

10 KEY PRINCIPLES

for effective and efficient implementation framework and PROs under UWWTD

AESGP, EFPIA and Medicines for Europe (representing the pharmaceutical industry) and Cosmetics Europe (representing the cosmetic industry) support the overall objectives of the Urban Waste Water Treatment Directive (UWWTD) and are committed to contributing to establishing of effective, efficient and manageable UWWTD implementation framework and Producer Responsibility Organisations (PROs), provided the Extended Producer Responsibility (EPR) scheme is applied in a fair, predictable, proportionate and non-discriminatory manner while ensuring access to medicinal and cosmetic products.

Therefore, pharmaceutical and cosmetic industries are asking that the substantial shortcomings and uncertainties identified during the legislative process are duly considered and addressed in the implementation by fully respecting applicable general principles of EU law, including the EU polluter pays principle, the EU principle of proportionality, the EU principle of non-discrimination and Member States' responsibilities for the definition of their health policy.

In line with the Commission's priorities laid out by Commission President von der Leyen in the Commissioner-designates' Mission letters for 2024-2029, we also call upon the EU and national authorities working on the UWWTD's implementation to ensure full alignment with EU's commitment to competitiveness and "making Europe faster and simpler". This includes ensuring fair dialogue and consultation with stakeholders at all times of the process, preventing any unintended consequences for availability and affordability of medicines and cosmetics and avoiding fragmented approaches that generate more costs and red tape for businesses.

1. Scope of the EPR schemes

It is important that some preliminary conditions are defined to identify the scope of an EPR scheme.

Firstly, within the definition of 'micropollutant' referred to in Article 9, par. 2, the relevant criteria for classification should be identified at the EU level.

Secondly, when it comes to the exemptions from the EPR obligation for producers that put on the market products containing micropollutants that are rapidly biodegradable, the industry must be involved in the definition of the implementing act referred to in Article 9 (2)(b).

Thirdly, regarding the modulation of the EPR fee, it is important that the hazardous element is considered and accurately assessed since each micropollutant has a different level of toxicity.

Fourthly, the level of the EPR fees should be correlated with the mandatory load and timeline targets for the deployment of quaternary treatment as defined in Article 8 (e.g., by 31 December 2033, the EPR shall cover 20% of discharges at urban wastewater treatment plants treating a load of 150 000 p.e. and above).

2. One Fee Calculation Model

There should be only one EPR calculation method at the EU level. The fee calculation should be modulated by the hazardousness of micropollutants in accordance with Article 9 (3)(c) and agreed by the paying industry representative bodies and in consultation with relevant authorities responsible for medicines and cosmetics, to ensure a workable and sustainable system.

The fee contribution should then be attributed to the respective national PRO based on the costs for quaternary water treatment in the concerned market and should not exceed costs foreseen by the EC in its impact assessment nor compromise the accessibility, availability and affordability of medicines, as assessed in accordance with Article 10(6)(f) of UWWTD, and cosmetics.

3. No Contribution for Past Investments

The contribution of producers to the costs of investments for quaternary treatment and/or sludge handling that already took place or have been planned before the establishment of the EPR schemes (Article 9(1)) and the definition of the national implementation programmes (Article 23(1)) should be zero.

Otherwise, the costs would infringe on the legal principles of non-retroactivity of law, legal certainty and legitimate expectations and would have a disproportionate impact on producers. In addition, for countries where the upgrade to tertiary treatment is not yet complete, contributions should not be extended to cover other stages than the quaternary treatment.

4. Single Not-for-profit PRO per Member State

There should be only one Producer Responsibility Organisations (PRO) per Member State, which would reduce red tape and unnecessary fragmentation leading to higher administration costs.

Existing PROs could be considered to further reduce the administrative costs of EPR.

To avoid conflicts of interest that may lead to excessive costs, PRO should be controlled exclusively by obligated producers (not water treatment companies or similar).

Given the complexity of creating and operating a new UWWT PRO scheme that has no equivalent today, the Commission should issue guidelines and/or recommendations in line with these key principles and in consultation with the industry.

5. Member State Funding for 20% of Costs

20% of quaternary water treatment costs resulting from cosmetic and pharmaceutical products should be borne by the regular national state funding to UWWTD.

