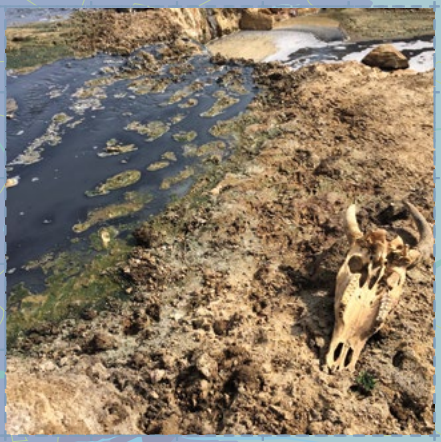
# HYDERABAD'S PHARMACEUTICAL POLLUTION CRISIS:

## HEAVY METAL AND SOLVENT CONTAMINATION AT FACTORIES IN A MAJOR INDIAN DRUG MANUFACTURING HUB



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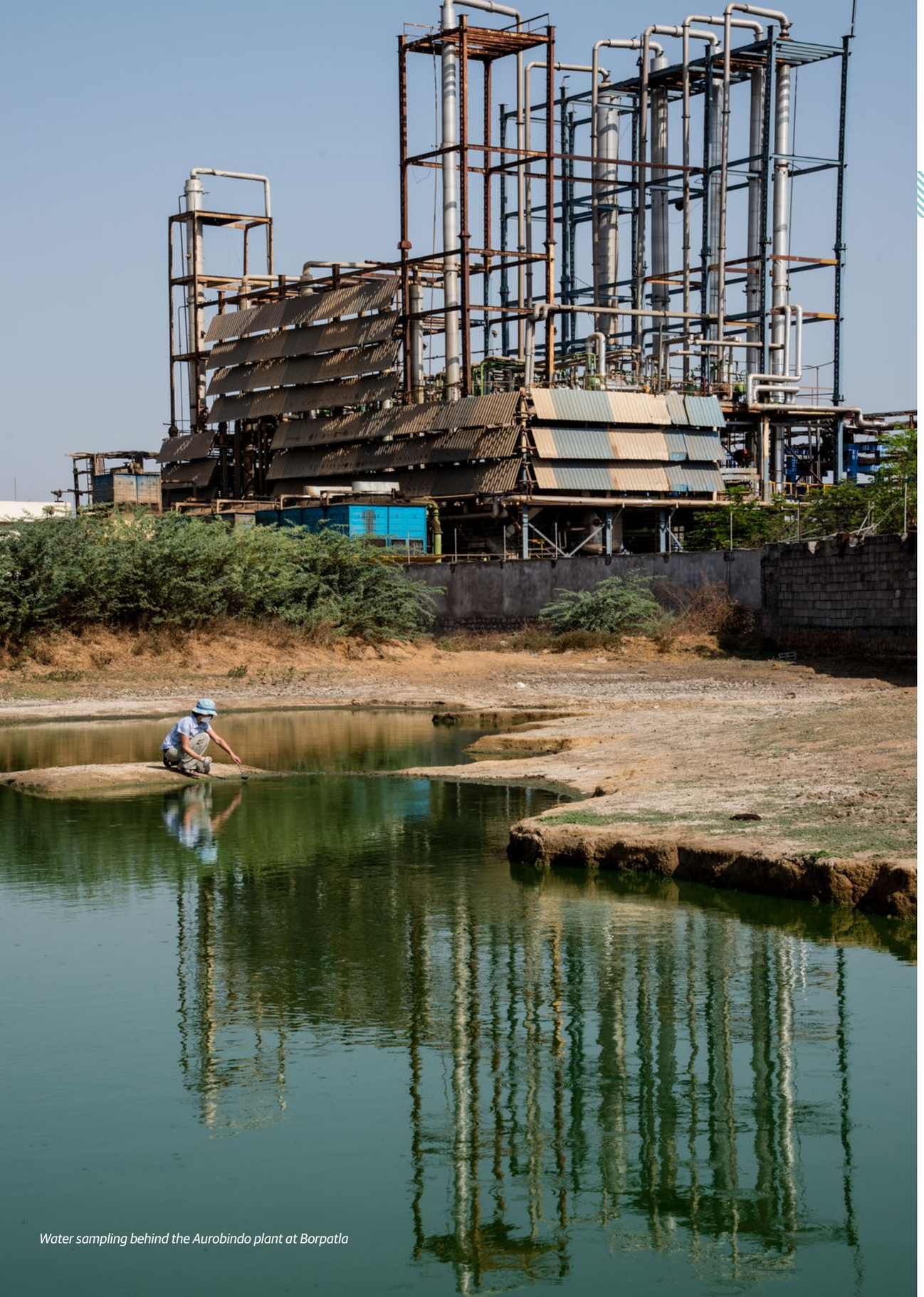


