

THE HEALTH PARADOX

Environmental and human rights impacts from pharmaceutical production in India and the need for supply chain transparency.

Report #96

**SWED
WATCH**

Swedwatch is an independent not-for-profit organisation that conducts in-depth research on the impacts of businesses on human rights and the environment. The aim of the organisation is to contribute towards reduced poverty and sustainable social and environmental development through research, encouraging best practice, knowledge-sharing and dialogue. Swedwatch has six member organisations: Afrikagrupperna, ACT Church of Sweden, Diakonia, Fair Action, Solidarity Sweden-Latin America, and the Swedish Society for Nature Conservation (SSNC). This report, which can be downloaded at www.swedwatch.org, is authored by Swedwatch. The report has been conducted together with SSNC and the organisation Gamana based in Hyderabad, Telangana state, India. SSNC stands behind the report and has participated in developing its recommendations.



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 Publisher: Alice Blondel
 Published: 19th of February 2020
 ISBN: 978-91-88141-29-3

This report has been financed by the Government of Sweden. Responsibility for the content lies entirely with the creator. The Government of Sweden does not necessarily share the expressed views and interpretations.



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Executive summary

While the international pharmaceutical industry is critical for securing the health and well-being of the global population, the manufacturing of medicine is also associated with environmental pollution and subsequent human rights impacts. At the same time, the pharmaceutical sector is permeated with opaqueness, which makes it more or less impossible for consumers, pharmacies and civil society organisations to hold drug manufacturers to account. Furthermore, due to a combination of price pressure and a lack of or poorly enforced regulations, there are currently few incentives for drug companies to assess, monitor or mitigate environmental pollution. As global demand for pharmaceuticals is expected to rise in line with population growth and the growth of non-communicable diseases, the impacts of unregulated effluent release can be expected to exacerbate if appropriate measures are not taken.

India is one of the world's leading producers of pharmaceuticals, with a major concentration of factories in the city of Hyderabad. The city has become known as a global pharma hub and has a well-documented track record of alarming effluent releases. Studies have identified extremely high concentrations of pharmaceuticals in local water supplies, such as antibiotics and anti-infectives. In a commonly cited study from 2007, tests on effluent from a treatment plant showed that the estimated total release of the broad-spectrum antibiotic ciprofloxacin in one day was enough to treat 44,000 people. This type of pollution is an often neglected but worrying potential breeding ground for antimicrobial resistance (AMR). AMR is projected to cause an estimated 10 million deaths annually worldwide by 2050, unless actions are taken.

The effects of pharmaceutical effluents on humans and the environment and the cocktail effects of industrial effluents are not fully understood. In the research for this report, Swedwatch met local communities and environmental and human rights defenders who have protested for decades about adverse impacts from the pharmaceutical industry in Hyderabad. Many suffer from respiratory problems and skin conditions as well as decreased access to water and threats to their livelihoods. Residents who used to depend on nearby lakes for irrigation, fishing, drinking and household use, stopped using the water when it became discoloured and foul-smelling. There are also growing concerns over future water shortages as climate change is expected to amplify the regional drought cycle – which is already impacting lives and livelihoods – amid fears that it may spark water-related conflicts. Besides loss of income from agricultural production, cattle and fishing, residents say they have suffered from a general loss of productivity due to illness and increased costs of health care.

The demand for affordable medicine globally, including from Sweden from which procures the lowest price drugs with expired patents, so called generics, with little regard for environmental protection requirements, has helped fuel an environmental race to the bottom – aided by a lack of local enforcement of environmental standards and opaque supply chains. India is today the largest supplier of generics globally and China is currently the leading producer of pharmaceutical substances (APIs) in the world.

While pharmaceutical pollution in India has drawn national and international attention and has led the Indian government to recently publish a draft bill to limit concentrations of antibiotics in waste discharged by factories, experts stress that pharmaceutical pollution from manufacturing is a global problem. Due to a lack of transparency and data, it is not known how widespread the pollution is, but high concentrations of pharmaceutical effluents have been discovered also in other parts of the world. The industry has taken measures to improve production and supply chain sustainability, but progress is slow and the precautionary principle is still disregarded by many manufacturers.

The pharmaceutical sector lags behind other industries in regard to transparency. Voluntarily published supplier lists are practically non-existent. Even though importers to the EU must supply authorities with details of their suppliers, these are kept confidential. The industry's standard response to calls for greater transparency is to cite security and competition issues, but these arguments are largely refuted by leading public health experts.

Despite the essential service it provides to global societies, the pharmaceutical sector must be subjected to the same level of scrutiny as, for example, the food and garment industries. Buyers, importing countries and local authorities should demand transparency and adherence to strict environmental and human rights standards to protect global public health and the rights of affected communities. The production of medicine should not impact the well-being of communities located near manufacturing facilities, nor risk resulting in long-term health impacts such as AMR.

Increased transparency, enhanced human rights due diligence in the pharmaceutical supply chain, and enhanced efforts by the sector to contribute to SDG 12 – responsible consumption and production – are critical for ensuring that the environmental costs of drug manufacturing are not transferred to people living in poverty.

Recommendations

To the EU

- Include amendments that require manufacturers to control and mitigate the release of pharmaceutical effluents into the environment to the EU principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (2003/94/EC). Such amendments should be based on the precautionary principle.
- Amend environmental risk assessments and risk-management plans for market licensing to cover pollution associated with manufacturing, and consider the outcomes of the environmental risk assessment in licensing decisions. The requirement should be applied also to pharmaceutical products and active pharmaceutical ingredients (APIs) that have already been granted market licences in the EU.

- Publicly disclose information regarding human rights and environmental risks throughout the life cycle of all pharmaceutical products and APIs that have been approved for sale and use in the EU. This should include full names of authorised production units, processing facilities and sub-suppliers.
- Develop EU-wide environmental criteria for pharmaceutical products and APIs that cover all stages of production and distribution.
- Adopt legislation on mandatory human rights due diligence to ensure that companies conduct gender-sensitive HRDD on their operations, supply chains and investments in accordance with the UN Guiding Principles on Business and Human Rights (UNGPs) and OECD Due Diligence Guidance for Responsible Business Conduct¹ or an equally recognized guidance, especially in countries and sectors with a high risk of human rights violations.

To governments in countries importing pharmaceuticals

- Adopt legislation on mandatory human rights due diligence to ensure that companies conduct gender-sensitive HRDD on their operations, supply chains and investments in accordance with the UN Guiding Principles on Business and Human Rights (UNGPs) and OECD Due Diligence Guidance for Responsible Business Conduct or an equally recognized guidance, especially in countries and sectors with a high risk of human rights violations.
- Strengthen efforts to promote the inclusion of environmental criteria in global manufacturing practices.
- Develop environmental criteria for pharmaceutical products and APIs that cover all stages of production and distribution.
- Enforce public release of detailed supply chain information and environmental risk assessments for all pharmaceutical products and APIs that are licensed for sale in the country. This should include full names of authorised production units, processing facilities and sub-suppliers.
- Ensure that environmental and human rights criteria are included and monitored in public procurement processes of pharmaceutical products.
- In Sweden, instigate an inquiry to establish environmental and social premiums in the generic substitution system.

To governments of countries producing pharmaceuticals

- Regularly assess and monitor pharmaceutical effluence released into the environment and monitor human rights due diligence of duty bearers. This should include testing the quality of water, air and soil. All information on environmental assessments and monitoring should be publicly disclosed. The monitoring process should include independent longitudinal health impact assessments in areas affected by environmental pollution.

- Improve access to effective grievance mechanisms for victims of business-related human rights abuses and ensure that human rights defenders reporting on such abuses can carry out their work safely and without fear of retaliation.
- Safeguard and ensure the basic human rights of communities affected by pharmaceutical industry pollution with due considerations to gender, age, ethnicity and socio-economic class.
- Regulate pharmaceutical emissions and/or increase and enforce penalties for manufacturers releasing illegal amounts of pharmaceutical effluence into the environment. This should include revoking the business licences of companies that fail to comply with regulations.
- Provide incentives, such as tax incentives, for manufacturers using clean technology and complying with environmental regulations.
- Sponsor research and knowledge transfer among businesses and state actors.
- Adopt legislation on mandatory human rights due diligence to ensure that companies conduct gender-sensitive HRDD on their operations, supply chains and investments in accordance with the UN Guiding Principles on Business and Human Rights (UNGPs) and OECD Due Diligence Guidance for Responsible Business Conduct or an equally recognized guidance, especially in countries and sectors with a high risk of human rights violations.

To pharmaceutical manufacturers and distributors

- In line with the UN Guiding Principles on Business and Human Rights, conduct (and require suppliers to conduct) HRDD to identify risks and address any impacts the business may have caused or contributed to, and publicly disclose the results. The HRDD should be conducted with a gender perspective, and should follow the OECD Due Diligence Guidance for Responsible Business Conduct or an equally recognized guidance. Any gaps identified should be addressed, based on consultation with impacted communities and in cooperation with organisations or other actors that are true representatives of affected rights holders.
- Ensure that affected rights holders are informed of, and have access to, an effective and meaningful grievance mechanism.
- Urgently seek to address and assess human rights impacts from pharmaceutical production, in production areas such as Hyderabad. Leverage should be increased through collaboration with business peers and other stakeholders.
- Develop clear provisions and processes across supply chains to control the release of pharmaceutical effluence into the environment. Track and disclose the results.
- Incentivise and ensure supply chain actors comply with mandatory and voluntary guidelines on managing environmental pollution. Ensure that the precautionary principle is applied in all operations and for all suppliers. If a supplier does not

comply with the requirements over time, consider ending the relationship with the entity causing harm, but only after assessing the possible negative impacts of doing so.

- Publicly disclose the results of environmental risk assessments and monitoring for all products.
- Regularly publish a searchable list of all sites that manufacture the company's products and audit results for each factory, including full names of authorised production units, processing facilities and sub-suppliers.

To the World Health Organization

- Require entities applying for WHO certification scheme to control and mitigate the release of pharmaceutical effluence into the environment with regards to the precautionary principle. This should also be clearly included as part of the WHO good manufacturing practices for pharmaceutical products. These practices should include environmental and social risk assessments involved in the manufacture of pharmaceutical products.

Acronyms

AMR	Anti-microbial Resistance
API	Active Pharmaceutical Ingredients
CPCB	Central Pollution Control Board
EMA	European Medicines Agency
EU	European Union
GMP	Good manufacturing practice(s)
HRDD	Human rights due diligence
MPA	Swedish Medical Products Agency (Läkemedelsverket)
NAPP	National Agency of Public Procurement
NGT	National Green Tribunal
OECD	Organisation for Economic Co-operation and Development
PSCI	Pharmaceutical Supply Chain Initiative
SDG	Sustainable Development Goal
TLV	Dental and Pharmaceutical Benefits Agency (Tandvårds- och Läkemedelsförmånsverket)
TNCs	Transnational Companies
TRIPS	Trade related Aspects of Intellectual Property Rights
UN	United Nations
UNGPs	United Nation's Guiding Principles on Business and Human Rights
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction

Global demand for medicine is growing. Aging populations, increased prevalence of lifestyle diseases and rising populations all contribute to an ongoing increase in spending on medicine and healthcare.² Furthermore, climate change is expected to contribute to negative health effects, such as increased prevalence of malaria and malnutrition.³ Between 2019 and 2024, worldwide sales of prescription drugs are projected to increase from US\$ 900 billion to US\$ 1,2 trillion.⁴ While the largest markets for pharmaceuticals are North America, Europe and Japan, the demand for quality medicine has also increased rapidly in emerging markets.⁵

Since the implementation of the World Trade Organisation's TRIPS Agreement in 1995, the pharmaceutical industry has become increasingly globalised, a development which has led to a rapid growth of manufacturing of generic drugs in emerging economies such as China and India.⁶ Today, India is the world's largest provider of generics with more than 10,000 manufacturing units and over 3,000 pharmaceutical companies.⁷

While this development has been vital to India's economy, it has also contributed to environmental pollution in and around the country's major pharmaceutical manufacturing hubs. In Hyderabad, known as the "bulk drug capital" of India, unprecedented amounts of pharmaceutical effluents have been released into the local environment⁸, resulting in high levels of pharmaceutical pollution and a presence of antibiotic-resistant bacteria. The industrial pollution has caused substantial degradation of local water resources, soil and air – violating local communities right to a healthy environment and livelihood and limiting their access to clean water.

In 2007, scientists found that effluent from a treatment plant in Hyderabad used by 90 drug factories, discharged into local lakes and rivers, contained antibiotics at concentrations higher than what would be expected in the blood of patients undergoing a course of treatment.⁹ The estimated total release of the broad-spectrum antibiotic ciprofloxacin in one day was enough to treat 44,000 people.¹⁰ Despite awareness for over a decade, the pollution has not ceased. In 2019, another study found very high levels active pharmaceutical substances made to treat fungal infections, hypertension, severe pain, epilepsy, cancer and HIV in an open well collecting factory discharge in the area of Hyderabad.¹¹ Apart from impacts on the local environment, the large release of antibiotics into water streams have created a dangerous breeding ground for antimicrobial resistance (AMR).¹²

Several factors have contributed to this detrimental situation. While local authorities in manufacturing hubs like Hyderabad have failed to ensure sustainability in pharmaceutical production, importing countries and regions such as Sweden and the EU have allowed the production to continue without effective environmental and human rights requirements.

Furthermore, several academic studies and media reports have highlighted the lack of transparency in the pharmaceutical production-distribution network;¹³ although the sector is highly regulated by various global and national institutions to ensure prod-

uct and patient safety and efficacy, importers of active pharmaceutical ingredients (APIs) and pharmaceutical products are not required to publicly disclose information on the countries of origin or the results of environmental risk assessments for each product. This lack of information prevents consumers from making informed decisions,¹⁴ rights holders from demanding accountability for adverse impacts, and for investors, pharmacies and public sector bodies to conduct efficient human rights due diligence on pharmaceutical procurement.

