GREENING THE PHARMACEUTICAL SUPPLY CHAIN: A COLLABORATIVE PATH TO SUSTAINABILITY

Insights from the "A Greener Pharmaceutical Supply Chain for People and Planet" workshop

Health Care Without Harm

CONTENTS

SUMMARY

The virtual workshop *'A greener pharmaceutical supply chain for the people and planet'*, organised by HCWH Europe on 18 September 2024, addressed the **pressing issue of pharmaceutical pollution**. Europe imports a significant proportion of its Active Pharmaceutical Ingredients (APIs) and generic drugs from third countries, mainly India and China. According to Medicines for Europe, 70% of dispensed medications are generics. This sector's environmental footprint extends beyond the continent.

This report summarises the workshop's conclusions. It examines the pharmaceutical industry's environmental impact, focusing on pharmaceutical pollution and the urgent need for greater transparency and sustainability in the supply chain. It analyses current initiatives aimed at reducing pollution, such as **responsible effluent management** in antibiotic manufacturing and **the role of sustainable procurement.** The report also emphasises the importance of **collaboration** among diverse stakeholders, including researchers, policymakers, and industry, to drive impactful change.

Key recommendations include strengthening EU legislation, promoting transparency, incentivising green manufacturing, and shifting towards preventative healthcare. Furthermore, it highlights the need for a holistic approach that considers the entire pharmaceutical lifecycle and engages all stakeholders to achieve a sustainable pharmaceutical industry, effectively balancing environmental protection with access to safe and affordable medicines.

AGENDA

OPENING

10:30 - 10:40 WELCOMING & INTRO
Opening remarks and overview
Mark Wilson, Executive Director - HCWH Europe

PRESENTATIONS

10:40 - 10:50
Pharmaceutical pollution in the environment: a global perspective
Erik Ruiz, Safer Pharma Programme Manager - HCWH Europe

10:50 - 11:05
Responsible effluent management in the antibiotic manufacturing industry
Andreas Haener, Environment Risk Assessor and representative at AMR Industry Alliance Manufacturing Work Group - Roche

11:05 - 11:15
Principles of sustainable procurement (HCWH approach)
Arianna Gamba, Director of Programmes - HCWH Europe

10:15 - 11:30
Sustainable procurement in pharmaceutical supply chains
Maja Monsen, Pharmaceutical Adviser - Norwegian Hospital Procurement Trust

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ROUNDTABLE AND Q&A

11:50 - 13:00 PLANNING FOR ACTION
A collaborative effort towards sustainable pharmaceutical supply chains

- Kelly Thornber, Co-Director - Pharma Pollution Hub Stefan Berggren, Director of Competence Center for Pharmacy in the Environment - Swedish Medical Products Agency
- Kirsty Reid, Director Science Policy - European Federation of Pharmaceutical Industries
- Lina Andersson, Co-Chair Medicines for Europe Sustainability committee - Viatris

INTRODUCTION

The global pharmaceutical industry is crucial for human health and well-being, yet it has a significant environmental impact. For instance, its carbon footprint accounts for an estimated 70% of the healthcare sector's emissions. Resource-intensive pharmaceutical manufacturing can also release active pharmaceutical ingredients (APIs) into the environment, contributing to the growing issue of pharmaceutical pollution and other health threats such as antibiotic resistance or, more broadly, antimicrobial resistance (AMR).

Even after treatment, these effluents may still contain residual pharmaceutical compounds, contributing to environmental contamination. This pollution, evidenced by the detection of APIs in 86.6% of river samples[1] analysed, poses a serious **threat to human health** that is exacerbated by the environment.

An ageing population, the rise of chronic diseases, and the health impacts of climate change are projected to drive pharmaceutical use significantly higher. For example, estimates suggest a 43-67% increase in pharmaceutical use in Germany alone by 2045[2].

