Press Release

Medicines for Ireland and Medicines for Europe welcome Irish Court referral of EU Water Directive to CJEU

Brussels, 22 May 2026

On 20 May 2026, the Irish High Court issued judgment granting a preliminary reference to the Court of Justice of the European Union (CJEU), querying whether the Extended Producer Responsibility (EPR) scheme of the Urban Wastewater Treatment Directive (UWWTD) is valid in light of the polluter-pays principle of the TFEU and the general principles of EU law, including proportionality, equal treatment, and non-discrimination.

The UWWTD requires producers of medicines and cosmetics to fund at least 80% of the cost of a new stage of municipal wastewater treatment, known as quaternary treatment, designed to remove chemical residues from the general wastewater network. The EPR scheme will only apply to producers of cosmetics and human medicines. While MFI and MFE have consistently supported strong environmental objectives, they are of the view that the EPR scheme places a disproportionate and discriminatory burden on the pharmaceutical sector and is contrary to general principles of EU law by excluding other sectors that are sources of micropollutants in urban wastewater.

Medicines for Ireland and Medicines for Europe rely on independent expert reviews, which identify significant flaws in the methodology used by the European Commission to apportion that burden, including an overestimation of the toxic load of pharmaceuticals excreted by patients in waste water and the exclusion of other contributing sectors from any equivalent obligation. At the same time, unlike other sectors, generic and biosimilar medicine producers face strict regulatory constraints that make the reformulation of active ingredients impossible.

In Ireland and across Europe, medicine prices are regulated, and margins are constrained; costs of this scale affect product viability and supply, particularly for the generic medicines on which patients and healthcare systems depend.

Donagh O'Leary, Chair, Medicines for Ireland, said, "*We welcome this ruling as a step toward the legal certainty that patients and medicine suppliers in Ireland need. It is essential that all legislation is applied in a way that is fair, proportionate, and consistent with EU law.*"

Adrian van den Hoven, Director General, Medicines for Europe, said, *"It is our view that producers of affordable medicines across Europe are being asked to fund a treatment system based on a methodology that independent experts have found deeply flawed. The CJEU is now the right forum to examine whether that is consistent with EU law, and we welcome the opportunity for it to do so."*

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Resource hub

- Memo on Urban Wastewater Treatment Directive
- Ramboll study on Micropollutants in Urban Wastewater
- Note on Bio Innovation list of substances found in Urban Wastewater

Medicines for Ireland

Founded in 2016, **Medicines for Ireland (MFI)** is the established industry voice within the Irish healthcare system. It represents the pivotal role and interests of manufacturers and suppliers of generic, biosimilar, and value-added medicines. With MFI members supplying the majority of medicine in Ireland to the HSE and patients directly, it is committed to effecting real change and reforms that guarantee patients have access to the medicines they need at affordable prices. MFI members form a key part of an efficient supply chain which ensures patients can access the medicines they need in a timely manner. For more information about Medicines for Ireland, visit www.medicinesforireland.ie.

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 http://www.medicinesforeurope.com and on LinkedIn and X @medicinesforEU.