Experts and advocacy groups are increasingly demanding that pharmaceutical companies publicly disclose the origin of production as well as environmental data in order to improve accountability in the sector, also advocating that environmental protection should be included in standards such as the WHO's and the EU's good manufacturing practices (GMP).¹⁵ Beyond regulation, they further highlight the importance of introducing economic incentives to improve environmental governance in the industry.¹⁶

The issue of environmental pollution from pharmaceutical manufacturing has also captured the attention of several international organisations, including the Organisation for Economic Co-operation and Development (OECD), that wants to see comprehensive environmental criteria added to existing international codes of practice and public procurement processes.¹⁷

It is evident that there are critical gaps in both existing voluntary and compulsory regulatory frameworks designed to mitigate and control the release of effluence from pharmaceutical production. While the issue of AMR and release of antibiotics and anti-infectives in the environment have gained some attention, there is still limited awareness on the widespread ecological and human health impact of pharmaceutical residues in the environment. Regulatory frameworks also fail to enforce mitigation of pharmaceutical effluents by manufactures and distributors of pharmaceutical products.

FACT

Antimicrobial resistance (AMR)

Antimicrobial resistance, or AMR, refers to when microorganisms such as bacteria and viruses, evolve resistance to antimicrobial substances, like antibiotics. AMR is considered a major threat to humankind and has been estimated to result in 700,000 deaths annually.¹⁸ If proper measures are not taken, the death toll could climb to 10 million people worldwide every year by 2050, which is more people than currently die of cancer.¹⁹ Even though it has been argued that pharmaceutical residues from production account for a small share compared to the residues from the other sources, the extreme concentrations that have been found next to pharmaceutical production sites stand out.²⁰ The large releases of antibiotics discovered in areas such as Hyderabad have contributed to development of multi-resistant bacteria, also known as superbugs. While the extent to which this pollution contributes to AMR locally and globally is not known, experts claim it poses an unacceptable risk since multiresistant bacteria can rapidly spread internationally.²¹ An estimated 80–90 percent of tourists returning from India carry multi-resistant bacteria in

their guts.²² Normally, people carry the bacteria without falling ill. However, if a person acquire an infection from bacteria residing in their own gut flora (which is common for example for urinary tract infections and in the case of sepsis), it can have fatal consequences, since antibiotics might be unable to treat the infection.²³

AMR already represents a grave threat to the Indian population, and resistance to multi-spectral antibiotics found in Hyderabad has been found throughout the country.²⁴ India faces the highest numbers of resistance-attributable neonatal sepsis deaths in the world - almost 57,000 neonates die each year owing to neonatal sepsis caused by bacteria resistant to first-line antibiotics.²⁵ International organisations including WHO and the World Bank have called for a global campaign to improve the management of pharmaceutical effluence, particularly antibiotics and anti-infectives, released by production facilities in order to mitigate the global health and economic risks of AMR.²⁶

The AMR Industry Alliance, a coalition of nearly 100 pharmaceutical companies, in 2018 developed a framework that promotes the responsible manufacturing of antibiotics (see fact box on page 51). In 2018, the Alliance published targets for antibiotic discharges.²⁷ Meanwhile, a 2020 benchmark report on pharmaceutical companies researching and/or producing antibiotics show that while some improvements can be seen in how companies address AMR, the pace does not match the scale of the challenge.²⁸ Most companies included in the benchmark had environmental strategies and set discharge limits for antibacterial discharge. However, few required their suppliers or external wastewater treatment plants to do so, nor did any company monitor antibacterial discharge from external wastewater-treatment plants. In terms of transparency, no companies in the benchmark published the levels of antibacterials in wastewaters discharged from their sites or the full results of audits conducted at these sites. Results of audits at suppliers' sites and the suppliers' identities were also not published by the companies.²⁹

FACT

Pharmaceuticals in the environment and impacts on health

There are several pathways of release of pharmaceuticals in the environment: through human and veterinary usage, in food production and through pharmaceutical production and pollution. The vast majority of the over 2,000 APIs administered worldwide have not been evaluated for their occurrence, fate and possible impacts on water quality, human health and freshwater ecosystems.³⁰ However, there is growing evidence that pharmaceuticals' occurrence in the environment have negative impacts. Laboratory studies have demonstrated the negative health impacts – such as reproductive toxicity, reduced growth, behaviour changes – of several different types of pharmaceuticals on animals.³¹ Reproductive toxicity in fish stocks has also been found in lakes.³² Due to the lack of scientific studies, there is great uncertainty regarding the health impacts of pharmaceutical residues on local communities and the global population.



Contaminated ground water from a borewell in Gaddapotharam village. In 2017, Changing Market Foundation sampled water from this borewell and found 10,900 micrograms/litre of hexavalent chromium which is beyond the maximum level of 50 micrograms/litre according to the WHO guideline. Villagers have stopped using this water for agricultural irrigation.

Methodology

This report is based on extensive literature analysis, field study in India, and interviews with key experts, state authorities and four pharmaceutical companies. Swedwatch reviewed a variety of grey literature, media reporting and academic articles to understand the global transformation of the pharmaceutical sector and its environmental impact. In September 2019, Swedwatch visited industrial areas in Hyderabad, India, a site of well-documented pollution, and conducted 16 semi-structured interviews, including local experts in the health sector; pharmaceutical intermediary manufacturer, senior academics, school teachers; local environmental and human rights defenders; and residents in three villages that have been directly affected by pharmaceutical industry pollution, and one control village which is unaffected by the pollution. Villages were selected together with Swedwatch's local project partner, Gamana. All four villages, including the control village, were located in the outskirts of Hyderabad. In each village, the research team interviewed a cross section of community members using semi-structured questions to understand how the pollution affects them.

Another 15 interviews were conducted to gain an understanding of the European and Swedish context of the pharmaceutical value chain and key actors' perspectives. Both state and non-state agencies and experts, including the Swedish Medical Product Agency (Läkemedelsverket), the Swedish Regional Council in Västra Götaland (Västra Götalandsregionen), which coordinates the Swedish regional councils' sustainability work on pharmaceutical production, and the Centre for Antibiotic Resistance at Gothenburg University, contributed. The Stockholm International Water Institute (SIWI) and the Brussels-based international non-governmental organisation Healthcare Without Harm were also consulted. In addition, Swedwatch interviewed private sector actors Swedish pharmacy chain Apotek Hjärtat and Nordea Asset Management. Swedwatch also contacted seven pharmaceutical companies that are active in the Swedish and global markets and have production facilities or suppliers in Hyderabad or other parts of India for interviews. Four of the seven companies agreed to participate in an interview: Recipharm, a globally-operating Swedish company focusing on pharmaceutical manufacturing and development, Orion Corporation, a globally-operating Finnish company focusing on generic pharmaceutical development, manufacturing and marketing, Fresenius Kabi, a healthcare company headquartered in Germany, that operates globally, specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition, and AstraZeneca, an Anglo-Swedish research-based pharmaceutical company (AstraZeneca however highlighted that they only have a very small share of suppliers in India).

Companies interviewed were provided with the opportunity to read and submit official comments for publication on Swedwatch's website prior to publication.

Frameworks

In order to analyse the responsibility for environmental pollution in the pharmaceutical supply chain and its effects on society, the United Nations Guiding Principles on Business and Human Rights, the Sustainable Development Goals, and the precautionary principle are applied. The so-called Global Manufacturing Practice also plays an important role in governing the production of medicinal products and is therefore also outlined below.

The UN Guiding Principles on Business and Human Rights

The UNGPs were adopted by the Human Rights Council in 2011 and serve as the most comprehensive framework clarifying corporate responsibilities regarding human rights to date. The principles apply to all businesses and have been incorporated into other guidelines, such as the OECD Guidelines for Multinational Enterprises which apply to all OECD countries and adhering countries.

The corporate responsibility to respect human rights

According to the UNGPs, business enterprises must respect human rights, and have the responsibility to prevent and mitigate the adverse human rights impacts associated with their company's activities.³³ At a minimum, all human rights specified in the International Bill of Human Rights along with fundamental labour rights detailed in the core International Labour Organization conventions should be considered when companies identify their potential human rights impacts.

Human Rights Due Diligence (HRDD) is at the core of the UNGPs and represents a fundamental tool that enables companies to respect human rights. According to the UNGPs, a HRDD should also cover human rights impacts that may be directly linked to a company's products. The process should include assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed.

Companies should prioritise severe human rights impacts. Severity depends on (i) how grave the impact is (scale), (ii) how widespread it is (scope) and (iii) how difficult it is to rectify the situation. In situations that have an increased risk of severe human rights impacts, it is critical for business to conduct heightened HRDD. A heightened risk might arise from, for example, an operational context including corruption, weak governance or suppliers with a poor sustainability track record. It could also arise from business activities commonly associated with human rights impacts such as land acquisition, resettlement and extensive water usage, or the presence of groups that are particularly vulnerable to business impacts due to political, social or economic marginalisation.³⁴

The UNGPs require companies to verify their effectiveness in addressing the human rights issues associated with their business activities, through tracking the effectiveness of their response, particularly regarding impacts on individuals from vulnerable or marginalised groups. The process should involve meaningful consultation with affected groups, and businesses should externally communicate how they address the impacts.³⁵ Companies' responsibility to remediate occurred human rights abuses depends on whether they have caused, contributed or been linked to the abuse in question.

FACT

Three types of responsibilities

The UNGPs define three different types of responsibility. When a business is causing the human rights abuse, it is the principal actor in the breach of human rights – either by its actions or its lack of action (omission). If a business is enabling, encouraging, or facilitating human rights abuses, it is said to be contributing to the problem – sometimes through or together with a third party. When a business is neither causing nor contributing to human rights abuse, it can still be directly linked to the human rights impact through its operations, products, and services via a business relationship.

Companies that cause (or may cause) an adverse human rights impact, should take the necessary steps to cease or prevent the impact. Where a company contributes or may contribute to an adverse human rights impact, it should take the necessary steps to cease or prevent its contribution. When a company is linked to the impact, it should use its leverage to mitigate the impact to the greatest extent possible.³⁶

The actions taken also vary according to the actor's leverage or ability to address impacts. A business has leverage if it can effect change in an entity's harmful practices. If the business has leverage to prevent or mitigate impacts it should exercise it, or otherwise seek to increase its leverage. If a business experiences that they lack opportunities to increase leverage, it should consider ending the relationship with the entity causing harm, but only after assessing the possible negative impacts of doing so.³⁷

According to the UN Office of the High Commissioner for Human Rights (OHCHR), there can be a continuum between contributing to and having a direct link to an adverse human rights impact. In a statement regarding the UNGPs from 2017, OHCHR the office clarified that a business involvement with an impact may shift over time, depending on its own actions and omissions. For example, if a business identifies or is made aware of an ongoing human rights issue that is directly linked to its operations, products or services through a business relationship, yet over time fails to take reasonable steps to seek to prevent or mitigate the impact, it could eventually be seen to be facilitating the continuance of the situation and thus be contributing to it.³⁸

States' duty to protect human rights

The UNGPs also clarify the duty of state authorities to protect human rights. States are responsible for preventing, investigating, punishing and redressing human rights abuses (UNGP 1). The UNGPs require states – which have the duty to protect and promote the rule of law – to consider a full range of preventative and remedial measures. According to the UNGPs, states should set out clear expectations for businesses

operating within their territory and provide effective guidance on how to respect human rights throughout their operations.³⁹ In 2014, the UN Human Rights Council called on all Member States to develop National Action Plans on Business and Human Rights to promote the implementation of the UNGPs.⁴⁰ Sweden adopted its National Action Plan in 2015.⁴¹ India is currently in the process of developing one, and published a draft in February 2018⁴².

According to the UNGPs, effective judicial mechanisms are at the core of ensuring access to remedy for victims of business-related human rights abuses. States have the duty to provide access to courts and other judicial mechanisms independent of economic and political pressures to seek rightful remediation. Under the UNGPs, states and business enterprises must provide effective grievance mechanisms to remedy business-related human rights abuses (UNGP 25–30). The effectiveness of remediation efforts can be assessed based on accessibility, affordability, adequacy and timeliness, and whether they address the needs of rights holders.

The Sustainable development goals and the role of business

The SDGs, adopted by all UN member states in 2015 as part of the 2030 Agenda for Sustainable Development, constitute a universal call to end poverty, protect the planet, and improve the lives and prospects of all people. Although progress has been made towards meeting the SDGs, actions are not yet advancing at the speed or scale required, according to the UN.⁴³ Among the 17 SDGs, Goal 12 aims to ensure sustainable consumption and production patterns. Actions to achieve this goal include reducing resource use, degradation and pollution throughout a product's life cycle while increasing the quality of life. It is also important to focus on the entire supply chain, from producer to final consumer, to provide consumers with adequate information, for example through standards and labels and engaging in sustainable public procurement.

Some of the specific targets for Goal 12⁴⁴, which are relevant for the pharmaceutical sector include:

- By 2020, manage chemicals and waste throughout their lifecycles in an environmentally sound manner, and significantly reduce their release into the air, water and soil in order to minimize their adverse impacts on human health and the environment (12.4);
- Promote sustainable public procurement practices (12.7);
- By 2030, ensure that all people have the relevant information and awareness about sustainable development and lifestyles in harmony with nature;
- Help developing countries strengthen their scientific and technological capacity to engage in sustainable consumption and production patterns (12.A);
- By 2030, achieve the sustainable management and efficient use of natural resources (12.2).

Business actors can positively or negatively contribute to all SDGs. Lack of efforts to achieve Goal 12 can subsequently impact a range of other SDGs, such as in the case of environmental pollution for example Goal 3 (good health and well-being), 6 (clean water and sanitation), 14 (life below water) and 15 (life on land).

