Pharmaceutical pollution: Healthcare action & Policy processes

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Content

- HCWH work and goals on pharmaceuticals
- APIs characteristics, current evidence, reports
- Global policy process
- European policy process
- HCWH Europe work pharma
- Potential for action, collaboration

Membership and Future Expansion

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Right to Environmental Health and Access to Health Care





Health Care Without Harm's Vision & Mission

Vision

Healthcare mobilises its ethical, economic and political influence to create an ecologically sustainable, equitable and healthy world.

Mission

Transform healthcare worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice.

HCWH Goal on Pharmaceuticals

Pharmaceuticals – Support the safe production, management and disposal of pharmaceuticals, reducing their environmental and health impact throughout the entire life cycle and fostering innovations for green products.

What is the issue with APIs?

- Active Pharmaceutical Ingredients (APIs) are designed to be highly biologically active at low concentrations
- APIs can be released into the environment at every stage of the life cycle (production, use and disposal)
- APIs are released during manufacturing processes
- Many APIs pass through the body unchanged, or as metabolites that may still be biologically active, 30-90% of an oral dose can be excreted in urine
- APIs are released into the environment from wastewater and sewage sludge
- In addition: inappropriate disposal of unused medicines

Current evidence

- More than 600 pharmaceutical and their metabolites have been found in the environment in 71 countries on all continents (in water, soil, sludge, and organisms) German Federal Environmental Agency (2014). Pharmaceuticals in the environment-the global perspective
- 300 million premature deaths will occur over the next 35 years as a consequence of antimicrobial resistance (AMR) - Review on Antimicrobial Resistance (2015).

Pharmaceuticals in the environment – the global perspective

Pharmaceutical	Diclofenac	17α-Ethinylestradiol	Diclofenac	Sulfonamide
Therapeutic group	Analgesics	Synthetic estrogen	Analgesics	Antibiotic
Non-target organism	Vulture (Gyps bengalensis)	Fathead minnow (Pimephales promelas)	Rainbow trout (Oncorhynchus mykiss)	Maize (Zea mays) Willow (Salix fragilis)
Effects	Population collapse due to renal failure	Population collapse due to feminization of male fish	Strong reactions of liver, kidney, and gills	Adverse effects on root gr Death of maize at high c
Study type	Wildlife	Whole-lake experiment	Laboratory	Greenhouse
Reference	Oakes et al. 2004	Kidd et al. 2007	Triebskorn et al. 2007	Michelini et al. 2012

Pharmaceutical	Fluoxetine	Oxazepam	Ivermectin	Enrofloxacin, Ciprofloxa
Therapeutic group	Antidepressant	Anxiolytics	Veterinary parasiticide	Antibiotics
Non-target organism	Leopard Frog (Rana pipiens)	European perch (Perca fluviatilis)	Dung fly and beetle	Cyanobacterium (Anabaena fl Duckweed (Lemna min
Effects	Delayed tadpole development	Altered behaviour and feeding rate	Mortality of eggs and larvae	Growth inhibition
Study type	Laboratory	Laboratory	Laboratory and field	Laboratory
Reference	Foster et al. 2010	Brodin et al. 2013	Liebig et al. 2010	Ebert et al. 2011

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Drinking water can contain pharmaceuticals

- Up to 25 different pharmaceuticals and their metabolites have been detected in drinking water around the world (4).
- Lipid-lowering and analgesic drugs have been found in drinking water in Germany (5).
- Anti-epileptic and anti-hypertensive drugs have been found in drinking water in Italy (6).
- Antibiotic, antiepileptic and beta-blocking drugs have been found in drinking water in the Netherlands (7).

(4) WHO. 2012.
(5) Heberer T et al. 1997.
(6) Huerta-Fontela et al. 2011.
(7) Mons M et al. 2003.

