7th Feb 2025

The Urban Wastewater Treatment Directive's Impact on Medicine Availability: A Call to Action to include the Directive in the Omnibus Package to protect major impact on patient's access to medicines

Dear Governmental Officials,

I am writing on behalf of Teva Pharmaceuticals, a strategic partner in Estonia healthcare landscape. Our commitment to patient health is deeply rooted, as our company works toward providing better health to our patients daily through Teva's diverse portfolio of medicines. As a testament to our leadership, we are one of the largest pharmaceutical manufacturers in Estonia, with data showing that one in every 11 patients relies on and benefits from a Teva product for their care.

We are reaching out to you about the **Urban Wastewater Treatment Directive (UWWTD)** and its negative impact on the availability of medicines in Estonia.

The newly adopted UWWTD is a piece of legislation that urgently needs improvement. While Teva supports the Directive's environmental goals, the text is unfair and contradicts the "polluter pays principle" by placing an excessive financial burden solely on two sectors (pharmaceuticals and cosmetics) to fund the modernization of urban wastewater treatment systems through an extended producer responsibility (EPR) scheme.

The EPR fees will have profound consequences on the availability of medicines. Given generic manufacturers' inability to systematically adjust prices, these fees will force manufacturers to phase out a significant number of generics medicines used every day by patients. Due to long manufacturing supply chain planning cycles this phase out may already happened starting 2025. Consequently, the burden of EPR fees will shift to the remaining medicines, whose increased volumes will render additional generic medicines economically unviable. This will create significant uncertainties for physicians and patients regarding the availability of treatments and unfortunately contradicts the shared ambition to secure supply diversity and healthcare resilience.

Sixteen Member States have issued concerning statements on the need to ensure that the law does not have dire consequences for the availability of medicines.

We acknowledge the importance of the implementation of this Directive, particularly in relation to the Extended Producer Responsibility (EPR) scheme. While Estonia has not yet posted an official statement regarding this matter, we invite the Estonian Government to share its position on the Directive. Your insights on the challenges posed by the EPR system, especially in the context of pharmaceuticals and wastewater management, would be invaluable and play a crucial role in shaping informed decisions moving forward.

However, we are concerned that critical warnings regarding the potential consequences of this Directive have been disregarded. Despite numerous alerts, these severe consequences have been overlooked in the legislative process, driven by a misguided political trade-off that prioritizes financial support for the water industry over patient access to medicines, supported by a biased impact assessment.

Simplification and reduced burden are crucially needed

While there is a valid reason to legislate for clean water, the poorly evidenced and highly flawed EPR system fails to target other sources of pollution, such as chemicals from textiles, cleaning and household products, metals, biocides, pesticides, sweeteners, and veterinary medicines. This will undermine the supply of critical medicines, leading to divestment in manufacturing, which will, in turn, undermine supply security, jobs, manufacturing, and growth.

In addition, 3 critical elements must be addressed via the Omnibus process:

1. **Highly Unpredictable Cost** the Impact Assessment predicts a quaternary treatment cost of €1.18 billion annually. However, our model shows this would already undermine the economic viability of many essential or critical medicines. The true cost, according to the German government and the European water industry, ranges between €5 billion and €11 billion per year. As an example, the **Extended Producer Responsibility (EPR) scheme** for the Netherlands is estimated to cost **€64,774,361**, while the **Dutch government projects a broader EPR cost of at least €400 million per year.** This massive cost would create a tsunami of generic medicine withdrawal and shortages, with catastrophic consequences for patient access to medicines and the sustainability of healthcare systems in Europe.
   It is critical for the EU Commission to delay the implementation of this legislation and **thoroughly reassess the impact on medicines**, in particular generic, as soon as possible.

2. **Burdensome Producer Responsibility Organization (PRO) System** The legislation requires manufacturers to establish at least 27 Producer Responsibility Organizations (PROs), each tasked with collecting EPR fees based on the quantities and hazardousness of medicines and cosmetics from thousands of companies. Estimating the quantities and hazardousness of cosmetics and pharmaceuticals will be a hugely complex exercise, resulting in disagreements and legal challenges. This will add significant administrative and financial burdens, increasing complexity and lack of harmonization across the single market.

3. **Unclear Fees Allocation** Under the EPR, levies must be calculated based on the quantities and hazardousness of medicinal and cosmetic products. However, it is not specified how hazardousness will be determined and how both criteria will relate to each other. While this grants flexibility to the PROs, it also creates legal uncertainty, making it impossible for companies to assess the precise fee on their products. The pharmaceutical and cosmetics industries only have until 31 December 2028 to set up the PROs and the EPR schemes in all member states.

We therefore urge the EU Commission to include the UWWTD in the EU Simplification Omnibus to Protect Patient Access to Medicines, by reassessing the full impact of the legislation and working out an economically viable solution.

There are many ways to improve water treatment without compromising public health, competitiveness, and simplification objectives.

Considering all the above arguments, we urge you to raise these concerns at the level of the EU Commission, enabling us to continue manufacturing and supplying high-quality, affordable medicines to the patients we serve in Estonia and Europe.

We deeply appreciate your attention to this pressing matter, and as a pharmaceutical company and a member of the Association of Pharmaceutical Manufactures in Estonia, we are ready to consult and cooperate on this topic.

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However, we wanted to flag the opportunity to include the UWWTD into the Omnibus simplification package already now as the window of action is very short.

Looking forward to your favorable response and the opportunity to contribute to enhancing the healthcare landscape in our country.

Kind regards,
Agita Birnbauma
General Manager of Teva Baltics