EurEau Position on Environmental Quality Standards for pharmaceuticals

Summary

EurEau supports the setting of Environmental Quality Standards (EQS) for pharmaceuticals provided several pre-conditions are met to avoid that the water sector will be the first and/or only stakeholder to take the burden for ensuring compliance.

Detailed opinion

Pharmaceuticals may pollute water resources, causing adverse effects on ecosystems and human health. They represent a challenge to water operators' mission to supply safe drinking water and return treated waste water safely to the environment.

EurEau supports setting Environmental Quality Standards (EQS) for pharmaceuticals. EQS provide a regulatory standard for pharmaceutical residues in the aquatic environment and express the quantifiable legislative target for taking a range of cost-effective measures to better protect aquatic life and human health.

The setting of EQS, however, must **not automatically translate into end-of-pipe measures at the level of Waste Water Treatment Plants (WWTP)**. Quite the contrary, in line with the EU Treaties, a holistic approach must be applied starting from the Precautionary, Preventive and Control-at-Source Principles, as reiterated by the Zero Pollution Hierarchy of actions to address pollution.

New approaches to preventively avoid hazards to drinking water resources are also pursued with the new EU Drinking Water Directive (DWD, 2184/2020) according to the so-called "risk-based approach" (Article 7). For substances present in concentrations that jeopardise the achievement of the drinking water quality targets (including guideline values for the DWD watch list substances), Member States are required to monitor pollutants in drinking water resources and consequently to take, as a priority, preventive measures, followed by mitigation measures if necessary, to control the risks. In this context, environmental quality standards for pharmaceuticals will provide a crucial support for the protection of drinking water resources.

At the same time, setting EQS for surface water could provide a framework at the catchment level and support the identification and the eventual substitution of the most hazardous pharmaceuticals. This would contribute to an orderly and logical coordination with the revision process of the Urban Waste Water Treatment Directive (UWWTD),

prioritising the substances and limit values ahead of the new legislative proposal, proving essential to waste water operators.

EQS should be considered as one of the tools of a holistic legislative and non-legislative approach to tackle pharmaceuticals in the environment.

EurEau calls on the European Commission to take swifter and bolder action at EU level and guide Member States to act according to the Strategic Approach to Pharmaceuticals in the environment (European Commission, March 2019). We believe it is important that necessary pre-conditions and follow-up actions, framing the consequences of setting EQS for pharmaceuticals, are considered as follows:

1. EQS should be based on sound scientific data and the Precautionary Principle. Enough high-quality environmental data for candidate pollutants should be available for different trophic levels and compartments (water, sediment/biota), according to the EQSD. We support the work of the JRC and DG Environment and reiterate the need to pay attention to the availability of standards for analytical methods and the levels of detection and quantification of the newly set EQS.
2. Once an EQS is established for a pharmaceutical substance, it will be subject to **monitoring in the environment to obtain representative information of the water body** (the EQS is not to be monitored or met in the WWTP effluent nor in mixing zones, according to the Technical Guidelines for the identification of mixing zones pursuant to Art. 4(4) of the Directive 2008/105/EC, document C(2010) 9369 from 22 December 2010).
3. Exceeding EQS (or where trends suggest exceedance is likely) in a given water body must always lead, as a priority, to control-at-source measures, to avoid that unsustainable end-of-pipe treatments at waste water treatment plants are used as a regrettable short-cut or easy-fix.
4. The environmental risk assessment (ERA) carried out for pharmaceuticals for human use should be a compulsory element of the risk-benefit analysis within the authorisation process. ERAs should rapidly be produced for pharmaceutical substances for human use authorised before 2006.
5. If a pharmaceutical is harmful to the water environment and is identified as a priority substance, it should be only sold under medical prescription.

   Their over-the-counter (OTC) sale must be banned.

   We appreciate the political intention behind the Roadmap on the revision of the general pharmaceutical legislation stating that "*the Commission intends to consider advertising, marketing and prescription practices of pharmaceuticals having a negative environmental impact*".
6. In order to be effective in tackling pharmaceutical residues pollution, the same mechanism foreseen under the Pesticides Regulation (Art. 44 Regulation 1107/2009/EC) should be put in place in the pharmaceutical legislation: if the

EQS for a pharmaceutical is exceeded, its authorisation should be reviewed and mitigation measures should be taken.

7. If a medicine is already sold under prescription, the European Medicines Agency (EMA) and the national agencies should publish recommendations for less environmentally hazardous alternatives if they exist, and/or for their environmentally safe uses.
8. The effectiveness of stricter requirements for WWTPs must be evaluated against the protection of water resources according to Art.7.3 of the WFD and the receiving water ecosystem.
9. Information on pharmaceuticals, gathered not only in the context of the ERA but also in the post-authorisation phase, should be transparent and accessible for water operators and competent authorities in order to understand the risks associated with water treatment and the generation of transformation products of active substances or their metabolites.
10. If additional end-of-pipe treatment is required, the **Polluter Pays Principle should be applied**, including through **Extended Producer Responsibility (EPR) schemes**, to recover the costs of additional water treatment to remove pharmaceutical substances. EurEau supports the work of the Commission on EPR under the revision of the UWWTD, covering pharmaceuticals and personal care products. The same approach should apply to drinking water treatment works (WTW) in case they have to take action as an exceptional means of last resort, e.g. when a risk assessment indicates possible negative consequences to human health.
11. Currently, chemical substances under the WFD are regulated on a substance by substance approach. The combined impact of cocktails of several chemicals and their transformation products should be considered and therefore EurEau encourages a group approach for chemical substances regulated in EQS and in chemical regulations such as REACH. Effect-based monitoring methods may add to the assessment of aggregated exposure and further research should be stimulated.
12. EQS are values that need to be complied with by competent authorities. Member States have to ensure that the various actions associated with the EQS compliance, including sampling and monitoring costs, are not automatically transferred to the water utilities but that they are subject to specific local arrangements.

About EurEau

EurEau is the voice of Europe's water sector. We represent drinking water and waste water operators from 29 countries in Europe, from both the private and the public sectors.

Our members are 34 national associations of water services. At EurEau, we bring national water professionals together to agree European water sector positions regarding the management of water quality, resource efficiency and access to water for Europe's citizens and businesses. The EurEau secretariat is based in Brussels.

With a direct employment of around 476,000 people, the European water sector makes a significant contribution to the European economy.