Mr. António COSTA
President
European Council

EU 27
Heads of States and Governments
European Union

Brussels, 09th February 2026

Subject: An urgent need to pause the Urban Wastewater Treatment Directive to safeguard access to essential medicines and European competitiveness

Dear President Costa,

Dear Heads of States and Governments,

Ahead of the European Council meeting of 12 February on Competitiveness, Medicines for Europe would like to draw your attention to a matter of strategic importance: the implementation of the revised Urban Wastewater Treatment Directive (UWWTD) and its impact on the availability of medicines. This Directive, which imposes a discriminatory and disproportionate extended producer responsibility fee on the consumption of medicine risks causing a tsunami of medicine shortages while dramatically harming the attractiveness of the European market for essential and critical medicines.

While the Directive pursues the widely supported objective for clean water, its design - based on highly contested assumptions and insufficient market analysis — will have unintended consequences. **Generic medicines**, **which account for 90% of critical medicines and 70% of prescriptions but operate on very low regulated margins**, **cannot absorb additional cost burdens without risking market withdrawals, shortages, or sharp price increases**.

Evidence emerging from national analyses confirms the scale of the risk. Government-backed assessments in Germany and the Netherlands indicate that the Commission's modelling substantially underestimates real-world impacts. **In the Netherlands, prices of certain critical antibiotics could increase by up to 220%, and first-line diabetes treatments by up to 900%.** Furthermore, attributing 58% of wastewater toxic load to four pharmaceutical molecules, using standards not recognised by the European Medicines Agency, raises **serious questions about the scientific basis underpinning the cost allocation model**. According to our estimates, based on the required standards, these four molecules represent less than 1% of the toxic load.

Crucially, proceeding under these conditions sends a damaging signal globally. At a time when the United States, Japan and China are actively deploying industrial policy tools, incentives, and regulatory alignment to attract pharmaceutical investment and secure supply chains, Europe risks moving in the opposite direction — imposing disproportionate costs on a vital strategic sector. This Directive totally undermines the Critical

Medicines and Biotech Acts. It will accelerate investment flight and exacerbate strategic dependency on external suppliers.

Uncertainty remains substantial, and early national implementation risks undermining access to essential medicines and increasing financial pressure on health systems. The Ministers of Health in sixteen Member States have raised serious concerns. **Access to essential and critical medicine is a right, not a privilege — it is a core responsibility of each government and a foundation of public trust.**

For these reasons, we call for decisive political leadership. We urge the European Commission to immediately **"stop the clock"** on this implementation to allow for a proper overarching impact assessment on medicine availability, affordability and healthcare budgets.

At a time of unpreceded geopolitical instability, Europe cannot afford regulatory fragmentation that undermines its own resilience. On the contrary, Europe must reinforce its strategic capacity to supply and secure essential medicines and remain globally competitive. We therefore call on your leadership to support a pause in implementation and the development of a balanced, evidence-based approach that protects patients, preserves supply security, and ensures that environmental objectives are achieved without compromising public health.
We stand ready to engage constructively and contribute to pragmatic solutions that meet environmental ambitions without compromising public health or Europe's strategic position.

Yours sincerely,

Adrian van den Hoven
Director General
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 Research and Development. 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.