Pharmaceutical pollution has significant implications for ecosystems. Hormones, for example, can act as endocrine disruptors, affecting the reproductive systems of wildlife. Also, the widespread use of antibiotics in both human and animal healthcare – approximately two-thirds of all antibiotic sales are for veterinary use – contributes to the rise of antibiotic resistance. This phenomenon threatens our ability to treat infections. Antibiotics can leach into soil and water, disrupting microbial communities crucial for soil fertility and water quality.

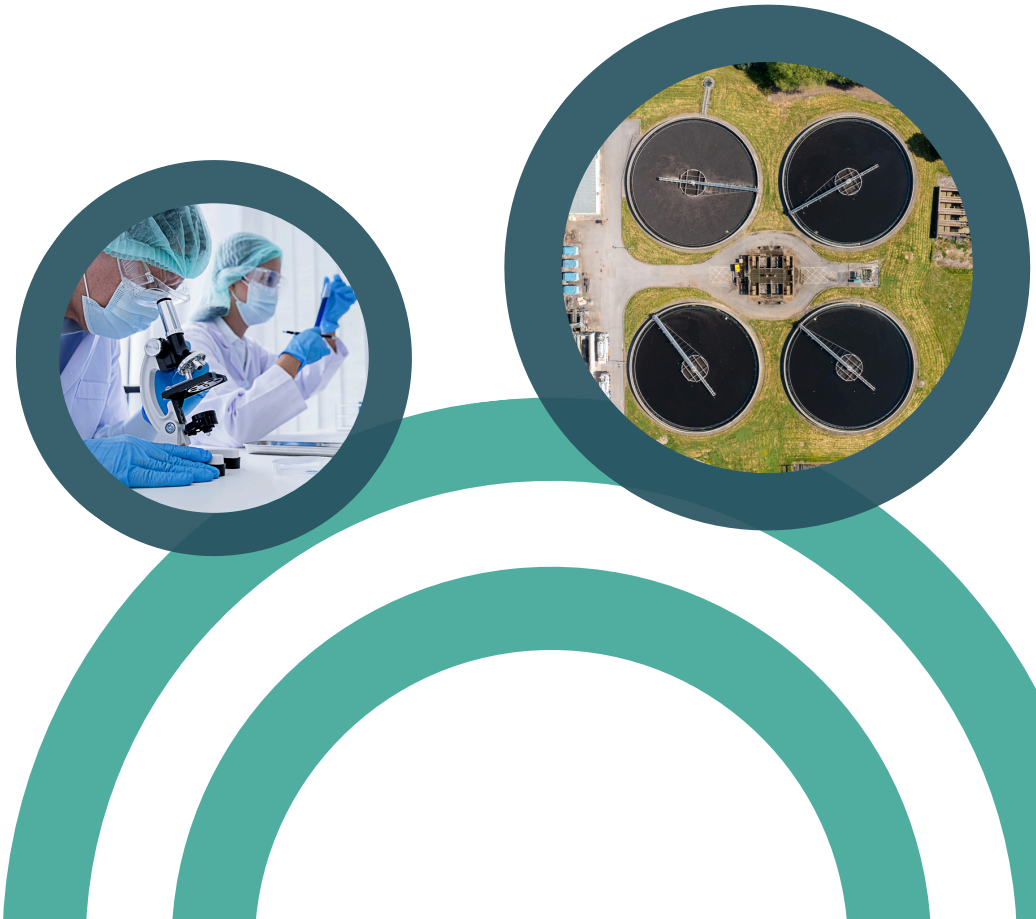
Given the urgency of this issue, this report will focus on presenting pathways to shift towards a greener, more sustainable supply chain. It will identify key action points and recommendations for stakeholders across the pharmaceutical sector to mitigate pollution and promote environmental responsibility.

