CONTENTS

SWEDWATCH

POLICY PAPER
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Towards increased transparency in the pharmaceutical supply chain

Executive summary

Pharmaceuticals are critical for securing the health and well-being of the global population. At the same time, manufacturing discharge released into the environment continues to negatively affect ecosystems and pose threats to human health, including the spread of multi-drug-resistant pathogens.

Fundamental to mitigating negative impacts from the manufacturing process is transparency. Without access to detailed information such as suppliers or environmental risk assessments (ERAs), it is impossible to hold polluters to account. In the last decade, the need for transparency regarding environmental information in the pharmaceutical sector has become increasingly imperative, as evidence of environmental pollution from manufacturing has continued to grow. However, the pharmaceutical supply chain

KEY RECOMMENDATIONS

- **In the Pharmaceutical Strategy for Europe, and the European general pharmaceutical legislation, strengthen requirements for marketing authorisation holders to report detailed supplier information and relevant information on the environment, including on industrial emissions.**
- **Agencies authorising medicines should publicly disclose supply chain details and environmental information provided by the marketing authorisation holders to strengthen oversight on industrial emissions.**

remains vastly opaque, making it impossible for consumers, procurers, and other stakeholders to know how medicines are produced, by whom, and at what cost.

Although companies and other legal entities seeking market licences are required to submit detailed information including ERAs to authorisation agencies, a Swedwatch review found that such information is rarely made public. This is in breach of international conventions such as the Aarhus Convention[1] as well as the EU Directive on Public Access to Environmental Information[2] that recognise the fundamental duty of public authorities to provide access to environmental information, including on impacts on the environment and human health.

Consequently, environmental and public health organisations have long called on the European Union (EU) to align legislative measures regulating industrial emissions from pharmaceutical manufacturing facilities that pose environmental and human rights risks.[3] In an effort to address these risks, the Pharmaceutical Strategy for Europe, adopted by the European Commission in November 2020, highlights the importance of adopting a lifecycle approach to medicines and the need to regulate manufacturing discharge.[4] Similarly, proposals to revise the EU general pharmaceutical legislation include considerations of environmentally safe production of medicines.[5]

This policy paper calls for strengthened regulatory and non-regulatory oversight to mitigate and control industrial emissions that occur during the production of medicines, and particularly advocates for increased transparency and the provision of environmental information in the pharmaceutical supply chain.