*Water sampling behind the Aurobindo plant at Borpatla*



# Executive Summary

This report explores the impacts of pollution from pharmaceutical production sites in the Indian city of Hyderabad, one of the world's largest "bulk drug" manufacturing hubs, which supplies tonnes of medicines to markets across the European Union and United States every year.

As part of its ongoing engagement with drug companies and their suppliers regarding pollution in the pharmaceutical supply chain, and following the publication of "*Impacts of Pharmaceutical Pollution on Communities and Environment in India*"[1] in March 2016, Nordea commissioned the Changing Markets Foundation to conduct a follow-up investigation in India, the results of which are presented here.

Based on findings from two field trips (one in April 2017, during the dry season, and one in September 2017, during the rainy season), interviews with NGO experts and people living or working in the affected areas as well as in-depth analysis of media coverage and academic studies, this report confirms the findings of the 2016 study by showing that pharmaceutical companies in Hyderabad are continuing to discharge untreated or inappropriately treated wastewater into the environment and that local and national authorities are failing to get the situation under control. It concludes that the situation in Hyderabad has not improved in the past two years – if anything, it has deteriorated. Furthermore, with plans afoot to expand the city's pharmaceutical production capacity over the coming years and the lack of credible regulation and measures to control manufacturing emissions, the future looks grim for the area's inhabitants.

The centrepiece of the report are results from the testing of water samples collected adjacent to pharma factories and some of the city's waterbodies in September 2017 which highlight the occurrence of a range of heavy metals and industrial solvents commonly used in pharmaceutical manufacturing. In some cases, these were found to be present at extremely high concentrations, orders of magnitude higher than maximum regulatory limits or safe exposure levels, which points to substantial human and ecological risk potential.

The mere presence of some of these substances is cause for alarm given their extreme toxicity. In addition, the occurrence of mixtures of chemicals shows a lack of adequate water treatment prior to discharge (or potentially no treatment whatsoever). Depending on the water flow in receiving water bodies, and the distance from the effluent source, the actual concentrations of these chemicals from the discharge source could be many magnitudes greater that the concentrations detected in samples.

These findings come amidst repeated warnings from the scientific community about the dire state of India's water resources. Numerous factors, including climate change, industrial activity and a growing population are placing unbearable pressure on the country's water, drying up rivers and lakes and precipitating a dramatic decrease in groundwater.[2] This is already causing acute social and economic distress which is only predicted to worsen over the coming years. Beyond the evident human health impacts, the corporate sector, including the pharmaceutical industry itself, also depends on a reliable supply of clean water. The effects

# HYDERABAD POLLUTION HOTSPOTS

**Summary of key pollution problems at pharmaceutical sites and water bodies reported in recent studies and the media**

**Aurobindo IA**
Solvents,
Hexavalent Chromium

**MSN Pharmachem (Rudraram)**
Resistant bacteria
antimicrobials

**MSN Pharmachem (Pashamylaram)**
Resistant bacteria,
antimicrobials,

**Mylan VII**
Heavy metals, solvents,
Hexavalent Chromium

**Isnapur Lake**
**Dead fish (over 50,000)**

drug resistant bacteria,
antimicrobials,
heavy metals, solvents,
Hexavalent Chromium

