Pharmaceuticals in the Environment
(human medicines)

Sante/B5

Pharmaceuticals Committee meeting
Brussels, 7 November 2019
The EU Strategic approach to Pharmaceuticals in the environment

Legal basis:
- 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:

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