AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

AESGP Position Paper

on the revision on Urban Waste Water Treatment Directive (UWWTD)

17 January 2023

Introduction

This paper concerns the position of the European Self-Care Industry (AESGP) on the proposed revision of the Urban Waste Water Treatment Directive (UWWTD) 2022/0345 (COD). Its main purpose is to provide co-legislators with AESGP's views on the pragmatic, proportionate and science-based application and implementation of an Extended Producer Responsibility (EPR) within the framework of UWWTD.

The UWWTD was adopted in 1991 and its evaluation in 2019 confirmed that the implementation of the directive has led to significant reduction of pollutants in effluents from cities, leading to improvements in the quality of EU's water basins. Since then, new contaminants of concern have emerged, notably micro-pollutants, mainly due to steep demographic increase in urban areas, scientific progress achieved by the pharmaceutical and overall chemical industries which leads to longer and better quality of lives in the Community, as well as more sensitive analytical detection techniques. To remove a major part of these contaminants in urban wastewater, the revised UWWTD proposal suggests applying EPR exclusively to two industrial sectors, quoted to be the major source of "hazardous micro-pollutants", namely manufacturers of human medicines and personal care (cosmetic) products.

As the European voice for non-prescription medicines manufacturers, AESGP is supporting the objective of UWWTD – to protect the environment and human health from the adverse effects of urban wastewater discharges – and is prepared to correspondingly participate in attaining this objective. AESGP believes that, to achieve this goal, every stakeholder concerned must play their fair part, starting from the people generating discharges to those responsible for treating urban wastewater – a view reflected in the specific points detailed below. When it comes to its responsibility as a manufacturer of medicines that are amongst sources of micro-pollutants, **AESGP calls for a proportionate and fair implementation of EPR. AESGP does not believe that the proposal of the European Commission is balanced and cost-efficient.**

The proposal should consider that the pharmaceutical industry provides medicines in the overall public interest, and should therefore:

- **Apply EPR to manufacturers of micro-pollutants based on the risk they pose to the environment and/or human health (1),**
- **Recognise all sources of hazardous micro-pollutants irrespective of sector, (2;3),**
- **Avoid administrative burden where it is not justified and ensure that funds collected through EPR schemes are used in the most cost-effective manner (4;5)**
- **Acknowledge that environmental policies promoting the development and use of products with negligible potential environmental impacts must be considered alongside the societal and health benefits of pharmaceuticals (6)**
- **And, ultimately, not jeopardize access to any category of medicines for people that need them, particularly those in smaller markets (7).**

AESGP Position

While AESGP welcomes the overall objective of the revision – to improve surface and ground water quality in the community, it has a number of concerns regarding the draft proposal and some suggestions for improvement:

1. The Directive for the first time in EU law defines a micro-pollutant as

> *a substance including its breakdown products, that is usually present in the environment and urban wastewaters in concentrations below milligrams per litre and which can be considered hazardous to human health or the environment based on any of the criteria set out in Annex one part 3 (health hazards) and 4 (environmental hazards) of the Regulation EC 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.*

AESGP believes that the proposed definition of micro-pollutant, with the consecutive hazard identification scheme based on the mere presence of a substance in effluents, while not considering its concentration, and the negative impact on living organisms it may entail, is disproportionate. This definition fails to assess the risk and does NOT provide a good reference for identification of actual micro-pollutants having an impact on the environment or human health via the aqueous route.

AESGP acknowledges the political choice made by the European Commission for an EPR system. For such a system to be feasible, it needs to operate by using manageable data bases and rules. However, to fulfil the requirements for an impact-based system, any hazard-based approach should be augmented by easily implemented risk-based rules, which will account for degree of hazard and exposure potential *(1)*.

Therefore, AESGP proposes that the definition and identification of micro-pollutants covered by an EPR system should be based on well-established risk-based principles, amended by certain hazard properties, as adopted by regulatory authorities in Europe under several regulations, such as for human and veterinary medicinal products *(2)*, agrochemicals *(3)*, biocides *(4)*, and general chemicals *(5)*. The system should also ensure that compounds having no impact, or the impact of which being reduced during its lifespan, can be delisted from any EPR system (see section 3).

(1) The followings are examples of workable procedures: the Critical Dilution Volume (CDV) approach used in the Detergents Ingredients Database (DID-List) [reference: Commission Decision (2011/382/EU)] or a prioritization procedure for chemicals based on the specific risks, as described for pharmaceuticals [references: Emily E. Burns, Laura J. Carter, Jason Snape, Jane Thomas-Oates & Alistair B.A. Boxall (2018) Application of prioritization approaches to optimize environmental monitoring and testing of pharmaceuticals, Journal of Toxicology and Environmental Health, Part B, 21:3, 115-141. Letsinger, S., Kay, P. Comparison of Prioritisation Schemes for Human Pharmaceuticals in the Aquatic Environment. Environ Sci Pollut Res 26, 3479–3491 (2019)], to identify compounds with potential impact on the environment.

(2) Environmental Risk Assessment under human and veterinary pharmaceutical legislations

(3) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1–50, as amended.

