



European Commission's actions to reduce pharmaceuticals in the environment

Hans Stielstra

*European Commission, Directorate
General Environment*

Overview

- Heightened interest due to
 - Environmental impacts
 - Health impacts (AMR)
- Two strategies
- Dozens of actions – legislation, soft law, research, knowledge
- Two ‘policy communities’ involved

Strategic Approach to Pharma in the Environment –

adopted March 2019

Six areas of action

- Increase Awareness and Promote Prudent Use of Pharmaceuticals
- Support Development of Pharmaceuticals Intrinsically Less Harmful for the Environment and Promote Greener Manufacturing
- Improve Environmental Risk Assessment and Its Review
- Reduce Wastage and Improve the Management of Waste
- Expand Environmental Monitoring
- Fill other Knowledge Gaps

Strategic Approach to Pharma in the Environment

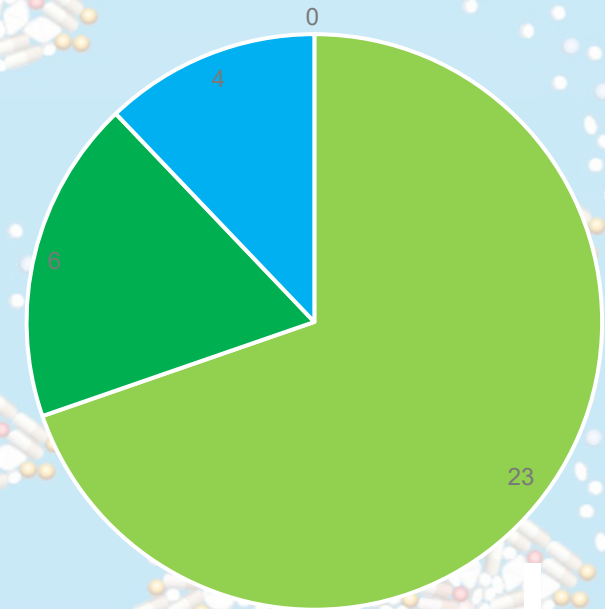
Update on Progress and Implementation

- Update published November 2020 together with **Pharmaceutical Strategy**

- <https://ec.europa.eu/environment/water/water-dangersub/pharmaceuticals.htm>

- Overall good progress

- All actions at least started
- Many well ongoing
- Some already completed



Legend:

Started
Ongoing
Good Progress
Implemented/Achieved

Update on Progress and Implementation – internal *Research*

- Horizon Europe – the evaluation of the “Green Pharmaceutical” call ongoing; results January 2022
- Green Deal Call – “Fostering regulatory science to address combined exposures to industrial chemicals and pharmaceuticals: from science to evidence-based policies” – projects just started
- LIFE – new call for proposal for 2021 – 2024

Update on Progress and Implementation – internal

Health policy actions

- Ad-hoc Working Group of national health officials to report to the Pharmaceutical Committee.
- Group addresses all actions from the Strategic Approach on Pharmaceutical in the Environment, deliverables 2022 – 2023 (e.g. Recommendations including exchanges of best practices and possible guidelines)

Update on Progress and Implementation - internal

European Medicine Agency actions

- Revision Guidelines on Environmental Risk Assessment for *human medicinal products* is ongoing - first draft in 2022.
- Elaboration of guideline on Environmental Risk Assessment for *veterinary medicine products* intended to be used in aquaculture has been initiated.

