



IMPACTS OF PHARMACEUTICAL POLLUTION ON COMMUNITIES AND ENVIRONMENT IN INDIA

RESEARCHED AND PREPARED FOR NORDEA ASSET
MANAGEMENT BY CHANGING MARKETS AND ECOSTORM

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Executive Summary

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India is in the grip of a severe water pollution crisis. A 2015 report from the Indian Government estimates that the number of contaminated waterways has more than doubled in the past five years and that half of the country's rivers are now polluted¹. A variety of factors have contributed to this critical situation, notably the staggering quantities of untreated sewage generated in this country of nearly 1.3 billion people. Another major cause is industrial pollution, the dark side of India's economic development.

In recent decades India's pharmaceutical industry has scaled new heights in step with a steady rise in population and thanks to its reputation as a low-cost manufacturing destination for multinational drug companies. In particular, its bulk drug production sector, which has a major hub in the southern Indian city of Hyderabad and a more recent presence along the coastline of Andhra Pradesh, has experienced a rapid ascent since the 1970s. While this has yielded obvious economic benefits for both Indian and overseas-based firms, as well as dividends for shareholders, scant attention has been paid to the impact of increased pharmaceutical production on the environment and inhabitants living in proximity to factories and industrial parks.

The emergence of a globalised pharmaceutical sector, which accelerated in the wake of the World Trade Organisation's agreement on trade-related

aspects of intellectual property rights (TRIPs) in 1994, has given rise to a sophisticated and geographically dispersed industry reliant on a highly complex supply chain network comprising thousands of suppliers worldwide.² Outsourcing of production to the emerging markets, where labour is cheap, workforces skilled, and environmental standards lax, has now become second nature for the pharmaceutical majors, many of which are based in the United States and Europe.

Indeed, the vast majority of the world's drugs are now manufactured in India and China. While China has become the dominant supplier of the Active Pharmaceutical Ingredients (APIs)^A used to make medicines, India has a sizeable share of API production itself, and has also carved out a niche in processing drugs, which it ships to markets around the world as finished products.

Pharmaceutical supply chains are as opaque as they are complex and while it is relatively easy to describe broad trends, granular detail is hard to come by. Information about the origin of APIs and the finished products that end up on our pharmacy shelves is kept confidential by drug firms, which are unwilling to open up their supplier relationships to public scrutiny. Regulators, who could easily demand greater transparency from the pharmaceutical industry, have so far shied away from taking action.

A The U.S. International Trade Commission defines APIs as "the primary, active ingredient(s) of a final pharmaceutical product, produced in the first stage of pharmaceutical production and usually in bulk quantities." (U.S. ITC, 2007). In this report they are largely synonymous with the term "bulk drug."



Close-up of effluent by the Hetero plant in Gaddapotharam

There are several elements to consider when assessing the pharmaceutical sector's environmental footprint. One is the energy used during production and processing. Another is the generation of waste-solid, liquid or airborne - from the manufacturing process. While pharmaceutical contamination of water has only recently permeated the public consciousness, it has been on the scientific community's radar for decades. There is now a compelling body of research on the negative effects resulting from the accumulation of pharmaceuticals in the environment, which range from the near elimination of entire species³ to the feminisation of fish⁴ and the spread of antimicrobial resistance (AMR).

This report looks at the latter aspect, focussing on the major public health threat posed by pollution from antibiotics manufacturing plants in India, which is believed to be contributing to soaring drug resistance rates in the country and further afield. This has serious implications for global health as antibiotic resistance genes spread around the world through travel and trade with India.

Based on evidence from an on-the-ground investigation in the southern Indian states of Telangana and Andhra Pradesh in early 2016, as well as thorough analysis of industry data and the latest academic research, this report documents local impacts of drug pollution including extreme

contamination of waterways and agricultural lands - and identifies some of the key players at the root of the problem. It draws links between polluting manufacturers and some of the large multinational pharmaceutical companies they have dealings with, highlighting the need to establish and implement strong environmental standards at every stage of the supply chain.

As is explored at length in this report, people living in the vicinity of dirty pharmaceutical manufacturing sites, who are often poor and reliant on subsistence farming, are those whose health is at most immediate risk from the toxic effluents and API-laden waste being deposited in their rivers, lakes, groundwater and fields. However, because of the way in which antibiotic manufacturing discharges trigger resistance in bacteria present in the environment, spreading to human pathogens which then travel the world, antibiotic pollution puts everyone at risk, wherever they live. This is why AMR is often compared to climate change, given the scale of the challenge it poses, and the coordinated global response which is required to tackle it.

AMR: a major global health threat associated with pharmaceutical pollution

The World Health Organisation's 2014 report on global surveillance of antimicrobial resistance revealed that "antibiotic resistance is no longer a prediction for the future; it is happening right now, across the world, and is putting at risk the ability to treat common infections in the community and hospitals."¹⁹ The WHO and other eminent global health experts warn that we are at the dawn of a 'post-antibiotic era', which will result in millions of fatalities every year. The UK's Independent Review on AMR projects a death toll of 10 million people per annum by 2050 if resistance is left unchecked, with a cost of up to \$100 trillion. This is a conservative estimate, which only takes into account part of the impact of AMR.²⁰

Rising resistance is taking a devastating toll on the Indian population, particularly the most vulnerable members of society. The first 'State of the World's Antibiotics' report published by the Washington-based Center for Disease Dynamics, Economics and Policy (CDDEP) in 2015 noted that 58,000 newborn babies in India died in 2013 as a result of drug-resistant infections, while Indian drug resistance rates for several major pathogens is on the increase.^B

Key causes of antibiotic resistance are inappropriate use of antibiotics in humans and overuse in intensive animal farming. Another, often overlooked cause, is pollution resulting from the pharmaceutical manufacturing process itself.

AMR is viewed by experts as one of the major threats to human health emerging from pharmaceutical pollution. Indeed, a 2013 report by the European Agency for Health and Consumers notes that "*Without any doubt, the development of AMR is by far the largest risk for humans of having medicinal products residues in the environment*"^C

As the AMR review stated in its watershed report on the environmental dimension of AMR at the end of 2015, pollution from the production of antibiotics "needs to be viewed as a straightforward issue of industrial pollution, and it is the responsibility of all actors in the supply chain to ensure that industrial waste is treated properly as a matter of good manufacturing practice."^D

B. CDDEP, 2015, State of the World's Antibiotics 2015, http://cddep.org/publications/state_worlds_antibiotics_2015#sthash.BmYsUzGz.dpbs
C. Executive Agency for Health and Consumers, 12.12.2013, Study on the environmental risks of medicinal products, http://ec.europa.eu/health/files/environment/study_environment.pdf
D. AMR Review, 08.12.2015, Antimicrobials in Agriculture and the Environment, <http://amr-review.org/sites/default/files/Antimicrobials%20in%20agriculture%20and%20the%20environment%20-%20Reducing%20unnecessary%20use%20and%20waste.pdf>

Apparent effluent pollution of large lake by Bollaram industrial area



India's pharmaceutical industry:

A geographically diverse, export-oriented sector with strong growth prospects

India is one of the world's leading suppliers of generic drugs, with generic drug revenues of US\$15 billion in 2014.

Over half of India's pharmaceutical exports are to highly regulated markets such as the U.S. and the EU.

Anti-infectives, which include antibiotics, antivirals and antifungals, are the largest segment on the domestic market, accounting for one-quarter of total turnover.

Multinational drug companies have flocked to Hyderabad, Visakhapatnam, and other manufacturing hubs since India opened its economy to overseas players in the mid-2000s. Some of the larger Indian firms are also competing at the global level.

India's Environment Ministry classifies pharmaceutical manufacturing as a "red category" activity owing to the hazardous waste it produces.

In 2009, a report by India's Central Pollution Control Board identified Visakhapatnam as being the most polluted industrial area in the state of Andhra Pradesh. Undeterred, the Bulk Drug Manufacturers Association recently called on the government of Andhra Pradesh to allot between 6,000 and 10,000 acres for the establishment of two pharmaceutical parks along the coast of Andhra Pradesh, in the vicinity of Visakhapatnam.

Telangana has proposed to set up India's largest integrated pharmaceutical city spread over 11,000 acres near Hyderabad, complete with effluent treatment plants and a township for employees, in a bid to attract investment of Rs 30,000 crore (\$4.5 billion) in phases.

Hyderabad, which is known as the bulk drug capital of India, accounts for nearly a fifth of India's pharmaceutical exports, netting revenues of \$15 billion in 2014. The Patancheru-Bollaram manufacturing hub on the outskirts of Hyderabad is one of the most polluted industrial areas in India. The bulk drug manufacturing industry is one of the main polluters in the cluster.

The pharmaceutical industry is one of the fastest growing segments of the Indian economy and has experienced rapid and sustained expansion since the second half of the 20th Century. The market is expected to grow to \$100 billion by 2025.

The sector is geographically fragmented, located in various clusters around India, including Hyderabad in the southern state of Telangana, Andhra Pradesh, Himachal Pradesh, Maharashtra, Gujarat, Madhya Pradesh, West Bengal, Tamil Nadu, Karnataka and Punjab. Hyderabad is considered to be the bulk drugs capital of the country. Overwhelmed by the manufacturing might of China, which is flooding the Indian market with pharmaceutical APIs, a new drive to boost India's bulk drug industry was announced in 2015, with a high-level committee recommending the establishment of large manufacturing zones or "mega parks" across the country.

The states identified on this map all contain major pharmaceutical manufacturing hubs. Given the prevalence of the industry across India, it is not an exhaustive representation.