The precautionary principle

The emergence of increasingly unpredictable, uncertain and unquantifiable, but potentially catastrophic, risks has confronted societies with the need to develop an anticipatory model to protect the environment against uncertain risks of human action. The emergence of the Precautionary Principle (PP) has marked a shift from post-damage control to pre-damage control of risks. The principle is often seen as an integral part of sustainable development, by safeguarding against serious, and particularly, irreversible harm that might jeopardize the situation for future generations. The principle is included in the 1992 Rio Declaration on Environment and Development, in which principle 15 states that “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”⁴⁵

The principle is furthermore integrated in Principle 7 of the UN Global Compact (UNGC): “Businesses should support a precautionary approach to environmental challenges.”⁴⁶ UNGC clarifies that this involves a systematic application of risk assessment, risk management and risk communication, stating “When there is a reasonable suspicion of harm, decision-makers need to apply precaution and consider the degree of uncertainty that appears from scientific evaluation.”⁴⁷ The level of risk considered typically relates to standards of environment, health and safety. Companies can for example support the precautionary approach by adopting a code of conduct or practice for its operations that confirms commitment to care for health and the environment, support scientific research, join industry-wide collaborations, deal with complaints and participate in multi-stakeholder meetings.⁴⁸

Global manufacturing practices

World Health Organisation

Good manufacturing practice (GMP) is a system aimed to ensure that medicinal products are produced and controlled according to quality standards.⁴⁹ It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated by testing the final product.⁵⁰ The World Health Organisation (WHO) has established guidelines for good manufacturing practice, used by many countries for their own requirements.⁵¹ Suppliers of pharmaceutical products seeking WHO certification must comply with production and quality requirements of GMP.⁵² The guidelines require companies to make provisions to manage their waste material.⁵³ The guidelines do not however, specifically require companies to conduct environmental risk assessments regarding their production of pharmaceutical products or to publicly disclose information about how they dispose of waste material.

Harmonised requirements can be for example be found in the Association of South-East Asian Nations (ASEAN), through the Pharmaceutical Inspection Convention and in the EU.⁵⁴

The European Union

If a medicinal product for human use is to be approved on the European market, it needs to comply with the EU regulations on GMP. The EU directive (2003/94/EC) is particularly relevant for branded products and quality generics imported and consumed in Europe. Unlike the WHO, the EU GMP specifies the need to assess and monitor the environmental impacts of pharmaceutical production⁵⁵ but the environmental risk assessment required for market authorisation of pharmaceutical products in the EU is currently limited to the use and disposal of the products⁵⁶ and does not include control or mitigation of risks involved in manufacturing.

The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonising GMP activities at EU level.⁵⁷ The most recent draft guidelines, developed by the EMA in November 2018, specifies the scope and processes involved in environmental risk assessments for pharmaceutical products. Here, too, the overall scope of environmental risk assessments required is limited to evaluating “the potential risks to the environment arising from the use of the medicinal product.”⁵⁸ Even though the scope of risk assessment range from aquatic and terrestrial ecosystems’ surface water, groundwater and soil to secondary poisoning through microbial communities in sewage treatment plants, the assessment excludes risks arising from the production processes.⁵⁹

The European Union Strategic Approach to Pharmaceuticals in the Environment, released by the European Commission in March 2019, calls for the examination of the scope of environmental pollution from pharmaceutical manufacturing not limited to antibiotics and anti-infectives.⁶⁰ It raises concerns about the release of pharmaceutical residues in water and soil, and further highlights the problem of the insufficient management of pharmaceutical effluence.⁶¹ Yet, the strategy has been criticized for lacking concrete steps to improve pharmaceutical production.⁶²



Local people continue to fish in the lake adjacent to the industrial area, and to graze cattle nearby.

2. Pharmaceutical production in India

The pharmaceutical industry has undergone significant transformation since the establishment of the TRIPS Agreement in 1995.⁶³ With the implementation of the agreement, the industry became globalised as patent regimes were harmonised across WTO member countries. Although TRIPS challenged pharmaceutical companies producing cheap counterfeit or “copycat” drugs in developing countries such as India, it also triggered these manufacturers to transition into contract manufacturing and research through joint ventures and mergers within domestic and foreign pharmaceutical companies. TRIPS also contributed to the transformation of the sector into three distinctive strands of value chains based on product type;

- branded medicine protected by patents;
- “quality generics” or off-patent medicines with international approval to be sold under a brand; and
- “low-value generics” or off-patent medicines sold in developing country markets at a low price.⁶⁴

For all three strands, raw materials and excipients (i.e. all non-active ingredients in a pharmaceutical)⁶⁵ are sourced from various suppliers in different parts of the world. These are used to produce intermediates or chemical compounds and APIs. These are then sold to final dosage manufacturers before being packaged and distributed to global markets. China is currently the leading producer and exporter of APIs by volume, accounting for 20 percent of the global API production.⁶⁶ India is the third-largest manufacturer of pharmaceuticals by volume in the world, particularly of generic drugs, and 80 percent of APIs used to manufacture these drugs are sourced from China.⁶⁷

An important distinction between the three strands of value chain is the governance mechanism from stringent to lenient compliance to international and national standards. While voluntary and mandatory standards regulate quality of products in branded products, and to a lesser degree quality generic, price is the only governing mechanism for the low-value generics value chain.

The rise of India’s pharmaceutical industry

Since India’s independence in 1947, the country has strategically promoted the development of pharmaceutical production to diminish the country’s dependence on foreign medicine. Initially, government policies promoted foreign direct investment and technology transfers from transnational companies. However, the 1970 Indian Patent Act denied product patents, and instead recognised process patents (the method of manufacturing a product) to reduce the dominance of transnational companies while promoting domestic manufacturers. The 1973 Foreign Exchange Regulation

The pharmaceutical supply chain



Three strands of pharmaceutical value chains and key traits

Key traits	Strand 1: Branded products	Strand 2: Quality generics	Strand 3: Low-value generics
End markets	Regulated markets in industrial economies, i.e. North America, Europe, Japan but also in emerging economies, i.e. India, China among the high-income groups	Regulated market in the industrial economies, i.e. North America, Europe, Japan and in both emerging and developing economies among the middle-income groups	Developing economies, usually via government tenders, e.g. sub-Saharan Africa
Products	Patent protected, global blockbuster drugs	Just off-patent branded generics, drugs for lifestyle diseases, i.e. cardiovascular disease, diabetes, etc.	Long off-patent and relatively long-existing products, i.e. anti-infectives and drugs for tropical diseases
Producers	Vertically integrated transnational corporations (TNCs), e.g. Big Pharmas based in industrial economies	Network integration across the supply chain through contracting to low-cost production sites	Companies based in emerging and/or developing economies, e.g. China, India
Lead firms	TNCs or Big Pharmas	Generic R&D/manufacturers/distributors from emerging economies and TNCs or Big Pharmas	Generic manufacturers from emerging economies
Governance and institutions	Producer-driven supply chain: voluntary and mandatory international standards and guidelines for drug safety and quality	Buyer-driven supply chain: compliance with international standards and regulations for drug safety and quality	Market-driven supply chain: price and modest/weak regulatory standards
Consumer expectations	High quality and safety of the product, good reputation	High quality and safety of the product, good reputation, low price	Uncertainty of quality and safety, low price

Source: Adapted from Haakonsson (2009); Horner and Murphey (2018)

Act further restricted foreign ownership of pharmaceutical companies and promoted domestic manufactures to produce generic medicine.⁶⁸ By 1990, Indian firms began to dominate the domestic market and also emerged as a major supplier of generic drugs to other developing countries.⁶⁹

In 1995, India became a member of the WTO and signed up to the TRIPS Agreement, which required the government to amend the Patent Act. The resulting Patent Act of 2005 recognised both product and process patents for up to 20 years. The new act, combined with an easing of restrictions on foreign ownership of companies operating in India, attracted foreign investors, particularly transnational companies, which began to outsource pharmaceutical production as well as research and development through contract manufacturing, joint ventures and mergers. The institutional changes following the WTO membership allowed transnational companies to collaborate with Indian firms and capture drug sales on the emerging Indian market and led to the rapid growth of pharmaceutical companies and drug manufacturing in the country.

While the pharmaceutical sector represents only a small share of the total value of Indian exports (4.9 percent in 2018),⁷⁰ it is rapidly growing and is one of the top eight industrial sectors attracting foreign direct investment.⁷¹ According to the India Brand Equity Foundation, India hosts more than 10,000 manufacturing units and over 3,000 pharmaceutical companies; it is the world's largest provider of generic medicines, accounting for 20 percent of global share in volumes.⁷²

Pharmaceutical exports from India increased from US\$ 724 million in 1995 to over US\$ 15 billion in 2018. Annual revenues are projected to reach US\$ 80–90 billion by 2030.⁷³

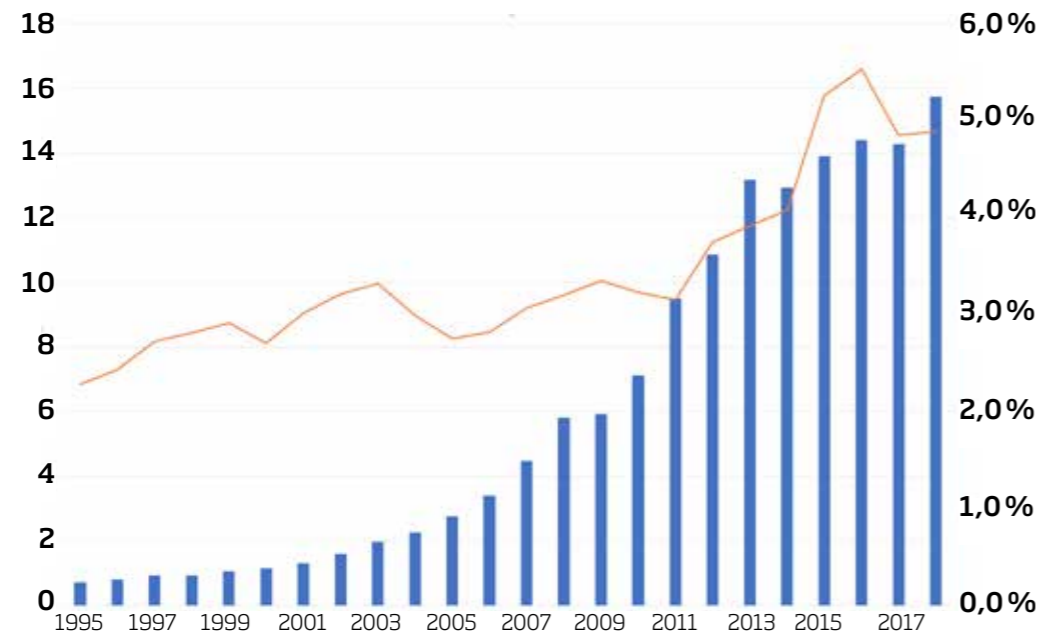
Environmental pollution and governance

There is mounting evidence that the pharmaceutical industry is causing environmental pollution. Particularly in and around the city of Hyderabad, situated in Telangana state in India, known as the country's "bulk drug capital", exceptionally high levels of pharmaceutical residue have been found in samples of nearby surface and ground water including broad spectrum antibiotics including ciprofloxacin.⁷⁴

Studies warn against the high level of antibiotics and anti-infectives leaching from manufacturing sites into nearby bodies of water, thereby spawning variants of AMR pathogens that potentially threaten local and global communities.⁷⁵ Furthermore, some studies have observed heavy metals and toxic contaminants in surface and groundwater surrounding the industrial zones.⁷⁶ While the sources of these heavy metals are difficult to distinguish given the wide range of manufacturers located in the area, including both pharmaceutical and non-pharmaceutical, these toxic contaminants are likely to have adverse long-term effects on human and animal health in local communities.

While numerous studies point to India's lax environmental regulations as the source of the problem, there is in fact a range of legislation regulating the pharmaceutical

Value and share of Indian exports of medicines and pharmaceuticals, 1995-2018 (billions US\$)



Source: UN Comtrade database

sector, dating back to the 1940s; as well as legislation for environmental protection. Relevant legislation includes the 1940 Drug and Cosmetic Act and the 1945 Drug and Cosmetic Rules.⁷⁷ In 2005 the government introduced amendments (Schedule M) to the Drug and Cosmetics Rules, which required manufacturers to comply with international standards of GMPs such as that of the WHO in order to ensure the safety of drugs.⁷⁸ The amendments stipulate the need to manage waste disposal in accordance with the requirements of the Central Pollution Control Board (CPCB) of India and the provisions set out in the Bio-Medical Waste Rules of 1996.⁷⁹ Schedule M also requires companies to conduct and document environmental monitoring as part of their standard operating procedures, together with a list of other requirements.⁸⁰ In January 2020, the Indian government published a draft bill introducing limits on concentrations of antibiotics in waste discharged by pharmaceutical factories.⁸¹

The CPCB was established in 1974 to regulate environmental pollution in India. In the wake of the 1984 Union Carbide industrial disaster in Bhopal, Madhya Pradesh, which killed more than 15,000 people and injured 500,000 after the release of toxic gas, the government passed the Environmental Protection Act in 1986 and established the Ministry of Forestry and Environment.⁸² The government also passed the National Green Tribunal Act and established the National Green Tribunal (NGT) in 2010 to protect people’s right to a healthy environment as stipulated in the country’s constitution.⁸³ The NGT is a hybrid environmental tribunal and court system that is independent

Key studies⁸⁴ from 2001-2018 highlighting environmental pollution from in Telangana State, India*