Highest levels of fluconazole ever found in the environment recorded here

**Borewell in Gaddapotharam village**
Heavy metals, solvents
Hexavalent Chromium

**Gaddapotharam Lake**
**Dead fish (1,000)**

**Circular well/tank, Gaddapotharam village**
Drug resistant bacteria, antimicrobials,
heavy metals, solvents, Hexavalent Chromium

**Hetero I**
Heavy metals,
solvents

**Borewell in Kazipally Village**
Solvents

**Effluent channel, Kazipally Village**
Drug resistant bacteria, heavy metals,
solvents, Hexavalent Chromium

**Ramky Hazardous Waste Plant**
Drug resistant bacteria,
heavy metals, solvents,
Hexavalent Chromium

**SMS Pharma Unit I**
Solvents, heavy metals

**Aurobindo III**
Heavy metals,
Hexavalent Chromium

**Gandigudem Cheruvu (lake)**
**Dead fish (230,000)**

In October 2017, almost every fish in Gandigudem lake died. The TSPCB found traces of chloromethane, an industrial solvent used by the pharmaceutical industry, in the fish. Local police registered a criminal case against Aurobindo, Mylan, SMS Pharma, Vantec and Sriram.

The TSPCB issued closure notices to 14 pharmaceutical units, including Lee Pharma, Vivin Laboratories, Kekula Pharma, Total Drugs, Rakshi Pharma and KRS Pharma.

**Dharani Nagar, Kukatpally**
Toxic foam

**Dr Reddy's Plant II**
Heavy metals,
Hexavalent Chromium

**Medchal Lake**
**Dead fish**
**(up to 60,000)**

**Shamirpet Lake**
**Dead fish**
**(up to 60,000)**

**Mylan III**
Heavy metals,
Hexavalent Chromium

**Ramakrishnapuram Lake**
Toxic foam

**Rampally Lake**
**Dead fish (up to 30,000)**

**Hussain Sagar lake**
Toxic foam, drug resistant bacteria,
solvents

**Golnaka I&D**
Drug resistant bacteria,
heavy metals

**Amberpet Sewage Treatment Plant**
Antimicrobials, drug-resistant bacteria

**Edulabad Lake**
Toxic foam,
dead fish (400,000)

**Musi River at Edulabad bridge**
Toxic foam, drug resistant bacteria,
heavy metals

Arutla
Peddakanjerla
Jinnaram
Dundigal
PATANCHERU
Maharajpet
Chinnamangalaram
Medipally
KUKATPALLY
JUBILEE HILLS
BANJARA HILLS
KOMPALLY
Devaryamjal
SHAMIRPET
Muduchintalapalli
Ponnal
Thimmaipalli
KAPRA
HYDERABAD
MOULA ALI
Bogaram
Ghatkesar
Edulabad
Daira
DILSUKHNAGAR

of water stress and pollution therefore present a substantial material risk for businesses operating or using suppliers in India.

India's Environment Ministry classifies pharmaceutical manufacturing as a "red category" activity owing to the hazardous waste it produces. Successive studies have shown that air, water and soil in Telangana state (of which Hyderabad is the capital) are significantly contaminated by toxic chemicals and heavy metals such as copper, lead, mercury and arsenic. One 2001 article recommended that "Most of the soils should be removed from agricultural production" in Patancheru, the industrial area on the outskirts of Hyderabad where many of the city's pharmaceutical factories are situated.[6] A report published in the Journal of the Geological Society of India in October 2017 showed that groundwater in the Nalgonda district to the east of Hyderabad contains toxics including lead, cadmium, vanadium and arsenic "in concentrations that are thousands of times higher than the maximum levels prescribed for drinking water quality by the World Health Organisation (WHO) and Bureau of Indian Standards (BIS)."[7] The paper reported that one likely origin of the pollution is "the release of reactive pollutants into the atmosphere by industries", listing the pharmaceutical industry as one of the area's key 'anthropogenic' activities.[8]

Pharmaceutical pollution, whether from the excretion of drugs or industrial activity, carries specific dangers for human health and ecosystems ranging from the near elimination of entire species[9] to the feminisation of fish[10] and the spread of antimicrobial resistance (AMR). Furthermore, pharmaceutical manufacturing also uses large quantities of solvents – which are often highly toxic chemicals – and heavy metals, whose long-lasting impacts on human health have been proven and whose use is therefore regulated in many countries.