PART 1 - The Indian Pharmaceutical Industry

I. The expansion of the Indian bulk drug industry

The pharmaceutical industry is one of the fastest growing segments of the Indian economy⁸ and has experienced rapid and sustained expansion since the second half of the 20th Century.⁹ A 2010 report by McKinsey and Company predicted high growth rates in the sector, with turnover increasing from \$12.6 billion in 2009¹⁰ to a projected \$55 billion by 2020, with the potential to reach \$70 billion in an "aggressive" growth scenario.¹¹ Even under a "pessimistic" scenario characterised by regulatory controls and economic slowdown, McKinsey expected the market to reach \$35 billion by 2020. The India Equity Brand Foundation (IBEF), a body set up by the country's Ministry of Commerce and Industry, estimates that industry revenues will expand at a rate of 12% per annum between 2012-20 to reach \$45 billion, outperforming its global competitors by a wide margin to hit \$100 billion by 2025.

Up until the 1970s, the majority of India's medicines were supplied by international corporations, with the domestic, mainly state-owned, industry producing cheap bulk drugs with the support of the WHO.¹³

From the 1970s onwards, changes to the country's patent laws to make medicines affordable to the poor,¹⁴ combined with the growth in contract manufacturing and outsourcing by multinational companies (MNCs) to low-cost Indian suppliers led to the rapid development of India's generic drugs sector, often described as the "backbone" of the country's pharmaceutical industry.¹⁵

Today, India is one of the world's leading suppliers of generic drugs, which account for approximately 75 per cent of its market by volume¹⁶ and revenues of \$15 billion in 2014.¹⁷ The country is responsible for around one-fifth of the world's production of

generics,¹⁸ which is considerably higher than its share the overall pharmaceuticals market (which stands at approximately 2%).¹⁹ India's Bulk Drugs Manufacturers Association describes the sector's recent growth as "phenomenal" and "one of the highest among the developing countries."²⁰ Anti-infectives, which include antibiotics, antivirals and antifungals, are the largest segment on the domestic market, accounting for around one-quarter of total turnover.²¹

Indian pharmaceutical manufacturing companies are present at each stage of the production process: APIs; pharmaceutical formulation intermediates (PFIs); and finished dose products (FDPs, the end product). PFIs are the intermediate product between an API and a finished dose. An API is the base ingredient of medicine that is biologically active, and the term bulk active (or bulk drugs/ingredients) is also used. Some Indian companies specialise in one or two of these three stages, while large vertically integrated firms such as Dr Reddy's and Ranbaxy cover all the stages

India imports around \$3.5 billion worth of APIs every year, mostly from China.²² These APIs, manufactured at very low cost in China²³, are processed by Indian companies and many are then sold on to foreign markets as 'finished dose products' (FDPs). India is a major supplier to the U.S.^E, Europe and other developed economies, not to mention Africa and other countries in Asia. This means that a substantial share of Chinese-origin APIs end up in products sold on the global market.

Industry representatives and government officials in India have expressed concern at the country's over-reliance on API imports from China, which they see as undermining the domestic industry. They also point to India's lack of a physical inspection mechanism to monitor Chinese sites for supplies into India, with approvals from the regulatory agency simply based on "written declarations on

E According to a report submitted to the U.S. Congress in late 2014, Indian customs data show that China's share of India's organic chemical imports and the U.S. share of India's drug exports have both risen over the past decade (see: China Economic and Security Review Commission, November 2014 Report to Congress).

a form."²⁴ Because of the export-oriented nature of the Indian drug industry, this implies that a majority of medicines available on the U.S. and European market contain APIs from factories in China and India where manufacturing conditions are substandard. This issue was explored in a 2015 report by the NGO SumOfUs which highlighted a number of pollution scandals at pharmaceutical manufacturing plants in China.²⁵ Antibiotic APIs are among the products for which India is dependent on Chinese imports.²⁶ Nonetheless, the country retains a sizeable share of antibiotic manufacturing and processing in locations dotted across the country. The southern Indian states of Telangana and Andhra Pradesh are a major hub for bulk drug manufacturing, which comprises a significant share of antibiotic production and processing.

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The lack of transparency in pharmaceutical supply chains makes it almost impossible to map the journey of a pharmaceutical product from factory to pharmacy shelf. Measuring a drug's environmental impact is particularly challenging where various stages of production are outsourced to suppliers in under- or poorly regulated markets. U.S. and EU regulations in the shape of the Good Manufacturing Practice framework (GMP) focus on drug safety but do not currently oblige companies to put in place environmental safeguards when producing their drugs, as is explained further below. Facilities in India and China that export to Western markets are hence regularly inspected, but these inspections are not allowed to sanction a factory for polluting practices, lack of waste water treatment or any other environmental problems the verification of these depends exclusively on local governments

The SumOfUs report shed some light over the antibiotics supply chain, exploring the relationship between polluting API factories in China and processing plants in India, which between them supply the majority of antibiotics (around 80 per cent) sold by multinational pharmaceutical companies on the global market. However, the report also called for greater transparency in

pharmaceutical supply chains in light of the difficulty involved in establishing links between companies, and the fact that polluting factories in the developing world seem to be acting in impunity.²⁷

II. The emergence of Hyderabad and Visakhapatnam as poles of bulk drug manufacturing

The Indian pharmaceutical industry is highly fragmented, with more than 20,000 registered manufacturing units nationwide.²⁸ It is also geographically dispersed: production takes place in multiple locations across the country, with the states of Maharashtra, Gujarat, Telangana, Andhra Pradesh, West Bengal and Tamil Nadu all registering a sizeable manufacturing and processing presence.²⁹ The city of Hyderabad in Telangana state, which was part of Andhra Pradesh until its division into two separate states in 2014,³⁰ emerged early on as a pole of bulk drug manufacturing.

In 1961, Indian Drugs and Pharmaceuticals Limited (IDPL), a government-owned company, was set up under the premiership of Jawaharlal Nehru with a mandate to "free India from dependence on imports and to provide medicines to the millions at affordable prices."³¹ Its establishment in Hyderabad (it also has offices in New Delhi and Rishikesh, Uttarakhand state) heralded the emergence and subsequent concentration of the generic drug industry in the city.³² A number of IDPL employees subsequently established their own companies, which now rank among India's leading pharmaceutical firms, including the founder of Dr Reddy's, one of India's largest drug companies.³³

Indira Gandhi, who represented the outlying Medak District constituency as a Member of Parliament in the 1980s was a keen proponent of the area's industrialisation.³⁴ Over the following years, the bulk drug industry grew from strength to strength from its stronghold on the outskirts of Hyderabad. Unfortunately, the same cannot be said for the environment and the health of local inhabitants,

which have suffered severe and sustained negative impacts as a result of the pharmaceutical industry's unbridled expansion in Telangana and Andhra Pradesh.

Hyderabad, which is known as the "bulk drug capital" of India, accounts for nearly one-fifth of India's pharmaceutical exports.³⁵ The city's Patancheru-Bollaram cluster, which is part of the Medak District, is home to a variety of industries³⁶ including over one hundred drug manufacturing units. It is the source of severe water pollution, and has on two separate occasions (in 2010 and 2013) been subject to a ban on further expansion by the Indian Ministry of Environment and Forests (MoEF) owing to its status as a 'critically polluted' area.³⁷ Several studies, including a detailed survey by Greenpeace in 2004³⁸ have highlighted the many ways in which people, animals, crops and land in the Medak District and other industrial zones surrounding Hyderabad have been afflicted by the pollution.

In recent years, Visakhapatnam, on the coast of Andhra Pradesh has emerged as a rival to Hyderabad's dominance of the bulk drug industry in the region. While its pharmaceutical industry is less developed compared to Hyderabad's, the Andhra Pradesh state government has big plans for the future and evidence gathered for this report clearly shows that waste from existing plants has already taken a significant toll on local villages and

fish stocks. Indeed, in 2009, a report by India's Central Pollution Control Board (CPCB) containing the Comprehensive Environment Pollution Index (CEPI) identified Visakhapatnam as being the most polluted industrial area in the state of Andhra Pradesh, closely followed by the Patancheru-Bollaram cluster.³⁹

In November 2015, drug makers in Telangana and Andhra Pradesh dominated a list issued by India's Central Pollution Control Board (CPCB) revealing the names of companies which had not responded to directions regarding the installation of continuous online pollution monitoring devices at their sites. In total, 59 companies from Telangana (45 located in Hyderabad's Medak District), and 13 from Andhra Pradesh (6 located in Visakhapatnam) failed to comply with the CPCB's request, an 'oversight' which the CPCB stated would result in the plant in question being shut down.⁴⁰ Two of the Telangana plants belong to SMS Pharmaceuticals, a company which in 2012 was issued with a closure order by the Andhra Pradesh Pollution Control Board (APPCB) in the interest of protecting public health and the environment, and on the grounds that it was violating the orders of the Supreme Court of India.⁴¹

Multinational pharmaceutical companies many of them headquartered in the U.S. and European Union have flocked to Hyderabad, Visakhapatnam, and other pharmaceutical manufacturing hubs since India moved to open its economy to overseas

F List of pharmaceutical companies from Telangana which did not respond to the CPCB's directions:

