

Press Release

Council adoption of Urban Waste Water Treatment Directive will generate a tsunami of essential and critical medicine shortages across Europe

Brussels, 5 November 2024

The generic, biosimilar and value-added pharmaceutical sector represented by Medicines for Europe condemns today's adoption of the EU Urban Waste Water Treatment Directive (UWWTD), which will require only the pharmaceutical and cosmetic sectors to finance the upgrades of several hundreds of wastewater treatment plants across Europe and their running costs. If implemented in the current form, the direct economic impact of the directive will lead to massive shortages of essential and critical medicines in Europe, due to lack of economic viability.

Generic medicines are the backbone of European healthcare systems, representing 7 out of 10 dispensed medicines and 9 out of 10 of critical medicines while accounting for just 19% of the market value. They are particularly vulnerable to the UWWTD tax, due to their high volumes and strictly capped prices. The medicines most at risk from this system are those needed by millions of European citizens, suffering with an array of diseases where generic medicines are an essential cornerstone of treatment. This includes cardiovascular disease, cancer, bacterial infections, diabetes, mental health, inflammatory bowel diseases and epilepsy and more.

Our sector is engaged in making water cleaner and safer in line with the objective of the UWWTD. To play their part, our companies strictly monitor, manage and minimise pollution in discharge waters at their manufacturing sites. Patients, who are obliged to take medicines for their health or to treat a disease and who consequently release pharmaceutical residues in European waterways, should not be penalised by this unworkable and discriminatory European law.

The Extended Producer Responsibility (EPR) system as adopted in Council today is an existential threat to Europe's generic pharmaceutical industry. It can lead to severe supply disruptions, compromise patient access to affordable essential and critical medicines and undermine Europe's efforts to improve its open strategic autonomy in the context of the Critical Medicines Alliance.

The costs of this system ranging between €5 billion and €11 billion per year, according to German government and European water industry sources, would create a tsunami of generic medicine shortages, have catastrophic consequences on patient access to medicines and the sustainability of healthcare systems in Europe. Despite numerous warnings, these severe consequences have been overlooked in the legislative process, driven by a misguided political trade-off that pits financial support for the water industry against patient access to medicines.

The adoption is even more perplexing since sixteen member states, Austria, Bulgaria, Czechia, Germany, Estonia, Spain, France, Greece, Italy, Latvia, Lithuania, Malta, Poland, Portugal, Romania and Slovenia¹ all expressed serious concerns about how this law will undermine the availability of essential medicines and the efforts of the European Parliament to protect patient access to medicines in the law.

Adrian van den Hoven, Medicines for Europe Director General, stated: *“I am disheartened to see this law adopted by the Council today. Generic medicines are the backbone of public health and access to essential and critical medicines, and we are already struggling with shortages because of inflation and the massive disruptions caused by the Covid-19 pandemic, the Russian invasion of Ukraine and other wars and disputes around the world. Essential and critical generic medicines cost just a few eurocents a day – they cannot pay for this water tax. The UWWTD adoption will hit the medicines that so many need to keep well: cardiovascular disease medicines, cancer medicines, including chemotherapy, diabetes medicines, and so many others. Medicines for Europe will assess all options available to us to correct the course set by this directive and to shield European patients from the massive wave of shortages that is coming.”*

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 Twitter @medicinesforEU.

¹ <https://data.consilium.europa.eu/doc/document/ST-14488-2024-ADD-1-REV-2/x/pdf>