Of particular relevance here, a series of studies over the past decade have linked uncontrolled manufacturing discharges from antibiotics factories in Hyderabad with the spread of AMR, a global health threat which could kill more people than cancer by 2050.[11] In its *Frontiers 2017. Emerging Issues of Environmental Concern* report, UN Environment identifies growing AMR linked to the discharge of drugs and particular chemicals into the environment as one of the most worrying health threats today[12], noting the role that heavy metals can play in "co-selecting" for drug-resistant bacteria alongside high concentrations of Active Pharmaceutical Ingredients (APIs).[13] At the report's launch, UN Environment Executive Director Erik Solheim drew particular attention to a pharmaceutical facility in Hyderabad, where testing of discharged water revealed that the concentration in the treated wastewater of ciprofloxacin, a vital broad-spectrum antibiotic, was strong enough to treat 44,000 people. [14]

Because of the globalised nature of today's pharmaceutical industry and inter-connected world where disease and drug resistance can spread rapidly, what happens in India concerns us all.

## Key messages:

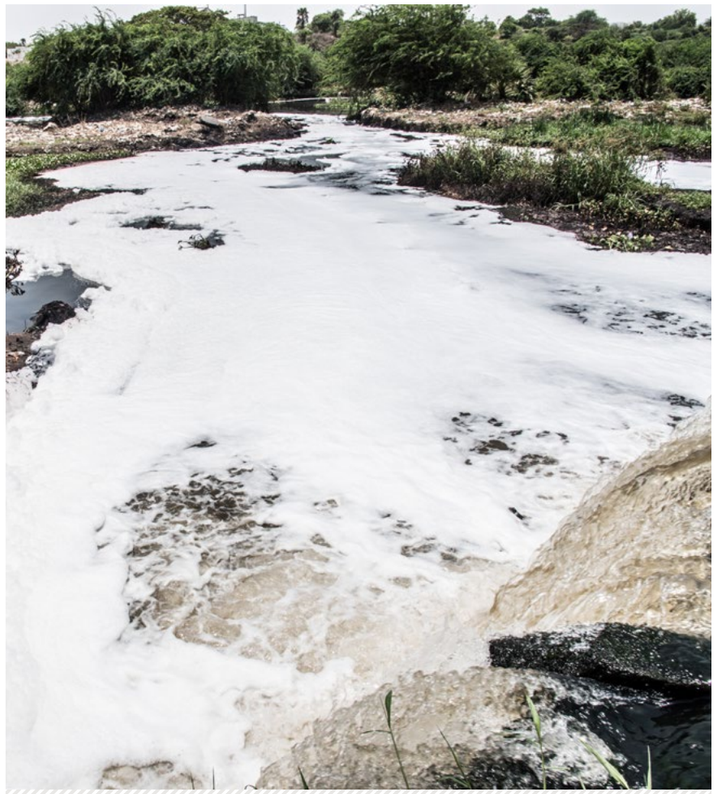
- Despite decades of campaigning by local and international NGOs and successful legal challenges at the highest Indian courts, the situation on the ground has not improved and pharmaceutical pollution is still rife in Hyderabad, affecting ecosystems and the human rights of local inhabitants. Given that a large share of these pharmaceuticals is manufactured for and sold to European and US health providers and pharmaceutical companies, it is clear that this is a supply chain issue that must be addressed in an appropriate way by the purchasers of these drugs.

