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CWPharma Conference

Pharmaceuticals in the Environment – work in the EU and at the Swedish Medical Products Agency

Stefan Berggren

Deputy Director Supervision

Responsible for the environmental work at the Swedish Medical Products Agency

Chairman of the European working group on PiE

Regional cooperation essential for increasing knowledge and solving problems

Pharmaceuticals in the environment is an emerging group of pollutants

Regional cooperation is essential to tackle the problem

We consider the work of CWPharma within EUSBSR as an important contribution to increasing knowledge and providing tools and recommendations for action on local, national, regional and EU-level

EU Strategic Approach on Pharmaceuticals in the Environment

The "*EU Strategic Approach on Pharmaceuticals in the Environment"* was published in 2019 as a communication from the European Commission to the European Parliament, the Council and the European Economic and Social Committee[1].

Will be linked to the new Pharmaceutical Strategy presented in the end of 2020

[1] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2019:128:FIN

European Pharmaceutical Committee – work based on the EU strategic approach on PiE

After the publication of the “EU Strategic Approach to Pharmaceuticals in the Environment“ the European Pharmaceutical Committee within human medicines has established an *ad-hoc* working group to address parts of this strategic approach

- Seven sub-working groups within human medicines
- Recommendations, exchange of best practices and possible guidelines as a mission – to implement the EU Strategic Approach to Pharmaceuticals in the Environment.

Overview of the work in the sub-working groups

Recommendations, exchange of best practices and possible guidelines

	Topic
1	Promote the development of guidelines for healthcare professionals on the **prudent use** of pharmaceuticals posing a risk to or via the environment
2	Explore, in cooperation with relevant stakeholders, how environmental aspects could become part of **medical training** and **professional development programmes**
3	Foster best-practice exchanges between Member States on how environmental considerations are taken into account in the **advertising and prescription** of medicinal products and the **choice of therapy more generally**, where appropriate
4	Explore the possibility of **reducing waste** by optimising the package size of pharmaceuticals so that medicines can be dispensed in quantities better matching needs, and by safely extending use-by (expiry) dates so that fewer medicines that are still usable have to be thrown away

Overview of the work in the sub-working groups

Recommendations, exchange of best practices and possible guidelines

	Topic
5	Facilitate the exchange of best practices among healthcare professionals on the environmentally **safe disposal of medicinal products and clinical waste**, and the collection of **pharmaceutical residues** as appropriate
6	Assess the implementation of **collection schemes** for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in **reducing inappropriate disposal**
7	Provide recommendations on the actions under the section 5.3 (“Improve the **environmental risk assessment** and its review for the human medicines”) that fall under the competence of the Member States

Swedish Medical Products Agency - work on environmental issues

To promote

- Better environmental tests to be used in e.g. ERA
- Increased knowledge on and access to environmental information
- Regulatory aspects of environmental risk assessment in risk-benefit analysis such as in risk mitigation measures
- Regulatory instruments including minimum requirements for manufacturing conditions
- Reduction of AMR

Swedish Knowledge Centre on Pharmaceuticals in the Environment

Transdisciplinary and cross-sectorial platforms

Regional, national & international

Focus areas

Increase and spread knowledge about pharmaceuticals in the environment

Encourage development and use of environmental criteria

Strengthen knowledge concerning sustainable production and use

EU Commission Pharmaceutical Strategy

EU Commission Pharmaceutical Strategy[1] in preparation, lead DG SANTE

- Commission adoption planned for fourth quarter 2020

In the draft version, the initiative aims to tackle 7 challenges in total

- Challenge 7, “The way environmental risks are addressed needs to be improved”:

  ... “the regulatory framework needs to address the **environmental implications of production, use and disposal of medicines**. **One of the major challenges is increasing antimicrobial resistance**.”

[1] European Parliament webpage concerning: Pharmaceutical strategy for Europe

Some areas with special interest to Sweden

Overall - Incorporate the vision of Agenda 2030 to address the importance of reducing pharmaceutical pollution and reducing AMR using a life cycle approach

Some of the points in the environmental area Sweden emphasises in the upcoming Pharmaceutical Strategy[1] are:

- Adopt a life cycle approach to regulate pharmaceuticals residues in the environment
- Work on possibilities to implement stronger rules on environmental risks in marketing authorisation
- Improve the supply chain transparency

In addition, the EU Parliament's resolution on the Strategic Approach on PiE adds pressure to act against pharmaceutical pollution

[1] European Parliament webpage concerning: Pharmaceutical strategy for Europe

Thank you for your attention!

E-mail adress: stefan.berggren@mpa.se