

EN

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Answer given by Executive Vice-President Šefčovič
on behalf of the European Commission
(8.10.2024)

There is ample evidence that certain pharmaceuticals are posing problems in rivers and thus to human and animal health¹. Starting with the Strategic Approach to Pharmaceuticals in the Environment² in 2019 and the subsequent European Green Deal³ including notably the Zero Pollution Action Plan⁴, there is a high-level of attention at EU level to the toxicity of pharmaceuticals in the environment and action is being taken to better monitor and reduce the presence of pharmaceutical residues in water bodies, including through funding research and innovation⁵.

The proposal to revise the list of Surface and Groundwater Pollutants⁶ includes for the first time certain pharmaceuticals compounds and proposes maximum concentrations to be respected. The Commission counts on the co-legislators to support the high level of ambition of this proposal in the forthcoming trilogues.

The recast Urban Wastewater Treatment Directive⁷ includes new obligations to remove micropollutants such as pharmaceuticals from all large urban wastewater treatment plants (above 150 000 inhabitants) but also for smaller plants when there is a risk for the environment or for human health. In line with the 'polluter pays' principle, industry will be required to contribute to the financing of the additional infrastructures needed to remove micropollutants. This will also incentivise research and innovation into toxic-free products.

The proposal for the revision of pharmaceutical legislation⁸ represents a significant step forward in mitigating the impacts of pharmaceuticals on the environment i.e. it requires the Environmental Risk Assessment for antimicrobial to cover the whole life cycle including manufacturing.

¹ <https://circabc.europa.eu/w/browse/677b0752-676a-4a17-a60a-08a833fcc204>

² European Union Strategic Approach to Pharmaceuticals in the Environment as required by Article 8c of Directive 2008/105/EC as amended by Directive 2013/39/EU: <https://ec.europa.eu/environment/water/water-dangersub/pharmaceuticals.htm>

³ https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

⁴ https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en

⁵ https://cordis.europa.eu/programme/id/HORIZON_HORIZON-CL6-2022-ZEROPOLLUTION-01-01/en, https://cordis.europa.eu/programme/id/HORIZON_HORIZON-CL6-2022-ZEROPOLLUTION-01-04/en and https://cordis.europa.eu/programme/id/HORIZON_HORIZON-CL6-2024-ZEROPOLLUTION-02-1-two-stage

⁶ COM(2022) 540 final of 26.10.2022.

⁷ for which a political agreement was reached by co-legislators and that is expected to be adopted soon, https://environment.ec.europa.eu/publications/proposal-revised-urban-wastewater-treatment-directive_en

⁸ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en