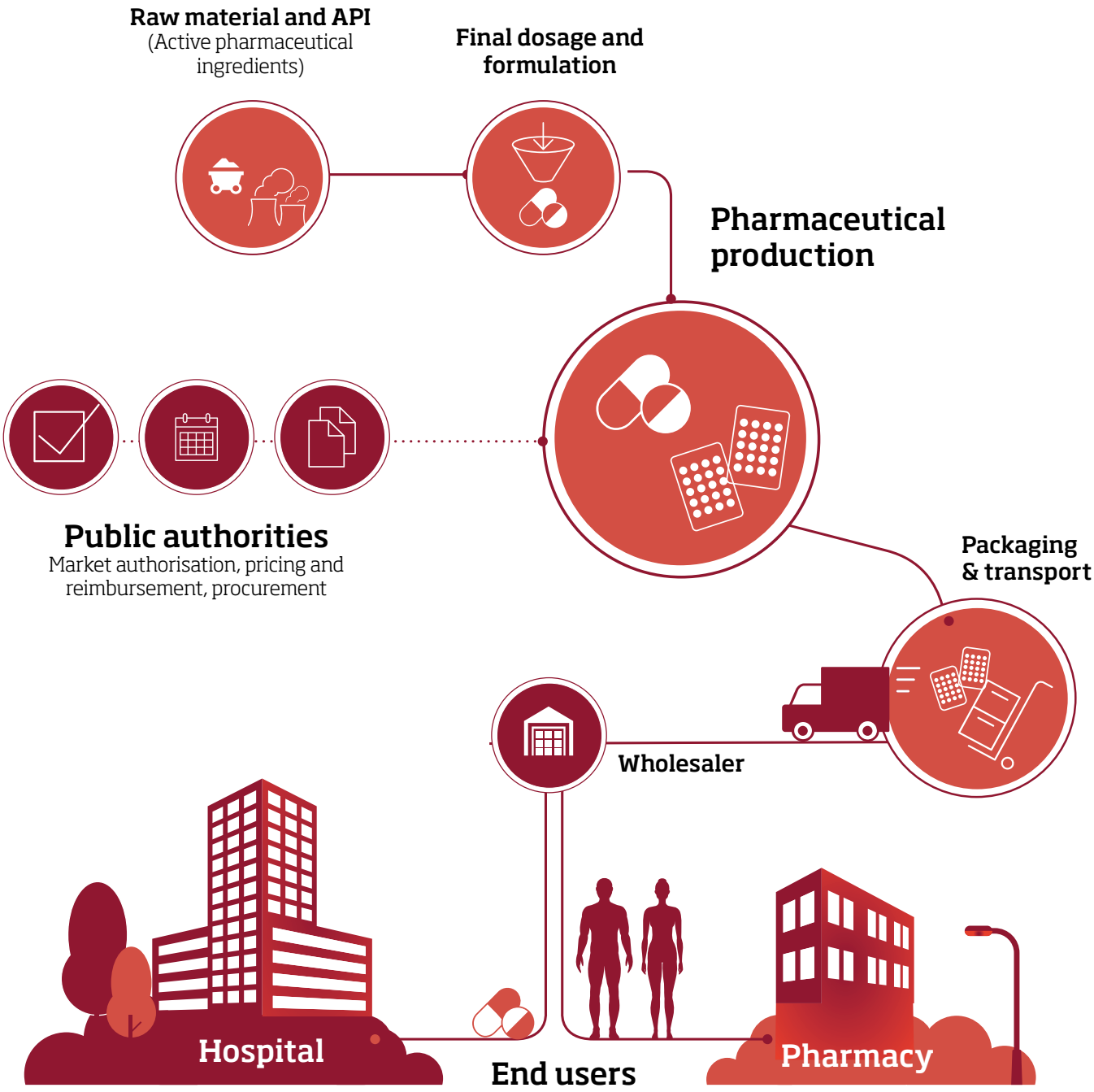
Pollution and oversight in pharmaceutical manufacturing

