

(...)

Subject: The European Commission must listen to Member States and the European Parliament by urgently pausing the UWWTD EPR scheme to protect the supply of thousands of essential and critical medicines in Europe

Dear (...),

Representing manufacturers of critical and essential medicines that supply approximately 70% of medicines dispensed in Europe and 90% of critical medicines through more than 400 manufacturing sites, we urge you to support an immediate pause in the implementation of the Extended Producer Responsibility (EPR) provisions under the Urban Wastewater Treatment Directive (UWWTD).

Without an urgent reassessment, the EPR scheme will risk reducing the availability of essential medicines and undermining one of Europe's most strategic manufacturing industries. The same concerns have been repeatedly expressed by both Member States and the European Parliament, even during the adoption of the Directive: the current framework threatens healthcare security and the industrial resilience of a strategic yet vulnerable sector for Europe, as demonstrated by the Covid-19 crisis.

There have been numerous political calls for a targeted review of the Directive, ranging from the Franco-German economic agenda endorsed by Heads of State to the concerns expressed by Health Ministers over the past two years. Most recently, at the 16th of June EPSCO Council, sixteen Health Ministers¹, led by the German delegation to the Council of the EU, raised serious concerns regarding cost uncertainty for healthcare systems, legal clarity and potential risks to the continued availability of medicines. Along the same lines, the European Parliament's 18th June resolution² called for a temporary pause of the EPR scheme and the need for evidence-based safeguards. We fully share these concerns and believe they should now be fully reflected in the Commission's approach.

At a time when the United States, China, India, and Japan are offering incentives to strengthen domestic pharmaceutical production, Europe risks imposing a regulatory cost that could force manufacturers to withdraw essential medicines and reduce investment, thereby weakening the attractiveness of the European market.

¹ [Impact of the extended producer responsibility under the Urban Wastewater Treatment Directive on the supply of medicinal products.](#)

² [Implementation of the Urban Wastewater Treatment Directive \(UWWTD\) and risks to the security of supply of medicines.](#)

More specifically, national assessments in the Netherlands³, Spain⁴ and Germany⁵, have indicated that the additional costs generated by this Directive would make the production of certain essential and critical medicines economically unsustainable in Europe, forcing producers to withdraw medicines or, where national pricing and reimbursement systems allow, implement significant price increases to maintain an economically viable supply. For example:

- In the Netherlands, the price of metformin – the most widely used treatment for diabetes - could increase by up to 900%.
- In Spain, the national expenditure for diabetes and pre-diabetes could rise from approximately €9 million to 231 million⁶, should metformin be permanently withdrawn from the market. Beyond this, there are serious doubts regarding the scientific basis of the Directive: the Commission claims that 4 pharmaceuticals would represent 58% of the chemical residues in wastewater, whereas calculations based on the European Medicines Agency methodology indicate that they account for less than 1%.

Environmental objectives applied to medicines must be based on robust scientific evidence, realistic economic assumptions, and a careful assessment of their impact on patients, healthcare systems, and pharmaceutical supply chains.

As called for by the European Parliament Resolution⁷, we therefore urge your leadership to immediately pause the implementation of the EPR scheme (Articles 9 and 10 of the UWWTD) and conduct a comprehensive, independent scientific and economic impact assessment. The review should evaluate the consequences for medicine availability, affordability, healthcare budgets, industrial competitiveness, and the resilience of Europe's pharmaceutical manufacturing base.

We cannot delay action. Investments in production planning must already include the costs of the UWWTD supply, volumes from 2028 will determine EPR contributions due in 2029. Without a thorough and urgent reassessment, we will seriously risk being forced by this European legislation to withdraw critical and essential medicines from the European market. The effects will not stop here, if we are forced to stop producing certain medicine lines, this would not only affect the availability of essential treatments but also call into question the viability of production facilities that employ thousands of people.

We respectfully ask for your support in ensuring that the Commission pauses the EPR implementation and reassesses this scheme before irreversible consequences occur for patients, healthcare systems, and the European pharmaceutical industry.

³ [Dutch Government study.](#)

⁴ [Spain's National Public Works Research Centre.](#)

⁵ [German Government study.](#)

⁶ [Impacto de la directive europea sobre tratamiento de aguas residuales urbanas en los medicamentos genéricos en España.](#)

⁷ [Implementation of the Urban Wastewater Treatment Directive \(UWWTD\) and risks to the security of supply of medicines.](#)

Yours sincerely,



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