
Pharmaceuticals in the Environment- Executive Roundtable Summary

Munich, Germany - November 29, 2018

Background

Environmental Pollution caused by human and veterinary pharmaceutical substances is an emerging environmental concern. A multi-stakeholder group including the speakers below met to share insights and discuss responsible business practices.

Participants

Host

-  **Bristol-Myers Squibb**
Carol Powell, VP Global Environmental,
Health, Safety & Sustainability

Moderators and Facilitators

- Bayer: Dr. Reinhard Laenge
- ERM: Oliver Phipps
- Merck: Dr. Kelly Block
- Travers Smith: Douglas Bryden
- WEC: Lori Michelin and Frank Werner

Speakers

- AstraZeneca: Prof. Dr. Jason Snape
- Boehringer Ingelheim: Jochen Schoenbronner
- Bristol-Myers Squibb: Carol Powell
- F. Hoffmann-La Roche: Dr. Bernhard Pellascio
- Health Care Without Harm: Dr. Adela Maghear
- Merck Group: Dr. Martin Hostalek
- Ministry of the Netherlands: Marc de Rooy
- Novartis: Dr. Jutta Hellstern
- University of Gothenburg: Prof. Dr. Thomas Backhaus

Key Points

Roundtable participants agreed that industry's best option to tackle the issue is a collaborative approach to increase data transparency, share knowledge, and educate the public about a responsible use of pharmaceuticals, in collaboration with all stakeholders involved in their product stewardship.

- (1) Life Cycle Solution:** Pharmaceuticals enter the environment via a variety of pathways, many of which are not under the direct control of the pharmaceutical industry (see Figure 1).
- (2) Best Practice Database:** Health Care Without Harm indicated that they would be releasing a best practice data base in early 2019 as a resource for stakeholders.
- (3) Own Operations:** Leading pharmaceutical companies treat wastewater from own operations to minimize release of pharmaceuticals to the environment, with excellent results when modern technology is used. This is a standard industry practice.
- (4) Own Supply Chain:** Leading pharmaceutical companies have made commitments to require treatment of wastewater from contract manufacturers/suppliers to minimize release of pharmaceuticals to the environment; this, however, is much more challenging when operations are not under direct control, production portfolio is not exclusive, and the market is driven by product quality and cost. Leaders are requiring effective treatment as part of their procurement contracts and have processes to exclude non-compliant suppliers.

