

STATEMENT

Proposals on wastewater treatment will jeopardise patient access to medicines without helping green transition

Brussels, 26 October 2022

Medicines have a unique value to public health and society at large. They are vital for our wellbeing, either to manage serious conditions such as cancer, diabetes, bacterial infections, cardiovascular diseases, auto-immune conditions, or to prevent illness and manage symptoms that allow everyone to carry on with their lives.

The stringent regulatory framework for medicines ensures they are safe and effective, bringing better health to millions of people. **The pharmaceutical industry continuously evaluates its processes to keep on minimising any unintended environmental effects of medicinal products, while ensuring patient access to medicines.**

The Commission proposal to charge medicines in the Urban Wastewater Treatment Directive will ultimately jeopardise patient access to medicines. Blanket levies on medicinal products based on patient excretion levels are unprecedented, disproportionate, unfair, and ineffective. This measure will be very detrimental to society, if increased burdens on companies mean that many essential medicines are no longer viable and result in shortages.

Medicines for human use must be exempt from the proposal in light of their essential role in public health.

Few active pharmaceutical ingredients would have risk for the environment, and these are very well under control given the concentration levels found in European waterways. Pharmaceuticals are only a small fraction of the substances that an improved wastewater treatment would remove.

So, Extended Producer Responsibility would create a discriminatory model, in which the pharmaceutical sector would finance wastewater treatment upgrades, that would remove micro-pollutants from other different origins (which remain the major unaccounted source of water contamination).

Also, applying Extended Producer Responsibility to human medicines, to incentivise the development of “green by design” products, does not account for the biological nature of medicines’ action nor for the complexity of medicines authorisation based on quality, safety, and efficacy requirements.

Our sector is committed to constructive dialogue with policy partners, to develop solutions to further reduce medicines environmental risk.

Detailed proposals outlined in the [Eco-Pharmaco-Stewardship](#) programme cover scientific research projects under the Innovative Health Initiative (IHI), guidelines for management of manufacturing effluents, awareness-raising on the proper household disposal of medicinal waste and proposals for an extended environmental risk assessment. This ambitious programme would achieve the required balance of reducing the environmental impact while maintaining patient access to medicines.

Quotes

ADRIAN VAN DEN HOVEN, Director General at Medicines for Europe, said *“It is frustrating that duplicative and unworkable proposals for levies on medicines to address wastewater management are thrown at the pharmaceutical industry. This undermines our efforts to reduce our environmental footprint and more worryingly, negatively impact patients who need medicines. It is a lose-lose proposal. We call on European leaders to safeguard patient access to essential medicine while working with the pharma sector during the green transition, and not against us.”*

NATHALIE MOLL, Director General at EFPIA, said *“The pharmaceutical industry acknowledges the importance of wastewater treatment as an essential part of demographic concentration in large urban areas. However, the proposed measure would affect the availability of certain medicines which would be counter to a key principle of the EU’s Strategic Approach to Pharmaceuticals in the Environment that policies must not jeopardise patient access to safe and effective pharmaceuticals. The pharmaceutical industry has put in place an extensive Eco-Pharmaco-Stewardship programme which over the past 15 years has made great progress in minimising effects of pharmaceuticals in the environment.*

JURATE SVARCAITE, Director General at AESGP, said: *“Doing our best to protect the environment is a societal obligation for which we are all responsible. We fully understand the challenges facing the wastewater industry. It must indeed upgrade its treatment levels to be able to provide cleaner water. It also needs to make its by-products safe for reuse (e.g. sludge) in order to achieve sustainability and circular economy goals. It seems to us, however, highly disproportionate that the modernization of sewage treatment plants, as well as their continued operations, should be funded solely by a sector which has proven that it is doing its utmost to mitigate environmental risks while ensuring the availability and accessibility to quality treatments for the population. The measures proposed in the Directive will undoubtedly have a direct impact on patients and will further increase economical pressure on our health systems, already weakened by the successive crises of recent years.*

We believe it is possible to do things differently. Countries like Switzerland, for example, have adopted a different cost-sharing funding model for improving urban wastewater treatment plants (UWWTPs) that is non-discriminatory and equitable.”

Resource hub

The full Eco-Pharmaco-Stewardship programme can be accessed [here](#).



About us

AESGP

AESGP, the Association of the European Self-Care Industry, is the representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe. It is composed of national associations and the main multinational companies manufacturing self-care products. AESGP is the voice of more than 2.000 companies operating in the consumer healthcare sector in Europe, affiliated with AESGP directly or indirectly through the national associations.

www.aesgp.eu and [@AESGP](https://twitter.com/AESGP)

EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Our vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

www.efpia.eu and [@EFPIA](https://twitter.com/EFPIA)

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information visit www.medicinesforeurope.com and follow us on Twitter [@medicinesforEU](https://twitter.com/medicinesforEU).