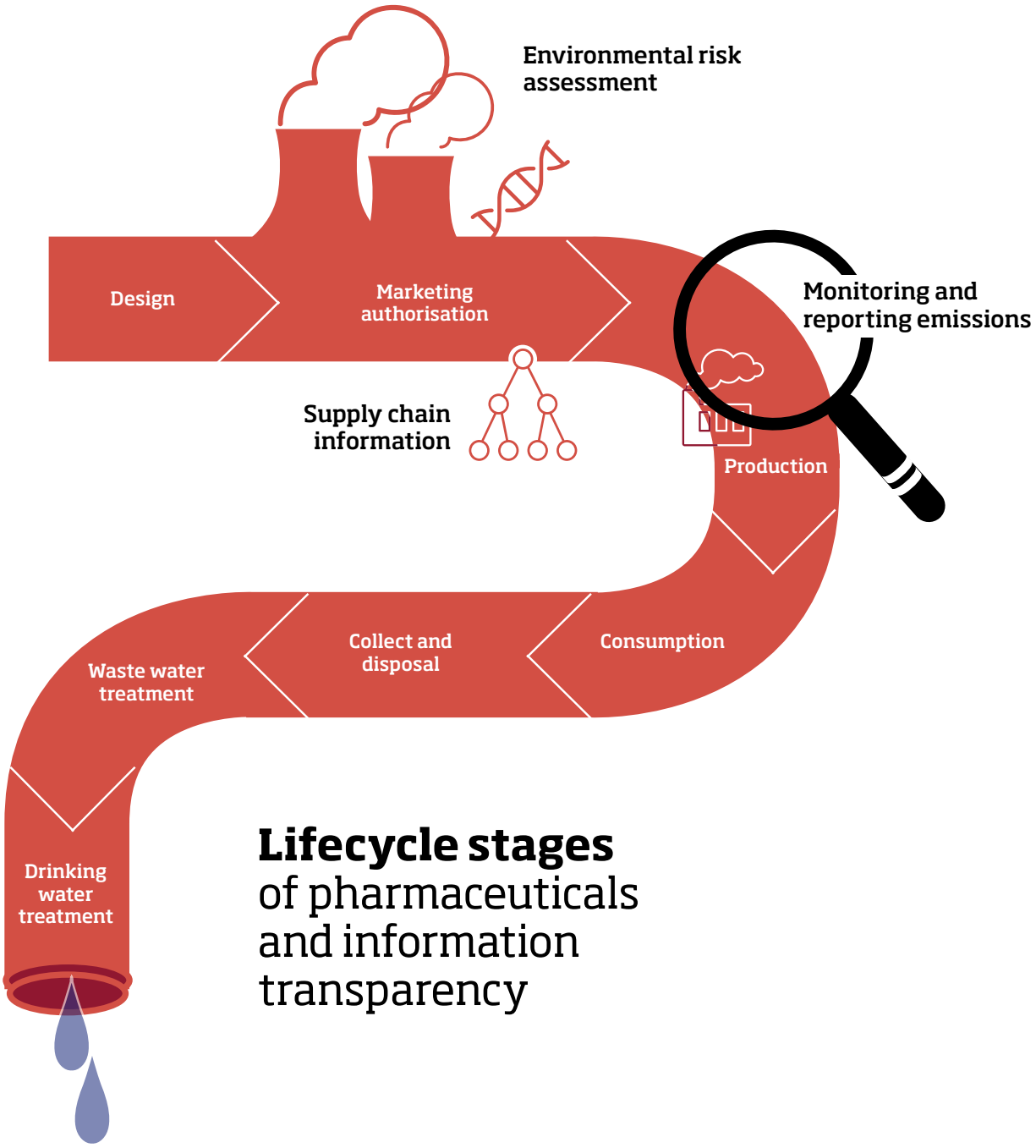
Unlike many other consumer goods, pharmaceuticals serve public health, and are regulated by the authorities to ensure safety and efficacy. It is often difficult for end users of medicines to be fully informed about all aspects of their production, and to exercise consumer power to influence the governance of the associated supply chain.[6] The knowledge-intensive characteristics of pharmaceuticals heighten the need for trained professionals in the pharmaceutical sector and public authorities to not only assess their safety, quality, and efficacy, but also to perform due diligence regarding their potential environmental and social risks. This includes the cumulative impact of industrial emissions on the ecosystem and human health (see Box 1).

There is ample evidence of pollution from industrial emissions in relation to the manufacturing of pharmaceuticals in scientific journals.[7] Reports and campaigns led by civil society organisations, including those representing local communities, as well as media coverage of the issue have further culminated into calls for increased regulatory and non-regulatory oversight and transparency of the supply chain.[8]

Although companies and other legal entities seeking market licences are required to submit detailed information to national and regional authorisation agencies, supply chain and environmental information remain largely inaccessible to the public.[9] This practice violates the public's basic right to access environmental information, which both the Aarhus Convention and the EU legislation on environmental information recognise (see Box 2).[10] It further goes against the procedural rights of individuals and groups to access information and seek remediation for adverse impacts of business operations as stated in the United Nations Guiding Principles on Business and Human Rights (UNGPs).[11] Without public access to information on supply chains, the manufacturing discharge, and the results of environmental and social risk assessments, the relevant actors cannot be held accountable for longstanding industrial emissions.