Reports looking at pharma pollution (I)

- BIO Intelligence Service (2013), Study on the environmental risks of medicinal products Final Report prepared for the Executive Agency for Health and Consumers http://ec.europa.eu/health/files/environment/study_environment.pdf
- Umweltbundesamt (2014) Pharmaceuticals in the environment – the global perspective. Occurrence, effects, and potential cooperative action under SAICM. http://www.pharmaceuticals-in-the-environment.org/en/home/dok/2.php
- The Royal Society (2014) Assessing risks and impacts of pharmaceuticals in the environment on wildlife and ecosystems http://rstb.royalsocietypublishing.org/content/assessing-risks-and-impacts-pharmaceuticals-environment-wildlife-and-ecosystems
- Health Care Without Harm (2014) Unused Pharmaceuticals Where Do They End Up? A Snapshot of European Collection Schemes https://noharm-europe.org/documents/unused-pharmaceuticals-where-do-they-end-snapshot-european-collection-schemes
- ChemTrust (2014) Pharmaceuticals in the Environment: A growing threat to our tap water and wildlife http://www.chemtrust.org.uk/wp-content/uploads/CHEM-Trust-Pharma-Dec14.pdf
- Umweltbundesamt (2015) Pharmaceuticals in the environment - avoidance, reduction and monitoring http://www.umweltbundesamt.de/en/publikationen/pharmaceuticals-in-the-environment-avoidance
- National Toxics Network (2015) Pharmaceutical Pollution in the Environment: Issues for Australia, New Zealand and Pacific Island countries http://www.ntn.org.au/wp/wp-content/uploads/2015/05/NTN-Pharmaceutical-Pollution-in-the-Environment-2015-05.pdf

Reports looking at pharma pollution (II)

- EU No pills project (2015) http://www.no-pills.eu/?page_id=7
- SumOfUs (2015) Bad Medicine report, How the pharmaceutical industry is contributing to the global rise of antibiotic-resistant superbugs https://s3.amazonaws.com/s3.sumofus.org/images/BAD_MEDICINE_final_report.pdf
- MistraPharma (2015) Project policy briefing http://www.mistrapharma.se/outcomes/policy-brief-27166372
- Concentrations of antibiotics predicted to select for resistant bacteria: Proposed limits for environmental regulation (2015) http://www.sciencedirect.com/science/article/pii/S0160412015300817
- AMR Review (2014, 2015, 2016) http://amr-review.org/Publications
- Pharmaceuticals in the Environment – global occurrences and perspectives (2015) http://onlinelibrary.wiley.com/
- SiWi (2016) Water and Pharmaceuticals – a shared responsibility http://www.siwi.org/publications/water-and-pharmaceuticals-a-shared-responsibility/

STRATEGIC APPROACH TO INTERNATIONAL CHEMICALS MANAGEMENT

- Global UN process, policy framework, started in 2006
- Goal: by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.
- SAICM Health Care Strategy
- International Conference on Chemicals Management (ICCM) 4 autumn 2015 in Geneva agreed on emerging issues: **Environmentally Persistent Pharmaceutical Pollutants (EPPPs)** among others, such as nanomaterials, EDCs, highly persistent pesticides, lead in paint, etc.
- ICCM5 in 2020: last one, results? Work beyond 2020? Work on pharma?

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Environmental Risks of Medicines in EU legislation

Before being placed on the European market, pharmaceuticals have to undergo an authorisation process.

The application must contain "an indication of any potential risks presented by the medicinal product for the environment", and "specific arrangements to limit it [the environmental impact] shall be envisaged" (Directives 2001/83/EC and 2004/27/EC).

"In any event this impact should not constitute a criterion for refusal of a marketing authorisation" (Directive 2004/27/EC).

In practice, this means that environmental risks are not part of the risk-benefit analysis for human medicines.

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EU unused medicine ruling

Collection systems for unused medicinal products

- Directive 2004/27/EC (relating to medicinal products for human use) introduces an obligation for Member States to implement appropriate collection schemes for unused pharmaceutical products.

Collection systems for unused medicinal products

- It does not provide any guidelines on implementation of schemes and a number of studies have pointed to significant differences between Member States.

Collection systems for unused medicinal products

- Detailed information regarding the implementation and efficiency of collection schemes for unused pharmaceuticals throughout Europe is highly scattered and deficient, preventing comparisons between countries and type of scheme implemented.
- It is not clear that all EU countries have implemented their obligations.