Key issues	Source
Ground and surface water contamination from industries in Patancheru and Bollaram industrial areas. The study collected 50 water samples from bore wells, dug wells and surface water bodies to analyse total dissolved solids. It also applied hydrogeology model and identified how contaminants migrate across the water system.	Rao, Dhar and Subrahman-yam (2001)
High morbidity related to cancer, asthma and heart disease in the study area where inhabitants are affected by cocktail of effluence from Patancheru Industrial Estate and surrounding area. Increasing level of respiratory illnesses observed among the sample population. The study covers nine villages in Medak district including four control villages and five study villages.	Greenpeace (2004)
A micro-economic analysis of environmental pollution in industrial areas of Telangana. The cost estimates based on household data collected in Kazipally and neighbouring village. The study points to limitations of institutions regulating environmental pollution and piecemeal compensation to affected communities.	Reddy and Behera (2005)
High level of broad-spectrum antibiotics (e.g. ciprofloxacin) and many other drugs found in treated wastewater from a facility serving 90 bulk drug manufacturers in Patancheru industrial area.	Larsson, de Pedro, and Paxeus (2007)
Severe industrial contamination of surface, ground and drinking water with a range of drugs, including broad-spectrum antibiotics in the Medak district.	Fick et al. 2009
Physiochemical contamination of four surface and two ground water sources in Patancheru industrial area (i.e. Patancheru, Ramachandrapuram and Kondapur mandals or hamlets in Medak district).	Reddy, Saibaba and Sudarshan (2012)
Review of pharmaceutical industry and assessment of pollution from pharmaceutical manufacturing in Hyderabad (Telangana) and Visakhapatnam (Andhra Pradesh).	Changing Markets Foundation (2016)
High level of fluoroquinolones in aquatic environment, especially in Musi River, originating from bulk drug manufacturing facilities.	Gothwal and Shashidhar (2017)
Contamination of water bodies in 53 villages, 9 rainwater reservoirs, 2 village ponds, 52 open wells and borewells (also drawing on Vijay 2009) and reported deterioration of animal health in Telangana (also drawing on studies carried out by students from the University of Hyderabad between 2008 and 2010).	Vijay (2017)
Presence of APIs, particularly high concentration of antibiotics and anti-fungals in wastewater originating from drug manufacturing facilities surrounding Hyderabad. Water samples collected from areas near pharmaceutical facilities, as well as in both rural and urban location. Samples indicate presence of pharmaceutical residue and multi-drug resistant pathogen. The study highlights potential global health risk of AMR.	Lübbert et al. (2017)
Presence of heavy metals and industrial solvents, and pharmaceutical residues in water samples. Samples taken from five manufacturers and water bodies surrounding Hyderabad.	Changing Markets Foundation (2018)

* List of studies summarised here are non-exhaustive

of the Ministry of Forestry and Environment and is supervised by the Ministry of Law and Justice.⁸⁵ While the NGT does not have criminal jurisdiction, it adheres to principles of “natural justice” and international environmental legislation including sustainable development, precautionary and polluter pays principles.⁸⁶

Although India has regulatory mechanisms and institutions that seek to mitigate environmental pollution from industries and ensure people’s right to a healthy environment, failure of regulatory practice has allowed widespread environmental pollution from the pharmaceutical industry to have negative impacts on local residents and the environment.

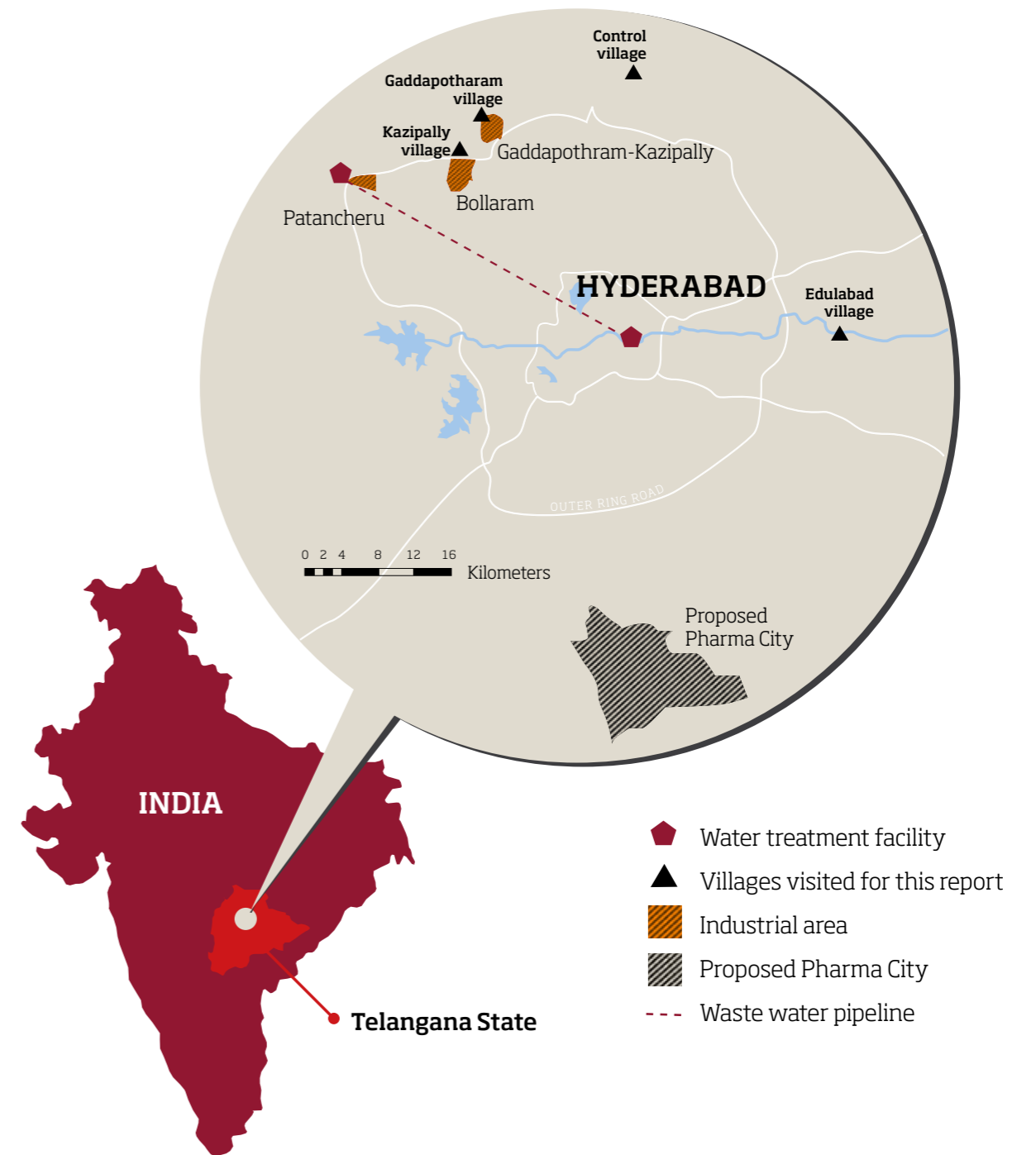
3. Swedwatch’s findings from Hyderabad

Communities located around the major industrial areas in Hyderabad, where many of the pharmaceutical manufacturers are located, have been directly affected by environmental pollution for nearly three decades. In the Patancheru-Bollaram industrial area alone, there are more than 100 industries, including 30 pharmaceutical manufactures.⁸⁷ Studies conducted in the area over the past 20 years point to widespread pollution from pharmaceutical manufacturing facilities and highlight potential cumulative effects from the pollution on human health and the environment. There is no official statistic on the extent of population affected by environmental pollution. Swedwatch estimates that approximately nine million people in areas surrounding Hyderabad are directly and indirectly affected by the widespread pollution.

While there are numerous villages affected by environmental pollution in the areas surrounding Hyderabad, this section builds on interviews carried out by Swedwatch in three selected villages affected by effluents from pharmaceutical manufacturing companies (Gaddapotharam, Kazipally, and Edulabad), and one unaffected village in Hyderabad in September 2019. The section outlines how the polluted effluents impact the human rights of people living near and downstream of the pharmaceutical factories.

Pollution from pharmaceutical manufacturing

The pollution in Hyderabad’s industrial areas is obvious to any visitor. Apart from a strong foul smell that often makes breathing uncomfortable, chemicals visibly flow into nearby surface water, and ground water is discoloured. As many local farmers have been forced to give up farming due to the water pollution and scarcity, abandoned plots are common in the area.



Located in southern India, Telangana state’s capital city is Hyderabad. The region is said to house more than 800 pharmaceutical, biotech and medical technology companies. Telangana is also known for having one of the largest life sciences sectors in Asia, accounting for 35-40 percent of the national pharma production.⁸⁸



Women interviewed by Swedwatch say working in the rice fields have cause skin rashes on their hands.

In addition to the numerous studies that have assessed the levels of pollution in the area, a Swedish pharmacy group, Apotek Hjärtat, commissioned the Research Institute of Sweden to analyse a 100 litre water sample from an open well collecting factory discharge in Gaddapotharam-Kazipally industrial area. The analysis, published in 2019, found active pharmaceutical substances made to treat fungal infections, hypertension, severe pain, epilepsy, cancer and HIV.⁸⁹ The contaminated water from the open well is said to be transported to effluent treatment facilities, but during its research visit, Swedwatch observed water leeching from the open well and from manufacturing facilities.

Although local pharmaceutical manufacturers in the industrial areas are said to employ zero-liquid-waste technologies and access common effluent treatment facilities, a local expert interviewed by Swedwatch objected to this notion, stating that “there is no such thing as zero liquid waste management” in Hyderabad.⁹⁰

The director of an intermediary manufacturer, based in the Gaddapotharam-Kazipally industrial area on the outskirts of Hyderabad, described the fierce market competition that drives manufacturers to violate environmental standards. For instance, to cut the administrative time and costs required to obtain a production licence (which generally takes at least six months), manufacturers often underreport the number of products they produce.⁹¹ The permit for waste treatment, including the number of tankers transporting waste water to the common effluent treatment plant (where the industrial wastewater is said to be collected and treated), is approved based on each manufacturing unit’s registered production capacity. The underreporting of production capacity therefore results in excessive chemical waste from manufacturing units, which is beyond the capacity of the effluent treatment plant. According to the director, this motivates manufacturers to dump hazardous pharmaceutical effluence into the environment, for example by digging a hole and dumping the waste directly underground, burning, or clandestinely releasing the chemical waste into local bodies of water.⁹² He further explained that manufacturers cut costs when possible, for example by not cleaning the chemical reactors during the night-time shift. This, explained the director, is “one of the reasons why the air smells during the night-time”.⁹³

According to the director, manufacturers are fully aware of the water contamination in local communities. He explained that manufacturers continue to pollute because “at the end of the day big companies will purchase products as long as they meet the quality standards required for the product. Everyone is illegally dumping the waste. The government is not solving the problem but use the opportunity to make money”.⁹⁴

From the industry’s perspective, the director argued that unless the Indian government provides subsidies and forces all manufacturers to adopt clean technology, no manufacturer will transition to cleaning up the manufacturing process for fear of losing business.⁹⁵

Access to clean water

Among the key impacts of environmental pollution from the pharmaceutical industry, the limited access to clean water stood out in interviews with local residents. In the two communities adjacent to the Gaddapotharam-Kazipally industrial area, residents used to depend on nearby lakes and rivers as the main water source for irrigation, drinking and household use, but stopped using wells fed by these water sources when the water became discoloured and foul-smelling.

A women’s rights defender in Gaddapotharam village stated that the lake located in the village is poisoned and that “the water is causing an early death”.⁹⁶ In Kazipally village, a woman interviewed by Swedwatch explained that villagers have stopped using the ground water because “it is poisonous”.⁹⁷ Residents no longer eat fish from local rivers and lakes, and have stopped using surface water from local sources for drinking and household purposes. Residents in these two villages now depend on government-managed piped water and on water filtration plants sponsored by pharmaceutical companies operating in the industrial area.⁹⁸ These interventions were introduced at different times after residents lodged complaints to the village authorities. However, residents in Gaddapotharam explained to Swedwatch that the water filtration plants provided by the companies often break down, sometimes “every fourth day or so”.⁹⁹

When clean water from the filtration plants is not available, residents need to purchase water brought in by trucks. Even when the water filtration plants in the village function, consumption is limited to 20 litres per day per household. One resident in Gaddapotharam village explained that the water “is insufficient to meet the needs of more than 1,000 village inhabitants”.¹⁰⁰

The women’s rights defender in Gaddapotharam also expressed frustration over the water scarcity. She explained that the water filtration plants provided by companies are a piecemeal solution and that the companies fail to address the root cause of environmental pollution from their pharmaceutical manufacturing plants, leaving communities vulnerable to water shortages.¹⁰¹

In addition to the general lack of access to clean water, the malfunctioning water system possibly present risks over the next years. A senior expert in agrometeorology interviewed by Swedwatch highlighted concerns over future water shortages as climate change will likely amplify the regional drought cycle; which is already impacting the life and livelihoods of people. The expected impacts from climate change may not only trigger more frequent water shortages in both Godavari and Krishna river basins, but also potentially induce water-related conflicts across the river basins, further jeopardising local communities’ access to clean water.¹⁰²

Although Edulabad village is located downstream the Musi river (part of Krishna river basin), it is also affected by industrial pollutions. Studies conducted over the last five years have shown pharmaceutical residues found in Musi river near Edulabad village.¹⁰³ A local environmental defender, “Musi” Shankar, who has actively protested against the state government on environmental pollution of the Musi river since

Environmental pollution in Gaddapotharam-Kazipally industrial area



A circular effluent tank at Gadapotharam industrial estate, collecting effluents from nearby pharmaceutical factories. The tank is completely open and exposed.



A man shows his legs, covered with rashes and lesions he believes are caused by polluted water.



Pharmaceutical factory at Kazipally



Untreated effluent channels in Gadapotharam industrial estate.

2002, claimed that instead of resolving the origins of the problem, industries including the pharmaceutical companies, continue to “threaten local community members’ right to life”.¹⁰⁴ He particularly highlighted the problematic nature of the 18-kilometre-long pipeline, completed in 2009, which releases discharge from a common effluent treatment facility in Patancheru to the Amberpet sewage treatment plant located near the Musi river. The discharge from the Amberpet plant now enters the Musi river. It is said that the combination of limited capacity of the treatment plants to process pharmaceutical residues, and the unlawful dumping practices, as highlighted in the previous section, potentially contaminates Musi River.