(4) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance, OJ L 167, 27.6.2012, p. 1–123, as amended.

(5) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, as amended.

In essence, such as system would identify substances and consider their risks and hazard for the environment and human health, which is in line with the objectives of the Water Framework Directive (as the main European legislation for the good quality of water) and the consecutive requirements of the UWWTD.

2. The Impact Assessment and proposal for the revision fails to provide solid evidence that pharmaceuticals are among the leading contributors of micro-pollutants. Therefore, AESGP feels that the pharmaceutical sector would be unfairly burdened with the total cost of the system, while some other Industries, which are also contributors to the micro-pollutant load, are not identified for financial obligations under EPR.

The Impact Assessment fails to recognize several evidence-based studies led by independent organisations, academia, regulators, and the pharmaceutical industry, suggesting that only 10% of the active pharmaceutical ingredients (APIs) could pose a potential risk to the environment *(6)* and that most medicines (> 80%) indicated a low environmental risk *(7)*.

The Impact Assessment is exclusively focused on two sources of micro-pollutants (medicines and personal care products) which were narrowed down from a relatively small list of chemicals that only represent a small portion (around 1,200 chemicals) of the chemical sphere. The narrow selection of chemicals is mainly driven by those that are the focus of academic and regulatory monitoring. Recent work by Meent et al. (2020) *(8)* took an exposure modelling-based approach, assessing the exposure to around 10,000 chemicals. Although still only a small percentage of the ca. 150,000 chemicals on the EU market, this paper demonstrates potential approaches which could be taken to assess the micro-pollutant contribution of chemicals that have yet to emerge as a concern because they have not been the focus of monitoring campaigns.

The Impact Assessment fails to address other sources of micro-pollutants such as metals, metal oxides, non-metals *(9)*, forms of carbon, and other industrial chemicals (as registered under REACH) *(10)* that can be found in many widely used consumer goods. Manufacturers of products containing hazardous micro-pollutants that may pose a risk to the environment and/or human health would benefit from the implementation of a quaternary wastewater treatment directly, without being subject to the polluter pays principle proposed EPR scheme, as it would remove other micro-pollutants not originating from use of medicines and personal care products. AESGP, therefore, calls for a non-discriminatory extension of EPR to any industry sector that places on the market products that contain micro-pollutants that pose a risk to the environment and/or human health, and that would require quaternary treatment for their removal.

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(6) Küster and Adler (2014), "Pharmaceuticals in the environment: scientific evidence of risks and its regulation": https://royalsocietypublishing.org/doi/10.1098/rstb.2013.0587

(7) Gunnarsson, et al (2019), "Pharmacology beyond the patient – The environmental risks of human drugs": https://www.sciencedirect.com/science/article/pii/S0160412019309493

(8) Meent et al. (2020), "Screening-Level Estimates of Environmental Release Rates, Predicted Exposures, and Toxic Pressures of Currently Used Chemicals": https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.4801

(9) Madeła et al. (2016), "Fate of engineered nanoparticles in wastewater treatment plant": https://www.infona.pl/resource/bwmeta1.element.baztech-89e45e76-ddae-456f-919c-db0fae31244e

(10) Deeb et al. (2017), "Suspect screening of micropollutants and their transformation products in advanced wastewater treatment": https://www.sciencedirect.com/science/article/abs/pii/S0048969717313803?via%3Dihub

3. The current plan disincentivizes industries not covered by the EPR system from developing new technologies to treat and/or replace micro-pollutants, since only the industries producing treatable micro-pollutants are targeted for this EPR initiative; untreatable micro-pollutant emissions are free to continue unabated as long as no treatment technology is available.

The draft specifically names metals and microplastics as micro-pollutants but excludes these substances only on a pragmatic basis (i.e., because treatment technology is not available). This leads to arbitrary inequity among industries emitting the substances identified as micro-pollutants of concern. By their nature as micro-pollutants, none (or very few) pose a risk on their own, but the combination could ostensibly lead to ecosystem stress under certain circumstances. In such cases, should they occur, all micro-pollutants together would be contributing to that stress, and any amelioration achieved by removing organic micro-pollutants would make the stress contributed by the untreatable micro-pollutants more tolerable.

The simple lack of treatment technology does not absolve other industries of responsibility for contributing to ecosystem stress and, in fact, is more concerning because there is no mitigation possible. At the least, industries contributing to untreatable micro-pollutant emissions should have financial responsibility following the same logic as for industries responsible for organic micro-pollutants, with funds used either for tertiary treatment that mitigates the multiple-stressor scenario or for research to develop appropriate treatment technologies. It would be in line with a general principle of Community Law that requires similar situations not to be treated differently unless such differentiation is objectively justified *(11)*. The lack of inclusion of other industry sectors into the EPR system will constitute unequal treatment of the pharmaceutical and cosmetics industries, since the EPR proposal does not provide an objective reason which would justify it.

4. The only country in Europe that has already started systemically removing micro-pollutants from urban wastewater is Switzerland.