This contribution would ensure fair implementation, with evidence-based prioritization of plant upgrades and choice of technology applied as well as reduce the impacts on the availability, affordability and accessibility of cosmetics and medicines and in Article 9 (1)(a) and further clarified in Recital 21 of the UWWTD.

6. Avoiding Free Riding

The EPR system should avoid free riding by introducing the concept of equal treatment of companies.

We believe that a common set of rules is needed and that all should have to follow certain requirements, e.g. reporting on the micropollutants contained in the products they put on the EU market, and:

- (i) on those micropollutants in products that do not meet the exoneration criteria due to their biodegradability, micro-pollution and hazardousness; and
- (ii) per type of product/substance (e.g., per marketing authorization) and not across the entire portfolio that a producer markets.

For those companies failing to report the required information, the corresponding amount of micropollutants on the market should be estimated based on, for instance, available product sales data by independent third party and administrative fees covering costs of obtaining such data and should be borne by those companies to avoid a risk of free riding.

7. Specific Responsibilities for EPR Systems

EPR systems should only be made responsible for the cost of wastewater treatment linked to their remit and their obligations towards achieving removal of micropollutants and should only cover:

- (i) the costs of quaternary treatment of urban wastewater;
- (ii) the costs for gathering and verifying data on products placed on the market; and
- (iii) other costs required to exercise their extended producer responsibility.

Running costs of wastewater treatment beyond direct costs arising from quaternary water treatment do fall outside the scope of EPR system. For example, costs related to movables, infrastructure room or services provided by the wastewater treatment plant personnel, direct energy costs and energy transition costs (considering that urban wastewater treatment facilities will have to become energy neutral by 2045) shall be excluded.

Independent authorities, including national courts of auditors where appropriate, should verify compliance with these principles.

8. Co-Responsibility for Cost Drivers

PROs are responsible for financing the removal of in scope micropollutants from urban wastewater, and as such should be co-responsible for the choice of the cost drivers (e.g. quaternary water treatment technology, oversee contracting of any third-party involved in the implementation of quaternary water treatment).

This is critical to ensure that EPR systems are implemented as optimally as possible, notably from a cost-benefit perspective, as explicitly prescribed by the Directive (Article 10 (5)). Should water treatment companies make unilateral decisions that are not supported by PROs, the latter should not be made financially responsible for said choices.

Furthermore, there needs to be direct accountability defined in national law for those who play a part in using the fees that they receive from EPR schemes. For instance, where wastewater treatment companies are responsible for water treatment, they should abide by the efficiency and transparency principles and penalties should be imposed punishing failure to adhere to these principles. This would optimise the operations notably via robust a quality control system to ensure that fees paid by the industry do not exceed what would be required to cover the costs of efficiently ran services.

9. Expanding Industry Contributors

Member States must ensure that all other polluters that are contributing to urban wastewater micro-pollution are included in their EPR schemes. The impact assessment of UWWTD estimates quaternary water treatment implementation costs across the EU to be equal to the total of 1 billion euros per year and it would be borne by the pharmaceutical and cosmetic industry alone.

Additional industries contributing to the total load of micro-pollutants should start contributing as soon as possible and before the foreseen evaluation by EC to expand the category of products subject to the EPR obligations by December 31, 2033. Early expansion of the products covered by the EPR obligations will proportionately reduce the financial contribution of producers of human medicines and cosmetics and will reduce the negative impact on the availability and accessibility of medicines and cosmetic products. Member States must broaden the application in line with the EU Polluter Pays Principle. This approach ensures that all producers pay for their responsibility for the micro-pollution and that their financial contributions are strictly proportionate to the pollution they cause. The current EPR system supported only by two sectors will disincentivise industries not covered by the EPR system from developing new technologies to treat and/or replace micropollutants. Furthermore, untreated micro-pollutant emissions will continue unabated as long as no treatment technology is available.

10. EPR financial obligations not extended beyond identified thresholds

Extended Producer Responsibility does not cover those cases where public authorities decide to extend quaternary treatment beyond identified thresholds in the directive for, e.g., water reuse purposes. Those quaternary water treatment installations fall under exclusive responsibility and financing of public authorities or water treatment management companies. Water re-use and other circularity obligations go beyond purpose of the EPR and will generate financial income for water management companies.

These principles aim to ensure that the implementation of the EPR scheme under the UWWTD is fair, efficient, and conducive to the sustainable management of urban wastewater without compromising access to medicinal and cosmetic products.