

Strategic Approach to Pharmaceuticals in the Environment

State of play and next steps

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Origin and Context

Origin

 Priority Substances Directive (2008/105/EC as amended by 2013/39/EU)

Context

- Circular Economy and 7th Environmental Action Programme
- Sustainable Development Goal n°6
- Action Plan on Antimicrobial Resistance
- Fitness Check of EU water legislation (2019) and evaluation of Urban Waste Water Treatment Directive



State of play and next steps

Roadmap published 28 April 2017

https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630 en

 Public consultation and stakeholder consultation published 22 November 2017

https://ec.europa.eu/info/consultations/public-consultation-pharmaceuticalsenvironment_en

https://ec.europa.eu/eusurvey/runner/PharmaInEnvTargetedConsultation2017

 Commission Communication on Strategic Approach to Pharmaceuticals in the Environment planned for end of 2nd quarter 2018



Overall approach

Problem to address

 The manufacture, use and disposal of active pharmaceutical ingredients leads in various ways to their release into the environment, and some may pose a risk

Subsidiarity check

Environmental pollution is transboundary

Key considerations

- Source control rather than end-of-pipe solutions where possible
- Actions might be taken in several policy areas



 Promoting more effective treatment of waste water, manure and sludge

Design

Designing "greener" substances

Waste treatment and reuse

Use

Authorisation

 Ensuring ERA robustness, consistency and transparency

3. Ensuring appropriate collection and disposal of waste pharmaceuticals

Whole lifecycle

- Improving our understanding of risks
- Promoting better overall management

Manufacturing

 Promoting "greener" manufacturing

 Promoting sustainable use

 Ensuring environmental risks and impacts observed post-marketing are identified and reported Marketing & Post authorisation

 Ensuring environmental risks are adequately taken into account and translated into mitigation actions



16. Please give each of the twelve possible actions below a score between 5 and 0, where 5 = high priority action, 3 = medium priority action which action areas they relate to in the background document, but are in most cases more specific.

· · · · · · · · · · · · · · · · · · ·	5	4	3	2	1	0
More research to better understand the risks						
2. "Greener" design of pharmaceuticals, e.g. to make them more biodegradable						
3. More stringent conditions for putting a pharmaceutical on the market						
4. Cleaner manufacturing						
5. Better risk mitigation, e.g. not allowing over-the-counter sale of pharmaceuticals that pose an environmental risk						
6. Better/more thorough post-market monitoring of pharmaceuticals in the environment and feedback to the regulatory process						
7. (a) Better training for medical professionals, e.g. about pharmaceuticals that are less harmful for the environment						
7. (b) Better information for the public, e.g. about how to dispose of unused medicines						
7. (c) Smaller packaging sizes, to reduce unnecessary waste/disposal						
8. Improved handling of waste pharmaceuticals						
9. (a) Improved sewage and wastewater treatment						
9. (b) Improvements in livestock farming to reduce the use/emission of pharmaceuticals						



Types of action

- Options in background document = starting point for decisions on strategic approach
- Strategic approach to be followed by proposals for measures as appropriate
- Measures likely to include continued/increased support for relevant research
- Measures could include "soft" measures, e.g. guidance, awareness raising
- Any legislative measures would require full impact assessment



Thank you for your attention

http://water.europa.eu/policy