

# vfa feedback on the EU Commission Open Consultation on the Urban Waste Water Treatment Directive COM(2022)541 (UWWTD)

## **The research-based pharmaceutical companies take their responsibility for the environment seriously**

The vfa is the Verband der forschenden Pharma-Unternehmen [Association of Research-Based Pharmaceutical Companies] in Germany and represents the interests of 48 of the leading research-based pharmaceutical companies worldwide and more than 100 subsidiary and affiliated companies in terms of health, research and economic policy.

The mission of the research-based pharmaceutical companies is to make a decisive contribution to the health of patients with their innovations. This is already happening today by exercising their responsibility for the environment. Thus, since 2010, CO<sub>2</sub> emissions resulting from the production of pharmaceutical products in Germany have fallen by more than 50%, while energy consumption has also fallen at the same time. The pharmaceutical industry's ecological footprint is correspondingly small in comparison to other sectors.<sup>1</sup> It also makes significant efforts to protect water. At the European level, the Eco-

Pharmaco-Stewardship programme should be named above all. It is supported by several pharmaceutical industry associations and has the goals, among others, to gain better knowledge of the environmental risks of medications and to further increase the environmental standards for production sites. Consequently, the pharmaceutical industry also regularly considers the development and manufacture of pharmaceuticals with the intention of preventing avoidable environmental impacts.

Against this background, the research-based pharmaceutical companies support the EU's intention to achieve a more sustainable, environmentally and climate-friendly Europe by means of the Green Deal.

## **The vfa rejects the Commission's proposal for Extended Producer Responsibility in the present form and proposes an alternative concept**

The proposal published by the EU Commission on 26 October 2022 for the reform of the EU Urban Wastewater Treatment Directive provides, among other

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<sup>1</sup> [Sustainable Pharmacy \(vfa.de\)](https://www.vfa.de)

things, for the implementation of Extended Producer Responsibility (EPR) for manufacturers of pharmaceutical and cosmetic products. The most important goal of the proposal is to finance, by means of a special levy on pharmaceuticals, a so-called quaternary treatment at municipal sewage treatment plants of a certain size (Articles 8 and 9).

The vfa regards extending producer responsibility, structured in such a way, to be disproportionate as well as harmful for the following reasons and therefore proposes an alternative concept.

### ***Threat to strategic autonomy and security of supply***

The EU aims for a resilient, innovative and competitive pharmaceutical industry whose medications should make it possible for citizens to live longer, healthier and more productive lives. Particularly in view of the current geopolitical upheavals and their negative repercussions for the supply of pharmaceuticals in Europe, it becomes clear how central this project is, in the present and in the future. With its concept of Extended Producer Responsibility, the EU Commission is directly counteracting these European and national plans. Ultimately, their proposals would unilaterally increase the cost pressure on the pharmaceutical industry, although it is impossible to quantify the exact extent of the additional financial burden and this is significantly underestimated by the Commission in its Impact Assessment. This would happen

in a phase of foreseeable high energy prices, high inflation and unpredictable economic risks in the future. At the same time, in the case of the pharmaceutical industry, it is not readily possible to pass on the costs, given the tight regulatory framework for pricing. Moreover, price increases would also lead to external costs to be borne by patients as well as the healthcare system.

### ***Lack of justification for a unilateral financial burden on the pharmaceutical industry***

It is inconclusive as to why the pharmaceutical and cosmetics industries should be unilaterally burdened with the funding of a quaternary treatment stage. There are many causes responsible for the discharge of trace substances into wastewater. Only a small fraction of micropollutants actually come from pharmaceutical residues. The share of 66%, as cited by the EU Commission, that pharmaceuticals are supposed to contribute to polluting wastewater is, like large parts of the Impact Assessment, not scientifically comprehensible and consequently this leads to misguided political decisions. In fact, an expert opinion commissioned by the vfa in cooperation with other pharmaceutical industry associations, shows that the report is not transparent and is based on a decidedly selective choice of studies.<sup>2</sup>

Furthermore, in the end, the manufacturers or emitters of trace substances

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<sup>2</sup> <https://www.vfa.de/de/wirtschaft-politik/micropollutants-in-urban-wastewater.pdf>

that do not originate from pharmaceuticals would also profit significantly and disproportionately from a quaternary treatment stage financed by the pharmaceutical industry. From our point of view, this is an unjustified unequal treatment of essentially the same circumstances.

