September 2024

Dear Government Official,

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 through Teva's diverse portfolio of medicines.

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

This autumn in the Council, Estonia Environment Minister will have to sign-off the proposal for the UWWTD.
We ask the government to reconsider its support for the Directive in its current form at that meeting, and call for a fair legislative text that should include all other polluting sectors in line with the EU polluter pays principle in order to avoid shortages of critical medicines that could put patients in danger. The stakes at risk are too high.

Please allow me to elaborate on our arguments below:

1) **The UWWTD violates 3 EU legal principles: the EU polluter pays principle, the EU principle of proportionality and the EU principle of non-discrimination.**
   - The Extended Producer Responsibility (EPR) obligations that the UWWTD imposes on producers of human medicines **violate the EU polluter pays principle** because they will require these producers to pay significantly more than the costs of the quaternary treatment of the micropollutants in wastewaters that result from their products, and the obligations do not take into account the contribution to micropollutants of other product sectors.
   - The obligations for human medicines producers **also violates the EU principle of proportionality** because they impose financial obligations that go beyond these products' contribution to micropollutants and create a financial burden that could threaten patients' access to medicines.
   - Finally, these obligations **violate the EU principle of non-discrimination** because producers of human medicines will have to pay at least 80% of the quaternary treatment of micropollutants in wastewaters without considering the contribution of other products to such pollution.

2) **The EU Commission feasibility study and economic calculations are flawed and the costs to be bared by medicines manufacturers are going to be much higher.**
   - The rationale for the sector-based Extended Producer Responsibility (EPR) is neither transparent nor supported by data. It also misses its main goal of incentivizing ALL polluters to invest in developing greener products.
   - The Commission claims that cosmetics and pharmaceuticals are responsible for 92% of micropollutant toxic load, without providing any evidence or methodology. However published reports (e.g. Micropollutants in Urban Wastewater by Ramboll, 2023) indicate much lower values so the Commission´s statement is not supported by scientific evidence.
   - Other sectors (pesticides, food, plastic and household products) have been clearly identified in the Feasibility Study conducted by the Commission as being the source of micro-pollutants, but they were completely left out without a satisfactory explanation. This is unfair and not compliant with the key EU principles, such as proportionality, equal treatment and polluter pays principle.
   - **The costs resulting from the EPR scheme will be much more than the Commission estimated.** The German Environment Agency estimates that the annual quaternary treatment costs in Germany alone could range between 885 and 1025 million €, which is **four times the**

Commission's estimate of 238 million for Germany and close instead to the Commission's estimate of 1213 million for the entire EU.

3) **Critical generic medicines are disappearing from Estonia and European market and the costs surging from the implementation of the UWWTD will exacerbate this negative trend.**

- The trends we observe In the EU regarding critical medicines are concerning. The rate of generic medicine withdrawals is accelerating due to external pressures: a combination of a price race to the bottom and significant regulatory cost increase.
- Our 2023 study "The Case of Europe's Disappearing Medicines Cabinet" highlighted that in the EU in the past 10 years, 26% of generics have been withdrawn. The situation is even worse in areas such as antibiotics or oncology generic medicines where 33% and 40% respectively have left the EU in the past 10 years.
- In 2024 we published a new study "Critical Medicines Health Check" which analyses the market trends for the generic medicines from the Union List of Critical Medicines published by the EMA in December 2023.

The generic medicines market in the EU is not in good shape:

- e.g. in mental health, 7% of the generic products on the Union List disappeared between 2013 and 2023 going further down like the number of generic products for the treatment of schizophrenia and bipolar disorder which declined by – 25%.
- e.g. for some critical oncology generics, the decrease is as steep as – 43%.
- e.g. 21% of generic oral liquid antibiotic products disappeared from the EU market in the past 10 years.

A reversal of this negative trend is not in sight.

While Teva is fully committed to enabling access to medicines, ensuring patients' safety and the green transition, as outlined in our 2023 Sustainability report , the costs resulting from the UWWTD fees will simply be unsustainable. Given our inability to systematically adjust prices to reflect these financial pressures, we find ourselves navigating an increasingly challenging economic landscape.
These costs are going to cripple investment for drug manufacturers. In times when EU leaders are calling the EU to re-gain competitiveness edge and when the Commission is working so hard with Member States and other stakeholders including Teva in the Critical Medicines Alliance, this Directive will go in the opposite direction. In its current form, this proposal stemming from the Green Deal will threaten Europe's health and industrial future.

In light of all the above arguments, we urge you to **raise these concerns at the Council vote in the autumn** and help to mitigate the impact of the oppressive UWWTD fees by including all additional responsible products/sectors in the EPR scheme, enabling us to continue manufacturing and supplying high-quality, affordable medicines to the patients we serve in Estonia and Europe.

You can still take the right steps to bring this unbalanced regulation into a legally compliant form and thus prevent the danger that essential medicines will fall victim to this Directive.
We strongly encourage you to familiarize yourself with the attached legal analysis by Covington & Burling LLP and **request an assessment of the Directive by the legal service of the Council** which then should be considered as part of the Commission's guidance for transposing the UWWTD.

We deeply appreciate your attention to this pressing matter.

Best regards, Agita Birnbauma, General Manager Teva Baltics