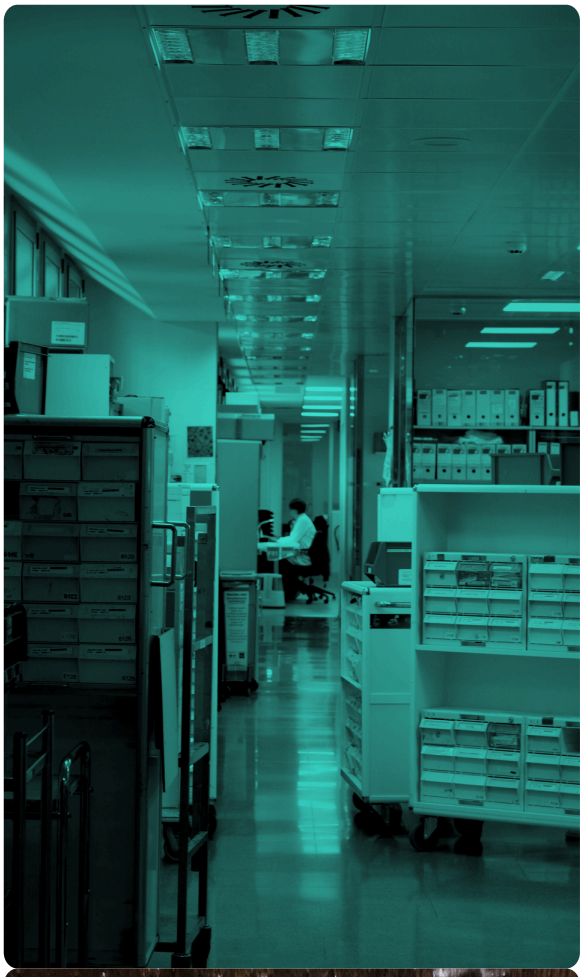
1 RESPONSIBLE EFFLUENT MANAGEMENT IN ANTIBIOTIC MANUFACTURING

The pharmaceutical industry recognises the critical role it plays in mitigating the spread of AMR through responsible effluent management.

A key player in this effort is the AMR Industry Alliance, a coalition of private-sector companies formed in response to the 2016 Davos Declaration. This alliance focuses on providing sustainable solutions to AMR through four key pillars: ensuring access to antibiotics, promoting appropriate use, driving research and development, and addressing manufacturing discharges.

To address the environmental impact of antibiotic manufacturing, the AMR Industry Alliance developed the Common Antibiotic Manufacturing Framework (2018). This framework **emphasises proper wastewater and solid waste management** to meet Predicted No-Effect Concentrations (PNEC) of antibiotics in surface water.





Initially relying on self-declaration, the framework evolved to address concerns about transparency and accountability by establishing a 'Private Industry Standard and Certification Scheme' in collaboration with the British Standards Institute (BSI). This scheme ensures that company-owned and third-party supplier sites adhere to strict wastewater and waste management practices, keeping antibiotic emissions below defined limits.
Various factors, including national action plans on AMR, healthcare system requirements, and antibiotic tender specifications, drive the adoption of this certification scheme.

Financial investors are also increasingly interested in sustainable practices. However, the extent to which these drivers reflect genuine commitment versus compliance with regulations or market pressures **remains to be seen**. While Nordic countries are incorporating the standard into their procurement processes, guidance on antibiotic manufacturing the UK's Five-Year Action Plan supports such standards, **global adoption is still uneven.**

Furthermore, the WHO has released guidance on antibiotic manufacturing, aiming to promote best practices. While broadly aligning with the industry's approach, the WHO sets higher standards, particularly regarding effluent dilution. Furthermore, the WHO's approach mandates chemical analysis of effluent concentration (ECA) in wastewater for compliance. The AMR Industry Alliance is currently engaging with the WHO to seek better alignment between these differing approaches.

2 SUSTAINABLE PROCUREMENT: A FRAMEWORK FOR CHANGE

Sustainable procurement is a strategic tool with the potential to transform the healthcare sector. In Europe, public healthcare spending represents 40% of the European GDP. Leveraging this buying power can drive markets towards more sustainable products and services, benefiting patients, the environment, and society.