In addition, the overwhelming amount of pharmaceutical trace substances end up in wastewater due to use on and by patients; this use of medications is with medicinal intent and according to medical instructions. The research-based pharmaceutical companies therefore have no immediate influence on the use of medications. This must be strictly oriented towards the goal of providing the best possible treatment, so that a steering effect such as that actually sought by Extended Producer Responsibility cannot occur. Moreover, the fundamental question arises in the case of pharmaceutical residues, as to who is the "polluter", in the sense of the Polluter Pays Principle, which, as a basic principle of environmental law, underlies Extended Producer Responsibility.

Ultimately, according to the EU Commission's proposal, medications are to be treated like any other economic good, regardless of the fact that they have an exceptional status due to their importance for human health. According to the OECD, an essential objective of general Extended Producer Responsibility is to create incentives for manufacturers to

take environmental aspects into account when developing their products.<sup>3</sup> In the case of pharmaceuticals, this is only possible to a very limited extent, since pharmacological efficacy takes priority here. As a rule, any simple replacement of substances with more environmentally friendly alternatives is not possible.

### ***A special levy on pharmaceuticals violates EU law***

As part of licensing pharmaceuticals at the European level, evidence of possible environmental risks must also be presented in order to identify potential hazards for the handling or disposal of a pharmaceutical product. However, since the European legislators have established the clear precedence of the protection of health and life over aspects of environmental protection, any potential environmental risks do not lead to the situation that effective human pharmaceuticals can be refused licensing on their account. A special levy on pharmaceuticals for the purpose of financing a quaternary treatment stage would violate this prioritisation in a legally impermissible way, as the German constitutional lawyer Prof. Dr. Udo Di Fabio stated in an expert opinion (2021).<sup>4</sup> Furthermore, with such a levy, the EU would be exceeding its legislative authority in the area of law on taxation and levies.

<sup>3</sup> [Extended Producer Responsibility - OECD](#)

<sup>4</sup> <https://www.vfa.de/de/wirtschaft-politik/limits-of-law.pdf>

### ***The User Pays Principle as a more effective and less bureaucratic alternative***

The Commission's proposal remains extremely vague in many places relating to the implementation of Extended Producer Responsibility; a large number of ambiguities have not been eliminated. Thus, it is completely unclear how exactly the financial expenditure for the installation and operation of a quaternary treatment stage and the monitoring of the wastewater is to be quantified and divided among the manufacturers of pharmaceutical and cosmetic products. Besides this, it remains open, for example, how to ensure an efficient application of funds which is limited to what is necessary. In any case, the bureaucratic effort as well as the expected transaction costs are very high.

The User Pays Principle offers a simpler, more efficient and fairer instrument for financing a quaternary treatment stage, according to which the actual user of a public service bears the costs of utilising it. This principle promotes greater personal responsibility in dealing with scarce natural resources. At the same time, the burden on consumers is kept within narrow limits, such as when financing the quaternary treatment stage through a reform of the wastewater levy.<sup>5</sup> The "Swiss model", for example, which has proven its worth in this respect, would provide orientation. According to this, the costs for investment in a quaternary treatment stage at municipal

sewage treatment plants of a certain size would be levied by means of a moderate wastewater levy on all connected residents and companies nationwide. The Swiss consciously decided against other models, since they were considered to be too expensive in relation to their usefulness, among other issues.

Health is a good to which our society attaches so much value that our healthcare system is based on the principle of solidarity. If any individual is affected by a disease, he or she thus receives the support of all. This understanding of protecting health as a task for society as a whole must also extend to the removal of pharmaceutical residues from wastewater.

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<sup>5</sup> [Micropollutants and wastewater levy \(umweltbundesamt.de\)](https://www.umweltbundesamt.de)