

## Press release

# Medicines for Europe calls for balanced safeguards on access to medicines in EU Water Resilience Strategy

04 June 2025, Brussels

Medicines for Europe, representing manufacturers of generic, biosimilar, and value-added medicines and accounting for 70% of dispensed medicines and 90% of critical medicines in the EU<sup>1</sup>, reacted to the European Commission's Water Resilience Strategy published today. This initiative tackles the growing challenges of drought, flooding and water quality across Europe. Our members are committed to responsible manufacturing and environmental protection, including robust risk assessments, water reuse strategies, and advanced effluent treatment technologies<sup>2</sup>.

Water is an essential component of pharmaceutical manufacturing. As set out in the European Medicines Agency (EMA) Guideline on water for pharmaceutical use<sup>3</sup>, it is used as an excipient, in synthesis, reconstitution, and cleaning. Ensuring access to high-quality water to maintain the sustainable and uninterrupted supply of medicines should be considered when proposing future water efficiency objectives.

Access to safe water and medicines are both fundamental rights. In this light, the Strategy's reference to a new Commission study on costs and impacts on concerned sectors of the Urban Wastewater Treatment Directive Extended Producer Responsibility (EPR) scheme is a step in the right direction. Available data clearly show that this scheme, introduced to finance quaternary treatment for residues from human consumption, will undermine patient access to medicines for diabetes, cardiovascular disease, epilepsy, and infections<sup>4</sup>.

The implementation of EPR needs to be paused while this assessment is conducted and a more effective and balanced solution must be found urgently, in line with the concerns expressed by 16 Member States<sup>5</sup> and recently by the European Parliament.<sup>6</sup>

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<sup>1</sup> European Medicines Agency, [Union list of critical medicines](#), December 2024.

<sup>2</sup> Well-established initiatives in cooperation with other pharmaceutical industry actors include the [AMR Industry Alliance](#) and the [Eco-Pharmaco-Stewardship](#).

<sup>3</sup> European Medicines Agency, [Guideline on the quality of water for pharmaceutical use](#), July 2020.

<sup>4</sup> For example, in the Netherlands the cost of diabetes medicine metformin is expected to increase by up to 900%, and the antibiotic amoxicillin up to 400%. See our [MEMO on Urban Wastewater Treatment Directive](#), February 2025.

<sup>5</sup> [Member States statements](#), October 2024.

<sup>6</sup> [European Parliament resolution on the European Water Resilience Strategy](#), May 2025.

Recourse to the polluter pays principle must ensure that access to medicines and supply chain resilience are not undermined. Regulation needs to be based on scientific evidence, which was not the case for the UWWTD. A recent Ramboll comprehensive literature review <sup>7</sup> found residues from many other sectors, including pesticides, food additives, veterinary medicines, personal care products, biocides, industrial chemicals, in wastewater. The study also found no public data to determine the relative contribution of pharmaceuticals compared to other residues and highlighted that research disproportionately focuses on pharmaceuticals, potentially underrepresenting other sectors.

Regarding possible future restrictions on PFAS, the derogations necessary for medicine manufacturing in Europe must be maintained while feasible alternatives are developed and approved in the future.

Adrian van den Hoven, Director General of Medicines for Europe, said: *“Water resilience is important for Europe and it should go hand in hand with medicine security. The Urban Wastewater Treatment Directive undermines patient access by imposing disproportionate levies on low-cost essential medicines. The announced reassessment of the impact on the pharmaceutical sector is a positive step. We call on the Commission to urgently review this legislation and to deliver balanced water regulation in future. The EU needs a strategy that protects water resources, ensures patient access and supports medicine manufacturing and strategic autonomy.”*

## 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](http://www.medicinesforeurope.com) and on LinkedIn and X @medicinesforEU.

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<sup>7</sup> See [Ramboll study](#) on Micropollutants in Urban Wastewater and [summary](#), March 2025.