



Brussels, 13 October 2023  
(OR. en)

---

---

**Interinstitutional File:**  
**2022/0345(COD)**

---

---

**13857/23**  
**ADD 1**

**ENV 1087**  
**SAN 569**  
**COMPET 956**  
**CONSOM 348**  
**AGRI 592**  
**CODEC 1785**

**NOTE**

From:	General Secretariat of the Council
To:	Council
No. prev. doc.:	13329/23
No. Cion doc.:	14223/22 + ADD 1 - COM(2022) 541 final + Annexes
Subject:	Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment (recast) <ul style="list-style-type: none"><li>- General approach</li><li>= Statement</li></ul>

**STATEMENT BY ESTONIA**

**Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment**

We express serious concerns in relation to the approach proposed in Article 9 on applying the extended producer responsibility (EPR) to pharmaceuticals. While the EPR can be a useful source of funding to cover the costs of wastewater treatment from micropollutants (quaternary treatment), it should not be an obligatory or only solution for the Member States. When applying the EPR, Member States should be able to consider their specific national context regarding technical feasibility and economic viability of setting up the EPR, as well as wider socio-economic implications, in particular the availability and affordability of essential and critical products.

Considering these aspects Member States should be able to decide on the use of alternative or additional funding sources to cover the costs of quaternary treatment and in justified cases be able to exempt certain product categories from the EPR.

Although the "polluter pays principle" is an underlying concept of environmental protection, we are not convinced it is suitable for pharmaceutical sector for the following reasons.

Firstly, **the clear added value of EPR in case of pharmaceuticals has not been confirmed by the feasibility study** (carried out as part of the Commission's impact assessment), as the effect of EPR on behavioural change would be very limited. On one hand, EPR is unlikely to significantly incentivise the substitution of pharmaceutical active ingredients in short- to medium-term, considering their specific innovation cycles. On the other hand, patients would not have the option to decrease their consumption of a medically indicated medicinal product or switch to another product. In this respect, **ethical aspects are not sufficiently considered**, as additional costs would have to be borne by patients, putting a disproportionate and unfair burden on population groups in a vulnerable situation due to their health condition.

Secondly, we note with concern that the chosen approach of the EPR system would cause **unequal treatment between Member States**. Additional barriers to market entry and price increase of certain pharmaceuticals could significantly worsen the availability and choice of treatment, especially in the context of small markets, which are already faced with frequent market withdrawals due to economic reasons. Furthermore, in Member States without a substantial local pharmaceutical production, the costs would rather be transferred from the manufacturer to other downstream actors. This would not serve the initial aim of producer responsibility, as in these circumstances the costs of EPR would very likely be transferred to the health care budget and increase patients' co-payments. Introducing mandatory EPR would thus have **negative socio-economic implications but also would intrude the Member States' competence** in financing healthcare. Additionally, **economic feasibility and administrative burden** should be considered, especially if the number of "producers" is relatively small. In smaller Member States and hence a lower consumption of pharmaceuticals, introducing EPR could lead to an unreasonable financial burden on a few actors on the market.

Thirdly, we note that in the general approach is not clear on **who is the subject of the extended producer responsibility** in the case of pharmaceutical supply chain, which involve many actors who make the product available on the market. Consequently, due to parallel trade this could lead to **double taxation**.

Because of these reasons Estonia is not able to support the General Approach on the Proposal for a Directive of the European Parliament and of the Council concerning urban wastewater treatment and abstains from the vote.

---