EU: Water pollute & monitor

- 2013 - Priority substance list, out of 2,000 substances that are harmful to aquatic ecosystems, 24 pharmaceuticals, none made it onto the list
- 3 are on watch list – diclofenac, two oestrogen chemicals used in contraceptive pills (17-alpha-ethinylestradiol (EE2) and 17-beta-estradiol (EE))

Spain: Gap science & practice

- 1992-2007 99% of Indian's vulture population died, diclofenac was banned for vet use, switch to meloxicam, breeding programme introduced
- Spain & Italy authorised the use of diclofenac for vet. use, 99% of Europe's vulture population live in Spain

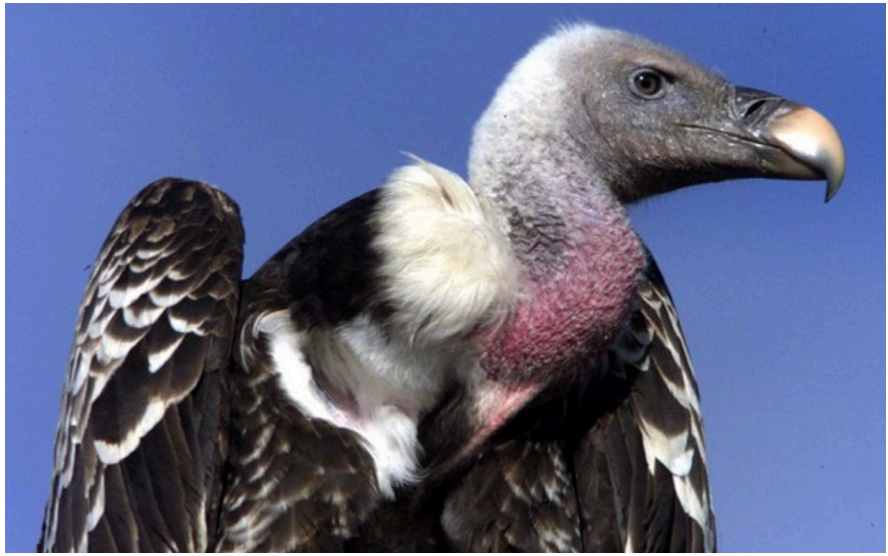

Image: The Telegraph UK

Swedish case study: Stockholm County Council

- 1200 substances,
- data missing for 50%, some missing substances are exempt, considered not a risk for environment
- Substances with degradation data - 90% degrading slowly or potentially persistent
- Substances with toxicity data - about 55% have high or very high toxicity
- Annual ‘wise list’
- Monitoring of Stockholm’ s water system

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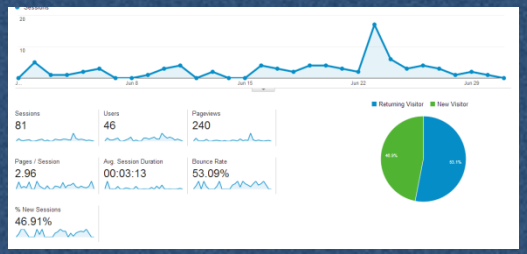
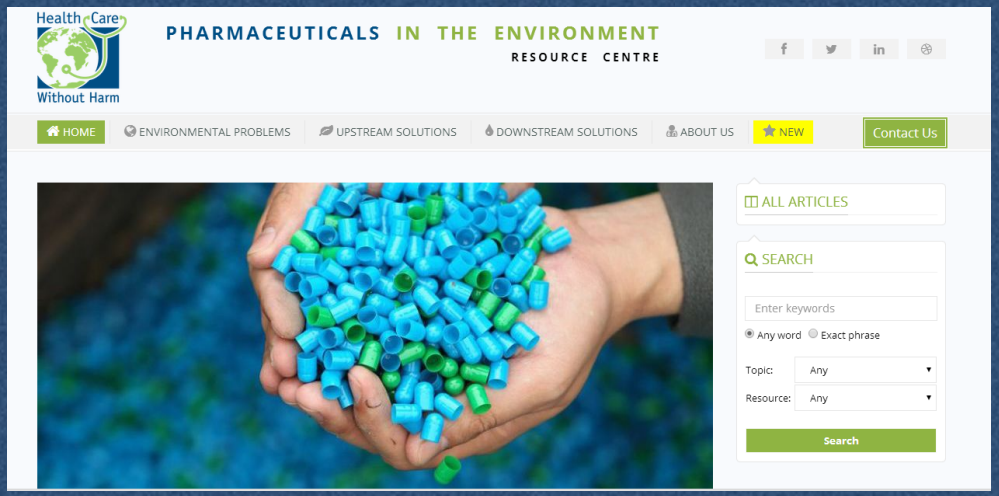
Pharma Resource Centre
www.pharmaenvironment.org