Key stakeholders
in the pharmaceutical supply chain





Lifecycle stages of pharmaceuticals and information transparency

Importance of transparency

Limited effect of voluntary measures to regulate pollution

An increased recognition of the risks to the environment and subsequent human rights posed by industrial emissions has prompted industry groups such as the Pharmaceutical Supply Chain Initiative and AMR Industry Alliance to discuss ways to control manufacturing discharge. Some ongoing discussions explore technological innovations to treat pharmaceutical residue and waste material, as well as designing environmentally benign pharmaceuticals.[12] Industry groups are also active in establishing risk-based targets and standards for discharge levels.[13] However, private, and voluntary initiatives have thus far had only limited effects on reducing the industrial emissions released during the early stages of production. Moreover, it is particularly difficult to monitor changes in practice due to limited transparency, as manufacturers do not publicly disclose the amount of discharge or the results of environmental audits.[14]

Supply chain transparency

While technological innovations to produce environmentally safe medicines are needed, experts point to the importance of increased visibility in the supply chain, disclosing information on suppliers and their specific location. Discussions about transparency in the pharmaceutical sector[15] have traditionally focused on drug safety, quality, and efficacy. The Covid-19 pandemic has exposed the vulnerability of the global supply chain of medicines and further heightened the need for increased supply chain transparency to assure predictable and secure access to essential medicines.[16]

Although authorisation agencies gather supply chain information, Swedwatch's review of such agencies' websites revealed that this information is rarely made public. While all of the nine agencies reviewed disclosed product information and product safety reviews, only the Medicines and Medical Devices Safety Authority (Medsafe) in New Zealand made details of supply chain actors for products available (see Appendix 1). The website adheres to New Zealand's Medicines Regulations 1984, which requires marketing authorisation holders to regularly update information in the registry including the addresses of manufacturers involved in different stages of the production and distribution of medicine.[17]

When authorisation agencies make supply chain information visible in this way, this allows procurement agencies, agencies responsible for pricing and reimbursement, pharmacies, civil society groups, and end-users to assess due diligence practices and therefore hold relevant actors in the supply chain accountable.[18] This accountability is not only limited to product safety, quality, and efficacy; it also extends to inspecting different suppliers' due diligence on environmental and human rights risks. It particularly allows different actors to identify where the risks of industrial emissions occur and potentially contribute to different actors avoiding being associated with upstream suppliers that exercise weak oversight on industrial emissions.[19]

Environmental oversight

To mitigate harmful impacts and further strengthen oversight of industrial emissions that occur during the manufacturing of medicines, discharge levels should be continuously monitored and reported. Although authorities such as the European Medicines Agency (EMA) require marketing authorisation holders to submit ERAs, the scope of the current assessments is limited to how the medicine is used; it does not include human rights and environmental risks that occur during the early stages of production. Furthermore, submitted ERAs and corresponding reports issued by the EMA are often not available to the public even upon request.[20]

The limited scope of ERAs and the inaccessibility of information from agencies such as the EMA contradict the basic premise of the Aarhus Convention, as well as the EU legislation on environmental information. This lack of transparency further limits authorities and other relevant actors from performing the necessary oversight on industrial emissions as mentioned in the previous section. Without transparency of supply chain and environmental information, longstanding industrial emissions from pharmaceutical manufacturing will continue to have adverse impacts on the environment and human health.

Towards green pharmaceuticals

Increased transparency of supply chain and environmental information is also essential to inform decision-making by public actors including procurers of medicines and agencies responsible for pricing and reimbursement. Although procurement and reimbursement policies vary across countries, there are ongoing discussions at the national, regional and international levels to develop guidelines to promote environmentally sustainable production and consumption of medicines.[21] For instance, the Organisation for Economic Co-operation and Development (OECD) has recommended establishing environmental criteria and performance indicators in public procurement systems to promote the environmentally sustainable production and consumption of medicines.[22] OECD also recommends incentives in the reimbursement schemes to promote environmentally sustainable production of pharmaceuticals.[23]