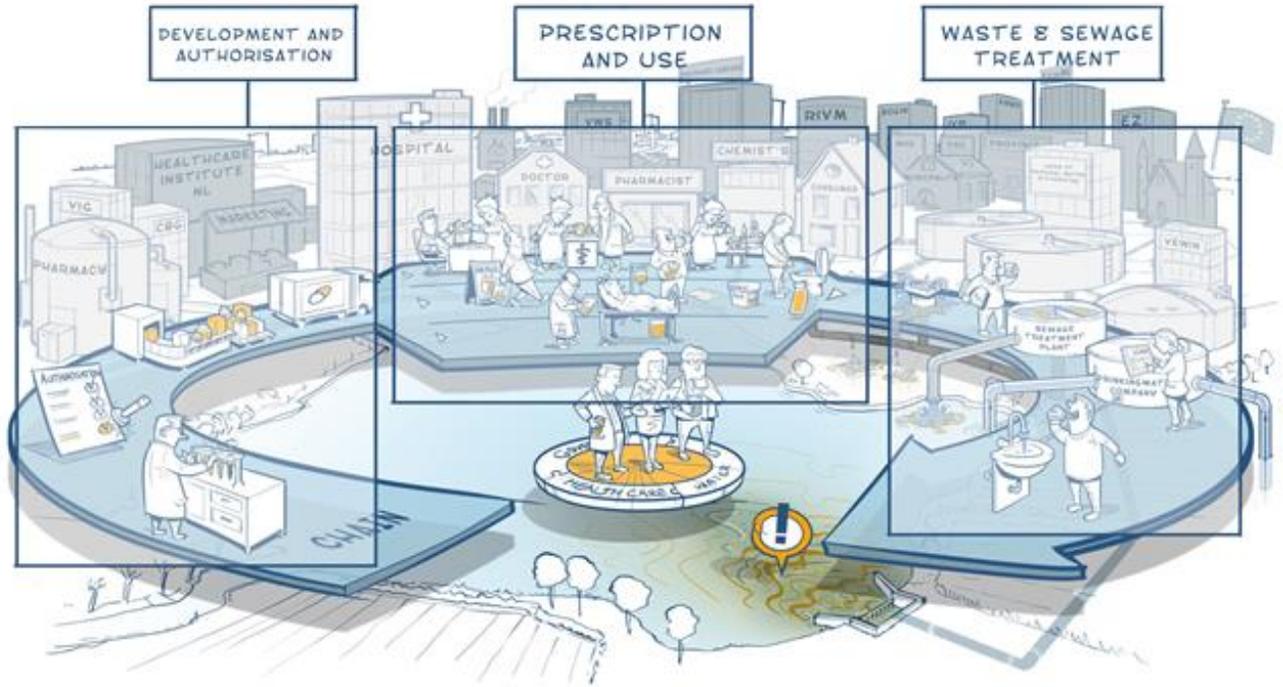
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- (5) **Emerging Regulations:** While progress has been slow on the European Directive to develop a strategic approach to water pollution from pharmaceutical substances, it is noted that regulations are under discussion in India as part of its AMR Action Plan.
- (6) **Responsible Substitution:** A regulatory model that governments may consider is “candidates for substitution” – similar to regulations that were implemented for pesticides. Responsible substitution allows necessary medicines to be available to patients, while minimizing use of certain medicines and driving innovation of more environmentally responsible products. Some caution was raised as patient efficacy and safety should be the primary concern and that environmental substitution might increase exposure and risks with other medicines and discriminate more innovative medicines authorized after 2006 that have chronic eco toxicity datasets. It was noted that some participants indicated that they experienced competitive advantage in certain markets (e.g. Sweden) for minimizing the impact of pharmaceuticals in the environment.
- (7) **Patient Driven Solutions:** It was noted some pharmaceuticals can be excreted in urine largely unchanged. While this is unlikely to move at scale, for certain drugs (e.g. radio contrast agents) collection of patient wastes at home for managed disposal is considered a solution with the potential to reduce pharmaceuticals in the environment.
- (8) **Municipal Wastewater Treatment:** Upgrade of municipal wastewater treatment plants could greatly reduce the release of pharmaceuticals into the environment as this is the aggregation point for the majority of patient, hospital and manufacturing wastes. This is a viable regulatory model in countries with developed infrastructure, however, in countries with no or limited infrastructure this solution would be costly.
- (9) **Environmental Data & Risk Assessment (ERA) data:** There are too few environmental data in the public domain and many pharmaceuticals in use pre-date the requirements for a comprehensive environmental risk assessment. By sharing ERA data the environmental risks associated by the presence of pharmaceutical residues in the environment, whether from patient use or manufacturing operations, can be assessed by all stakeholders against recognized regulatory endpoints. It was also noted that ongoing monitoring of literature studies describing environmental impacts and measured concentrations of drugs in environmental matrices can be used to ensure that environmental risks resulting from patient use are managed beyond the point of authorization.
- (10) **AMR Roadmap:** The AMR Industry Alliance is a private sector coalition set up to provide sustainable solutions to curb antimicrobial resistance, with over 100 biotech, diagnostics, generics and research-based pharmaceutical companies. The AMR has established shared goals that include: An Industry Declaration, A Roadmap and Commitments for Manufacturing and the Environment. Several participants have adopted the AMR antibiotic discharge targets. The group welcomes participation from more companies. For details: WWW.AMRINDUSTRYALLIANCE.ORG.

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Figure 1. Chain of Pharmaceuticals in the Environment



Source: Dutch Ministry of Infrastructure and Water Development, 2018