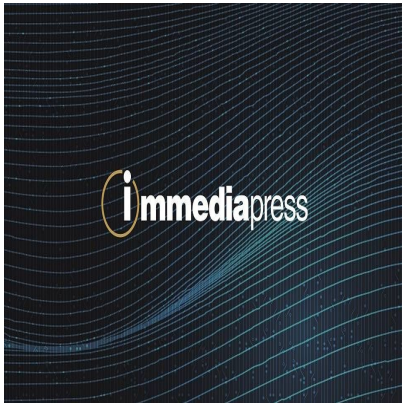




Zentiva Demands EU-Level Stop-the-Clock on the UWWTD to Protect Medicine Availability

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

PRAGUE, Feb. 23, 2026 /PRNewswire/ - Zentiva, a leading European manufacturer of high-quality and affordable medicines, responds to the decision of the General Court of the European Union concerning the Urban Waste Water Treatment Directive (UWWTD) reiterating that the UWWTD, in its current form, poses a significant risk to the secure supply of essential medicines in Europe.

Following the adoption of the Directive, despite major concerns raised by 16 EU Member States, in 2025 Zentiva filed a legal action to request annulment of the Directive to safeguard the secure supply of essential medicines for the patients who depend on them every day.

The recent decision clarifies how the Court interprets legal standing under EU law. It concludes that Zentiva and other generic and off-patent medicine manufacturers are not considered individually affected, and therefore do not have a direct judicial route to challenge the Directive even though its impact on the sector and on the medicines we supply across Europe is real and substantial. Importantly, the Court did not assess the substance of the case including whether the Extended Producer Responsibility (EPR) scheme under the UWWTD is compatible with EU law or whether the cost model is workable, proportionate, or safe for securing the continuity of medicine supply.

Zentiva CEO, Steffen Saltofte, who is also President of Medicines for Europe, stated: "The UWWTD Directive has been approved and is already in the implementation phase. Its foundation is an assessment that has been scientifically disproven multiple times, yet it obliges the pharmaceutical and cosmetics industries to cover at least 80% of the costs for wastewater treatment in the fourth treatment stage. From the very beginning, we knew this was not feasible for the off-patent medicine industry. Our prices are mostly regulated, and the price for a daily dosage of an off-patent medicine is in the cent range. We simply cannot absorb these costs."

If implemented without correction, the Directive may render many essential medicines economically unsustainable to produce. The result would directly affect patients across all EU Member States, reducing access to affordable treatments and increasing the risk of medicine shortages. Ultimately, patients would pay the price.

The Court outcome does not resolve these long-standing issues – it leaves the substance of the Directive and its practical impact unaddressed, reinforcing the need for a political and policy-level correction before full implementation causes harm.

The generics industry counts for 70% of all dispensed medicines, and 9 out of 10 critical medicines. If no further measures are taken and the Directive in its current form is transposed into national legislation across 27 countries, it is highly likely to lead to massive shortages.

Saltofte further commented: “As the CEO of a European-based company and President of Medicines for Europe, the representation of the off-patent medicine industry, I will not sit back and watch this happen. We will continue to insist on a solution that we must develop together – not in silos, and not without industry. This issue requires all stakeholders at one table to pause the implementation, repair it at EU level, and relaunch it in a workable way across Europe – ensuring clean water without jeopardizing the availability, accessibility, and affordability of healthcare for the people in Europe who depend on these medicines every day.”

What needs to happen next

The Directive has been adopted and is entering national implementation, making political leadership and dialogue more urgent than ever.

Zentiva calls for:

About Zentiva

Zentiva provides health and wellbeing for all generations, with focus on developing, producing, and delivering high-quality, affordable medicines to more than 100 million people in over 40 countries across Europe and beyond. Zentiva has four wholly-owned manufacturing sites and a broad network of external manufacturing partners to ensure supply security. Zentiva employs more than 5,400 unique talents, bonded together by a commitment to the people who depend on our medicines every day. Visit us at www.zentiva.com

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Data di creazione

Febbraio 23, 2026

Autore

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