- Pollution from antibiotics production is particularly problematic because it fuels the spread of antimicrobial resistance (AMR), which can easily travel far beyond India's borders. For instance, a 2010 study by Swedish researchers showed that seven out of eight travellers to India returned to Sweden carrying drug-resistant bacteria in their gut.[15] Many pharma manufacturers in Hyderabad produce antibiotics in addition to other generic ('bulk') drugs and irresponsible production practices could be an additional factor fuelling a major global health crisis.

- The pharmaceutical industry is not being adequately held to account by the Indian Government or regulators. In fact, recent developments indicate that regulation targeting the pharmaceutical industry is actually becoming more lax, and pollution levels are set to rise even further, as the government lifts restrictions on plant expansion[16], and weakens national pollution index (Comprehensive Environmental Pollution Index, or CEPI) indicators.[17]

- In Europe and the United States, pharmaceutical pollution, particularly in relation to the spread of AMR, is receiving increased attention and policy responses to address the problem are under consideration. For example, in its response to the Review on Antimicrobial Resistance's final report, published in May 2016[18], the UK Government recommended the establishment of targets for maximum levels of antimicrobial API discharge associated with the manufacture of pharmaceutical products and urged pharmaceutical companies to improve monitoring of API emissions from directly-operated manufacturing facilities as well as those of third party suppliers, and support the installation of proper waste processing facilities to reduce or eliminate API discharge.[19] In another significant move, the Access to Medicine Foundation's Antimicrobial Resistance Benchmark 2018 compares company strategies and processes relating to wastewater management. The Foundation will use this data to further the discussion on the role of manufacturing in the environmental impact of antibiotic production.[20]

- By failing to crack down on manufacturing emissions, Indian pharma manufacturers risk jeopardising supply contracts with companies and procurement bodies in Europe, the US and other regulated markets. For example, European NGOs have recently called for major procurement bodies including the UK's National Health Service (NHS), German health insurance companies, and French hospitals to blacklist the worst offending polluters and embed environmental criteria in all contracts with pharmaceutical suppliers.[21] Several of these organisations are now reviewing the situation. In Sweden, the country's regions have come



***A 2011 report found that almost 70 percent of India's surface water resources and a growing percentage of its groundwater reserves are contaminated by biological, toxic, organic, and inorganic pollutants.[3] By 2015, this figure had risen to 75-80 percent based on official statistics.[4] Furthermore, an assessment by the country's Central Pollution Control Board (CPCB) reported that the number of rivers defined as "polluted" in India had more than doubled in the previous five years, from 121 to 275.[5]***