Box 1: Cumulative impact of industrial emissions

In its Health Paradox report, Swedwatch highlighted the environmental and human rights impacts of the longstanding industrial emissions from pharmaceutical manufacturing facilities in the Greater Hyderabad region in India.[24] Pharmaceutical residue and other substances that are discharged from manufacturing facilities affect people's basic access to clean water, food, and livelihoods. Long-term exposure to pharmaceutical residue and other substances also has adverse impacts on local community members' health and wellbeing. The recent documentary An Unequal Fight and a study carried out by the VIDHI Center for Legal Policy demonstrate that long-term industrial emissions from pharmaceutical manufacturing facilities continue to adversely affect the lives of local communities.[25]

Box 2: International and regional legislation on environmental information

The Aarhus Convention, or Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters, was adopted in 1998. It guarantees the right of public access to environmental information and stipulates that public authorities should communicate this information in a comprehensible manner. Similarly, EU Directive 2003/4/EC on Public Access to Environmental Information, adopted in 2003, acknowledges the Aarhus Convention and the public's right to access environmental information held by public authorities. The directive defines "environmental information" as a broad set of information in different forms including written, visual, aural, and electronic. The types of information it refers to include the state of the environment; factors, measures or activities that affect (or are likely to affect) the environment; designs to protect the environment; and information on the state of human health and safety, as well as other elements affected by the state of the environment.

Conclusion

Pharmaceuticals are essential for public health and ensuring an adequate supply of and access to essential medicines at affordable prices will always be central to pharmaceutical policies. However, the environmental and human rights risks associated with the manufacturing of medicines urgently need to be addressed. It is commendable that after years of campaigning by civil society and public health organisations, the Pharmaceutical Strategy for Europe now calls for a lifecycle approach, which requires relevant actors to increase their oversight to mitigate the long-neglected risks of industrial emissions from manufacturing. A fundamental aspect in this endeavour entails increasing the transparency of the supply chain and environmental information from the early stages of the pharmaceutical lifecycle. The public has both the right to access information and the right to seek remediation for adverse impacts on the environment. Therefore, public authorities have a duty to make information available, and to ensure that the environmental and subsequent human health risks are evaluated, monitored, and mitigated. Without public access to environmental information throughout supply chains, relevant actors cannot be held accountable for negative impacts of industrial emissions on human health.

Recommendations

To improve the due diligence on the environment and human rights in the pharmaceutical sector, and particularly to mitigate industrial emissions associated with the manufacturing of medicine, Swedwatch recommends the following:

- In the revision of the EU general pharmaceutical legislation and the on-going discussions on implementing the Pharmaceutical Strategy for Europe, strengthen demands for transparency of information, including supply chain and environmental information. The adjustment must strengthen the requirement for marketing authorisation holders to report detailed supplier information. Additionally, the reporting requirement should include levels of industrial emissions, namely pharmaceutical residue and other substances that are released into the environment during the manufacturing process. Such requirements should also be applied retroactively to medicines already approved for market sales.

- Agencies authorising medicines should make information public, including:

– Supply chain information about pharmaceutical products approved for sale in the EU. The information should include a detailed list of suppliers, including active pharmaceutical ingredient and raw material producers, as well as manufacturers involved in final dosage and formulation. The information should not only include their names but also their detailed location.

– Up-to-date environmental risk assessment reports by marketing authorisation holders, and corresponding assessment reports from authorising agencies. Environmental risk assessments should include information regarding the actual amount of annual industrial emissions and maximum concentrations in the released wastewater from manufacturing, and how it is measured.

- Procurers of medicine and agencies responsible for pricing and reimbursement should improve due diligence on the environmental and social risks in the supply chain. Decisions about the procurement of medicines, and how they should be subsidised and reimbursed should not merely be based on safety, efficacy, and price. Procurers of medicines together with agencies responsible for pricing and reimbursement of medicines should introduce a system that reward suppliers to proactively report environmental and social risks that occur during the manufacturing process.

- Expand the mandate for existing public agencies responsible for environmental protection to monitor and evaluate pharmaceutical residue and other substances that are released into the environment during the production stage. The evaluation results should be publicly disclosed to hold businesses accountable.

