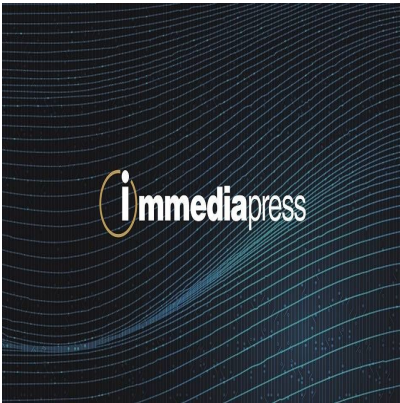




Zentiva appeals EU court decision on Urban Wastewater Directive

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

Appeal defends patient access, affordability of medicines and fundamental EU legal principles

PRAGUE and BRUSSELS, April 27, 2026 /PRNewswire/ - The EU Urban Wastewater Treatment Directive (UWWTD) continues to raise serious concerns. Zentiva and other companies in the off-patent medicines sector have therefore filed an appeal before the Court of Justice of the European Union (CJEU), which seeks to set aside an earlier order of inadmissibility and enable substantive judicial review following annulment action brought by the companies in March 2025.

Through Council statements and EPSCO* debates, 24 of the 27 EU Member States have raised concerns, expressed doubts, or requested further clarification on the Directive or its impacts. Despite this, the Directive is now being implemented at national level. The Directive in its current form poses a serious risk to the availability, affordability, and accessibility of medicines across Europe - on which millions of people depend every day. The companies therefore request a pause, repair and relaunch of the Directive.

Zentiva, a leading European manufacturer of generic medicines, fully supports the objective of further reducing micropollutants in urban wastewater, but strongly rejects the extended producer responsibility (EPR) scheme as a disproportionate and unjustified application of the 'polluter pays' principle. Micropollutants originate from a wide range of industrial and consumer sources -not only from the use of human medicines and cosmetics. The EPR scheme would mean that medicine and cosmetics producers have to pay for the removal of micropollutants not caused by them while other producers will not bear any cost. Overall, the EPR-scheme violates the 'polluter pays' principle and risks undermining patient access to essential medicines, placing a disproportionate burden on the generic medicines sector - the backbone of European healthcare - without delivering meaningful environmental benefits.

Steffen Saltofte, CEO of Zentiva and President of Medicines for Europe, said: “Generic medicines are the foundation of affordable healthcare in Europe. When disproportionate costs are imposed on essential medicines, supply becomes economically unviable and patients ultimately pay the price. Environmental protection and public health go hand in hand – one should not be sacrificed for the other.”

Generic medicines account for around 70% of all medicines dispensed in Europe and nine out of ten medicines on the EU list of critical medicines (IQVIA, 2024). These medicines make a significant contribution to public health. Yet generic manufacturers operate under strict price regulation and very low margins. Unlike other industries, they cannot increase prices to absorb additional costs due to statutory price and reimbursement controls in most Member States.

Independent studies in several countries indicate that the costs of the UWWTD have been significantly underestimated, creating a risk of medicine shortages, higher healthcare costs, and a loss of competitiveness for an entire industry sector.

While fully committed to protecting the environment, Zentiva highlights that the UWWTD’s EPR scheme does not incentivise “greener” medicines. Under the current regulatory framework, medicines cannot be reformulated within meaningful timelines or replaced without many years of research, regulatory approval, and patient safety assessments. As a result, the Directive risks increasing costs without delivering corresponding environmental benefits, while creating negative consequences for patients and healthcare systems.

The appeal seeks to set aside the General Court’s order of inadmissibility and to enable substantive judicial review following the annulment action brought by Zentiva and other companies in March 2025. Through this annulment action, Zentiva challenges Articles 9 and 10, in conjunction with Annex III of the UWWTD, which establish the extended producer responsibility (EPR) by allocating at least 80% of the costs of the new, so-called quaternary wastewater treatment to pharmaceutical and cosmetic producers.

Despite being directly and individually affected, Zentiva and other generic companies were denied the opportunity to have the substance of their case heard. Zentiva seeks judicial review of the Directive to ensure compliance with fundamental EU legal principles, while safeguarding continued patient access to affordable medicines.

Zentiva remains firmly committed to environmental responsibility. According to EcoVadis 2025, its sustainability program ranks among the top 2% of the pharmaceutical industry.

*Employment, social policy, health and consumer affairs council – a meeting of national government ministers.

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. Zentiva has four manufacturing sites and a broad network of external manufacturing partners to ensure supply security. Zentiva employs more than 5,400 unique talents in over 30 countries, bonded together by a commitment to the people who depend on our products every day. Visit us at www.zentiva.com or on LinkedIn.

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