HCWH Europe supports this by developing sustainable procurement criteria and resources for various product categories. Key resources include the European healthcare phase-out list of chemicals of concern, the Procuring for Greener Pharma report and the Sustainable Procurement Index for Health, a tool for monitoring and addressing environmental and social impacts. HCWH also emphasises the importance of engaging suppliers in dialogue about sustainability concerns.

THE NORWEGIAN CASE

The procurement landscape in Norway has shifted significantly towards national procurement of medicines, with 90 million units procured annually for Norwegian hospitals. This landscape presents challenges such as decreasing drug prices, climate change concerns, the digitalisation of healthcare services, and balancing patient and hospital needs.

To address these complexities, Norway prioritises criteria beyond price in tenders, with price sometimes weighted as low as 25%. Security of supply is ensured through framework agreements and a procurement model designed to avoid pushing prices to unsustainably low levels. Since 2017, Norway has focused on including **environmental and quality criteria in tenders,** a process detailed in publicly available reports.

Key breakthroughs include the development of standard Nordic criteria for the environmental impact of antibiotic production, launched alongside a corresponding certificate. Examples of specific criteria include requirements for environmental management systems, a detailed feedback mechanism for suppliers, and the evaluation of the AMR Industry Alliance and BSI certificate. The results of the first evaluation showed varied supplier compliance, with some failing to provide necessary information.

Including such criteria can increase costs, but Norway recognises this as a **necessary step to mitigate supply risks**, particularly for antibiotics. Furthermore, suppliers are required to submit plans for reaching zero emissions, with future work aimed at expanding this area and utilising the life cycle assessment standard being developed by NHS and BSI.

3 WHAT'S NEXT: A PATH FORWARD

To ensure the long-term environmental sustainability of the pharmaceutical industry, collaborative action is essential. This section highlights key recommendations and strategies identified through dialogue among diverse stakeholders, including industry representatives, governmental agencies and researchers.

Key themes emerging from the discussions center on the **need to strengthen EU pharmaceutical pollution legislation**. While existing EU legislation and guidelines on environmental risk assessment (ERA) provide a starting point, they are insufficient to address the growing environmental impact of this sector. As the United Nations Environment Programme (UNEP) has emphasised, the pharmaceutical industry remains unregulated mainly regarding its environmental footprint.

Based on this, a comprehensive review of existing legislation should be undertaken to identify gaps and inconsistencies. New legislation should consider the long-term (next 25 years) and address the entire pharmaceutical lifecycle ("cradle to grave"), including increasing pharmaceutical use and wastewater treatment.

Generally, the European Green Deal can provide a critical framework for driving sustainable change within the pharmaceutical industry, and its potential to catalyse this transformation is significant.

Furthermore, as mentioned above, **procurement processes represent a powerful tool for driving sustainable practices**. Incorporating environmental criteria into procurement decisions incentivises sustainable practices across the pharmaceutical supply chain.

Transparency and accountability are also vital, with company-level reporting referencing global standards like the AMR Industry Alliance certification scheme to enable comparability and informed decision-making. The Corporate Sustainability Due Diligence Directive (CSDDD), if implemented correctly, can further increase transparency and accountability in pharmaceutical supply chains, though its precise impact remains to be seen. Careful implementation of the CSDDD is crucial to avoid unintended consequences, such as disruptions to global supply chains or reduced patient access to essential medicines. To balance these considerations, a nuanced approach to reshoring is needed. Reshoring should be viewed strategically as a means to support both global supply chains and patient access to medicines rather than solely as a regional initiative. Any increase in European pharmaceutical production must **prioritise green practices**. This requires incentivising innovation in manufacturing, particularly with a focus on greener processes, to ensure that pharmaceutical production within the EU adheres to the highest environmental standards.