*Frothing effluent stream emptying into the Musi River near Edulabad village*

## Overview of results from recent studies investigating pharmaceutical pollution in Hyderabad

| Locations | Sampling sites | Findings from Gothwal and Shashidhar paper (2016) | Changing Markets investigation (October 2016) | Findings from Lübbert study in Infection journal (2017) | Changing Markets investigation (September 2017) |
|---|---|---|---|---|---|
| | | *Tested for concentration of antimicrobials* | *Tested for bacteria resistant to specific antibiotics* | *Tested for drug-resistant bacteria and concentration of antimicrobials* | *Tested for heavy metals and solvents (heavy metals indicated were found at levels above regulatory limits, as were many solvents)* |
| Bachupally / Jeedimetla | Mylan III | – | – | – | Hexavalent Chromium, Zinc, Nickel, Copper |
| | Aurobindo III | – | – | – | Zinc, Hexavalent Chromium, Nickel |
| Borpatla Zone | Aurobindo IA (site perimeter) | – | – | – | Hexavalent Chromium, Nickel , Solvents |
| Rudraram Zone | MSN Pharmachem (Rudraram) | – | – | Resistant bacteria and antimicrobials detected | – |
| | MSN Pharmachem | – | – | Resistant bacteria and antimicrobials detected | – |
| Pashamylaram Zone | Isnapur Lake | – | Resistance to cephalosphorins and fluoroquinolones detected | Resistant bacteria and antimicrobials detected (including highest reading of fluconazole ever recorded in the environment) | Arsenic, Nickel, Zinc, Hexavalent Chromium, Solvents |
| | Mylan VII | – | – | – | Arsenic, Nickel, Zinc, Hexavalent Chromium, Solvents |
| Patancheru/ Bollaram Zone | Dr Reddy's II | – | – | – | Nickel, Zinc,Hexavalent Chromium |
| Gaddapotharam Zone | Mylan I | – | Resistance to cephalosphorins and fluoroquinolones detected at large lake in vicinty of plant | – | – |
| | Borewell in Gaddapotharam village | – | – | – | Zinc, Hexavalent Chromium, Solvents Arsenic, Cadmium |
| | Circular well/tank Gaddopatharam | – | Resistance to fluoroquinolones detected | Resistant bacteria and antimicrobials detected | Arsenic, Nickel, Hexavalent Chromium, Solvents, Zinc |
| | Ramky Hazardous Waste Plant | – | Resistance to cephalosphorins detected | – | Arsenic, Cadmium, Nickel, Hexavalent Chromium, Solvents |
| Gaddapotharam Zone | Hetero I | – | – | – | Arsenic, Nickel, Hexavalent Chromium, Solvents |
| | Borewell in Kazipally Village | – | – | – | Solvents |
| | SMS Pharma Unit 1 | – | – | – | Arsenic, Nickel, Solvents |
| | Effluent channel, Kazipally Village | – | Resistance to cephalosphorins and fluoroquinolones detected | – | Arsenic, Nickel, Zinc, Hexavalent Chromium, Solvents |
| Bonthapally Zone | Hetero | – | Resistance to cephalosphorins detected | – | – |
| Central Hyderabad | Hussain Sagar Lake (channel leading to Golnaka I&D) | – | Resistance to cephalosphorins and fluoroquinolones detected | – | Hexavalent Chromium, Solvents |
| | Hussain Sagar Lake (nallah) | – | Resistance to cephalosphorins and fluoroquinolones detected | – | Cadmium, Nickel, Zinc, Hexavalent Chromium, Solvents |
| | Golnaka I&D | – | Resistance to cephalosphorins and fluoroquinolones detected | – | – |
| | Amberpet STP side outlet | – | Resistance to cephalosphorins, carbapenems and fluoroquinolones detected | – | – |
| | Amberpet STP discharge pipemouth | 7 types of fluoroquinolones detected (including extremely high levels of ciprofloxacin) | Resistance to cephalosphorins, carbapenems and fluoroquinolones detected | – | – |
| Musi/ Edulabad Zone | Musi tributary at Edulabad bridge | – | Resistance to cephalosphorins, carbapenems and fluoroquinolones detected | – | Hexavalent Chromium |
| | Paddy field near Musi | 7 types of fluoroquinolones detected | – | – | – |
| Polepally Zone | Aurobindo Unit VII | – | Resistance to cephalosphorins, carbapenems and fluoroquinolones detected | – | – |

together and introduced environmental criteria and audits in their contracts.[22]

After many decades of inaction, it is encouraging to see that the dangers linked to pollution from pharmaceutical manufacturing are beginning to receive the attention they deserve; the negative impacts of uncontrolled pharmaceutical manufacturing discharges have been clearly exposed as a supply chain problem that must be resolved between manufacturers in third countries and their clients in key export markets. However, despite recent moves by some pharmaceutical companies to start moving towards more responsible production, the industry and regulators are not moving fast enough to address a threat of such magnitude. Multinational pharmaceutical companies which outsource API production to Indian suppliers have a duty to take rapid action to put a stop to pollution in their supply chains. Governments and medical agencies must change the way drug manufacturing is currently regulated and include environmental criteria in Good Manufacturing Practices (GMP) to ensure that manufacturers address wastewater treatment.