The environmental defender from Edulabad village described that people used to fish and use the water from Musi river for household needs in the past. However, no one currently uses the water from the river, and all three communities interviewed by Swedwatch have observed several major incidences of fish die-offs in nearby lakes and river.¹⁰⁵ A young herder grazing cattle along the Musi river in Edulabad interviewed also mentioned that he made sure that his cattle did not drink “contaminated” water from the Musi river to avoid the cattle from dying.¹⁰⁶

The Chairman of the Water Management Committee in Edulabad village, who has been in charge of managing irrigation canals that receives water from Musi river, mentioned that while there has been little change in the seasonal flow of water, the quality of the water has changed during the last two decades. He observed that the water flowing into the canal is sometimes reddish during the dry season and smells bad. There is also sludge in the canal, which is sometimes flammable, possibly due to the levels of combustible chemicals that it contains. The chairman of the Water Management Committee added that it contacted the State Pollution Control Board in the past to address the source of pollution in the river system, but the problem has not been resolved.¹⁰⁷

Livelihood

Interviews with individuals in the three villages visited by Swedwatch further highlighted that environmental pollution from pharmaceutical manufacturing sites has not only impacted the quality of water and people’s access to clean water, but also their livelihoods. In Gaddapotharam, one farmer explained that he had invested in a borewell to cope with the polluted water from the lake and river, but after the water from the well “became yellow”, it could no longer be used for irrigation.¹⁰⁸ As a result of the contamination, his family can no longer cultivate rice and other crops, and have thereby lost their source of income. While the local government provided a lump sum to compensate for the loss, it was, according to the farmer, by no means enough to compensate for the family’s loss of livelihood.

Farmers that have lost their livelihood in communities such as Gaddapotharam and Kazipally claim they have been forced to find wage labour opportunities elsewhere. Those farmers that continued to cultivate rice stopped using irrigated water for dry season rice cultivation, reducing

the agricultural yields by half. Farmers in the downstream village Edulabad have similarly been affected by the water contamination and experienced reduced agricultural yields. Those who have continued to cultivate rice note a deteriorated quality of the grains, making it difficult to sell their harvests at a reasonable price.¹⁰⁹ Given the decreased production, households now need to purchase rice to meet their daily household needs.

Households interviewed in the three villages also mentioned failing health and death of livestock, particularly large livestock that also serves as key household asset. A woman raising buffaloes in Edulabad noted irregularities with the quantity and quality of milk produced by her stocks over the past ten years. According to the woman, her stocks produce less milk, and it has an unusual odour which makes it difficult for her to sell the milk.¹¹⁰ In Edulabad, a young cattle herder who had lost cattle was told by the local veterinarian that it was due to “an organ failure”, which, according to the herder, likely was a consequence of the pollution.¹¹¹ In Kazipally, one woman described that after two of her cattle died, she sold the remaining ones out of fear that the high level of industrial pollution would impact their health. Based on interviews in the area, residents increasingly consider that keeping cattle – traditionally a key household asset – has become a risk.

Households in all three villages interviewed by Swedwatch also mentioned loss of food and loss of income from fisheries. After observing several major fish die-offs in the past three decades due to the contamination, many have stopped fishing in waterbodies. Many families, including a woman and her family members interviewed in Kazipally, have subsequently stopped eating fish.¹¹²

Life and health

In addition to the loss of income from agricultural production, cattle, and fishing – which directly impacts families’ nutrition and means of survival – several residents interviewed by Swedwatch mentioned a general productivity loss from illness and increased costs of health care. Persons that come in direct contact with water were said to experience health problems ranging from rashes and skin disease, to joint pains and paralysis, and were at times unable to work.¹¹³

Residents in the villages adjacent to Gaddapotharam-Kazipally industrial area also complained of poor air quality that affected everyday life and caused chronic migraines.¹¹⁴ Inhabitants of Gaddapotharam village particularly noted that the stench from the pharmaceutical factories was particularly strong during the rainy season and in the evenings.¹¹⁵

Community interviews also highlighted the long-term psychological effects of environmental pollution. Some interviewees expressed anger and a sense of hopelessness



A woman fills up a container of clean filtered water.

Left: Several reverse osmosis treatment stations have been installed by pharmaceutical companies in Gaddapotharam village. Pictured here is a station sponsored by Mylan as part of its corporate social responsibility initiatives. The facility operates a few hours each morning and evening when villagers can come and collect water.

as environmental pollution continues to persist despite years of protests, and that studies carried out by various organisations, scholars and government authorities are ignored. A man from Gaddapotharam village noted that “many organisations came and collected information, but no justice has been done”.¹¹⁶

The outlook on livelihood among community members in the three villages (i.e. Gaddapotharam, Kazipally, and Edulabad) that were interviewed by Swedwatch was grim compared with those in the control village that has not been directly impacted by pharmaceutical manufacturing. While community members from the control village, located on a ridge and seemingly spared from groundwater contamination from the industrial areas, were aware of the pollution in communities near pharmaceutical manufacturing sites, they felt that their community was not affected. They claimed that they did not experience any water-related illnesses, pollution, human or animal related health problems or other issues raised by members of the affected villages, such as water shortages. Similarly, they did not foresee water related conflicts with communities affected by environmental pollution in the future.¹¹⁷

Environmental pollution in Gaddapotharam-Kazipally industrial area



The Musi river receives the bulk of untreated effluents. Local politician and environmental defender “Musi” Shankar has protested against environmental pollution of the river since 2002, claiming that instead of resolving the origins of the problem, industries “threaten local community members’ right to life”.



Water channel from Musi river frothing with effluents at Edulabad



Effluents from the pharma industry flowing into Isnapur Lake in Pashamylaram industrial estate



A local farmer with his cow at Edulabad.

While Swedwatch has only interviewed a handful of community members from three villages affected by environmental pollution, the numbers of communities affected both directly and indirectly are presumably much higher and calls for further studies that examines the extent of both direct and indirect impact of environmental pollution from pharmaceutical manufacturing on human and animal health over time.

FACT

Land rights at risk

While environmental pollution from pharmaceutical manufacturing remains unabated, the pharmaceutical industry in India continues to expand. The state of Telangana is proposing to develop a “world-class pharma manufacturing hub”, the Hyderabad Pharma City complex (here after Pharma City project), which will contain pharmaceutical manufacturing plants, a zero-liquid discharge common effluent treatment plant, as well as university research and development facilities.¹¹⁸ The project, which covers nearly 8,000 hectares across the agricultural land of more than 10 villages located south of Hyderabad, has been approved and developers have begun to acquire land from communities.¹¹⁹ According to a human rights defender who owns agricultural land on the proposed site, the government of Telangana claimed that the agricultural land belongs to the state, as this was part of the land that was distributed to socially and economically marginalised population groups, the Scheduled Castes and Scheduled Tribes (traditionally considered as the lowest in the Hindu caste system), through a national program in the 1960s. Under the program, people were granted the rights to till the land, and reap harvest from the land. However, the state government retained its right to reclaim the land for national development purposes.¹²⁰

The defender affected by the Pharma City project further explained that the Telangana state government informed the community members that the new development would bring jobs for the residents. The local government also began to purchase and acquire land in villages through private negotiations even though the Land Acquisition, Rehabilitation and Resettlement Act of 2013¹²¹ requires entities to provide social impact assessments and obtain the consent of 80 percent of the affected population of the proposed project site prior to any land acquisition process.¹²² As a result of private negotiations, some landowners who entered private negotiations with the government received compensation. However, the process was far from transparent. For example, according to the human rights defender, “they [state government] said okay, you have 20 acres land but because this is rocky, and because you are not using it... we’ll pay you half....There were times [when] for 20 acres of land they paid for only 1 acre.”¹²³

The lack of transparency in the land acquisition process led a group of local residents including the human rights defender to take the case to the High Court in Telangana state in 2016. The court ruled against the state government and forbade from proceeding with the project until it had paid rightful compensation to the local communities. The High Court also suspended the state government to purchase land from landowners through private negotiations. Unimpeded, the state government introduced new state legislation to purchase land through an issuance of executive order.

Despite the High Court decisions against the state government to prohibit private negotiations and to proceed with unlawful land acquisition, the state government continued to press ahead with the Pharma City project by appealing to the central government to amend the Land Acquisition Act to remove the requirements for a social impact assess-

ment and for the consent of 80 percent of the population.¹²⁴ The amendment not only authorized private negotiations, but also approved one-off compensation payments to affected people. According to the human rights defender, the developer of the Pharma City project has acquired more than 3,600 hectares of the proposed land area through private negotiations, which was considered to be “illegitimate.”¹²⁵

The case of the Pharma City project demonstrates how land rights are at risk, especially for those population groups belonging to the Scheduled Castes and Scheduled Tribes that are both economically and socially marginalised. It also demonstrates the conflicting role of duty bearers. While rights holders may have been granted access to judiciary mechanism to seek lawful compensation and remediation, their rights to property was violated by other state actors that fail to respect and protect the rights of residents. This goes against the Article 17 of the Universal Declaration of Human Rights, which states that everyone has the right to own property alone as well as in association with others, and that no one shall be arbitrarily deprived of their property. Ensuring that no one is deprived of their property, and their livelihood, is an important step toward fulfilling SDG 1, which aims to end poverty everywhere.

Summary of findings

Findings from interviews with affected communities and the case of Hyderabad Pharma City, demonstrate that, while regulatory institutions exist, certain state actors - including local authorities - continue to turn a blind eye to the environmental mismanagement and pollution.

Swedwatch’s interviews indicate that state authorities are able to circumvent existing laws and legislation to enable industrial development, while externalising the environmental problems to economically poor and socially marginalised population such as Scheduled Castes and Scheduled Tribes. One of the experts interviewed for this study claimed that “environmental pollution is everyone’s problem, yet no one’s baby”.¹²⁶ The expert further criticised that the pharmaceutical industry has “captured” regulatory bodies and the judiciary, which allows the manufacturers to pollute without paying for the damage. Other experts claimed, “the cost of life in India is cheap”, highlighting the persisting inequality that normalises business practices that aggravate widespread environmental pollution.¹²⁷

Swedwatch’s research and interviews reveal that widespread environmental pollution from pharmaceutical manufacturers violates local community members’ right to a healthy environment, including their access to clean water, air and soil. It further threatens their fundamental right to life through long-term exposure to pharmaceutical residues and other hazardous materials that are released into the environment. Furthermore, while laws and legislation acknowledge the rights to land, as well as their rights to protest and appeal to seek justice, rights holders and their advocates are continuously sabotaged, threatened and ignored. The pharmaceutical industry’s pollution in India has been described as a form of “slow violence” that particularly victimises marginal populations including the Scheduled Castes, and especially women and children, over a long period of time.¹²⁸ This situation is facilitated not

only by the social injustice and politics in India, but also by structural injustice of the global pharmaceutical production and trade, and regulatory lapse of global institutions, such as the GMP.

As India seeks to develop its National Action Plan on Business and Human Rights, state authorities in India must ensure that courts are independent of economic or political pressure from within and from business actors, and that activities of human rights defenders are not obstructed. In accordance with the UN Guiding Principles of Business and Human Rights, state authorities in India and businesses operating in India should also provide effective non-judicial grievance mechanisms to remedy business-related human rights abuses for all people regardless to their social standing, gender or age. What constitutes effective, for example accessibility, affordability, adequacy and timeliness of remediation processes, should consider the needs of rights holders.¹²⁹

FACT

The human right and environment nexus

Contamination of air, water and soil from industrial waste interferes specifically with rights to life, health, food, water, housing and development. In 2018, the UN Special Rapporteur on Human Rights and the Environment presented framework principles on states’ obligations under human rights law related to the enjoyment of a safe, clean, healthy and sustainable environment.¹³⁰ States must “monitor and effectively enforce compliance with the standards by preventing, investigating, punishing and redressing violations of the standards by private actors as well as governmental authorities”.¹³¹ Furthermore, widespread environmental pollution in Hyderabad goes against the Declaration of the United Nations Conference on the Human Environment of 1972 – the **Stockholm Declaration** – which recognises the environment’s importance for human rights.¹³² The Declaration states that the natural environment is essential to a man’s well-being and enjoyment of basic human rights, including the right to life. This declaration laid the foundation for the development of a new human right: the right to a safe, clean, healthy and sustainable development. The right to a healthy environment has since been recognised in national and regional legislation around the world including that of India. Considering the extensive areas affected by environmental pollution from pharmaceutical manufacturing, Indian authorities must regulate business enterprises to proactively mitigate release of pharmaceutical effluent into the environment.

Furthermore, according to the **OECD Guidelines for Multinational Enterprises**, companies should assess and address the foreseeable environmental, health, and safety-related impacts associated with their goods and services over their full life cycle. Companies should also prepare an environmental impact assessment if their activities may have significant environmental, health or safety impacts.¹³³ However, as demonstrated here in the case study, pharmaceutical companies fail to consider the full extent of environmental and social impact involved in the production of pharmaceutical products. Furthermore, the long-standing contamination of water from the industries in Hyderabad violates the basic human rights of local population to access clean water and sanitation, which is a fundamental precondition for rights to life and health.

4. Stakeholder interviews

To deepen the understanding of the root causes of ongoing environmental pollution in pharmaceutical production – as well as potential solutions – this section presents findings from interviews with several key players within the pharmaceutical value chain. In order to understand what possibilities public authorities within the EU have to impose environmental criteria, interviews were held with the Swedish Medical Products Agency (MPA, Läkemedelsverket) and Västra Götaland Regional Council (Västra Götalandsregionen, VGR), which coordinates public procurement of pharmaceuticals for Swedish Regional Councils. Furthermore, the perspectives of four pharmaceutical companies, an investor and a pharmacy are presented, as well as comments from Joakim Larsson at the Centre for Antimicrobial Resistance (University of Gothenburg) who has conducted extensive research on pollution and incentives in the industry.

Swedish public authorities

In Sweden, three public entities play important roles in the pharmaceutical value chain: the Swedish Medical Products Agency (MPA), the Dental and Pharmaceutical Benefits Agency (TLV, Tandvårds- och Läkemedelsförmånsverket) and public procurers (i.e. state and regional councils) across the country. The mandates of the authorities are to a large extent regulated by harmonised European legislation as well as national regulations.