Beyond legislative action, a paradigm shift is needed in healthcare, moving from a focus on treatment to an emphasis on prevention. **Incentivising preventative measures** can reduce the overall demand for pharmaceuticals, thereby lessening their environmental burden. This can be achieved through public health campaigns that promote healthy lifestyles, disease prevention, and increased investment in preventative healthcare services. Identifying and addressing health issues early on can reduce the need for pharmaceutical interventions.

Finally, **collaboration is essential** for achieving both access to medicines and environmental sustainability, as demonstrated by initiatives like the Pharmaceutical Supply Chain Initiative (PSCI). To optimise existing pharmaceutical networks while developing new tools, bridging the gap between researchers and non-research stakeholders, including policymakers, industry, civil society, and the public, is essential.

For example, the Swedish Knowledge Centre for Pharmaceuticals in Environment provides a valuable model, focusing on education, research, and collaboration to address knowledge gaps and promote sustainable practices. Similarly, the PLATINEA platform in Sweden demonstrates the success of multi-stakeholder collaboration, bringing together academia, industry, healthcare professionals, government, and procurement agencies to build trust, exchange perspectives, and identify solutions, particularly in the context of antibiotic stewardship.

To further enhance collaboration and drive impactful research, several key recommendations emerge:

- Acknowledge the lack of comprehensive ecotoxicological data for many pharmaceuticals and invest in research to fill these gaps.
- Recognise the essential role of scientists in data collection and actively involve them in projects that drive environmental progress, such as CHEM 21 and ongoing initiatives under the Innovative Health Initiative.
- Integrating expertise from economists, anthropologists, and political scientists can help address the societal and ethical dimensions of greening pharmaceutical supply chains.

To tackle pharmaceutical pollution effectively, a holistic, systems-level approach is necessary. This means **considering the entire lifecycle of pharmaceuticals**, from manufacturing to disposal, and engaging all stakeholders—from regulators and industry to healthcare providers and the public. Achieving this requires independence, transparency, openness, and compromise to build trust between sectors. A balanced approach that considers the needs of industry, the environment, and patients is necessary.

KEY RECOMMENDATIONS

Achieving true sustainability within the pharmaceutical supply chain is undoubtedly complex, requiring a multi-level approach and stakeholder commitment. However, significant progress can be made by taking decisive action in key areas.
To move towards a greener pharmaceutical sector, the following recommendations are crucial:

1 Public healthcare systems should leverage their purchasing power

This way the could drive the market towards environmentally responsible pharmaceutical products and services.

2 Enforce strict effluent management

The pharmaceutical industry must adhere to rigorous standards, such as those developed by the AMR Industry Alliance, to minimise pharmaceutical pollution from manufacturing

3 Strengthen EU legislation on pharmaceutical pollution

A comprehensive review and update of existing legislation is urgently needed to address the full lifecycle of pharmaceutical pollution and ensure long-term sustainability. The EU's pharmaceutical legislation revision must strengthen ERAs and include factors like AMR, ecotoxicity, and the potential for endocrine disruption

4 Improve transparency and accountability

Public reporting of environmental performance in a standardised and comparable manner should be a standard practice of pharmaceutical companies.

5 Prioritise green practices

Incentivising innovation in manufacturing and pharmaceutical production

6 Effective solutions rely on collaboration and knowledge-sharing among all stakeholders

Encouraging dialogue throughout the supply chain helps develop sustainable strategies while incorporating diverse viewpoints into decision-making.

7 Prioritise preventative healthcare

Investing in public health initiatives that promote healthy lifestyles and disease prevention can reduce overall pharmaceutical demand and its associated environmental impact.

Building a greener pharmaceutical sector requires collective effort.
By implementing these recommendations, we can transform pharmaceutical supply chains into sustainable and resilient systems that protect both human health and the environment.

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PUBLISHED:
January 2025

PHOTO CREDITS:
Envato Elements, Canva and HCWH Europe

Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Climate, Infrastructure andEnvironment Executive Agency (CINEA). Neither the European Union nor thegranting authority can be held responsible for them.

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