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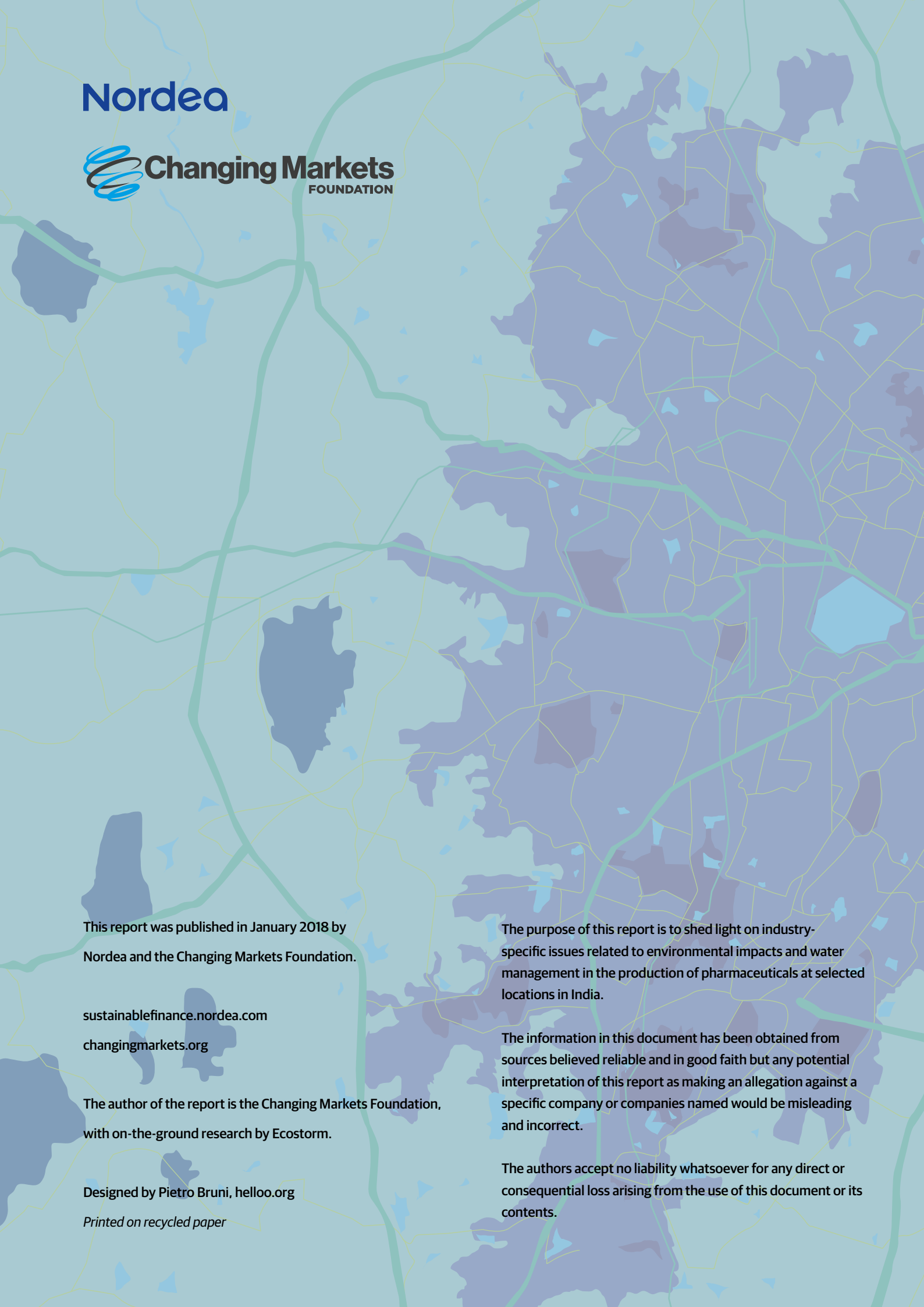

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The purpose of this report is to shed light on industry-specific issues related to environmental impacts and water management in the production of pharmaceuticals at selected locations in India.