ECJ Advocate General's opinion proposes to annul the EPR cost allocation under the EU wastewater rules

Medicines for Europe calls for urgent pause of the EPR scheme to protect medicine supply

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Today, the Advocate General, Juliane Kokott, confirmed in her opinion on Poland's challenge before the Court of Justice of the European Union (CJEU – case number C-193/25) serious concerns about the design and proportionality of the extended producer responsibility (EPR) scheme for medicines. As a result, the Advocate General proposes to annul article 9.1 letter a) and Annex III of the Urban Wastewater Treatment Directive (UWWTD) which allocates at least 80% of the costs of the quaternary treatment to the pharmaceutical and cosmetic industry.

Although the opinion is not binding for the CJEU's final judgment, it materially strengthens the case for pausing implementation of the EPR scheme. Member States and the European Parliament are already calling for action before the scheme affects patients' access to medicines. The Commission should therefore pause implementation and conduct a thorough review to ensure the scheme protects the environment without creating avoidable risks to medicine supply and availability.

The situation remains urgent for patients and manufacturers. Investments in production planning must already include the costs of the UWWTD supply, volumes from 2028 will determine EPR contributions due in 2029. Companies will therefore need to decide much sooner which medicines to manufacture, how much to supply and where to invest. Without a solution, manufacturers may make precautionary withdrawals, reduce medicine supply and weaken Europe's production of critical medicines at a time when the EU is seeking to strengthen health security and resilience.

Adrian van den Hoven, Director General of Medicines for Europe, said: "*Today's opinion strengthens the case for stopping the clock on this Directive to avoid consequences for the availability of medicines for patients. The Commission should use this opportunity to properly review the EPR scheme before companies are forced to make decisions that could affect medicine supply or health security.*"

Notes for editors

Resource hub:

- ECJ Advocate General opinion on Poland's challenge before the Court of Justice of the European Union (CJEU – case number C-193/25)
- Ramboll study on Micropollutants in Urban Wastewater
- Note on Bio Innovation list of substances found in Urban Wastewater
- Memo on Urban Wastewater Treatment Directive

What is the UWWTD and the EPR scheme it creates?

- The UWWTD introduces an "extended producer responsibility" (EPR) on the sale of medicines and cosmetics, to pay for the late-stage ("quaternary") treatment of urban wastewater. In practice, generic medicine manufacturers will need to collect levies on the sale of medicines to finance

infrastructure investments and operational costs of the water industry. Levies apply to the sale of medicines because pharmaceutical residues in wastewater comet from patient consumption. Manufacturing site effluents are closely monitored and minimised by manufacturers in accordance with strict emission laws. Hence, the EPR fees will be based on the volume of medicines consumed by patients in each member state.

- This levy is particularly problematic for the generic medicines industry, which supplies most of the essential medicines for patients. The UWWTD does not set a maximum EPR contribution which means that the total cost could be substantially higher than the costs estimated by the Commission (between €1.48 and €1.8 billion/year by 2045). Member State cost estimates are 3 to 6 times higher than the Commission estimates. Based on economic modelling of the real impact of the UWWTD, the Directive will cause a tsunami of medicines shortages.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on LinkedIn and X @medicinesforEU.