- Innogent Laboratories Pvt. Ltd; Gennex Pharmaceuticals Ltd; Sreekara Organics; Hexagon Drugs Laboratories; Tekbond Laboratories Pvt Ltd; Sudershan Drugs & Intermediate Ltd; Jupiter Bio Sciences Pvt Ltd; Maitthri Laboratories; Yag Mag Labs Pvt Ltd; South Whale Chemicals; Eshwar Pharmaceuticals; KRR Drugs & Intermediates Pvt Ltd; Vayajyanthi Drugs Pvt Ltd; Sri Gayathri Drugs Pvt Ltd; Auctus Pharmaceuticals Ltd; RMS Research Labs; Vivimed Labs; Fleming Laboratories Pvt Ltd; Arene Life Sciences Ltd; Chromo Laboratories India Pvt; Hitesh Chemicals Pvt; Everest Organics Ltd; SV's Remedies; S.S. Oraganic Ltd; Sriitha Chems Pvt; Auctus Pharma; Anu's Laboratories Limited; Srinivasa Organics; SMS Pharmaceuticals Ltd; Artemis Biotech Ltd; Dymes Pharmachem Ltd; SMS Pharmaceuticals Ltd; Vivin Laboratories (P) Ltd; Medchal Chemicals & Pharmaceuticals Ltd; Perkin Laboratories; Divi's Laboratories (P) Ltd; Chandak Laboratories Ltd; Chiral Biosciences Ltd; Sree Jaya Laboratories; Inter Labs (P) Ltd; Plasma Labs (P) Ltd; Pravah Laboratories (P) Ltd; Sanorg Laboratories (P) Ltd; Sammi Bio Organics; Anica Labs (P) Ltd; Salus Laboratories (P) Ltd; Discovery Intermediates (P) Ltd; Yegna Manojavam Drugs & Chemicals Ltd; Viwyn Pharma Pvt Ltd; Ortin Laboratories Ltd; Sri Supraja Pharma (P) Ltd; Optimus Drugs (P) Ltd; Archimedes Laboratories Ltd; M/s. Aster Industries; M/s. Hermes Chemicals company (P) Ltd; M/s. SR Laboratories; M/s. SVR Laboratories (P) Ltd; M/s. Fugen Laboratories (P) Ltd; M/s. VC Laboratories (P) Ltd.

List of companies from Andhra Pradesh:

- Auctus Pharma Private Limited; Anu's Laboratories Limited; Sionc Pharmaceuticals Private Limited; Sri Vyjayanthi Labs Pvt. Ltd; Synthrix Pharma Labs India Pvt. Ltd; A.R. Life Sciences Pvt Ltd; Siflon drugs; Tyche Industries Ltd; Kostal Pharma Ltd; Andhra Medi Pharma India (P) Ltd; Nutra Specialties Pvt.; Tini Pharma Ltd.

[India Central Pollution Control Board (CPCB) Notice to polluting industries, 30.10.2015, http://cpcb.nic.in/Newspaper_Advt_Online_Monitoring.pdf]

players, partly by making its patent regime more amenable to foreign firms in the mid-2000s⁴² and by allowing 100% inward foreign direct investment (FDI). It is estimated that foreign multinationals will hold 35% of Indian pharmaceutical market share by 2017, compared with 28% in 2009.⁴³ Abbott Laboratories, Pfizer and GlaxoSmithKline are identified as key international players in India.⁴⁴ They, along with other foreign majors including Mylan, Sanofi, Daiichi Sankyo, Merck and Co., and Bristol Myers-Squibb have flooded the country with billions of dollars-worth of FDI in recent years and sealed alliances with large Indian manufacturers including Dr. Reddy's, Aurobindo and Ranbaxy to name just a few. Conversely, a number of the larger Indian firms such as Dr Reddy's and Aurobindo, have made forays into foreign markets and are now competing at the global level.⁴⁵

III. An export-oriented industry with global ambitions

The pharmaceutical industry only became truly globalised after the establishment of the WTO in 1995 and the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).⁴⁶ In the following years, rapid re-organisation of the industry took place, covering three different product types: "branded products with patent protection, where the innovator has a monopoly on the product during the patent period; quality generics (off-patent products with international approvals, which may be sold under a brand but where equivalent products of the same quality are available); and low-value generics (off-patent products sold mainly in developing country markets, where price is the determining factor setting the entry barriers for market access)".⁴⁷ With no new classes of antibiotics discovered since the 1980s, most antibiotics manufacturing falls in the second and third group.

Following the amendment of the country's

intellectual property laws to bring them in line with the TRIPs agreement in the 1990s, Indian pharmaceutical manufacturers were no longer allowed to manufacture and market reverse-engineered versions of drugs patented by foreign companies.⁴⁸ This made it considerably more difficult for Indian companies to copycat new drugs and make "new" generics.⁴⁹ In light of this, many of the country's leading manufacturers now focus on contract production for Western drug companies or have entered into research and development agreements, mergers and acquisitions, and other alliances with foreign partners.⁵⁰

A common route used by Indian pharmaceutical manufacturers to capture the generic market is to invent a new delivery system for an existing drug. One frequently cited example of this is the agreement between Indian manufacturer Ranbaxy Laboratories and German pharmaceutical giant Bayer on ciprofloxacin, a wide-spectrum antibiotic belonging to the fluoroquinolone group of antibiotics⁶ used as a first-line defence against anthrax.

In 1999, Ranbaxy and Bayer signed a 20-year agreement for the development and marketing of the Indian company's oral variant of ciprofloxacin, the original version of which was discovered by Bayer.⁵¹ The Ranbaxy formulation had proved to be much more effective than the original, and recognizing the potential benefit of the product, Bayer entered into a licensing agreement with Ranbaxy to market the product worldwide against a payment of \$65 million.⁵² Under the terms of the deal, Ranbaxy received exclusive marketing rights for the product in India and CIS countries while Bayer kept the rights in the U.S., Europe and Japan.⁵³ Ranbaxy subsequently gained worldwide notoriety when it was fined \$500 million by the U.S. authorities for falsifying data and allowing serious manufacturing deficiencies to occur at its facilities in India.⁵⁴

G. Fluoroquinolones are powerful antibiotics used to treat a wide range of infections. Their use has been associated with serious side-effects and health experts therefore recommend that they should be used as antibiotics of 'last resort', i.e. for only the most serious illnesses.

Since the expiry of Bayer's original patent on ciprofloxacin in 2004, numerous approvals have been given for the development of generic versions of the drug to companies including the Indian subsidiary of U.S. giant Mylan, Germany's Sandoz (the generics arm of Switzerland's Novartis), Israel's Teva Pharmaceuticals, and Indian giants Lupin Ltd.⁵⁵ and Dr Reddy's Laboratories.⁵⁶

Over half of India's pharmaceutical exports are to highly regulated markets such as the U.S. and the EU.⁵⁷ In order to export to the regulated markets, Indian manufacturers must prove that they are compliant with Good Manufacturing Practices (GMP), which define the minimum standard that a medicines manufacturer must meet in its production processes. Compliance is monitored and periodic inspections are carried out by various national, regional, and international authorities, including the U.S. FDA, the EU and its Member States, and the WHO. Under GMP, products must be of consistent high quality; appropriate to their intended use; and meet the requirements of the marketing authorisation (MA) or product specification.⁵⁸ GMP violations and product bans are a common occurrence in India's pharmaceutical manufacturing sector. In the second half of 2015 alone, Indian pharma firms including Dr. Reddy's, Sun Pharma, Zydus Cadila, Wockhardt Ltd and IPCA Lab were all issued with warning letters by the US FDA⁵⁹ and the EU introduced a ban on 700 generic drugs supplied by Indian companies.⁶⁰

There are currently no GMP provisions regulating environmental emissions from the production of medicinal products, which means that authorities in the regulated markets have no formal power to police the environmental impact of pharmaceutical manufacturing outsourced to countries such as China and India.

India exported over \$15 billion worth of drugs in the financial year 2014-15, with Europe accounting for 20 per cent of this (around \$3 billion). Of this,

formulations of generic drugs constituted about \$1 billion and APIs formed \$2 billion, according to industry data.⁶¹ The United States are also a key market for the Indian pharmaceutical industry. A 2014 report to the U.S. Congress describes how: "India is now the preeminent supplier of generic drugs, serving as an export platform for U.S.-based multinationals, as well as Indian competitors." To regulate Indian drug exports to the United States more effectively, the FDA has established offices in New Delhi and Mumbai, and stationed one full-time medical products investigator in New Delhi.⁶²

Antibiotics make up a sizeable share of India's drug exports. According to UN Comtrade data the U.S. imported \$37 million worth of antibiotics from India in 2014 and the UK imported \$43.8 million.⁶³ Under the trade partner World', antibiotic trade value for India is \$858,827,114 with a total net weight of 11,041,080 kg.⁶⁴

India's top ten pharmaceutical exporters:

1. **Dr Reddys Laboratories Ltd**
2. **Lupin Ltd**
3. **Mylan Laboratories Ltd**
4. **Aurobindo Pharma Ltd**
5. **Cipla Ltd**
6. **Hetero Drugs Ltd**
7. **Sun Pharmaceutical Industries**
8. **Glenmark Generics Ltd**
9. **Ranbaxy Laboratories**
10. **Serum Institute Ltd⁹⁵**

In post-Independence India, the pharmaceutical industry was viewed as a 'sun rise industry' with the potential to provide skilled jobs as well as technology transfer and the ability to generate foreign exchange.⁶⁶ However, several decades on, many Indian commentators are critical of the industry's track record on several fronts.

Critics have described how the costs of the rapid expansion of India's pharmaceutical sector have

been ignored and view the development of India's manufacturing capacity as mainly providing an opportunity for Western economies to move away from dirty goods manufacturing by exporting it to India.⁶⁷ This has generated "significant costs for local populations in terms of loss of assets, health, natural resources and quality of the environment."⁶⁸



Close-up of the water flowing into Isnapur Lake, Pashamylaram

PART 2 - Pollution in Hyderabad and Visakhapatnam

I. A long history of pollution

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 and Andhra Pradesh 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"⁶⁹ in Patancheru, the industrial area on the outskirts of Hyderabad described at length in the following pages. More recently, the environmental and health impacts related to antibiotic production have also emerged as an issue of growing concern, against the backdrop of rising mortality caused by growing antimicrobial resistance across India and around the world.

