Pharmaceuticals in the environment
Make ideas work!

Swedish activities

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Swedish Ministry of the Environment and Energy
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“.. hand over to the next generation a society in which major environmental problems have been solved, without increasing environmental and health problems outside Sweden’s borders.”

Photo: Bent Christensen
A Non-Toxic Environment

- The occurrence of man-made or extracted substances in the environment must not represent a threat to human health or biological diversity.

- Concentrations of non-naturally occurring substances will be close to zero and their impacts on human health and on ecosystems will be negligible.

- Concentrations of naturally occurring substances will be close to background levels.
By 2020 increased environmental considerations in the pharmaceutical legislation in EU and international conventions
Swedish MPA’s proposals for increased environmental consideration

- Make the information on environmental impact of medicinal products accessible
- More appropriate and better environmental tests, revising the ERA guideline
- Consider environmental risk in risk-benefit to manage risk mitigation
- Regulatory instrument setting minimum requirements for manufacturing conditions
Database on EU-level

- Information on environmental assessments for pharmaceuticals in EU

→ would facilitate updates of voluntary information systems and establishment of relevant limit values based on effect levels of the substances

→ Easier to find information on environmental risk assessments etc.
Minimum requirements for production

- Requirements for environmental certification of the production facilities introduced in the legislation on Good Manufacturing Practice.

- Could eliminate today’s shortcomings in treatment of residues

- Would competitively benefit the companies that have already invested in sufficient wastewater treatment equipment
Swedish proposals in the review of Regulation on veterinary medicinal products

- Antimicrobial resistance – preventive use of antibiotics
- Minimize environmental pollution from the manufacturing of pharmaceuticals; new regulation setting emission limits
- Restrictions on persistent, bio-accumulating and toxic (PBT) chemicals
- Access to information from Environmental Risk Assessment (ERA)
Eliminating pharmaceutical residues by advanced waste water treatment

• Already implemented in Switzerland
• Swedish government is sponsoring pilot projects 2014-2017
• Government commission to the Swedish EPA to analyse needs, technical solutions, advantages and drawbacks by May 2017
Correct Use of Medicines to the Benefit of Patient and Society

”… ensure environmental sustainable use of pharmaceuticals”

Chaired by Ministry of Health and Social Affairs

Includes projects related to environment, e.g. risk assessment for non-prescription medicines, best use of antibiotics and environmental consideration in production of pharmaceuticals
Environmental information on pharmaceuticals

- available on www.fass.se (the Swedish medicines information portal open to the public) since ten years

- voluntary environmental classification scheme developed by branch organisation, reviewed by independent body

- aim was to develop transparent model for public, healthcare sector and researchers
Swedish experiences and recommendations in summary

• Co-operation with ministries and authorities of health and social affairs, industry, researchers, healthcare providers, water management bodies, is key

• Precautionary measures could and should be taken within EU regulations on human and veterinary medicinal products and/or internationally

• Development of end-of-pipe solutions, e.g. advanced waste water treatment may be necessary
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Health Care Without Harm Europe

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