HYDERABAD’S PHARMACEUTICAL POLLUTION CRISIS:

HEAVY METAL AND SOLVENT CONTAMINATION AT FACTORIES IN A MAJOR INDIAN DRUG MANUFACTURING HUB
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” 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 than 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. 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...
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 Srim. The TSPCB issued closure notices to 14 pharmaceutical units, including Leo Pharma, Vivin Laboratories, Kekula Pharma, Total Drugs, Rakshi Pharma and KRS Pharma.

The highest levels of fluconazole ever found in the environment were recorded here.
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. 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 toxic 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)." 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.

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 to the feminisation of fish 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. 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, noting the role that heavy metals can play in "co-selecting" for drug-resistant bacteria alongside high concentrations of Active Pharmaceutical Ingredients (APIs). At the report’s launch, UN Environment Executive Director Erik Solheim drew particular attention to a pharmaceutical facility in Hyderabad, where testing of discharging water revealed that the concentration in the treated wastewater of ciprofloxacin, a vital broad-spectrum antibiotic, was strong enough to treat 44,000 people.

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

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. By 2015, this figure had risen to 75-80 percent based on official statistics. 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.

Frothing effluent stream emptying into the Musi River near Edulabad village

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. 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, and weakens national pollution index (Comprehensive Environmental Pollution Index, or CEPI) indicators.

• 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, 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. 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.

• 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. Several of these organisations are now reviewing the situation. In Sweden, the country’s regions have come
### Overview of results from recent studies investigating pharmaceutical pollution in Hyderabad

<table>
<thead>
<tr>
<th>Locations</th>
<th>Sampling sites</th>
<th>Tested for concentration of antimicrobials</th>
<th>Tested for bacterial resistance to specific antibiotics</th>
<th>Tested for heavy metals and solvents (including highest levels above regulatory limits)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gaddapotharam Zone</td>
<td>Mylan III</td>
<td>Hexavalent Chromium, Zinc, Nickel, Copper</td>
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<td>Aurobindo III</td>
<td>Zinc, Hexavalent Chromium, Nickel</td>
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<td>Rudramram</td>
<td>Resistance to cephalosphorins detected</td>
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<td>Resistance to cephalosphorins and antimicrobials detected (including highest levels above regulatory limits)</td>
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<td>Musi tributary at Edulabad bridge</td>
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<td>Resistance to cephalosphorins and antimicrobials detected (including highest levels above regulatory limits)</td>
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<td>Ambarpet STP discharge outlet</td>
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<td>Resistance to cephalosphorins and antimicrobials detected (including highest levels above regulatory limits)</td>
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<td></td>
<td>Musi/ Edulabad Zone</td>
<td>Resistance to cephalosphorins detected</td>
<td></td>
<td>Resistance to cephalosphorins and antimicrobials detected (including highest levels above regulatory limits)</td>
</tr>
<tr>
<td></td>
<td>Paddy field near Musi</td>
<td>Resistance to cephalosphorins detected</td>
<td></td>
<td>Resistance to cephalosphorins and antimicrobials detected (including highest levels above regulatory limits)</td>
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<tr>
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<td>Aurubindo Unit VIII</td>
<td>Resistance to cephalosphorins detected</td>
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<td>Resistance to cephalosphorins and antimicrobials detected (including highest levels above regulatory limits)</td>
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Hyderabad's pharmaceutical pollution crisis

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. Multi-national 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.

References

4. Times of India, 28.06.2015, 80% of India’s surface water may be polluted, report by international body says: https://timesofindia.indiatimes.com/home/environment/pollution/80-of-India-surface-water-may-be-polluted-report-by-international-body-says/articleshow/37448532.cms
5. The Guardian, 07.04.2015, Half of India’s rivers are polluted, says government report https://www.theguardian.com/world/2015/apr/07/half-india-rivers-polluted-new-government-report
13. The Active Pharmaceutical ingredient is the “biologically active” component of a drug, i.e. the component which makes it the desired effect
21. See for example letter from Changing Markets and Health Action International to the Chief Executive of NHS England, which was also sent to all Chief Execs of NHS Trusts and the UK’s Minister for Health in November 2016. Responses received indicate that this is viewed as a serious concern and that action could be taken to restrict polluting companies’ access to supply contracts: http://haiweb.org/wp-content/uploads/2016/11/Letter-to-Chief-Executive-NHS-England-on-Pharma-Pollution.pdf
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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.

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