The social and environmental costs of the development of Hyderabad's bulk drug industry are plain to see in the neighbourhoods and villages surrounding the industrial areas, and have been well-documented over a period of decades. However, the response from both the central government and the state authorities has been woefully inadequate, not to say complicit, and over the years, irresponsible drug manufacturers have enjoyed free rein to continue pumping vast quantities of untreated or inadequately treated pharmaceutical waste into the environment. Inhabitants living and working in the vicinity of drug manufacturing units in Hyderabad, Visakhapatnam, and other locations have borne the brunt of this. It has affected their livelihoods in the form of livestock deaths and decreased agricultural yields,⁷⁰ and damaged their health, with reported impacts ranging from higher abortion rates to birth defects and stunted growth in children, as well as greater incidence of skin diseases.⁷¹

Campaigners in Telangana and Andhra Pradesh have been fighting against pharmaceutical pollution for decades, to little avail. In 1986, Citizens Against

Pollution (CAP) launched the Patancheru Anti Pollution Committee. The following year, nearly 2,000 people marched 40km from Patancheru to the Andhra Pradesh State Assembly and presented a list of demands to then Chief Minister N. T. Rama Rao. These included the construction of an effluent treatment plant for each industrial unit, adequate compensation for degraded agricultural land and the supply of safe drinking water to affected villages."⁷²

Unfortunately, 30 years on from that march, there is little proof that the effluent treatment plants which have since been built are adequate for the task in hand, with evidence showing that they are unable to handle the large volumes of waste being generated by the bulk drug manufacturing industry.

A further problem is the way in which monitoring of pollution from pharmaceutical manufacturing is undertaken. Private, so-called independent laboratories are paid by the industry to carry out Environmental Impact Assessments (EIA) of the pharmaceutical plants and give them a clean bill of health, providing certificates that say plants are well within the standards despite potential issues. This evidence is then considered expert testimony in court whenever the waste management standards are called into question. Hyderabad University academic Vijay Gudavarthy, an authority on Hyderabad's bulk drug industry notes that this is similar to the relationship between ratings agencies and banks in the lead up to the 2007-08 financial crash. Because the private labs and rating agencies are paid by the industry they are meant to regulate to carry out the tests, they have a disincentive to give negative reports because after a while they will no longer be asked to carry out the audits.⁷³

Organisations charged with monitoring pollution have absolutely no teeth and in some cases are in league with the industry they are supposed to be monitoring. Even when the authorities do intervene, the cases reach the Supreme Court only to be watered down at the critical stage and the

necessary action is not taken. According to Rishabh Khanna at Envirohealth Matters, cases against the pharmaceutical industry have been in the courts since at least the 1980s. This led to an agreement in 1997 that the government and industry would

pay compensation to impacted communities but the compensation was never released. More recently, farmers represented by a local NGO have taken a case to India's Green Tribunal^H and the case is still being heard at the time of writing.⁷⁴

HYDERABAD - A LONG SAGA OF POLLUTION, MANUFACTURING BANS, AND LEGAL ACTION

1961: Establishment of Indian Drugs and Pharmaceuticals Limited (IDPL), a government-owned company with a mandate to "free India from dependence on imports and to provide medicines to the millions at affordable prices."

1973: Formation of Andhra Pradesh Industrial Infrastructure Corporation (APIIC). Patancheru begins to grow into a "mega industrial estate."⁷⁵

1975-1995: APIIC creates 6 industrial estates in 'backward regions' around a thirty-mile radius of Hyderabad, the largest of which is the 440-hectare estate in Patancheru.⁷⁶

1987: Indian High Court orders 20 industries to stop releasing their effluents into the Nakkavagu River and directs the Andhra Pradesh Pollution Control Board (APPCB) to report to the court on the nature and degree of pollution in the Patancheru area.⁷⁷

1990: Submission of a public interest litigation (PIL) by the Indian Council for Enviro-Legal Action before India's Supreme Court against pharmaceutical producers and common effluent treatment plant management in Patancheru and Bollaram for pollution of groundwater and surface water caused by manufacturing effluent.⁷⁸

1994: Establishment of a common effluent treatment plant (CETP) in Patancheru.

1996: APPCB imposes ban on establishing new industries generating high water pollution. Ban extends to 4 districts (Mahabubnagar, Nalgonda, Rangareddy and Medak) surrounding Hyderabad city.⁷⁹

1997: Supreme Court bans the establishment or expansion of bulk drug manufacturing units in Patancheru-Bollaram estate and asks the industries to implement zero liquid discharge (ZLD), which means they have to treat the wastewater and reuse it.

2000: Several Hyderabad-based NGOs initiate litigation against polluting industries.

2007: Swedish study "Effluent from drug manufactures contains extremely high levels of pharmaceuticals" (Larsson et al.⁸⁰) raises awareness of impacts of pharmaceutical pollution in Patancheru-Bollaram cluster, with a focus on its contribution to antibiotic resistance in bacteria.

H. India's National Green Tribunal was set up in 2010 and is dedicated to "the effective and expeditious disposal of cases relating to the subject of forest, environment, biodiversity, air and water." It has wide jurisdiction to deal not only with violations of environmental laws, but also to provide compensation, relief and restoration of the environment in accordance with the 'Polluter Pays' principle, as well as powers to enforce the precautionary principle (see: WWF India, Green Tribunal, http://www.wwfindia.org/about_wwf/enablers/cel/national_green_tribunal/)

2008: Amberpet Sewage Treatment Plant is inaugurated. The STP receives effluent from the Patancheru-Bollaram CETP through an 18km pipeline.

January 2010: India's Ministry of Environment and Forests (MoEF) imposes moratorium on setting up new industries or expanding existing ones in 8 "critically polluted areas" in India, including the Patancheru-Bollaram cluster.

July 2011: Moratorium lifted on the basis of pollution control measures proposed by the state pollution control boards.

2012: NGO Citizens Forum for Better Patancheru Constituency makes submission to Andhra Pradesh High Court highlighting the plight of villagers in Kazipally, Sultanpur and 15 surrounding villages on the banks of the Nakka Vagu River as a result of pollution from bulk drug manufacturing industry.

July 2012: Andhra Pradesh Pollution Control Board orders closure of 12 pharmaceutical manufacturing units in Hyderabad in the interest of protecting public health and the environment on the grounds that they violated pollution norms. The affected units are:

- 2 facilities of Aurobindo Pharma
- 4 facilities of Hetero Labs
- 1 Cirex Pharmaceuticals
- 1 Covalent Laboratories
- 1 Divis Pharmaceuticals
- 1 Sri Krishna Pharmaceuticals
- 1 Innogent Laboratories
- 1 SMS Pharma.

5 companies in Visakhapatnam, including Mylan, are also asked to suspend operations by the Vizag District Administration.⁸¹

September 2013: Moratorium on industrial expansion in Patancheru-Bollaram cluster re-imposed in light of Central Pollution Control Board (CPCB) survey showing high pollution levels at 8 industrial clusters. Indian government notes: "The CEPI [pollution] scores indicate (for the eight clusters) that even after a period of two-and-a-half years of implementation of action plans, there is no improvement in the environmental quality."

2013: Citizens Forum for Better Patancheru Constituency files complaint regarding bulk drug manufacturers in Patancheru-Bollaram before the National Green Tribunal (NGT) in Chennai.

11 November 2013: National Green Tribunal "orders notice" to Andhra Pradesh Government on Citizens Forum complaint.

July 2014: Moratorium on industrial expansion at Patancheru-Bollaram and other clusters is effectively lifted following election of Narendra Modi as Prime Minister and reformulation of pollution index.

November 2015: CSE analysis of Telangana State Pollution Control Board (TSPCB) inspection reports pertaining to 15 Bulk Drug Manufacturers operating in Patancheru-Bollaram cluster shows most companies producing ingredients for which they do not have permission, using more water than the permitted limit and dumping more effluents and hazardous waste than allowed.

January 2016: On-the-ground investigation in Hyderabad and Visakhapatnam for the purposes of the current report confirms that pharmaceutical pollution is still rife in these areas.



II. The investigation

This part of the report presents key findings of in-depth documentary analysis and an on-the-ground investigation into the environmental and health impacts of bulk drug manufacturing undertaken in early 2016 in Hyderabad, Telangana state, and Visakhapatnam, located some 600km away on the coast of Andhra Pradesh. Its objective was to ascertain the true extent of pollution in the region, following detailed background research in late 2015. As the following will make clear, the situation on the ground is critical. The effluent treatment systems that were set up to process industrial waste are a signal failure, and there is also systematic dumping of chemical effluent by pharmaceutical factories in rivers, lakes and groundwater. Pollution impacts are so severe as to be visible to the casual observer not just in the areas immediately adjacent to the factories and treatment plants, but many kilometres further afield. Rivers channel pollution over long distances, as witnessed in numerous villages along the banks of the Musi River, whose inhabitants live miserable lives blighted by ill health and poor nutrition. Subsistence farming and fishing, on which many local people's survival depends, is on the brink as their animals die and their crops repeatedly fail.

The investigation had several areas of focus: the industrial areas and the pharmaceutical factories which operate there; the effluent treatment plants set up to process the waste from these areas; and the impact of pollution on villages and water bodies surrounding the industrial areas. The findings are presented broadly according to these categories. Site visits, face-to-face meetings with officials, academics and medical professionals, as well as interviews with local inhabitants, farmers, fishermen, and environmental activists paint a picture of an area that is drowning in pollution. Finally, the investigation also focused on trying to identify links between polluting factories and the global markets to which they supply drugs.