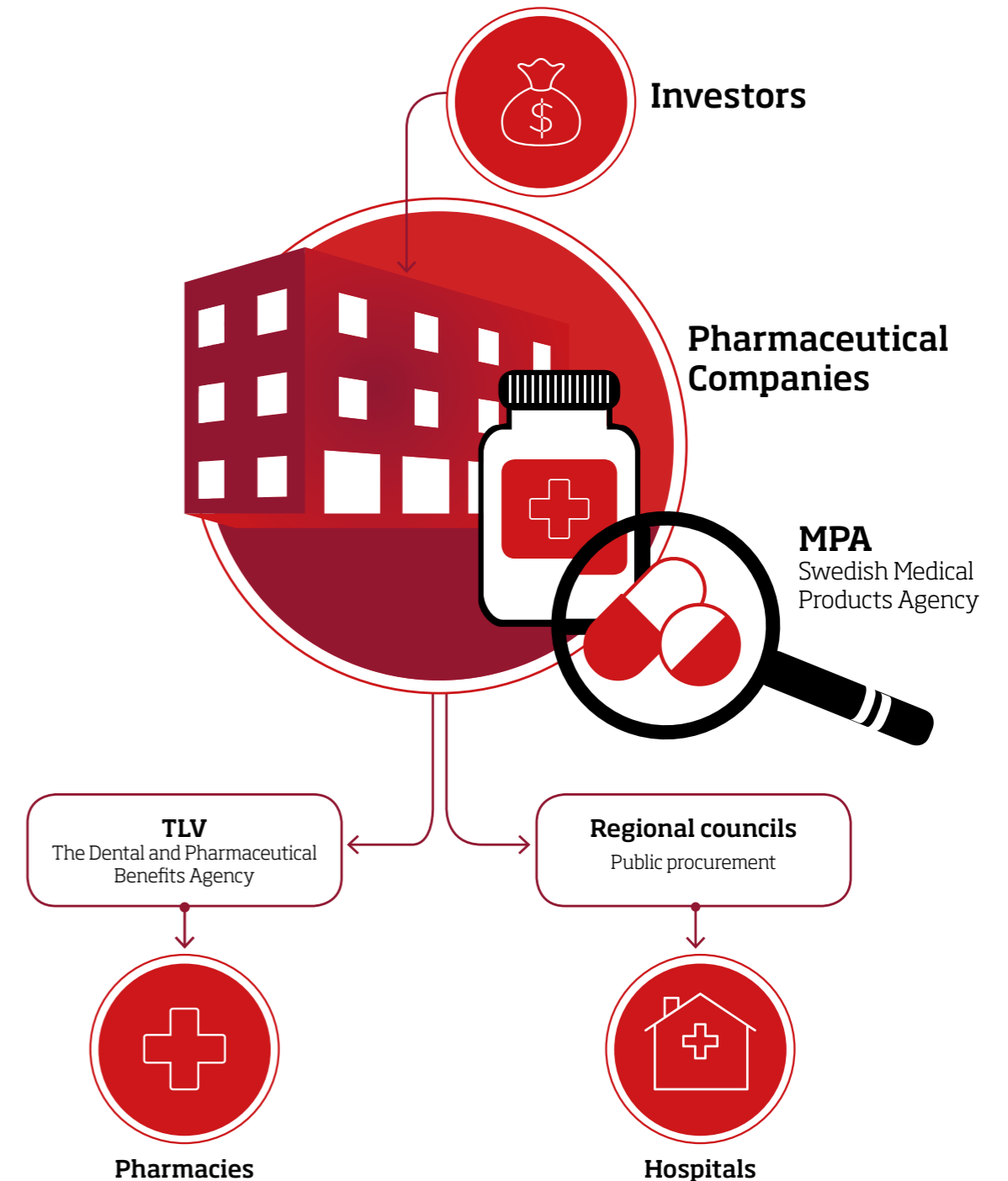
The Swedish Medical Products Agency

The Swedish Medical Products Agency (MPA) is responsible for approving and controlling pharmaceutical development, manufacturing and sales according to European regulations.¹³⁴ It is tasked with supervising pharmaceutical and medical products for both humans and animals, which includes conducting audits before and after product approval. The MPA coordinates with other EU authorities to ensure drug safety, and is responsible for providing drug information, including on the supply chain of products approved for sale in Sweden.¹³⁵ As governed by EU regulations, environmental or social impacts of pharmaceutical manufacturing are not included in the approval or inspection processes of pharmaceuticals. According to Kia Salin, Scientific Director of Sustainability at the MPA, this means that the agency's inspectors cannot document or follow up on sub-standard waste treatment even if this is observed during site inspections.¹³⁶

Although it is part of MPA's mandate to provide "drug information for the general public", data on production sites and suppliers is to a large extent classified, due to the protection of business interests. As a result, other stakeholders, such as the general public, pharmacies and public procurers, have very limited access to information on manufacturers and API suppliers.¹³⁷ However, the question of confidentiality has not been legally tested since 2011, explained Salin, and the outcome could possibly be different if the issue was examined by a court again.¹³⁸

The Swedish System

for prescription medicine



Since 2007, the MPA has had a so called “sectorial responsibility for environmental issues” associated with the development, manufacture and sale of pharmaceuticals. This includes a responsibility to meet the target set by the Swedish government to include provisions regulating environmental pollution in legislation on pharmaceutical products for human and veterinary use by 2020, at the EU and international levels.¹³⁹ The agency cannot engage in political advocacy. While Salin commended the EU and the Swedish government for incorporating environmental aspects into EU legislation on pharmaceuticals for animal health, she said efforts to regulate pharmaceuticals and medicinal products for humans are not on par.¹⁴⁰

With regards to environmental pollution from pharmaceutical manufacturing in countries such as India, Salin was critical of the fact that proper regulation is still missing more than 20 years after large effluent releases were first discovered: “Sweden is contributing to negative impacts on habitats in these countries. In light of the SDGs and Sweden’s environmental objectives with the Generation goal, it is important that we make all efforts we can to improve the situation”.¹⁴¹ She highlighted a general resistance from the industry to include more comprehensive environmental criteria in GMP.¹⁴² For example, she said, the European Commission’s 2018 strategy on pharmaceuticals in the environment was heavily diluted down from the strategy originally proposed in 2014.¹⁴³

FACT

The Dental and Pharmaceutical Benefits Agency

The Dental and Pharmaceutical Benefits Agency (TLV) determines which medicine, medical products and treatments should be subsidised by the Swedish government. It is also responsible for setting the retail margins for all pharmacies, as well as the types of pharmaceutical products that should be included in the Swedish generic substitution system. This system, introduced by the Swedish government in 2002, applies only to prescription drugs. Under the system, all pharmacies in Sweden must offer customers the least expensive pharmaceutical products with an equivalent medicinal effect and function as the branded original products.¹⁴⁴ TLV issues a list of pharmaceutical products that are available through the generic substitution system each month, and pharmacies must stock these products for their customers.

Medicines are selected for this list based only on their price and efficacy. The environmental and social impacts of drug manufacturing cannot be taken into account, under current regulations. Although the Swedish government tasked the MPA and TLV in early 2018 with conducting an initial feasibility study to evaluate environmental premiums in the generic substitution system, the agencies are still awaiting a government decision to conduct the actual study.¹⁴⁵

Public procurers

In Sweden, around 20 percent of all pharmaceuticals are purchased through regional councils for hospitals and other public health care facilities.¹⁴⁶ The National Agency for Public Procurement (NAPP) under the Ministry of Finance provides national guidelines on public procurement in Sweden. In recent years, the agency increased its incorporation of sustainability criteria into public procurement processes.¹⁴⁷

The Swedish Regional Councils coordinate their work on sustainable public procurement through the collaborative platform “Hållbar upphandling” (Sustainable Public Procurement).¹⁴⁸ The councils have identified pharmaceuticals as one of eight prioritised procurement risk categories.¹⁴⁹ In a risk analysis from 2015, the regional councils identified several human rights and environmental risks in pharmaceutical production. These included: high emissions of pharmaceuticals, increased existence of resistant bacteria and risk of subsequent pandemics, corruption, right to clean water, health, land and safe working conditions and difficulties in cultivating crops as well as crops containing to high levels of contamination. The analysis concluded that there are good reasons to apply the precautionary principle and limit antibiotic emissions from production sites.¹⁵⁰

Västra Götaland Regional Council (VGR) is responsible for coordinating the Swedish regional councils sustainability work on pharmaceutical procurement. According to Lena Göransson Modigh, Sustainability Manager at VGR, the level of transparency in the pharmaceutical sector is generally low.¹⁵¹ The regional councils have initially no knowledge of the production sites and supply chains of tenderers. However, they request the information as part of their contract clauses, meaning the councils have the right to demand the information once there is a contract in place.¹⁵²

In late October 2019, NAPP introduced a new set of sustainability criteria for pharmaceuticals. The new criteria makes it possible to, in some cases, reward tenderers for sharing information on, for example, where APIs are produced and what their environmental practices are prior to contracting.¹⁵³ According to the agency, information on pharmaceutical discharges is not yet included in the criteria due to its current controversial nature, but it will be in the future.¹⁵⁴

The regional councils have to date reviewed approximately 50 pharmaceutical suppliers, according to VGR. The initial follow-up process includes self-assessment by the contractors. Based on the results of the self-assessments, additional audits may be carried out at the contractors’ offices and/or factories. Thus far, VGR has carried out a total of four factory audits, two in Europe and two in India during 2017/2018. In India, deviations concerning labour rights and work environment were found. The audits have not included impacts on local communities.¹⁵⁵

According to Göransson Modigh, contractors providing pharmaceutical products have become more accustomed to questions regarding environmental management and they are less resistant to provide supply chain information. In order to increase sustainability in pharmaceutical production, she said the following measures: 1) inclusion of environmental criteria in international code of practices such as GMPs; 2) improvement of supply chain transparency and public disclosure of information on the origins of drugs and under what environmental circumstances the drugs and their active ingredients are produced; 3) strengthened legislation in production countries to effectively regulate environmental pollution; and 4) the implementation of sustainability criteria in procurement.¹⁵⁶

Pharmaceuticals on the Swedish market

According to the Swedish Medical Product Agency, in July 2019 around 25 percent of the substance manufacturers for antibiotics sold on the Swedish market were based in China and 20 percent in India. Other countries of origin were Mexico, Japan, Slovenia and Croatia.¹⁵⁷ In a 2018 study, in which a Swedish group of scientists analysed the origins of APIs in pharmaceuticals sold on the Swedish market in 2010, India was found to be the largest supplier of generics and the largest supplier in terms of number of doses.¹⁵⁸

The aim of the study was to determine if price pressure and generic substitution were related to environmental performance and perceived corruption levels of production countries. It found that there was indeed a link, but that the relationship was largely explained by whether the product was original or generic. Original, branded, products were more often produced in countries with higher standards.¹⁵⁹

According to the study, a third of generic pharmaceuticals sold at the Swedish market were produced in regions of the world with generally poor environmental performance, including India, China and Puerto Rico. An even larger share was produced in countries with poor corruption performance. For antibiotics, however, about one-third of both original and generic products were produced in countries with overall poor environmental performance. Importantly, the analysis pointed out that the lack of studies investigating API discharges from manufacturing sites prevented generalisations of where risks are the greatest, and that increased transparency, among other measures, was needed in order to improve sustainability in the sector and properly inform decision making.¹⁶⁰

In 2011, Swedish Radio found that out of the ten largest producers of active ingredients in pharmaceuticals on the Swedish market, four were present in Hyderabad. Two producers used a heavily criticized effluent plant in the area that according to a Swedish scientific study released 44 kilograms of antibiotics into streams every day.¹⁶¹ In a campaign launched by Apotek Hjärtat in 2019, it was stated that over 70 percent of pharmaceuticals at the Swedish market were produced in Hyderabad.¹⁶²

Nordea Asset Management

Nordea Asset Management has EUR 204.8 billion in assets under management and is part of the Nordea Group, the largest financial services group in the Nordic region and one of the largest banks in Europe.¹⁶³ The company began to take an interest in environmental pollution related to pharmaceutical manufacturing after a delegation from Nordea visited Hyderabad in 2015. After the visit, Nordea wanted to review the supply chains of pharmaceutical companies that the bank was invested in. As Nordea found the information from the companies insufficient, it commissioned an independent investigation of pharmaceutical manufacturing in Hyderabad, India.¹⁶⁴ According to Nordea, the study revealed unacceptable impacts of pharmaceutical manufacturing in Hyderabad.¹⁶⁵

“In addition to the very negative impact on people and communities, pharma pollution is also a driver of antimicrobial resistance – one of the largest global threats today”, Magdalena Kettis, Active Ownership at Nordea Bank, told Swedwatch in an interview.¹⁶⁶

According to Nordea, it communicated the report to the CEOs of a number of pharmaceutical companies as well as the industry-led Pharmaceutical Supply Chain Initiative (PSCI) (see fact box on page 51). Nordea called on the companies to: (1) contribute to the protection of water resources in India, (2) adopt an industry position and action plan to address pharmaceutical water pollution in India, including setting discharge reduction targets for relevant production sites and suppliers, and (3) recognise their ability to change the situation, the need to build capacity in the supply chain and to engage with local regulators, authorities and civil society organisations.¹⁶⁷

While there has been some improvement in the sector, environmental pollution in India is far from being mitigated, said Kettis. When the bank financed a follow-up study in 2018, findings indicated that pollution was still rife.¹⁶⁸

Kettis also pointed out that actors such as the Swedish MPA and public procurers kept useful information on pharmaceutical supply chains secret. She questioned the need for this secrecy and stressed that the information should be accessible to both investors and consumers.¹⁶⁹

In addition to its call for increased transparency, Nordea emphasised the need for 1) stronger (and improved implementation of) legislation in production countries, 2) inclusion of environmental criteria in GMPs, and 3) incentives to change production patterns. Companies should continue to train suppliers and cooperate with local organisations and decision-makers, as well as introduce reduction targets for emissions. Finally, Nordea highlighted the importance of investor engagement as well as media and civil society’s role in increasing knowledge and public pressure.¹⁷⁰

Apotek Hjärtat

Apotek Hjärtat AB is Sweden’s largest private pharmacy chain, owned by Swedish retailer ICA Gruppen AB. In 2019, the company launched a campaign in Sweden to highlight pollution in pharmaceutical production and to market its sustainability label “Välj med hjärtat” (Choose with your heart).¹⁷¹ For the campaign, Apotek Hjärtat analysed a 100 litre water sample from an open well outside pharmaceutical factories in Hyderabad, and found traces of pharmaceutical substances to treat cancer, HIV, epilepsy, severe pain, hypertension and fungal infections.¹⁷²

Apotek Hjärtat also presented a survey conducted by the Swedish polling institute Novus. The survey showed that eight out of ten Swedish consumers think they have the right to information on how prescription drugs impact the environment. The survey also found that three out of four consumers would like the possibility to choose an alternative pharmaceutical product, if the product was known

to have negative environmental impacts. Also, six out of ten consumers thought that Sweden should increase environmental demands when purchasing pharmaceuticals and one-quarter were willing to pay more for a drug if environmental impacts were clearly declared.¹⁷³

According to Cecilia de Pedro, Head of Sustainability at Apotek Hjärtat, the purpose of the campaign was to draw the public's attention to a problem that it has been unable to solve itself, and to reach politicians in order to find a political, rather than a consumer-driven, solution to the problem. de Pedro described the industry as less transparent than other industries, such as the clothing and food sectors, and pointed out that the pharmaceutical industry has been able to keep information confidential due to companies' patent rights. She argued that the industry today has no excuse not to be more open about how and where pharmaceuticals are produced.¹⁷⁴

Swedish pharmacies are obliged to follow directions from TLV on which specific prescribed drugs they must provide for their customers. Therefore, they are, unlike many other industries, limited in their purchasing options; they cannot discard suppliers who do not share relevant information.