Appendix 1

Review of Authorisation Agencies' Websites

Country	Agency	Name of search service	Product information	Product safety review	Supply chain information
Australia	Department of Health, Therapeutic Goods Administration	Australian Register of Therapeutic Goods search	X	X	
Canada	Department of Health	The Drug and Health Product Register	X	X	
EU	European Medicines Agency	Medicines search	X	X	
Finland	Finnish Medicines Agency	Fimea Medicine search	X	*	
France	Agence nationale de sécurité du médiament et des produits de santé	Répertoire des Spécialités Pharmaceutiques	X	X	
New Zealand	Ministry of Health, Medicines and Medical Devices Safety Authority	Medsafe, Product/application search	X	X	X
Sweden	Swedish Medical Products Agency	Läkemedelsfakta	X	**	
UK	Medicines and Healthcare Products Regulatory Agency	Medicines and Healthcare Products Regulatory Agency Products website	X	X	
USA	Food and Drug Administration	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations search	X	X	

***Reference to European Database of Suspected Adverse Drug Reaction Reports**
****The website provides a list of recalled and deregistered products, and a separate reference to the EMA's periodic safety update reports.**

Source: Australian Government, Department of Health, Therapeutic Goods Administration; Government of Canada, Department of Health, The Drug and Health Product Register; European Medicines Agency; Finnish Medicines Agency; Agence nationale de sécurité du medicament et des produits de santé; New Zealand Government, Ministry of Health, New Zealand Medicines and Medical Devices Safety Authority; Swedish Medical Products Agency; Medicines and Healthcare Products Regulatory Agency; U.S. Food and Drug Administration

Endnotes

1 United Nations Economic Commission for Europe, Convention on Access to Information, Public Participation in the United Nations Economic Commission for Europe, Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Aarhus Convention. UNECE: Geneva, 1998.

2 European Union, Directive 2003/4/EC, Public Access to Environmental Information, Official Journal of the European Union, 2003.

3 See Changing Markets Foundation et al., "Joint Statement: Europe Must Align Policies to Tackle Pharmaceuticals in the Environment and Antimicrobial Resistance", Brussels, 2018. The statement makes reference to the EU Directive 2010/75/EU Industrial Emissions, among other legislations and initiatives.

4 European Commission, "Pharmaceutical Strategy for Europe", Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Brussels: European Commission, 2020. European Parliament will be voting for a resolution on the Pharmaceutical Strategy for Europe in November 2021.

5 Directorate General Health and Food Safety, "Evaluation and Revision of the General Pharmaceutical Legislation", 2021.

6 Interview with Rory Horner, September 2021; See also Horner, R., "India's Pharmaceutical Industry and the Enduring Public Regulation Challenge", in Business Responsibility and Sustainability in India. Springer, 2019, pp. 275–304

7 A meta-data analysis using key words including "pollution", "pharmaceutical", "manufacturing" and "discharge" in the Web of Science database shows more than 70 English language articles written in the last decade. See some of the recent studies including Larsson, D. G. J. and Flach, C.-F. "Antibiotic resistance in the environment", Nature Reviews Microbiology (2021); Anliker, S. et al., "Assessing Emissions from Pharmaceutical Manufacturing Based on Temporal High-Resolution Mass Spectrometry Data", Environmental Science and Technology, 54/7 (2020), pp. 4110–4120; Ogunbanwo, O. M. et al., "High Concentrations of Pharmaceuticals in a Nigerian River Catchment", Environmental Toxicology and Chemistry (2020); Booth, A., Aga, D. S. and Wester, A. L., "Retrospective Analysis of the Global Antibiotic Residues that Exceed the Predicted No Effect Concentration for Antimicrobial Resistance in Various Environmental Matrices", Environment International, 141 (2019); Thai, P. K. et al., "Occurrence of Antibiotic Residues and Antibiotic-Resistant Bacteria in Effluents of Pharmaceutical Manufacturers and Other Sources around Hanoi, Vietnam", Science of the Total Environment, 645 (2018), pp. 393–400; Bengtsson-Palme, J. et al., "Shotgun Metagenomics Reveals a Wide Array of Antibiotic Resistance Genes and Mobile Elements in a Polluted Lake in India", Frontiers in Microbiology (2014), p. 648.