Update on Progress and Implementation

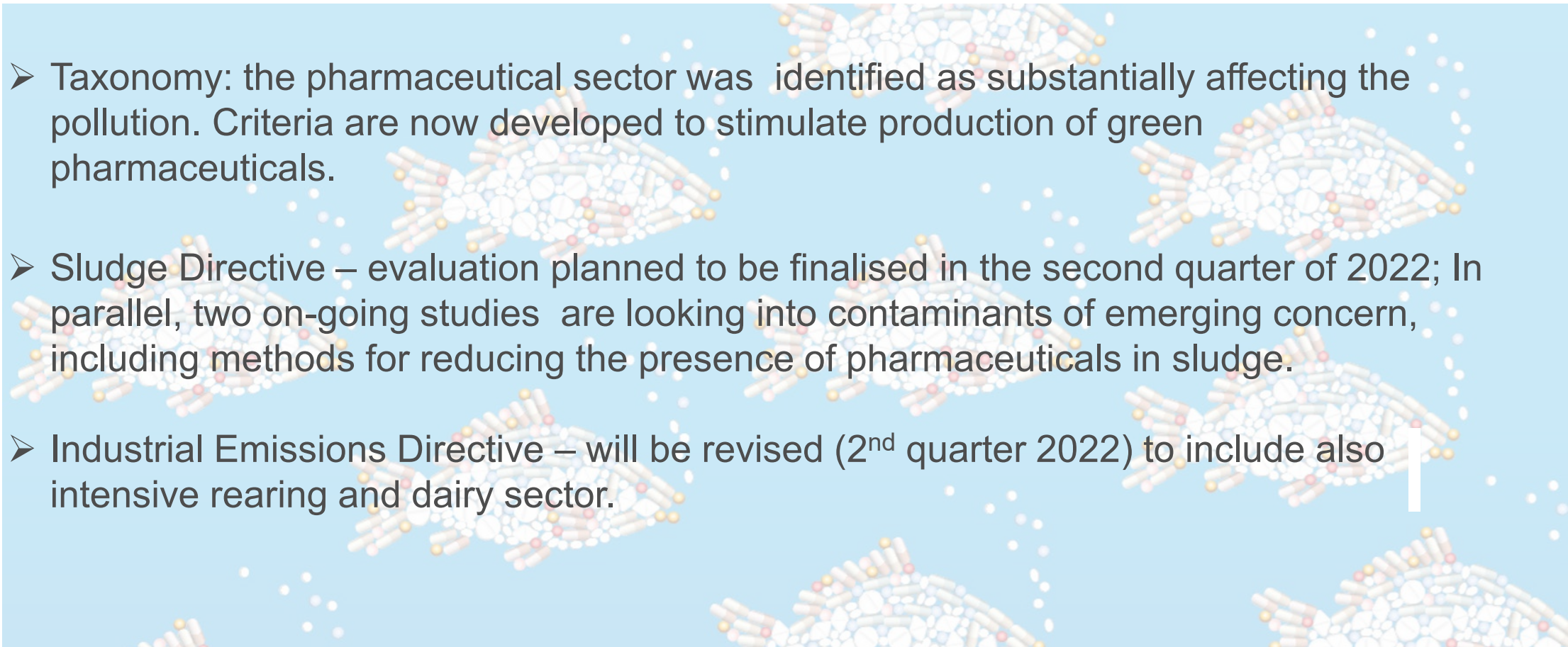
Environmental policy work

- 3rd Quarter 2022: revision of the list of substances in groundwater and surface water
- Summer 2022: revision of the ‘Watchlist’ surface water: pharmaceuticals to be included in the Priority Substances list e.g. diclofenac, ibuprofen, various antimicrobials and an anticonvulsion medication
- 2nd Quarter 2022: revision of the Urban Waste Water Treatment Directive – more (currently untreated) water will be treated; in urban centres water will be treated more thoroughly.



Update on Progress and Implementation - internal

Environmental policy work

- 
- Taxonomy: the pharmaceutical sector was identified as substantially affecting the pollution. Criteria are now developed to stimulate production of green pharmaceuticals.
 - Sludge Directive – evaluation planned to be finalised in the second quarter of 2022; In parallel, two on-going studies are looking into contaminants of emerging concern, including methods for reducing the presence of pharmaceuticals in sludge.
 - Industrial Emissions Directive – will be revised (2nd quarter 2022) to include also intensive rearing and dairy sector.

A Pharmaceutical Strategy for Europe

adopted November 2020

- Four main objectives:
 - ✓ access to affordable medicines for patients,
 - ✓ supporting competitiveness, innovation and sustainability of EU pharmaceutical industry and the development of high quality, safe, effective and **greener medicines**
 - ✓ enhancing crisis preparedness and response mechanisms, incl security of supply;
 - ✓ ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

- Is complementary to the Zero Pollution ambition, notably through the impact of pharmaceutical substances on the environment.

- Includes also a chapter on environmentally sustainable medicines

A Pharmaceutical Strategy for Europe

adopted November 2020

- Two flagship actions by 2022 to revise the pharmaceutical legislation to
 - improve transparency and oversight of the supply chain including to ensure overall environmental sustainability
 - strengthen the environmental risk assessment requirements
- Promote the prudent use of antibiotics and communication to healthcare professionals and patients.



Thank you



© European Union 2020