From Apotek Hjärtat's perspective, it cannot fulfil its sustainability and human rights responsibilities when other actors in the supply chain withhold critical information. de Pedro claimed "... we do not know how the products we sell are made. We [Apotek Hjärtat] have been trying to get this information since 2015 by sending out self-assessment questionnaires similar to the ones the Swedish regional councils use, but we do not receive clear answers. We cannot make proper judgements based on the information we receive".¹⁷⁵

According to de Pedro, pharmaceuticals should "simply not" end up in the environment, especially not in large quantities, since the risks are too high and impacts not adequately researched. de Pedro was herself on the team of scientists that found extreme levels of antibiotics in Hyderabad's water system in the mid-2000's.¹⁷⁶ She was dismayed at the environmental pollution from pharmaceutical manufacturing in India and commented that "...the problems for the environment and people in Hyderabad are the same as 14 years ago, if not worse. According to our Indian partners, the emissions are still ongoing. People are exposed to risks they do not need to be exposed to, and of which we do not know the consequences".¹⁷⁷ She further expressed her astonishment that the situation had not improved in India and questioned the ethics of not acting upon the issue.

de Pedro pointed out that even though industry groups like the AMR Industry Alliance have developed effluent targets, these targets, as well as so called zero-liquid discharge, can be difficult for Indian companies to comply with. Indian company representatives have expressed uncertainty about how to meet the requests. In order to improve the current situation, increased knowledge and competence, including improvement of manufacturers' ability to mitigate and control environmental pollution, is important. But above all, increased transparency and environmental regulation on prescription drugs is key, de Pedro argued.¹⁷⁸

The Centre for Antibiotic Resistance Research, University of Gothenburg

Professor Joakim Larsson, director of the Centre for Antibiotic Resistance Research at the University of Gothenburg, is a scientist renowned for his research on pharmaceuticals in the environment. In 2007 he published an academic study with a group of Swedish scientists that analysed wastewater from a treatment plant near Hyderabad and found extremely high concentrations of drugs, including the broad-spectrum antibiotic ciprofloxacin.¹⁷⁹ Since then his team of researchers have published around 30 scientific papers relating to pharmaceutical pollution from manufacturing sites.

Since their first study, knowledge and understanding of the subject has increased across stakeholder groups. Larsson for example pointed to the development of industry initiatives such as the PSCI and AMR Industry Alliance (see fact boxes on page 51), the Indian government's stated intention to regulate antibiotic discharges from manufacturing sites; increased number of initiatives in European countries, such as Sweden, Norway and the UK, and increased media coverage.¹⁸⁰

However, according to Larsson, the level of knowledge is still alarmingly low, partly because there still is no regular monitoring or reporting requirements placed on pharmaceutical emissions. Individual research has shown that large releases of pharmaceuticals from manufacturing take place in for example USA, Europe, India, China and Korea, but the picture is still incomplete regarding how widespread the pollution is: "It is quite worrying that when researchers go out and take a look, they often tend to find high concentrations. That suggests it is fairly common when you have drug production, that you also have large releases of drugs".¹⁸¹ While industry actors have argued that the total amount of pharmaceutical residues released from manufacturing sites is small compared to those released from other sources, Larsson contends that 1) there is not enough data to properly assess how large and widespread emissions of residues from pharmaceutical production sites are, and 2) it is not the proportional share but the *concentration* of pharmaceutical residue at a specific site that determines risks.¹⁸²

In the case of antibiotic emissions Larsson stated: "The major risk with antibiotic pollution in the environment is that it could trigger the transfer of new resistance genes from harmless "environmental bacteria" into human pathogens, thereby making infections even more difficult to treat. It is enough if such emergence of a new form of resistance happens at one place on earth, once. When a new gene has made it to a pathogen and the resistant bacteria infects humans, we're stuck with it. This means that to reduce risks for emergence of resistance, we really need to focus on high-risk places, even if they are few".¹⁸³ Whereas most chemicals released into the environment from pharmaceutical plants could cause local impacts, multidrug-resistant pathogens are borderless, and given the right enabling conditions, they have the potential to not only threaten the lives of pollution-affected communities but also global public health, according to Larsson.

“Places where large releases of antibiotics occur can be really terrifying. We know that the environments polluted by high levels of antibiotics from drug manufacturing are among the most extreme ones found on earth when it comes to the presence of multi-resistant bacteria, quite possibly the most extreme of all. It is hard to say exactly how big the risk is for us, but it is an unnecessary - and in my mind – an unacceptable risk.”¹⁸⁴

Larsson further stated that despite the unprecedented amount of pharmaceutical residue found in the environment by a series of studies, few longitudinal and cross-sectional studies examine the health impacts of pharmaceutical pollution. The fact that Greenpeace’s report on Medak District, Telangana Province from 2004 (see table on page 24), has not yet been replicated is disappointing, said Larsson, since it makes it difficult to determine the extent to which pollution released from pharmaceutical manufacturing factories triggers the emergence of multi-drug resistance as well as how it impacts the health of residents in nearby communities.

According to Larsson, the first thing that needs to improve in order to tackle pharmaceutical pollution is transparency: public disclosure of supply chains in the pharmaceutical sector is needed in order to permit public scrutiny, which in turn will boost performance. This could be achieved by requiring companies to publicly disclose supply chain information through EU legislation: “the information on who is producing the APIs in your pills is already there at the European Medicines Agency (EMA) as well as national agencies such as the Swedish Medicine and Pharmaceutical Agency (MPA). It is basically just a touch of a pen, a decision at the EU level, and then all of that information is available to everyone”.¹⁸⁵

However, Larsson highlighted that pharmaceutical companies generally are opposed to increased transparency concerning their production and supply chains. The most common arguments raised being (1) they do not want to “give away” sub-contractors to other companies, (2) it would violate anti-trust laws, and (3) to protect medicines from being physically stolen. However, Larsson argued that at least the two first arguments do not outweigh the benefits to society of making this information public. Larsson does not agree with the anti-trust argument, as “the whole idea is to make the information available to everyone, not just to a few other companies”.¹⁸⁶

Furthermore, Larsson was also critical of the fact that companies are not currently incentivised to make investments in green technology. As an example, Larsson mentioned the Swedish generic substitution system in which the principle criteria for product selection are price and affordability.

“Companies are not favoured for good environmental performance. For example, in the Swedish generic substitution system, we don’t care about if companies invest in efficient pollution control or not. The Swedish state has basically said ‘we only care about the lowest price, we could not care less about your pollution. We only want the cheapest ones.’ I think that makes governments with such a system, like in Sweden, partly responsible for the pollution.”¹⁸⁷

Larsson further believed that the inclusion of environmental criteria would not compromise international codes of conduct like the GMP, since full compliance would still be needed in order to sell pharmaceuticals. Although it is important to introduce this type of lowest level of control, it would probably not create sufficient incentives for companies to really boost their environmental performance to the level needed; nor would it increase transparency in the sector.¹⁸⁸

Larsson considers lack of awareness among stakeholders on pharmaceutical pollution, and the risks associated with it, to be an important reason for the slow development in regulating pharmaceutical pollution, pointing out that the problem cannot be addressed simply by informing the decision-makers: “It’s not enough to reach politicians, because you also need to reach the voters. We need increased awareness among the public and media needs to highlight the issue”.¹⁸⁹

FACT

Industry initiatives

The Pharmaceutical Supply Chain Initiative (PSCI)¹⁹⁰

The PSCI was formed as a non-profit business membership organization in 2006 and is legally established in the United States. The purpose of the initiative is to bring the pharmaceutical industry together to define, implement, and champion responsible supply chain practices. Currently, 40 pharmaceutical and health care companies are members of the initiative. The PSCI has developed the Pharmaceutical Industry Principles for Responsible Supply Chain Management covering ethics, labour, health and safety, the environment and management systems. Other than labour rights, the principles do not cover human rights. PSCI has also developed implementation guidance for the principles and an e-learning tool that is available to PSCI members and suppliers. The initiative has also created guidance tools to assess performance and risk and an audit sharing program.

The AMR Industry Alliance¹⁹¹

The AMR Industry Alliance is one of the largest private sector coalitions set up to provide sustainable solutions to curb antimicrobial resistance. Over 100 biotech, diagnostics, generics and research-based pharmaceutical companies and associations are members. The alliance gives members a platform for information sharing, helps monitor global AMR developments; develops thought leadership in research and science, appropriate use, access and the environment; and collects company data to develop an industry-wide overview of progress in the fight against AMR.

Company perspectives

In order to gain an understanding of the industry's views on environmental and human rights practices, transparency and regulations in the sector, Swedwatch contacted pharmaceutical companies for interviews. Two of the companies that chose to respond are based in Scandinavia: Recipharm, a Swedish company that operates globally focusing on pharmaceutical contract manufacturing and development, and Orion Corporation (Orion), a Finnish company focusing on generic pharmaceutical development, manufacturing and marketing that engages in contract manufacturing globally. Furthermore, Fresenius Kabi, a healthcare company headquartered in Germany that operates globally and AstraZeneca, an Anglo-Swedish research-based pharmaceutical company, responded to Swedwatch's questions. This section draws on the interview responses and publicly accessible information to highlight companies' perspectives and practices on environmental pollution, human rights practices and supply chain transparency.

Companies interviewed for this study

Company	Total Revenue 2018 (Euro)	Public disclosure of information		Support on policies	
		Suppliers	Origin of products	Environmental criteria in GMP	Environmental premium in the Swedish generic substitution system
Astra Zeneca	19,4 bn	No*	No	No	Yes
Orion Pharma	977 mn	No	No	No	No comment
Fresenius Kabi	6,5 bn	No	No	No	No comment
Recipharm	650 mn	No	No	No	Yes

*AstraZeneca reports on number of critical suppliers per country and whether they comply with AstraZeneca's Safe API Discharge Assessment. However, names or addresses of suppliers are not publicly disclosed.

Global supply chains

The interviewed companies did not specify the volume of supplies from India or China. AstraZeneca stated that the company does not source APIs for any of their major brands from India or China, only for a small number of older products where no alternative sources exist.¹⁹²

Recipharm stated in interviews with Swedwatch that it primarily receives lists of API suppliers from its customers (i.e. other pharmaceutical companies). These suppliers can't be replaced by Recipharm, since this is linked to regulatory approvals by

authorities and must be managed by the customer. Recipharm primarily sources from Europe, although an increasing amount of API suppliers are located in India and China. The company stated it was not fully aware of where their European suppliers in turn are supplying from, stating that API processes are often complex and can consist of four different tiers.¹⁹³ Recipharm tries to collaborate with other companies on API sourcing and challenges associated with API production, especially for antibiotics. This has, however, proven to be quite difficult, since the European Federation of Pharmaceutical Industries and Associations, which represents the pharmaceutical industry operating in Europe, has agreed that sharing information on suppliers between companies may violate the competition laws and so should be avoided.¹⁹⁴

Fresenius Kabi replied that its network spans around 70 production sites including compounding centres in Europe, North America, Latin America, Asia Pacific and Africa, and that it sources raw materials and APIs worldwide due to its international presence and infrastructure.¹⁹⁵ Orion reported that the majority of its sales value come from products manufactured at its own plants in Finland, but that it sources worldwide, commenting that one drug product contains 4-10 ingredients that are commonly purchased from highly specialised chemical plants from all over the world.¹⁹⁶ The company said it has full internal transparency and traceability of its supply chain, including suppliers, down to raw material providers.¹⁹⁷

Orion pointed out that low pricing and implemented contracting procedures, especially for generic drugs, have made pharmaceutical value chains very "fragmented, global and complex". Furthermore, due to society's economic pressure and demands, components need to be manufactured in high volumes which has resulted in few, very consolidated sources globally.¹⁹⁸ Neither Fresenius Kabi nor Orion wanted to comment specifically on suppliers in Hyderabad.