As anticipated from the outset, we have found the extreme lack of transparency regarding supplier-buyer relationships to be a significant stumbling block in terms of ascertaining which foreign-based companies are purchasing drugs from the polluting factories identified below. Where we have firm indications as to the identity of overseas buyers which may be outsourcing production to sites in Hyderabad and Visakhapatnam, we include these in the narrative. However, it is obvious that important pieces of the puzzle are still missing. Nonetheless, it is clearly the case that because of the key role outsourcing plays in today's global pharmaceutical market, as well as the increasing presence of Indian companies in 'developed' markets, a significant portion of the production from the sites identified is highly likely to be ending up on pharmacy shelves in the United States, Europe, Australia, Canada and beyond. Pharmaceutical pollution in India is very much a global problem. It can be especially critical with regard to antimicrobial resistance in cases where the effluent also contains large amounts of antibiotics. Within the scope of the current report, the investigation team was not able to test water and soil samples for the presence of antibiotic residues. However, there are numerous units manufacturing antibiotic APIs in the areas described. What is more, recent research by Swedish scientists, including a seminal 2007 report ("*Effluent from drug manufactures contains extremely high levels of pharmaceuticals*"⁸²) indicates that antibiotic pollution in the industrial areas investigated is rife, and existing effluent treatment systems are not fit for purpose.

Our analysis shows several major polluters emerging from the pack in Telangana and Andhra Pradesh: Aurobindo, Dr Reddy's, Hetero Drugs Ltd, and Mylan Laboratories Ltd (the Indian subsidiary of U.S.-based Mylan), which are examined in depth below. All are major pharmaceutical companies, and all have a significant presence in overseas markets, either through partnerships with foreign multinationals, or in their own right, following acquisitions. Aurobindo's U.S. client McKesson and the European operations of



Name: Bonthapalle Village

Description: Village people avoid eating the food they grow here, which is mostly sold elsewhere, and there are many health problems linked to the high pollution levels, including miscarriages, cancers, deaths of livestock etc. The village well is contaminated and unusable, and a bore well has had to be dug a long way from the village as a result. Hetero operates a factory here. Few if any locals are employed at the plant, despite assurances that they would be at the time of land purchase. The plant has informers within the village, and villagers who complain are threatened by local police who are complicit with the plant owners.



Name: Patancheru-Bollaram Industrial Cluster (PBC)

Description: In 2010 the Ministry of Environment and Forests banned the creation of new industries or the expansion of existing ones in the PBC. The ban was renewed in 2013 after a review showed no improvements had been made. In November 2015, an analysis of Telangana State Pollution Control Board inspection reports by an Indian NGO found that drug manufacturers operating within the PBC were producing pharmaceutical ingredients for which they did not have permission, using more water than the permitted limit, and dumping more effluents and hazardous waste than allowed.



Name: Isnapur Lake

Description: The lake receives waste flowing in through open nallahs from the Patancheru Industrial Area. The chemical effluent forms thick crusts in some places and chemical reactions can be observed occurring under the surface. The lake bed is thickly coated in a black tarry sediment which seems to go down to a considerable depth.



Name: Chaitanya Nagar Colony

Description: Chemical effluent was observed pouring along an open nallah. The surface of the stream was covered in heaps of thick white froth and there was an overpowering chemical smell. A small pond had collected adjacent to the main stream, and farmers were running plastic hose pipes from this highly contaminated water source into adjacent land where they were growing guava and other fruit and vegetables.



Name: Ramky Hazardous Waste Plant, Dindigal

Description: The investigation team observed what appeared to be chemical effluent in standing water pools in open land behind the site, starting only a couple of feet away from the perimeter wall. There was also what looked like a large hill inside the site, higher than the top of the perimeter wall, which is understood to be additional waste being piled up above ground level. There are high levels of security at the plant.

Name: Patancheru-Amberpet Pipeline

Description: The pipeline channels effluent from the Patancheru Common Effluent Treatment Plant to the Amberpet Sewage Treatment Plant and from there into the Musi River.



Name: Patancheru Common Effluent Treatment Plant (CETP)

Description: The Patancheru CETP processes effluent from around 100 pharmaceutical plants in addition to waste from a variety of other industries.

Hyderabad: A city drowning in pharmaceutical pollution

Village or neighbourhood Lake or river Industrial zone Waste treatment plant



No photos allowed



Plant operating above capacity



Over-consumption of water



Corruption



Contaminated water



Illegal dumping of waste



Dead crops



Sick animals



Health problems



Chemical effluent



Bad Smell



Name: Kazipally Village

Description: The water table has been contaminated with industrial effluent since the 1980s, a situation greatly exacerbated by the arrival of the pharmaceutical industry. Villagers can no longer drink from the lake, from their wells or even from the bore well which was provided for safe drinking water. They have very limited weekly access via tap to a pipeline connected to the municipal water supply. Villagers report many serious health issues, including miscarriages, skin disorders, cancers and intestinal problems. The livestock suffer from the same problems. Most, not to say all, food grown in the village is unfit for human consumption.



Name: JETL - Jeedimetla Effluent Treatment Limited

Description: The team filmed tankers entering and leaving the site from the public highway but were forced to stop following a confrontation with security guards.



Name: Gaddapotharam Industrial Area

Description: A large volume of chemical effluent was observed to be flowing from the entire industrial area into an open concrete well, about 25 feet deep, filled to the brim with effluent. The overflow is diverted through a side channel which leads off towards the edge of the hill and from there runs in a strong steady flow down an open nallah into the wide valley below.

Name: Hussain Sagar Lake

Description: Adjacent to the bottom of the Hussein Sagar Lake, the investigation team observed construction work underway at an intersection where water flowing from the lake joins an open nallah heading towards the Musi River. At this point the flow is joined by an underground pipe, the contents of which appear to be chemical effluent, with black tarry sediment.



Name: Edulabad Village

Description: Since the Amberpet STP was opened, villagers have had their livelihoods destroyed and experienced major health problems. Fish in the village tank regularly die as a result of chemical effluent flowing into the water body. The investigation team was told 'in front of 'buffalo' and 'and tastes bad' in the sentence: 'The milk produced by the animals fetches a very low price as it smells and tastes bad. Children have eyesight problems, old and young people have joint pains and skin diseases, people and animals have frequent diarrhoea.



Name: Bachupally

Bachupally, Hyderabad, Telangana, India

Description: An Aurobindo plant manufactures antibiotics here. The site is very highly guarded, with two different sets of personnel as well as security cameras. Waste water, potentially chemical effluent, was observed to be flowing from the plant.

Secunderabad

Edulabad village



Name: Uppal neighbourhood

Description: At Uppal the investigation team observed high levels of what appeared to be chemical effluent being discharged from a stream into an open nallah which heads down towards Amberpet Sewage Treatment Plant. This effluent emanates from other industrial areas at Nacharam and Mallapur, and joins with the waste coming from Jedimetla and the Patancheru-Amberpet pipeline, entering the STP, and ultimately being discharged into the Musi River. Much of the flow actually bypasses Amberpet and is discharged directly into the Musi.



Name: Peddagudem Village

Description: Locals had skin conditions caused by working in the water in their paddy fields. The water table is totally contaminated and all crops are affected: rice is blackish in colour and spoils very fast. The village has to pay to have drinking water delivered by tanker. Tankers are regularly observed coming down from the industrial areas to dump waste illegally straight into the river.

DILSUKHAGAR

Name: Musi River

Description: The Musi River, a tributary of the Krishna River flows from west to east right through the heart of Hyderabad. Historically, the Musi was seasonal and rain-fed, and irrigated approximately 24,000 hectares of adjacent farmland, but now due to the massive increase in waste water volume being added to the flow by Hyderabad City and the Amberpet STP, it has become a perennial river irrigating 150,000 hectares, so many farmers have turned their crops over to rice paddy.



Name: Amberpet Sewage Treatment Plant (STP)

Description: In 1997, a Supreme Court order resulted in the construction of an 18-kilometre pipeline to channel effluent from the Patancheru common effluent treatment plant (CETP) to the mega STP at Amberpet, reported to be Asia's largest. Almost twenty years on, the Musi is critically polluted and the Amberpet STP is clearly not fit for purpose. When the investigation team visited in early 2016, it was closed for four days for essential maintenance. Throughout this period, wastewater entering the plant was being diverted through side channels leading towards the river.



Heavy Security



Contaminated Food

Actavis¹ which Aurobindo acquired in 2014⁸³ have also been identified as key players marketing drugs produced in polluting factories in India on the U.S. and EU markets. Actavis ceded its generics operations in seven EU Member States to Aurobindo in 2014, and the two companies also concluded a long-term strategic supply arrangement.⁸⁴ Over the 24 months following the deal, Aurobindo planned to replace half of Actavis' products with its own low-cost high-margin products to bring down its overall costs.⁸⁵ This is not to say that other drug manufacturers operating in the area are not also guilty of generating large quantities of pharmaceutical pollution in fact, all the evidence indicates that the practice is ubiquitous throughout India. However, until the industry and regulators decide to lift the veil of secrecy over the identity of companies purchasing from factories in India and China, we will be left in the dark concerning the origin of the drugs we consume.

1. Actavis is now trading as Allergan. (see: BBC, 23.11.2015, Pfizer seals \$160 billion deal to create drugs giant, <http://www.bbc.co.uk/news/business-34900344>)

A. MANUFACTURING PLANTS AND THE COMPANIES THAT OPERATE THEM

a. HYDERABAD AREA: Patancheru-Bollaram Cluster, Gaddapotharam, Jeedimetla, Bonthapalle, and Bachupally

Around 270 industries including pharmaceuticals, paints, plastics and chemicals operate in the Patancheru-Bollaram industrial cluster.⁸⁶ The largest pharmaceutical companies operating in the cluster are Dr. Reddy's, Aurobindo, Hetero, Mylan (and its subsidiary Matrix), Ranbaxy Laboratories and SMS Pharmaceuticals.⁸⁷ Nearby industrial areas which were also visited for the purposes of the investigation include Gaddapotharam, Jeedimetla, Bonthapalle and Bachupally.

