

Executive summary of background document for public consultation on pharmaceuticals in the environment

The main background document draws attention to the risk posed by some pharmaceuticals to the environment, for example to fish populations, and to the possibility that human health might be affected via the environment. The document presents 30 possible policy options for achieving more environmentally sustainable use of pharmaceuticals, important among other things to help the EU achieve the UN Sustainable Development Goals, in particular Goal 6 ("Clean Water and Sanitation"), as well as objectives in EU legislation such as the "good status" objective in the Water Framework Directive. The consultation results will be used to identify a shorter list of policy options for possible follow-up in proposals for measures, subject to impact assessment as appropriate.

At EU level, the issue of pharmaceuticals in the environment is only partially addressed in legislation and policy. Practices are further influenced by many other factors, which could be acted upon to leverage more sustainable and prudent management and use of pharmaceuticals, in line with the circular economy. Based on a review of the recent literature and preliminary consultation of stakeholders, 10 main potential action areas were identified and 30 possible policy options were considered in detail. This summary presents the action areas and outlines the nature of the options covered.

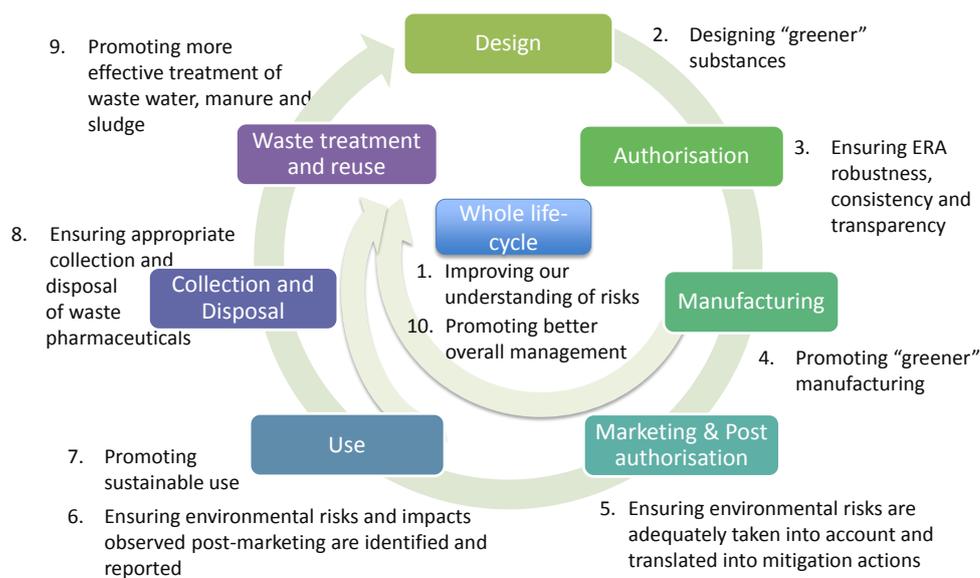


Figure 1: Ten main action areas across the life cycle of pharmaceuticals

- 1. Improved understanding of the risks from pharmaceuticals to the environment (2 options):** Fostering research activities and collaboration between public and private entities should enable additional knowledge to be gained on the issue of the occurrence, fate and impacts of pharmaceuticals as well as spread of antimicrobial resistance via the environment and its consequences for human and animal health. Existing research results are critical to the development of the EU strategic approach to pharmaceuticals and additional research will further benefit its follow up.
- 2. Designing "greener" substances (1 option):** Some scientists are developing molecules with reduced intrinsic environmentally hazardous properties, exploring how to minimise their impacts on the environment. This concept of Benign-by-Design could be further

encouraged and tested by the industry in collaboration with research communities and wastewater treatment sector.

- 3. Ensuring the scientific robustness, consistency and transparency of risk assessments (5 options):** Since 2005 for veterinary pharmaceuticals (veterinary medicinal products) and 2006 for human pharmaceuticals (human medicinal products), Environmental Risk Assessment (ERA) provides valuable information as a part of the marketing authorisation process for pharmaceuticals for both human and veterinary use. It could provide further added value through more stringent criteria for evaluation (including major metabolites, degradation products and excipients), more accessible and comprehensive reporting of relevant environmental data and better documentation of dossiers on pharmaceutical substances. The extent to which the ERA influences the authorisation of human pharmaceuticals could be reconsidered.
- 4. Promoting greener manufacturing processes (3 options):** Several voluntary initiatives from the industry indicate that practices can be improved to reduce emissions in the EU and/or along the global supply chain. This could be better reflected and encouraged in sectoral reference documents (European Eco-Management and Audit Scheme, Best Available Techniques reference document, EU principles and guidelines for good manufacturing practices).
- 5. Ensuring environmental risks are adequately taken into account and translated into mitigation actions (post-authorisation) (4 options):** The ability to properly mitigate environmental risks could be improved through further data collection (catching-up procedure for relevant pharmaceuticals placed on the market before ERA was required, update of environmental risk assessments based on latest scientific data and post-consumption monitoring), through more appropriate risk mitigation measures and obligations to report on their implementation.
- 6. Ensuring environmental impacts observed post-marketing are identified and reported (3 options):** The surveillance of environmental issues at post-marketing stage, or "eco-pharmacovigilance", is key to addressing the potential impacts of pharmaceuticals once in the environment and to ensuring that the predicted risk at the authorisation stage matches environmental data. This could be improved through better information exchange between relevant Member State agencies and authorities, strengthening of environmental requirements in pharmacovigilance systems and including relevant pharmaceuticals in watch lists for surface and groundwater.
- 7. Promoting sustainable use of pharmaceuticals (3 options):** Experience demonstrates that properly informing doctors, veterinarians, pharmacists and patients may contribute efficiently to the modification of procurement and consumption practices, and thus to a decrease in the release of pharmaceuticals into the environment. It also has significant benefits for the appropriate disposal of unused pharmaceuticals by households.
- 8. Ensuring appropriate collection and disposal of unused pharmaceuticals and pharmaceutical waste (2 options):** More appropriate collection and disposal of unused pharmaceutical products could be promoted through stronger enforcement of waste collection schemes for human and veterinary pharmaceuticals, and/or classification of certain pharmaceuticals (in products) as dangerous to ensure that waste consisting of or containing them would be considered as hazardous waste and properly disposed of.
- 9. Promoting more effective management of waste water, manure and sludge (6 options):** Better knowledge of antimicrobials and AMR microorganisms in the effluent and organic waste from potential "hotspots" such as large waste water treatment plants, hospitals, pharmaceutical manufacturing sites and intensive livestock farms could help inform more efficient strategies to prevent environmental contamination by pharmaceuticals, as well as guidelines on wastewater treatment at hospitals and healthcare centres. Better source control (through better handling of manure, sewage sludge, and water reused for irrigation) and economically-viable advanced water treatments could be promising options for the removal of pharmaceuticals entering the aquatic environment and agricultural soils.

10. Promoting better overall management of pharmaceutical emissions into soils and the aquatic environment (1 option): Several EU Member States and neighbouring countries have already taken action towards better protection of water resources from pharmaceuticals. Guidance could be developed in the framework of the Common Implementation Strategy for the Water Framework Directive (WFD) bringing together the best practices and advice to enable water managers to better manage pollution by pharmaceuticals at national and river basin level.

The background document provides more information, including factsheets on the individual options. Each factsheet explains the context, describes the option and its aims, provides a brief preliminary assessment of strengths, weaknesses, opportunities and threats (a SWOT analysis), and lists information sources and references.