**

Rule 142

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on behalf of the PPE Group

**Subject:** Implementation of the Urban Wastewater Treatment Directive and risks to the security of supply of medicines

The revised Urban Wastewater Treatment Directive<sup>1</sup>, which entered into force on 1 January 2025, introduces an extended producer responsibility (EPR) scheme requiring pharmaceutical and cosmetic producers to cover at least 80 % of the costs of quaternary wastewater treatment. The directive, furthermore, allows Member States to oblige the industries concerned to cover up to 100 % of these costs.

While it is evident that the directive pursues legitimate environmental objectives, serious concerns persist regarding the robustness of the underlying cost estimates, the proportionality of the EPR scheme and its potential impact on the availability, affordability and security of supply of medicines, in particular essential and low-margin generic products. These concerns have been raised repeatedly by Members of the European Parliament, by stakeholders and by several Member States, and remain unresolved despite the Commission's updated cost study published in December.

In this context:

1. How does the Commission justify proceeding with the implementation of the EPR scheme in the absence of a comprehensive, product-level and independently validated impact assessment addressing the divergent cost estimates and their implications for medicine supply?
2. Does the Commission intend to propose a temporary suspension of or 'stop-the-clock' on the implementation of the EPR provisions until such an assessment has been completed and duly assessed by the legislator?
3. How does it intend to ensure the effective and enforceable inclusion of non-EU producers in the EPR system in order to prevent free riding and competitive distortions to the detriment of EU-based manufacturers?

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<sup>1</sup> 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>).