The Patancheru industrial area itself contains many pharmaceutical companies and a variety of other polluting industries. Of the 106 units sending effluent to Patancheru Common Effluent Treatment Plant (CETP), the majority are pharmaceutical companies so it is clear that pharmaceutical



Polluted waterbody at Bollaram industrial area

chemical waste is a constituent element of the general effluent pollution described here.

The Bollaram industrial area was by far the worst that the investigation team witnessed: a vast site filled with dirty industry including pharma, cement, paint, agrochemicals, steel, electricity substations, and paper. The air is thick with dust and pollutants, constantly thrown up by hundreds of trucks going backwards and forwards over dirt tracks crisscrossing the cluster, and the chemical smell is overpowering. Slum dwellings of corrugated iron line the roadsides.

A list of all companies sending effluent to the Patancheru CETP from the Patancheru-Bollaram cluster, as well as a list of bulk drug units accused by a major Indian NGO of being the worst flouters of environmental regulations using the CETP was obtained during the research phase preceding the investigation. These companies are currently being challenged before India's National Green Tribunal as part of a case brought by local activists and farmers impacted by pharmaceutical pollution in Medak District, of which Patancheru is part.

The "worst polluters" list is derived from an analysis of Telangana State Pollution Control Board (TSPCB) inspection reports by India's Centre for Science and Environment (CSE) in November 2015.⁸⁸ This found that 15 drug manufacturers^L operating within the Patancheru-Bollaram cluster had egregiously flouted environmental regulations and Indian Supreme Court orders. CSE found that most companies were: manufacturing pharmaceutical ingredients for which they did not have permission; using more water than the permitted limit; and dumping more effluents and hazardous waste than allowed. Two of the units were operating without clearance from the Ministry of Environment, and Forests (MoEF). The analysis also cast doubt on the quality of the TSPCB inspection reports, which contained a number of significant discrepancies.⁸⁹

Many of these companies are repeat offenders when it comes to environmental pollution and violating pollution control board norms, and have featured in multiple legal cases, media reports and exposes down the years.⁹⁰ Along with reports by the state Pollution Control Boards and India's Central Drugs Standard Control Organisation, the list served as one of the guiding documents in the planning of the investigation. Key highlights of the CSE analysis are therefore woven in with our own findings and the company profiles set out below.

• **AUROBINDO**

Headquartered in Hyderabad, Aurobindo is one of India's largest vertically integrated pharmaceutical companies, targeting \$2 billion in revenues by 2015-16⁹¹ and \$3 billion by 2017-18.⁹² The company is scaling up capacity in readiness for more launches in its U.S. market, and plans to make India its sourcing hub for the European generic drug business it acquired from Actavis Plc in 2014.⁹³ Since launching its European commercial operations in 2006 with the acquisition of Milpharm in the UK and Pharmacin in the Netherlands in 2007, and following the Actavis deal, Aurobindo has further expanded its footprint in continental Europe, and has operations in Member States including France, Italy, Spain, Portugal, Belgium, Romania, Malta and Germany. The total value of the company's European operations recently reached the 500 million mark, making it Europe's largest Indian generic pharmaceutical manufacturer.⁹⁴

Aurobindo first entered the market manufacturing semi-synthetic penicillin at the end of the 1980s⁹⁵ and today its products include antibiotics (notably cephalosporins), anti-retrovirals and anti-allergics. It has nine units for the production of APIs and intermediates, and seven units for formulations which it claims are "designed to meet the requirements of both advanced as well as emerging market opportunities."⁹⁶ The company exports to over 150 countries across the globe with more than

L. The 15 drug manufacturers identified by CSE as violating environmental regulations are: Hetero Drugs Ltd (Units IV and I); Hetero Labs Ltd (Unit I); Aurobindo Pharma Ltd (Units I and IX); SMS Products (Unit II); Dr Reddy's Laboratory (Units I and III); Cirex Pharmaceuticals Pvt Ltd; Mylan Laboratories Ltd; Divis Pharmaceuticals; Covalant Laboratories; Saraca Laboratories; Sri Krishna Drugs Ltd (Unit II); Astrix Laboratory. [Down to Earth, 25.11.2015, Supreme Abuse, <http://www.downtoearth.org.in/news/supreme-abuse-51876>]

86% of its revenues derived from international operations.⁹⁷ Its customers include "premium multinational companies" and many of its facilities have been approved by regulatory agencies such as the U.S. FDA, the UK Medicines and Healthcare Products Regulatory Authority (MHRA) and Health Canada. It also has multiple approvals under the EU GMP framework.⁹⁸

Aurobindo operates several manufacturing plants on the outskirts of Hyderabad,⁹⁹ with two new units approved for construction in Mahabubnagar District, to the south-west of the city.¹⁰⁰ It also operates a plant in Pydibhimavaram Village, 80km north-east of Visakhapatnam, and in the Jawaharlal Nehru Pharma City, both of which are described in detail below. In total, the company plans to build three new formulation plants in Telangana and Andhra Pradesh and to ramp up production at existing ones (including Unit I described below). The new plants will be located in:

- Jadcherla (Mahabubnagar District), near Hyderabad: this will be a semi-synthetic penicillin plant;
- Visakhapatnam: the new plant will be an oral finished dosage facility for export to European markets;
- Naidupet (Nellore District): oral finished dosage facility.¹⁰¹

In 2009, a deal was struck whereby Pfizer would licence a selection of generic drugs including four injectable antibiotics from Aurobindo as part of the U.S. company's "grand plan" to expand into generics with lower manufacturing costs.¹⁰² The agreement expanded on a five-product U.S. deal entered into in July 2008 with Aurobindo, with which Pfizer first worked in 2006 through its animal health division.¹⁰³ However, it was beset with problems. The antibiotics were to be supplied from Aurobindo's Unit VI which manufactures cephalosporin antibiotics - in Hyderabad but the U.S. FDA suspended imports from the facility due

to bad manufacturing practices.¹⁰⁴ At the time, annual sales to the U.S. market from Unit VI were estimated to be in \$30 million¹⁰⁵ and initial reports speculated the deal would last until 2014.¹⁰⁶ The FDA ban lasted until March 2013, effectively killing the deal.¹⁰⁷ As one source familiar with Pfizer put it: "[Pfizer's] choice of suppliers "suggests an inability to separate the wheat from the chaff."¹⁰⁸

Generic drugs account for a substantial portion of Aurobindo's revenues. In 2014-15, its generics formulations business saw growth of 77.7% across all global markets, with 42% growth in the United States and a remarkable rise of 375% in Europe. Key growth markets were France, Germany, the Netherlands, the UK, Spain, Italy and Portugal. The company also reports growing external demand for its active ingredients, which is being met by its expanding Pydibhimavaram facility (Unit XI), located 80km north-east of Visakhapatnam (see below).¹⁰⁹ Aurobindo currently has a total of 232 abbreviated new drug application (ANDA)¹¹⁰ approvals (201 final approvals including 10 for Aurolife Pharma LLC and 31 tentative approvals) from the US.¹¹¹ In fact, Aurobindo Pharma is among India's most prolific filers of Drug Master Files (DMFs)^M and ANDAs.¹¹² Four of Aurobindo's six "key" formulation plants in India manufacture antibiotics¹¹³, with other sites manufacturing antibiotic APIs, as described below.

Aurobindo's UK subsidiary, Milpharm Ltd., supplies the antibiotics ciprofloxacin and cefalexin to the UK market. Aurobindo also supplies antibiotics to NorthStar Rx in the US, a U.S.-based generic drug company which is a subsidiary of pharmaceutical distribution giant McKesson.¹¹⁴ In 2015, it was reported by SumOfUs that NorthStar Rx was marketing amoxicillin capsules, amoxicillin and clavulanate potassium tablets and amoxicillin and clavulanate potassium powder for suspension on the U.S. market, all of which were produced by Aurobindo. Furthermore, Aurobindo held import licenses for several Chinese API manufacturers

M. A Drug Master File (DMF) is a document prepared by a pharmaceutical manufacturer which provides the relevant regulatory authority with confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. An Abbreviated New Drug Application (ANDA) is an application for a generic drug approval from the relevant regulatory authority relating to an existing licensed medication or approved drug. Once approved, an applicant may manufacture and market the generic drug product in the relevant market.

which had been identified as discharging high levels of antibiotic-laden effluent into their surroundings in China, namely: Sinopharm Weiqida, Harbin Pharmaceutical Group, NCPC and CSPC.¹¹⁵ In fact, Aurobindo holds a 10% strategic stake in Sinopharm designed to provide it with an uninterrupted supply of raw materials at competitive prices.¹¹⁶ The Indian company also has a Shanghai-based subsidiary called ALL Pharma (Shanghai) Trading Co. Ltd.¹¹⁷

Aurobindo has a number of manufacturing subsidiaries worldwide, including a company called APL Swift Services in Malta, which it sees as a "gateway" to the European market. APL was set up in 2008 with a remit to manufacture finished formulations and provide services including lab testing, quality assurance for the release of products onto the EU market.¹¹⁸ Aurobindo Vice-President Venulopalan Muralidharan said the company chose the island because of "its pool of hardworking, English-speaking workers, reduced income tax, investor-friendly legislations, and the widely acknowledged quality standards of the Malta Medicines Authority, among others."¹¹⁹

This suggests that Aurobindo is importing formulations and APIs from its Indian manufacturing plants to Malta for processing and then selling them on to other European markets. A list of manufacturing and importation authorisations issued by the Maltese authorities in January 2016 lists APL Swift Services as being in possession of a licence to both manufacture and import drugs.¹²⁰ The export of packaged medicaments is worth US\$497 million to the Maltese economy, making them one of the country's top three exports.¹²¹

❖ AUROBINDO ON THE GROUND - HYDERABAD AREA

Aurobindo says that it will do "whatever it takes to keep [its] employees and the environment safe and healthy."¹²² However, all the evidence points to the contrary. Our on-the-ground investigation has

uncovered damning evidence that its manufacturing sites in India are causing systematic pollution of their surroundings and the local water supply, a scandal to which the company seems to be turning a blind eye. If, as appears to be the case, it is also outsourcing production to smaller units in the area, the total amount of pharmaceutical manufacturing waste it is responsible for can be assumed to go beyond the quantities that are generated by its own production units. In addition to the Aurobindo plants listed below, a plant operated in Gaddapotharam by Senor Organics, a subsidiary of Aurobindo¹²³, is also recorded as sending its waste to Patancheru CETP.