Objective: Keep track of scientific articles, reports and books related to pharmaceuticals in the environment

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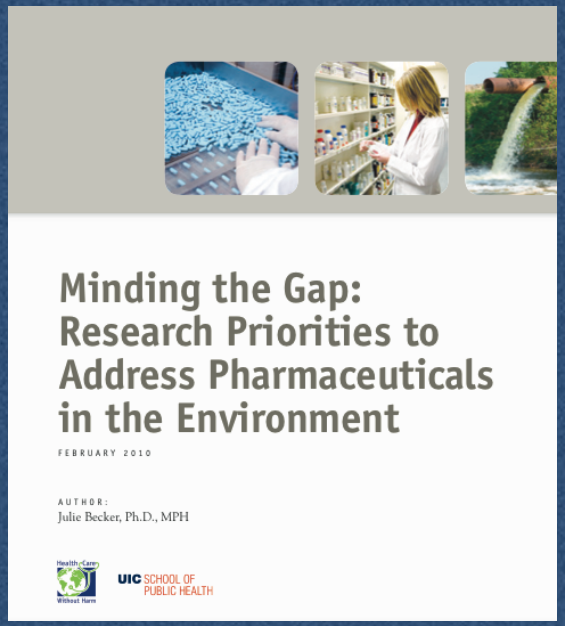
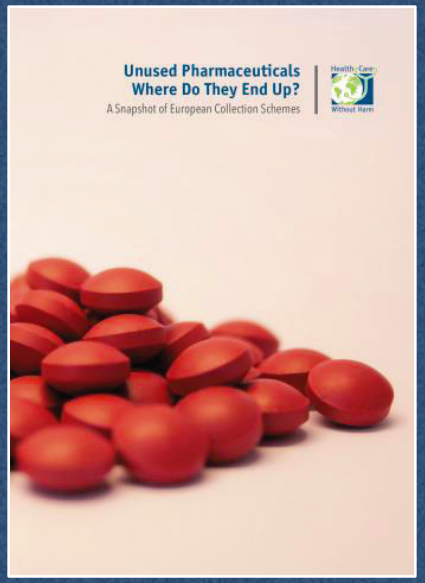
Publications



Pharma Research Priorities



Unused Pharmaceuticals Report

Pharma Leaflet (4 languages)

Actions by different stakeholders: Industry (I)

- End local pollution, clean up the production side
- Take full responsibility for the supply chain
- Fully integrate environmental management into daily business
- Apply NHS guidelines on carbon reduction
- Be transparent on environmental reporting, including 3rd party evaluation
- Invest in R&D with the goal to develop pharmaceuticals, that are benign by design

Actions by different stakeholders (II): Healthcare Sector

- Rational use of pharmaceuticals
- Train and educate healthcare sector about impact of pharmaceuticals in the environment
- Explore options for treatment (i.e. depression)
- Evaluate Wise list and other projects that look at the connection between treatment and environment
- Educate patients about impact of pharmaceuticals in the environment
- Collection of un-used medicine

Actions by different stakeholders (III): Policy makers

- Measure, monitor, legislate
- Protect environment and human health for future generations (apply precautional principle)
- What cost are we as society (global community) prepared to pay to avoid being exposed to pharma pollution? (long-term exposure, cocktail effect, no control group, uncertainty)

Conclusion

- With current APIs we cannot avoid pharmaceutical pollution - we can only minimise it at every stage.
- This is a global problem, that need global action
- Educate, monitor, legislate and act at all levels
- Develop green pharmaceuticals (long term)
- Engage different stakeholders, it needs joint action.

Thank you for your attention!

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https://noharm-europe.org
http://greenhospitals.net/en/


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19th -21st October
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