It is calculated that, to upgrade the most impactful water treatment facilities to quaternary water treatment level in Switzerland (130 out of 715), it will cost 1.2 billion CHF francs in total over a period of 24 years (2016-2040). Additional recurring costs (e.g., additional energy consumption, the selected process maintenance, such as filter consumables, waste management etc.) will depend strongly on the size of UWWTP, technology of choice, etc., but this cost is always significantly lower than the implementation costs of a quaternary treatment system. Since 2016, 14 WWTPs have implemented the necessary measures in Switzerland. Of these, 12 have built an elimination stage for micro-pollutants; while the other two WWTPs were closed and connected to another WWTP – for this, a sewer line was built instead of the measure required at the WWTP.

The Impact Assessment estimates that costs of EPR at EU level will be around 1.18 billion EUR annually from 2040 onwards. By that time, UWWTP should have achieved energy neutrality, increased re-use of treated water and sludge and, as a result, reduced operating costs and generated additional profits. Based on the Swiss experience and logic, **AESGP argues that EPR should, therefore, be used only for the upgrade of the urban wastewater treatment from tertiary to quaternary level. Then, the quaternary water treatment running costs should be borne by operators of urban wastewater treatment plants**

(11) See inter alia Case C-313/04 Franz Egenberger (2006) ECR I-6331, paragraph 33). "A difference in treatment is justified if it is based on an objective and reasonable criterion, that is, if the difference relates to a legally permitted aim pursued by the legislation in question, and it is proportionate to the aim pursued by the treatment" (see Case C -127/07 Société Arcelor Atlantique et Lorraine and Others, paragraph 26).

and these are likely to be covered by system efficiencies gained due to implementation of circularity principles. **Furthermore, wastewater treatment efficiency monitoring process should be an exclusive responsibility of a Member State competent authority and should fall outside of the EPR scope.**

5. It is suggested that producers of products containing hazardous micro-pollutants exercise EPR via Producer Responsibility Organisations. The proposed stakeholder-based model governance will undoubtedly create high administrative costs associated with establishing, managing, and supervising such organisations.

Experience gained by the pharmaceutical industry from the implementation of the Falsified Medicines Directive *(12)* and the establishment of European and National Medicines Verification Organisation *(13)* suggests that this may not be the most cost-effective or efficient governance model. The governance costs of European Medicines Verification System (EMVS) have, by far, exceeded projected costs in the initial impact assessment by the European Commission.

EPR has already been applied in the case of medicines in the form of take-back schemes for expired and/or unused medicines in EU Member States to avoid inappropriate household disposal through solid waste or water effluents. Some of these take-back schemes are established and financed by the different stakeholders of the medicines value chain – manufacturers, wholesalers, and pharmacies – under their social and environmental responsibility programs, by setting up Producer Responsibility Organizations (PROs) *(14)*.

To reduce administrative costs of EPR, AESGP suggests using existing PROs for medicines and/or exploiting other existing Industrial levy collecting schemes at Member State level that would allow exercising EPR efficiently. Furthermore, it is important that industry not only pays the bill issued by wastewater treatment facilities but has an active role in deciding on the practicalities of quaternary water treatment such as choice of technology and other modalities.

6. The pharmacological, immunological, or metabolic nature of the action of medicines, that prevents or treats the disease or addresses its symptoms, may sometimes have unintended consequences on other species.

Medicines interact with human biological systems in complex ways, and their formulations ensure APIs are administered and delivered where they are needed in the human body. Medicines represent decades of medical and pharmaceutical science that make them a healthcare tool for society that is not easily (or cheaply) replaced, if substitution is possible at all.

AESGP members have adopted Eco-Pharmaco-Stewardship practices and deploy green chemistry principles to minimize the impact of pharmaceuticals on the environment. However, it must be ack-

(12) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products Text with EEA relevance, OJ L 174, 1.7.2011, p. 74–87.

(13) European Medicines Verification Organisation (EMVO): https://emvo-medicines.eu/

(14) OECD (2022), "Management of Pharmaceutical Household Waste": https://www.oecd.org/environment/management-of-pharmaceutical-household-waste-3854026c-en.htm

nowledged that environmental policies promoting the development and use of products with less potential environmental impact have to be considered alongside the societal and health benefits of pharmaceuticals. In addition, the risk of APIs to the aquatic compartment is assessed via other pharmaceutical legislation in Europe, which is currently being strengthened.

7. Finally, AESGP is concerned that, if not applied proportionally and fairly, EPR will translate into a *de facto* tax for the pharmaceutical industry which will impact those patients using the medicines affected by the measure, contradicting the European Pharmaceutical Strategy goal of reducing access inequalities.

It would also have a negative impact on the EU's goal to enhance the resilience of pharmaceutical supply, a key asset for Europe's competitiveness, health and preparedness for future health crises and it will likely affect availability on smaller markets first.

AESGP remains committed to working with all partners along the value chain of medicines, and environmental stakeholders and all industry groups contributing to micro pollution of urban wastewater, as well as the EU institutions, to address environmental concerns arising from the presence of micro polluting pharmaceuticals in water while responding to people and health system needs and ensuring access to medicines.

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About

The **Association of the European Self-Care Industry (AESGP)** is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, an area also referred to as consumer healthcare products.

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