



European  
Commission

# Pharmaceuticals in the Environment

*(human medicines)*

**Sante/B5**

Pharmaceuticals Committee meeting  
Brussels, 7 November 2019

# The EU Strategic approach to Pharmaceuticals in the environment

Commission Communication COM(2019)128 final (March 2019)

## Legal basis:

- Environmental EU legislation: Water Framework Directive and the Priority Substances Directive
- Pharmacovigilance
- DG Environment and DG SANTE closely collaborate on its adoption and implementation
- The EU strategic approach also underlines the commitment from the Commission to tackle AMR from a One Health perspective.
- **Problem definition:**
  - Residues and traces of several pharmaceuticals found in environment across EU
  - Need for more information and monitoring of pharmaceutical residues in the environment
  - Threats of anti-microbial resistance in the environment and public health

# The EU Strategic approach to Pharmaceuticals in the environment

Identified **6 areas of action** with 33 further measures at the EU and Member States level that **addresses the whole life-cycle of pharmaceuticals**:

- Increase awareness and promote prudent use of pharmaceuticals;
- Support the development of pharmaceuticals intrinsically less harmful for the environment and promote greener manufacturing (including aspects on the Good manufacturing practices);
- Improve environmental risk assessment and its review;
- Reduce wastage and improve the management of waste;
- Expand environmental monitoring;
- Fill other knowledge gaps, while ensuring that actions to address the risk do not jeopardise access to safe and effective pharmaceutical treatments for human patients and animals

**Close cooperation with European Medicines Agency**

# Initial actions

## **DG SANTE collaborates with DG ENV regarding actions**

- Workshop (May 2019): (organised jointly with NL) for MS and stakeholders to discuss the EU Approach
- Presentation of the Communication in HMA and EMA MB
- Meetings with stakeholders: water industry, NGOs, pharmaceutical industry
- Presentation to MS in the context of One-Health Network on AMR (October 2019)
- Exchanges with International partners: WHO, China, IPRP
- Ongoing revision and discussions on the ERA guidance of EMA
- Implementation of new Veterinary Medicinal Products Regulation
- Research and Innovation: Planning of Horizon Europe – possible Partnerships on AMR and follow-up to the Innovative Medicines Initiative
- Pharmaceuticals Committee meeting (November 2019)

## Way forward

- It is proposed to establish a Working Group under the Pharmaceutical Committee focused on the measures where further coordination is needed at national level and discuss best practices.
- For the measures at the EU level, EMA will have follow-up actions that will be further coordinated with DG SANTE and the MS.



# Information

EU Strategic Approach:

[https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic\\_approach\\_pharmaceuticals\\_env.PDF](https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF)

Contact

- [Marilena-Silvia.Lungu@ec.europa.eu](mailto:Marilena-Silvia.Lungu@ec.europa.eu)
- [Anneli.Torronen@ec.europa.eu](mailto:Anneli.Torronen@ec.europa.eu)