- **Aurobindo Unit I:** The CSE analysis of Telangana State Pollution Control Board inspection reports found that the unit produces an additional API without consent, consumes more water, and generates more waste than consented¹²⁴ Shortly before CSE published its report in late 2015, Aurobindo's Unit I was given the go-ahead by the Ministry of Environment's 'green panel', the Expert Appraisal Committee (EAC) to invest Rs. 300 crore (approximately \$40 million) in expanding production from its current 96 tonnes per month to 421.2 tonnes per month¹²⁵, a significant increase which raises big questions about the amount of pharmaceutical waste that will be generated in the future and how that waste will be treated, as well as the quantity and provenance of water that will be required for production. Currently, antibiotic APIs make up a significant share of production at the Unit I plant and will continue to do so in the future: the Environmental Impact Assessment Report commissioned by Aurobindo shows that antibiotics will account for 90 of the 421 tonnes per month that will be produced. It notes that water will be procured from ground water



Stream of polluted water flowing into Isnapur Lake just below Pashamylaram industrial area

and from outside suppliers in tankers and that the nearest village (Borapatla) is just 500 metres away from the site. The Manjeera River, which is a key source of drinking water for Hyderabad, is 2.5km from the site.¹²⁶

- **Aurobindo Unit V** is located a few hundred metres from Isnapur Lake, Pashamylaram, just inside the Patancheru industrial area. Desk research indicates the Aurobindo V plant produces drugs for the U.S. and has FDA approval. The investigation team was not able to observe any gullies of effluent emanating directly from the factory premises towards nearby polluted gullies leading to the lake, but it should be noted that very often companies run pipes underground from their sites, which emerge elsewhere on the industrial area and join into the gullies there. An informant who worked on the premises of Unit V explained that two adjacent independent factories were both subcontractors of Aurobindo. This suggests that smaller plants not bearing the Aurobindo logo are carrying out work for them, which could potentially form part of the export supply chain, and these smaller operations would potentially be polluting more heavily, since they are not under the same level of scrutiny as the

larger companies.

- **Aurobindo Unit IX:** According to the CSE report, this plant generates over four times more hazardous waste than allowed and treats its waste inappropriately. Lack of data related to the type of products manufactured raises doubt surrounding the quality of inspection by the Telangana State Pollution Control Board (TSPCB).¹²⁷
- **Aurobindo Unit XII, Bachupally:** Desk research indicates that this unit manufactures Nafcillin and Ampicillin antibiotic injectables for the US, and Amoxicillin with FDA approval. Aurobindo describes it as a "dedicated facility spread over 15,228 square meters for manufacturing oral and sterile beta-lactam formulations."¹²⁸ During the investigation, an open gully was observed, appearing to emanate from inside the Aurobindo site, along which waste water was flowing, potentially chemical effluent. Bachupally is directly adjacent to the Bollaram industrial area and more or less merges into it. The Aurobindo site is extremely highly securitised, with two different sets of personnel, one team in camouflage and another in blue uniforms, very prominent around the perimeter and at the entrance, as well as cameras. A gully was observed at

the front right corner of the plant, which appeared to be emanating from inside the site, or certainly from between the site and its neighbour, mostly covered but open at the point where it joins the main gullies, and apparently containing effluent.

- **Aurobindo Unit VIII:** In 2007 the unit received GMP clearance from the UK Medicines and Healthcare Products Regulatory Authority (MHRA), which the company said completed "one of the important formalities of supplies to be made in the European Union and observer states" given that the certificate is also recognized by several other regulatory agencies and customers globally. The facility had previously been inspected successfully by the U.S. FDA and the WHO.¹²⁹ A large water body lies on the other side of the road from the plant. At the time of the investigation, there were no visible signs of effluent on the lake surface; however, a number of local informants told the team that locals don't drink the lake water, or eat the fish they catch here because it is polluted. Instead, fish is sold far away and information about where it was caught is kept quiet. Locals also report that they develop skin problems when they swim in the water.

• **DR REDDY'S**

Dr Reddy's was founded in 1984 by Anji Reddy, who had previously been an employee of Indian Drugs and Pharmaceuticals Ltd, the body set up to foster the expansion of the Indian drug industry in 1961. It is a vertically integrated company and was the first Indian drug manufacturer to be listed on the New York Stock Exchange in 2001. The company clearly has global ambitions: a document from its 2015 Investor Day makes clear that it intends to substantially expand its operations worldwide.¹³⁰ In 2009 Dr. Reddy's labs signed a

deal with GlaxoSmithKline under which Dr. Reddy's would manufacture and supply drugs to GSK which in turn would license and co-market the drugs across Africa, the Middle East, Asia-Pacific and Latin America.¹³¹ In 2010, Dr Reddy's bought GSK's penicillin manufacturing facility in Bristol, Tennessee.¹³²

Dr Reddy's business model is focused on the production of low-cost generic drugs, which make up the largest share of the company's product offering. However, low-cost production does not translate into low profits. The company had global revenues of US\$ 2.4 billion in 2015¹³³ and seems to be doing well out of the production of bulk drugs if a 2012 study on drug pricing by India's Ministry of Corporate Affairs is anything to go by. That revealed massive profit margins on 21 common drugs manufactured by Indian companies. Although national pricing regulations say that companies can only keep a profit margin of maximum 100 per cent over the cost of production of a drug, mark-ups of 200 to 500 per cent were found to be very common. The report identified Dr Reddy's as being in receipt of the highest profit margin identified 509 per cent for Ciprolet, Dr Reddy's version of the antibiotic ciprofloxacin.¹³⁴ This is the very same drug that was discovered in sky-high concentrations at Patancheru treatment plant by a team of Swedish researchers in 2007.¹³⁵ Dr Reddy's markets ciprofloxacin in the UK¹³⁶ and U.S. markets.¹³⁷

Dr Reddy's lists the amoxicillin based antibiotic Clamp 625 as one of its top brands.¹³⁸ The company makes a lot of final dose generics so there is a high degree of chance the bulk drugs they make in Hyderabad are used within the company's vertically integrated supply chain. As in the case of Aurobindo, Dr Reddy's appears to outsource some of its API production to smaller companies in India. Its 2011-12 Sustainability Report describes how the company outsourced the manufacturing of ciprofloxacin to a plant in Gujarat, for example. The company notes that one of the benefits of this approach was that it "significantly reduced the effluent load at

[Dr Reddy's manufacturing units] but provides no detail about how the effluent was treated at the external plant, except to say that it "complied with all statutory environment norms."¹³⁹ Arene Life Sciences, a bulk drug and intermediate manufacturer that produces the antibiotics ciprofloxacin and levofloxacin, and which also uses the Patancheru CETP, states that its customers include "several multinational companies in India & abroad" and lists Dr. Reddy's as a domestic customer.¹⁴⁰ Arene is also exporting products to "Europe, Japan and Middle East etc." Lee Pharma, which also produces antibiotics and uses Patancheru CETP, equally lists Dr Reddy's as a customer.¹⁴¹

Dr Reddy's 2013-15 sustainability report acknowledges that "good health is impossible without clean water, clean air, and a healthy soil", explaining that the company sets itself "ambitious environmental goals that go beyond statutory requirements and back[s] them up with strategic investments in talent and equipment." Moreover, they claim to "regularly conduct plant audits to evaluate performance vis- -vis these targets, and plug gaps if any."¹⁴² However, the fact that Dr Reddy's manufacturing plants have repeatedly been in the public eye for polluting their natural surroundings, prompts serious questions about the company's stated commitment to "Mother Earth."

❖ DR REDDY'S ON THE GROUND - HYDERABAD AREA

Dr Reddy's operates four manufacturing units on the outskirts of Hyderabad,¹⁴³ two of which (Unit I and Unit III) send waste to Patancheru CETP.¹⁴⁴ If, as appears to be the case, it is also outsourcing production to smaller units in the area, the total amount of pharmaceutical manufacturing waste it is responsible for can be assumed to go beyond the quantities that are generated by its own production units.

In November 2015, Dr Reddy's received a warning letter from the U.S. FDA relating to two of its API manufacturing plants and one formulation plant located in Andhra Pradesh and Telangana^N. The regulator said that it had found several violations with regard to good manufacturing practices at the plants and "strongly recommend[ed]" that the company evaluate global manufacturing operations to ensure compliance with [GMP] regulations and requirements, "comprehensively and immediately."¹⁴⁵ Two of the units identified were located in areas described in this report as suffering severe pollution impacts from pharmaceutical manufacturing (Pydibhimavaram Village and Visakhapatnam, Andhra Pradesh).

- **Dr Reddy's Unit I:** According to CSE's analysis, this plant produces more than three times the level of hazardous waste permitted.¹⁴⁶



Gully with potential effluent running adjacent to Hetero plant

- **Dr Reddy's Unit II:** The investigation team drove around the perimeter of the Unit II plant which manufactures APIs. The

N. These were: CTO Unit VI, located at APIIC Industrial Estate, Pydibhimavaram Village, Andhra Pradesh; CTO Unit V, located at Peddadevulapally Village, Telangana, and Unit-VII located at Plot No. P1 to P9, Phase III, Duvvada, VSEZ, Visakhapatnam, Andhra Pradesh.

gullies surrounding the site were dry on inspection, but join into many other gullies of effluent all running downhill towards a large effluent lake at the edge of the industrial area.

