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Water Task Force
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CEEP ADDITIONAL REMARKS ON THE PHARMACEUTICAL STRATEGY PUBLIC CONSULTATION

CEEP, the European Centre of Employers and Enterprises providing Public Services and Services of general interest (SGI), welcomes the opportunity to submit its input to the public consultation on the new Pharmaceutical Strategy by the European Commission. The answers provided in the Questionnaire and in this additional remark paper are written from the point of view of the public water and waste-water providers. After carefully considering all questions, CEEP would like to submit some additional remarks to the questionnaire in the following paragraphs:

Section: International Dependency and Manufacturing

Question 1:

CEEP would highly encourage an incentivisation of green pharmaceutical design, manufacturing and production in the EU. The topic of pharmaceutical residues in the environment is an emerging concern in Europe due its increase with an ageing population that uses more pharmaceutical products and will be intensified by lower river flows due to climate change. Since these substances are one example of micropollutants that can directly or indirectly enter the water cycle through many pathways it will be important to take precautions within the Pharmaceutical Strategy. Then, once in the water cycle, they can pose a risk to drinking water resources and aquatic ecosystems.

Hence, the Pharmaceutical Strategy must link to the future strategies of the EU Green Deal such as the Strategy on Sustainable Chemicals and the Zero pollution Strategy. CEEP **kindly asks the Commission to come up with a Strategy on Green Pharmacy and to support research activities on biodegradable pharmaceuticals and environmental sustainability in general.**

Question 2:

What CEEP would understand of high-quality pharmaceuticals are pharmaceuticals that have been produced in an environmentally friendly way and do not harm the environment after their use (Green manufacturing & Green substances) with no losses in their effectiveness. For example, pharmacological research done at the Technical University in Dresden focusses on these criteria. The "benign-by-design"-approach takes the biodegradability of a new substance from the beginning of development into account. Such approaches need to be encouraged EU-wide.

Approval criteria of pharmaceuticals should also take into account the environmental impacts of such substances on water bodies. This should also apply to generics, since due to this missing criterion in the approval procedure CEEP members from the public water sectors trace these substances and their degradation products. **In the event of environmental pollution, manufacturers should also be responsible for financing "depollution measures"**.

Finally, the aspect of producer responsibility through so-called EPR (extended producer responsibility) schemes applies also to generics. CEEP thinks that producers remain responsible for their products even after the use phase. To this end, **funding mechanisms, including comprehensive EPR schemes, should be set up to avoid that other actors, including waste-water treatment plants, have to bear the financial burden of preventing the release of pharmaceuticals into the environment.**

Section: Innovation in early Development and Authorisation

Question 10:

Supporting green manufacturing & green pharmaceuticals: **The Strategy should support efforts to design, develop and manufacture pharmaceuticals that are non-hazardous or that quickly degrade into non-hazardous substances**. Support for relevant R&D and innovative technologies is key, since the development of green pharmaceuticals is not a top priority for pharmaceutical companies.

Ban of specific substances: **The approval suspension or ban of specific substances that have proven to result in adverse/negative environmental and health effects, should be possible (such as diclofenac which could be substituted by more easily degradable substances).** In case in which an outright ban is not feasible, a certain conditionality could be applied to its use. For example, this could mandate that such substances can only be administered in facilities that possess decentralised wastewater pre-treatment (such as hospitals, caring or nursing homes).

Question 12:

As suggested by question 12 digital technologies offer a variety of opportunities for the development and use of medicines. **The use of digital technologies such as AI and real-world data is key for the design, development and manufacturing of green pharmaceuticals.** The transparency for consumers and relevant stakeholders can be enhanced through the digtal provision of information on important aspects such as active ingredients, metabolites, break-down rates, or also health information such as tolerances, dosages for consumers of the drugs, and explanations of methods of consumption for consumers. Moreover, anonymised prescription data could be collected regionally to allow wastewater treatment plants to enhance the adaptation of their treatments and thereby filter environmentally harmful substances more effectively.

Question 16:

CEEP emphasises that a prior knowledge of the health and environmental effects of these cell therapies is essential, especially due to the possible release of cellular pathogens in the wastewater cycle.

Section: Environmental Sustainability of Medicines and Health Challenges

Question: 17

CEEP believes that a holistic approach is needed for addressing the entire life cycle of pharmaceutical products, from design and production, to prescription and use, until waste treatment. The Strategic Approach to PiE clearly recognised this. This new EU Strategy should be based on the precautionary principle and the control at source principle, while the financing of measures should be primarily based on the polluter pays principle, in accordance with Art. 191(2) TFEU.

In this context, CEEP would like to draw the Commission's attention on the following issues:

- **Green manufacturing & Green pharmaceuticals**: The Strategy should support efforts to develop pharmaceuticals that are non-hazardous or that quickly degrade into non-hazardous substances. Green Public Procurement and Ecolabels for pharmaceuticals should be implemented to enable informed choices by prescribers and patients.
- **Extended producer responsibility (EPR)**: This scheme is based on a life cycle approach, which funds investment needs of waste-water treatment plants and the financial contribution of the pharmaceutical industry is essential. This means that producers remain responsible for their products even after the use phase. To this end, funding mechanisms, including comprehensive EPR schemes, should be set up to avoid that other actors, including waste-water treatment plants, have to bear the financial burden of preventing the release of pharmaceuticals in the environment. Furthermore, such scheme incentivises pharmaceutical companies to invest more in green manufacturing and biodegradable pharmaceutical substances.
- **Restriction of high-risk over-the-counter pharmaceuticals:** For pharmaceuticals that have a negative environmental impact, prescription by physicians should be made compulsory, in line with the relevant OECD recommendations. In particular, this applies to high-risk pharmaceuticals, such as antibiotics and other persistent, bio accumulative and toxic pharmaceuticals. More generally, any pharmaceutical products should be prescribed and used only when needed. A more considerate and restrictive use of pharmaceuticals should be strongly encouraged.
- **Public awareness raising**: Awareness raising campaigns and initiatives for the general public, medical personnel and pharmacists are essential. The latter should also be trained on the prudent use of pharmaceuticals and how to communicate about this.
- **Take-back schemes for unused medicines:** This is an essential element of the life cycle approach and should be taken into account when developing the Strategy, since it supports the sustainable disposal of unused pharmaceuticals that have expired.
- **Further actions could include:** EU-wide rules on smaller packaging sizes, proper disposal of unused pharmaceuticals

Question 18:

CEEP would welcome a **more prudent use of AMR in general and therefore support all measures with this objective.** When developing new pharmaceuticals / antibiotics/ antimicrobials, it should be recognised that an EU approach is needed to avoid multi-resistant bacteria.
Moreover, CEEP calls upon the Commission to raise a sufficient level of awareness to the public, healthcare practitioners and pharmacists through campaigns that informs them on appropriate use of antimicrobials and the correct disposal of unused medicine.
Furthermore, this approach needs to address the over usage of antibiotics in intensive livestock farming.

Summary Question 22:

CEEP underlines that the environmental sustainability of medicines should be the main focus, which all other measures support. The authorisation procedure should take into account the environmental criteria.
Furthermore, there is a need for regulatory requirements obliging manufacturers to test pharmaceuticals and their metabolites (watch list) in water and that they recommend necessary treatment methods (today sustainability is not an approval criterion in and of itself, but it would have to be defined).