8 See for example, Changing Markets Foundation et al., "Improving Transparency and Access to Affordable, Quality, and Sustainable Medicines in Europe: Joint Position Paper on the Pharmaceutical Strategy for Europe." Brussels: Health Care without Harm, 2020.

9 Oelkers, K. and Floeter, C., "The Accessibility of Data on Environmental Risk Assessment of Pharmaceuticals: Is the Marketing Authorisation Procedure in Conflict with the International Right of Access to Environmental Information?", Environmental Sciences Europe, 31/1 (2019).

10 United Nations Economic Commission for Europe 1998; European Union Directive 2003/4/EC.

11 United Nations, Guiding Principles on Business and Human Rights. Office of the High Commissioner: Geneva, 2011.

12 Pharmaceutical Supply Chain Initiative, Annual Report 2020. London: PSCI, 2020. See also Prioritisation and Risk Evaluation of Medicines in the Environment (PREMIER) project co-funded by the Innovative Medicines Initiative of the European Union; European Federation of Pharmaceutical Industries and Association. https://imi-premier.eu/

13 AMR Industry Alliance, 2020 Progress Report. Geneva: AMR Industry Alliance, 2020.

14 Access to Medicine Foundation. Antimicrobial Resistance Benchmark 2021. Amsterdam, 2021.

15 OECD, Pharmaceutical Residues in Freshwater: Hazards and Policy Responses, OECD Studies on Water. Paris: OECD, 2019.

16 Horner 2019; Horner, R., "The World Needs Pharmaceuticals from China and India to Beat Coronavirus." London: The Conversation, 2020; Årdal, C. et al., "Supply Chain Transparency and the Availability of Essential Medicines", Bulletin of the World Health Organization, 99/4 (2021), pp. 319–320.

17 See New Zealand Government, Medicines Regulations 1984. New Zealand, 1984. Marketing authorisation holders are referred to as "sponsors" in the Regulation.

18 Oral correspondence with Lena Göransson Modigh, Västra Götalandsregion, May 2021; written correspondence with the Swedish Pharmacies Association, Sep-

tember 2021; Interview with Joakim Larsson, September 2021; written correspondence with environmental defender, November 2021; Interview with Jean Yves Stenuick, Health Care Without Harm Europe, November 2021.

19 Nijsingh, N., Munthe, C. and Joakim Larsson, D. G., "Managing Pollution from Antibiotics Manufacturing: Charting Actors, Incentives and Disincentives", Environmental Health, 18/1 (2019), pp. 1–17.

20 Oelkers and Floeter 2019; Oelkers, K., "The Accessibility of Data on Environmental Risk Assessment of Pharmaceuticals – are Environmental Risk Assessments Information on Emissions with Respect to International and European Environmental Information Law?", Regulatory Toxicology and Pharmacology (2020), 111.

21 Oral correspondence with Health Care Without Harm Europe, April 2021; Lena Göransson Modigh, Västra Götalandsregion, May 2021. See also OECD 2019; European Commission, Buying Social - A Guide to Taking Account of Social Considerations in Public Procurement (2nd Edition). Commission's public procurement guide.

22 OECD 2019.

23 Ibid.

24 Lagerqvist, Y. F. and Åkerblom, A. The Health Paradox: Environmental and Human Rights Impacts from Pharmaceutical Production in India and the Need for Supply Chain Transparency. Stockholm, 2020. https://swedwatch.org/wp-content/uploads/2020/02/96_Pharma-report.pdf.

25 Rana, E., Courts on Polluting Industries: Patancheru and Bollaram Industrial Area, Did Polluter Pay? New Delhi: Vidhi Center for Legal Policy, 2020; See also "An Unequal Fight." Film by Vidhi Center for Legal Policy, 2020. https://www.youtube.com/watch?v=hhU1TqBqKVo

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