Transparency

With regards to supply chain transparency, the companies have different views on what information should be disclosed to the public. Recipharm responded positively about disclosing information on how the company operates, but did not have a publicly available supplier list, which would require consent from both its clients and suppliers. Recipharm's Head of Sustainability, however, stated that he could not see any reason why the pharmaceutical sector should be treated differently than other sectors in terms of transparency.¹⁹⁹

Orion does not disclose its supplier list to the public and stated that the information is considered confidential in order for the company to be able to cover its broad drug product portfolio.²⁰⁰

Fresenius Kabi highlighted that the pharmaceutical sector is already transparent to respective authorities and viewed a general obligation to publish supplier lists as potentially disadvantageous, stating that "...not only the interested public parties could use this information, but it would also be possible for competitors to gain valuable insights. Supplier information is subject to further constraints such as legal or property rights as in-depth information about the products could be inferred from that information".²⁰¹

In 2019, AstraZeneca launched a “transparency map” on its website, providing information on operations and sourcing.²⁰² The map shows key production sites and critical suppliers. However, names, addresses or types of suppliers are not specified.²⁰³ The reason for this level of transparency is, according to the company, that it wants to be visible about where it operates globally, but also respect the confidentiality agreement it has in place with its suppliers, and to protect the security of medicines supply. According to the company itself, AstraZeneca is the only company in the industry to disclose “this level of supply chain information.”²⁰⁴ AstraZeneca states on its website that the reason for publishing the map is to build trust with its stakeholders and the company commits to increasing its level of transparency going forward.²⁰⁵

Currently, none of the companies interviewed display the level of transparency needed for interested stakeholders to scrutinize their production and/or supply chains.

Environmental and human rights practices

All companies were aware of the issue of environmental pollution from pharmaceutical production and had either internal or third-party auditing systems in place to cover first tier suppliers, and in some cases second tier suppliers.

Orion reported that all its current Indian suppliers are audited and that the company conducts on-site audits on formulated products of pharmaceutical substances, APIs and at intermediate supplier sites. In terms of environmental management, Orion mentioned that the company treats industrial wastewater through highly developed processes and invests in environmental responsibility across products’ life cycles.²⁰⁶

Recipharm requires all its production sites to be certified according to the ISO 14001 environmental management standard and in India, Recipharm operates its own local water treatment plants and recirculates the water which is used for irrigation. Recipharm acknowledged the scarcity of fresh water in India and claimed to use pre-treated ground water in order to reduce their usage of fresh water.

Fresenius Kabi stated that it encourages the use of environmentally-friendly technologies throughout the production process, stating that “It is our approach to avoid antibiotic contaminated wastewater. In general, sites do not discharge antibiotic contaminated wastewater without treatment to the environment”.²⁰⁷ Furthermore, the company replied that a special focus is given to AMR, which the company will intensify going forward, for example through joining AMR Industry Alliance,²⁰⁸ which AstraZeneca and Recipharm are also part of.²⁰⁹

AstraZeneca was the only company reporting on key performance indicators on safe API discharges, 100 percent for own sites, and 90 percent for first tier suppliers. The reason behind the lower threshold for suppliers, is that AstraZeneca trains new suppliers on environmental compliance.²¹⁰ However, the company reports that in 2019, 97 percent of their suppliers had safe discharge. The corresponding number for own sites was 100 percent. The performance is externally verified and annually reported on, according to the company. Furthermore, expectations to participate and meet the safe discharge requirements are written into AstraZeneca’s supplier contracts.²¹¹

Orion, Fresenius Kabi and AstraZeneca all have public human rights statements.²¹² Recipharm stated that the issue of respecting human rights is covered in their internal and external (supplier) code of conducts. The company has not yet performed a structured human rights risk assessment on their operations and supply chain. According to Recipharm’s Head of Sustainability, it “should be done”.²¹³

On questions related to HRDD practices, the companies referred to their general auditing programmes. None of the companies reported any negative impacts on local communities as part of their due diligence findings. All four companies reported that they have grievance mechanisms in place, available for all stakeholders. Recipharm reports that the only complaints it has received from local communities surrounding its facilities in India relate to noise levels from production sites.²¹⁴ AstraZeneca stated that: “We are aware of only one complaint in regard to a supplier location made from an internal AstraZeneca employee in the last seven years, no grievances have originated directly from the local communities in which we operate.”²¹⁵

Views on regulations and incentives

AstraZeneca, Orion and Recipharm do not support inclusion of environmental or social criteria in good manufacturing practice (GMP).²¹⁶ The companies argued that GMP should solely focus on product quality and patient safety.

Orion responded that the company sees value in driving sustainability in the supply chain through its own sustainable procurement processes and not through GMP, adding that including environmental criteria into GMP could be problematic, as the industry is already highly regulated and that such inclusion could result in companies shifting away from more impactful measures to increase sustainability in the supply chain. Moreover, Orion stated that environmental criteria in Europe are not seen as mature enough to be implemented in GMP and European level practices or guidelines do not exist. Inclusion of environmental criteria would therefore “kharm current GMP, create confusion and take focus away from GMP.”²¹⁷

AstraZeneca agreed that the GMP is not the most appropriate regulatory framework for regulating environmental and social impacts, since environmental concerns are site specific, whereas the GMP tends to implement a standard practice and best available technologies that are site independent.²¹⁸ AstraZeneca pointed out that this could lead to significant unnecessary investments. If it even is possible, AstraZeneca stated, implementing such criteria would take time and put the whole GMP framework at risk if not adopted internationally, which potentially could result in trade and patient access related issues.²¹⁹

The companies offered different perspectives on how pharmaceutical companies can best achieve responsible production to mitigate environmental and social impacts. Recipharm, for example, argued that the EMA can enforce environmental requirements by utilizing the environmental risk assessments companies must submit as part of their application to authorise each new pharmaceutical product for sale in Europe. In Recipharm’s words, these assessments are currently not used for any purpose, which “makes no sense”.²²⁰

AstraZeneca expressed the view that national regulation, such as setting safe discharge limits and permits coupled with responsible sourcing and procurement, appeared to be a more appropriate alternative and could be easier to implement.²²¹ If done correctly, Recipharm and AstraZeneca were both positive towards including environmental premiums in the Swedish generic substitution system, as this would drive best practice and help create the impetus for positive change.²²² Fresenius Kabi and Orion did not express any opinions concerning the system.

Recipharm, AstraZeneca and Fresenius Kabi all saw value in driving sustainability in the supply chain through green procurement processes, if it would be adequately rewarded. Well-defined requirements and criteria, consistent with national/and or international regulation globally, would incentivise actors across the supply chain to be responsive to the environmental and social impacts of their production.²²³ Orion also saw that unified, well-defined requirements could benefit all, but highlighted that it will take time and resources to develop effective models.²²⁴ AstraZeneca pointed out the importance of harmonising green procurement practices internationally – at a minimum at the EU level.²²⁵

Orion said that new regulations generally impose significant cost burden for companies, which needs to be taken into account in order to avoid negative consequences for the market: “When the cost of manufacturing increases and if the contracting and pricing processes of countries do not allow price increases for generics, it would eventually make several products non-profitable and reduce the available products and, in worst case, mean that some of the products would cease to exist on the market totally. This means that the pricing and contracting processes should allow room to accommodate this type of investments in new regulations and rules.”²²⁶

Fresenius Kabi commented that “Sweden is amongst the most advanced countries in Europe when it comes to sustainability and environmental requirements in public procurement” and that responding to such requirements can result in better supplier evaluation.²²⁷

In order to improve sustainability in the sector, AstraZeneca stressed that suppliers need to be actively engaged and educated as partners.²²⁸ Some of the key tasks that the company has communicated to its suppliers are: commitment to work with science-based targets; water assessments in high-water stressed regions to assess and address any negative impacts on access to water by neighbouring communities; implementation of waste management programs involving reduction, reuse, donation and recycling; application of green chemistry principles wherever possible in the manufacturing of products; increase the margins of safety for drugs being released from drug production facilities; increased transparency and recognition of responsible environmental and social sourcing within national and EU-wide procurement of medicines.²²⁹ Orion emphasised the importance of working together with other stakeholders, for example through PSCI, increased knowledge and constant improvement of waste water management.²³⁰

5. Conclusions

Substantial price pressure within the pharmaceutical sector has been, and still is, a driver for outsourcing pharmaceutical production to countries with lower production costs, such as India and China. In this regard, the pharmaceutical industry faces the same challenges as other globalised manufacturing industries, such as the textile and electronic sectors, since lower production costs are often connected to lax enforcement of environmental and human rights regulations.

Despite years of reports and protests, pollution from pharmaceutical production is still significant in large manufacturing hubs like Hyderabad, India, supplying the global market with medicine. While creating jobs and income, the situation is impacting local residents’ right to a healthy environment and access to clean water. It also risks threatening their right to an adequate standard of living, livelihood, and most importantly, to life and health.

Multiple studies have found extreme concentrations of pharmaceutical substances in the local environment, but the health effects on humans have not been adequately assessed. However, interviews with local communities indicate that people affected by pollution experience negative health impacts such as respiratory problems and chronic skin conditions. Furthermore, the extreme concentrations of antibiotics and the presence of multi-resistant bacteria found in the area have created a potential breeding ground for AMR, which risks causing devastating health impacts locally and globally.

The well-known challenges of pollution from pharmaceutical factories in Hyderabad and the absence of longitudinal studies of potential health impacts call for vigilance from companies manufacturing and sourcing pharmaceuticals in this area, and elsewhere.

Negligence of the precautionary principle is still an issue in pharmaceutical production. Industry initiatives, such as PSCI and AMR Industry Alliance, that seek to improve sustainability in pharmaceutical supply chains and provide sustainable solutions to curb antimicrobial resistance, are steps in the right direction. It should be underlined that focusing on the global risks of AMR is not enough; the industry must also proactively mitigate human rights impacts on local communities caused by pollution from pharmaceutical manufacturing. While medicine is vital to humankind, its production should not risk making people and animals ill.

The current state of environmental pollution in the pharmaceutical supply chain hinders the realisation of SDG 12, which seeks to ensure sustainable consumption and production, as well as other SDG’s including Goal 6 and 3 that see to ensure clean access to water and wellbeing.

Swedwatch’s case study in India confirms that while judicial mechanisms are in place, regulatory mechanisms have failed to respect and protect human rights while duty bearers, including state authorities, have failed to provide effective remediation for those affected by environmental pollution from pharmaceutical manufacturing. In

addition, company measures to facilitate access to clean water have to date only provided temporary solutions for affected communities and do not address the source of the environmental pollution that occurs during the manufacturing processes.

Based on stakeholder interviews in this report, the root causes for the continuing environmental pollution and lack of accountability are the: (1) lack of transparency in pharmaceutical production and supply chains, (2) sole focus on price in the procurement of pharmaceuticals, and (3) lack of comprehensive environmental criteria in legislation on and in procurement of medicinal products. Clearly information on pharmaceutical production and supply chains, even though shared with authorities in importing countries, remain exceptionally opaque to other stakeholders, such as pharmacies and investors, reducing their ability to conduct effective HRDD.

Companies interviewed for this report, in line with the industry at large, were sceptical towards increased transparency regarding contracted suppliers, primarily due to competition and confidentiality reasons. They also argued that GMPs are not the most appropriate frameworks for regulating environmental and social impacts. Integration of environmental criteria in national regulation, public procurement and in the Swedish generic substitution system were considered better options, if adequately implemented.

Other stakeholders interviewed argued that increased transparency and inclusion of environmental criteria in GMPs are key in improving sustainability in pharmaceutical production. Several interviewed stakeholders and published reports also cited intense political lobbying from the industry as a reason for lack of reforms. Furthermore, stakeholders highlighted lack of awareness on the risks of pharmaceutical pollution among the general public and politicians as another reason for lack of action.

What should companies do?

Pharmaceutical manufacturing in Hyderabad takes place in an environment where corruption, weak governance and extensive water usage by manufacturers with a poor track record pose severe human rights risks. According to the UNGPs, a company's responsibility to prevent and mitigate adverse human rights impacts is independent from state actors' obligations to protect human rights. The lack of adequate state measures does therefore not preclude transnational and local pharmaceutical companies from having a responsibility for adverse impacts which the companies have caused or contributed to.

International pharmaceutical companies that are or have been operating or sourcing from the region must assess how they have contributed to the current situation. This includes conducting effective HRDD in line with the UNGPs. Furthermore, the impacts of the companies' own purchasing practices on supplier performance should be reviewed to secure that sustainable business practices are incentivised. Where companies find their leverage over suppliers to be limited, for example due to small purchasing volumes, they should try to increase their leverage by collaborating with other buyers.

Companies must also coordinate across the sector to improve business practices. The precautionary principle should be followed, safe discharge limits should be set, and environmental and human rights compliance should be followed up in own operations and with suppliers. Businesses should proactively communicate how they are addressing the issue of environmental pollution along with the results of their human rights due diligence and publish detailed information on production sites and supply chains.

What should states do?

In order to achieve SDG 12, state and corporate actors must take coordinated action to facilitate the responsible production of pharmaceuticals. States need to ensure that their policies and legislation promote the sound management of chemicals and waste throughout the product life cycle.

Long-term commitments to control and mitigate environmental pollution from pharmaceutical production can help achieve availability and sustainable management of water (SDG 6) and healthy lives and wellbeing for all (SDG 3). Such commitments will help reduce deaths and illnesses from exposure to hazardous chemicals and pollution.

States in manufacturing and importing countries must enforce the rule of law and prevent companies from releasing unsafe pharmaceutical waste during the production process. Furthermore, they will need to enforce the monitoring and assessment of business practices, and foster enabling conditions for companies to reduce and prevent unnecessary emissions and discharge into the environment. Moreover, international and national frameworks such as the GMPs need to consider environmental and social impacts from the entire product cycle. Public actors must take steps to increase transparency in the sector and thereby improve accountability. Furthermore, they must make sure that their purchasing practices incentivise, rather than discourage, sustainable business practices.

States must adopt and enforce legislation ensuring that businesses respect human rights and comply with environmental standards through the whole product cycle of pharmaceuticals. The increasing and aging global population and the emerging threat to global health posed by climate change makes the situation even more urgent. Business as usual imperils the human rights of affected communities, threatens global public health and the global economy, and jeopardises the fulfilment of the SDGs.

Swedwatch calls on all actors, including consumers, to increase their awareness of the issue, and to demand accountability of the actors involved to transform supply chain governance in the pharmaceutical sector. Coordinated efforts are needed to effectively control and mitigate environmental pollution from the production of pharmaceuticals and its subsequent impacts on humankind and the planet.

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