Coalition of the European River Memorandum (ERM)
Public Consultation:
Revision of the EU general pharmaceuticals legislation
Update April 2023

A. Key additional measures:

- **Developing and promoting preventive approaches and drug-free therapies**
- **Developing "safe and sustainable by design"** approach **including bio-based pharmaceuticals** (according to EU Chemicals Strategy for Sustainability) **and promoting** "**greener pharmaceuticals"** (according the Strategic Approach to Pharmaceuticals in the Environment/PiE) **including medicines with natural ingredients like phytopharmaceuticals**
- **Make extended Environmental Risk Assessments (ERAs)** an indispensable **prerequisite of approval** (MA).
- **Authorisation criteria** of pharmaceuticals **including generics must also consider the environmental impacts of substances and their degradation/transformation products on drinking water resources: No persistent, mobile or toxic substances** according to the PMT/vPvM criteria as suggested by Delegated Regulation amending Regulation 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2023:093:FULL&from=EN
- **Environmental Risk Assessments (ERAs) must be improved (PiE) and strengthened** and the results should be made easily publicly available. **Combined effects from multiple substances** (cocktail effects) need to be included. ERAs also need to be conducted **for pharmaceuticals approved before 2006**. **Suspension of approval of substances** with negative effect on environment/health should be possible.
- **Availability by prescription only, a ban on advertising and clear labelling of environmental risks for pharmaceuticals with negative effects on environment**.
- **More prudent use/ending overuses by guidelines for prescription, esp. for antibiotics/antimicrobials** (only when absolutely necessary and without alternative), **incl. targeted forms of application** (e.g. patches prepared with active ingredients instead of thickly applied cream that goes directly into the drain when showering)
- **Ban on preventive use of veterinary antimicrobials in intensive livestock farming.**
- **Green and clean manufacturing/production** (PiE) of "**safe and sustainable by design"** pharmaceuticals (according to EU Chemicals Strategy for Sustainability)
- **Adjusting package size** to the durability (durability after opening of the medicine package) and expected consumption rate when prescribing/selling the product.

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- Proper **disposal of residual pharmaceuticals** requires **concrete disposal information on each package insert** (for the entire region in which it is on sale) as well as at the point of sale (e.g. at the counter of pharmacy).

- **Extended producer responsibility (EPR)** to allocate costs (for the elimination of chemical residues) to polluters (profits): introduce the "Fund Solution" developed by German Association BDEW. This is required to meet the provisions of Art. 191 TFEU and the **principles** of precaution, preventing pollution at its source and – especially – **polluter pays**.

- Dedicated water **pre-treatment at larger hospitals**, as part of Extended Producer Responsibility

- Use of **urine bags** after medical imaging with contrast media.

B. General remarks:

The ERM Coalition represents as coalition of drinking water suppliers in the main European river basins the interests of 188 million people of 18 European countries depending on clean and safe drinking water in the river basins of the Rhine, Danube, Elbe, Meuse, Scheldt and Ruhr. Their common understanding is laid down in the European River Memorandum (ERM) and the European Groundwater Memorandum (EGM). Both memorandums are designed as guidelines for legislation. In recent years, a number of micropollutants has emerged in drinking water resources including pharmaceuticals. The EU Strategic Approach to Pharmaceuticals in the Environment (03/2019) concludes that "there is sufficient evidence that action should be taken to reduce the risk from pharmaceuticals in the environment". The IAWR is underlining this and points out the need for ambitious action to be taken now in the revision of the EU general pharmaceuticals legislation. This includes

- **mainstreaming all Green Deal elements** like the Zero pollution Action Plan into the full range of EU policies.

- a **true life cycle approach**.

- the **Strategic Approach to Pharmaceuticals in the Environment (PiE)**, the **Strategy on Endocrine Disruptors** and the **European One Health Action Plan against Antimicrobial Resistance**.

- implementing the **quantitative reduction target on micropollutants including pharmaceuticals** adopted by the EU and the Netherlands, Germany, Luxembourg, France, Austria, the Belgium region Wallonia, Switzerland, Liechtenstein 2020 at the Rhine Ministerial Conference in Amsterdam. Pls. see programme "Rhine 2040" and Communiqué, https://www.iksr.org/en/icpr/rhine-2040.

➔ Efforts must prioritise **preventing pollution at its source** (market access) and **use-orientated measures** with the goal to minimise and eventually stop emissions of drinking water relevant substances into the aquatic environment