Need

- Increasing amount of pharmaceuticals end up in the environment (population growth, ageing population, urbanization)

- Most of the load comes from normal therapeutic use via excretion to wastewater as APIs and their metabolites

- Pharmaceuticals can have adverse environmental effects (e.g. antimicrobial resistance, endocrine disruptors, secondary poisoning)

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Need

- Growing demand for knowledge and for open data on the environmental characteristics (PBT) and risks that pharmaceuticals pose (EU strategic approach to pharmaceuticals in the environment)

- Classification needed in order to be able to make choices based on environmental aspects **when possible** (doctors (rec), pharmacists (OTC), consumers (OTC), public procurement)

- Currently we are lacking in tools to support sustainable decision making when choosing pharmaceuticals

Need

- Knowledge and open data on the environmental effects of manufacturing (global challenge) as well as other stages of drug's life-cycle in order to assess the environmental impact of pharmaceutical <u>products</u>

- Education on pharmaceuticals in the environment (PiE) for health care professionals (Generation Green Initiative since 2015, to implement environmental aspects to pharmacy education at the University of Helsinki)

Approach (Background)

Swedish Environmental Classification of Pharmaceuticals (APIs)

fass.se

- Voluntarily published environmental data of APIs from industry
- Published on fass.se website administered by Lif (Läkemedelsindustriföreningen)
- Classification based on risk assessment (PEC/PNEC)
- Also phrases on assessment of hazard: P (persistence), and B (bioaccumulation)
- Data utilized for national purposes in Norway
- Guidance by Lif for companies: https://www.fass.se/pdf/Environmental_classification_of_pharmaceuticals-120816.pdf

janusinfo.se

- Environmental data of APIs from research and industry
- Published on janusinfo.se website targeted for health care professionals
- Classification based on index number (0-9) derived from PBT assessments
- Risk assessment from fass also presented

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Approach

EPIC project: Survey on prospects for implementation to Finland

- Survey identified 4 possible approaches to implementation

1. Direct utilization of data on fass.se/felleskatalogen.no combined with a one-off calculation of risks in Finland -> 1st step?

2. Creation of a similar classification as in Norway (based on data from fass but with risk assessment for Finland, published and updated on Finnish website) -> 2nd step?

3. Creation of our own National Finnish Environmental Classification System (could be based on wider range of data from various sources, could also include more diverse risk assessments) -> 3rd step?

4. Creation of "Nordic Environmental Classification System"

Approach

Identified important characteristics for the classification system based on stakeholder consultations

- Open, reliable, comprehensive, research-based data
- Publically available
- Easy to use
- Different levels for different user groups
- Information in Finnish

Benefits

Environmental Classification System – implementation to Finland

- New information on national environmental risks of pharmaceuticals

- Enable development of tools to be used in sustainable decision making, **when possible,** to drive the use of pharmaceuticals towards environmentally less harmful substances

- Increase knowledge on effects of PiE among health care professionals and public (publically available data in Finnish combined with suitable communications and education)

- Open data on environmental load, fate, risks and hazards of pharmaceuticals could also be used in research and wastewater management

Collaboration

Stakeholder consultations in EPIC-project on classification

- 3 Roundtable discussions were realized (February 2019) with:
    - Health care professionals (Association of Finnish Pharmacies and The Finnish Medical Society Duodecim)
    - Authorities (Finnish Medicines Agency Fimea and Ministry of the Environment)
    - Industry (Orion and Pharma Industry Finland)
- Interviews about the Swedish Environmental Classification of Pharmaceuticals in Stockholm (May 2017) with:
    - Lif (The research-based pharmaceutical industry), IVL (Swedish Environmental Research Institute)
    - SLL (Region Stockholm Assembly)

Collaboration

Next steps

- International: EU/Nordic collaboration?
- National: authorities, health care professionals, industry, researchers
- **Collaboration between relevant stakeholders is important for developing and implementing a reliable, functional and well-suited environmental classification of pharmaceuticals in Finland**
- Next steps: to evaluate the possible implementation approaches and find answers to open questions on costs, requirements for resources and know-how, and administrating organization(s).

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Thank you!

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