- **Dr Reddy's Unit III:** According to CSE, the lack of data related to non-consented products and hazardous waste generation raises doubts regarding the quality of inspection by the TSPCB.¹⁴⁷

- **HETERO DRUGS LTD.**

Hetero Drugs Limited was founded in 1993 and is based in Hyderabad.¹⁴⁸ It has 25 manufacturing facilities worldwide¹⁴⁹ and turnover of over \$1 billion. It is targeting revenues of over \$2 billion for 2015-20. In 2005, it was licensed by Swiss company Roche to make a generic version of Tamiflu, the drug deployed during the swine flu epidemic.¹⁵⁰ Products it manufactures include generics of the antibiotics levofloxacin, linezolid

and moxifloxacin.¹⁵¹ The company develops, manufactures, and markets APIs, intermediate chemicals, and generic finished dosages in India. It offers APIs in the areas of antiretroviral and oncology products to the global pharmaceutical market; finished dosages in various therapeutic areas, including antiretroviral, gastro-intestinal, cardiovascular, antidepressants/antipsychotics, anti-diabetics, pain management, anti-infectives, dermatology, and oncology; and oncology products, including injectables, solid/liquid oral dosages, ointments, soft gelatine capsules, and inhalers.¹⁵²

Like Aurobindo's Maltese subsidiary, Hetero subsidiary Hetero Malta Ltd is in possession of an importation licence from the Maltese authorities, which suggests that it is exporting drugs from India to Malta for distribution on the European market.¹⁵³ Unlike Aurobindo, Hetero does not appear to be manufacturing pharmaceuticals in Malta, which would suggest that it is importing finished dose products manufactured and processed in India.



The company states that it has a "strong global presence" in over 120 countries. exports its products to the United States, Canada, Japan, and Australia, as well as Europe, Latin America, the Middle East, the Far East, Africa, the CIS, and internationally.

❖ **HETERO DRUGS LTD. ON THE GROUND - HYDERABAD AREA**

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Hetero Unit I at Bonthapalle:

Desk research indicates that this unit manufactures Levofloxacin and Moxifloxacin and has been WHO inspected. A source told the investigation team that he had observed boreholes within the premises of the plant into which chemical waste was being dumped. The team observed standing pools of what appeared to be chemical effluent and waste water close to the site, separated from it by a walled plot of inaccessible air force land. Local informants confirmed that a stream emanating from the plant runs across the air force plot and emerges on the other side forming the pools of effluent viewed. From here the waste seeps into adjacent farming and grazing lands. The effluent pools increase in volume significantly during the monsoon season to form a lake. Pollution from this site forms part of a multiple case (32 elements) currently before the Green Tribunal. An informant told the team that he had entered the Hetero premises with members of the pollution control board as part of the court case, and observed large boreholes which had been sunk inside their compound and into which chemical effluent was being poured, ultimately to sink down and pollute the groundwater table, seeping across into adjacent land during monsoon.

- **Hetero Unit IV (Bonthapalle):** According to CSE, this unit operates without environmental clearance; manufactures eight APIs for which it does not have consent; finally, its volume of waste is not commensurate with the production amount, which is three times over the limit. According to an employee at the plant, there are a number of borehole wells inside the site into which chemical effluent is being dumped. The investigation team was shown pipe openings behind the site from which chemical effluent has been observed being discharged into the adjacent open land during monsoon season. The site is 10-12 years old. The villagers say they have experienced continuous pollution since its inception. A wall behind the plant gives on to a wide tract of land which floods during monsoon season forming a large lake called the Nallah Punta. An informant told the investigation team that at that time the plant releases large quantities of effluent via the wall openings which enter into the flood plain and merge with the rainwater. The entire lake becomes polluted with the effluent, in addition to which there is effluent emanating from the ground which seeps from the site and merges with the lake water. The informant has heard from a plant employee that the site has between 15-20 boreholes inside, between 70-100 feet deep. Ostensibly they were sunk for the company to obtain water for its processing, but, the informant said, in fact waste is poured into them, and seeps into the surrounding subsoil.

In 2012 the entire Nallah Punta was rated completely contaminated by leaks from this plant by the pollution control board, and the company had to remove all the water by tankers, however this has not stopped the pollution continuing each



Gates of Hetero plant in Gaddapotharam

year, and the company has also extended its perimeter into the surrounding common land/forest without permission. An informant alleges that the Telangana Chief Minister Mr Chandra Shekha Rao has a commercial interest in the Hetero factories - as with the Hetero plant in Visakhapatnam (see section on Visakhapatnam below). This, if true, might explain the apparent impunity with which Hetero pollutes in this village despite much public campaigning and attempts at prosecution.

- **Hetero Unit I (Gaddapotharam):** CSE's analysis shows that the amount of APIs this unit produces is more than seven times the consented amount. Its water consumption and waste generation are accordingly very high. The investigation team observed what appeared to be chemical effluent flowing along an open concrete gully beside the plant. This was then tracked back to the side gates of the site. At this junction, a covered pipe within the Hetero

plant led out and joined onto the effluent gully, and was partially exposed just inside the gate, where the team could see effluent emerging to join the main flow. When the effluent was stirred with a stick it began to bubble with what appeared to be some kind of chemical reaction.

- **Hetero Labs Ltd Unit** (Hetero Labs is part of the Hetero Group): CSE reports that this unit operates without environmental clearance. It recently applied to expand production capacity to 6,473 kg/day for up to 72 products, which will increase its water consumption and waste generation.
- **Cirex Pharmaceuticals Unit** (Cirex is part of the Hetero Group): According to CSE, this unit treats its effluent inappropriately. Furthermore, the lack of data in the TSPCB report casts doubt on the quality of inspection. Drug supply websites list the company as a supplier of ciprofloxacin (antibiotic)¹⁵⁴ and pentoxifylline (used in cardiovascular treatment).¹⁵⁵

- **MYLAN LABORATORIES LTD.**

Mylan Laboratories Ltd is the Indian subsidiary of Mylan Inc, a global generic and specialty pharmaceuticals company registered in the Netherlands and with operational headquarters in Hatfield, Hertfordshire in the United Kingdom. All active ingredients are manufactured in India (4 facilities in Hyderabad; 4 in Vizag; and one in Mumbai). The third largest pharmaceuticals exporter in India for fiscal year 2014, the company claims that one in 13 prescriptions in the US brand name or generic is filled with a Mylan product. In Australia it is the No.1 supplier, by volume, to Australia's national pharmaceuticals program.¹⁵⁶ Mylan acquired a controlling stake in Hyderabad-based pharmaceutical company Matrix in 2006, giving the company a firm footing in the APIs market.¹⁵⁷

Founded in the 1960s in West Virginia, USA, Mylan Labs makes ciprofloxacin and amoxicillin antibiotics.¹⁵⁸ It also makes a generic version of AstraZeneca's Atacand for Novartis' generic drug subsidiary Sandoz which is manufactured in Hyderabad and was the subject of a Class III voluntary recall in 2014 by Novartis.¹⁵⁹ In 2013 Mylan issued recalls for 11,650 cartons of ciprofloxacin tablets because the drugs "were produced and distributed with active ingredients not manufactured according to Good Manufacturing Practices".¹⁶⁰ Arene Life Sciences, the bulk drug and intermediate manufacturer that produces ciprofloxacin and levofloxacin and uses the Patancheru CETP (see above) also lists Mylan as a domestic customer.¹⁶¹

- ❖ **MYLAN LABORATORIES LTD. ON THE GROUND - HYDERABAD AREA**

- **Mylan Unit I:** Gaddapotharam industrial area. Desk research indicates that this facility is manufacturing the antibiotic moxifloxacin, and has been WHO inspected.

The investigation team did not observe any effluent directly connecting to the Mylan site in this cluster, however as explained in the section above on Hetero I located at the same industrial area, there are heavy volumes of chemical effluent apparently being discharged within the area and polluting the valley below via open channels. As mentioned elsewhere, it is quite possible that this site would conceal the origin of its effluent discharge by running the piping underground and connecting to the main gullies elsewhere within the network.

- **Mylan Unit III (Jeedimetla industrial area):** Desk research indicates that this facility is manufacturing APIs and has been inspected by the WHO. An open gully was observed with what looked like chemical effluent behind the site adjacent and parallel to the perimeter. It was difficult to say whether the gully emanated from inside since it was covered at the junction between the site wall and its entrance into the gully at right angles, but potentially it is Mylan effluent. This joins up to the network of gullies full of effluent running through the industrial area.

CSE's analysis identified a non-specified Mylan Laboratories plant operating within the Patancheru-Bollaram cluster which generates about three times more hazardous waste than permitted.

- **Astrix Laboratories Unit** (Astrix is a subsidiary of Mylan and specialises in manufacturing anti-retroviral APIs¹⁶²). The CSE analysis highlighted a lack of data related to the type of products manufactured at the Astrix plant, which casts doubt on the quality of inspection by TSPCB

- **NEULAND**

Neuland describes itself as a "pure play API company" - which means that it only manufactures APIs - and as a "preferred and reliable API source for leading pharmaceutical companies worldwide."¹⁶³ It produces the antibiotics ciprofloxacin, moxifloxacin and ofloxacin.¹⁶⁴ In 2013, a subsidiary of Japan's Mitsubishi, APIC, invested in Neuland as part of a drive to build up its pharmaceutical business.¹⁶⁵ The company's Annual Report 2014-15 states that it has nearly 40 commercial products being sold to around 450 generic and innovator companies in 70 countries, primarily in the highly regulated markets of Europe, North America and Japan.¹⁶⁶ In 2015, 46 per cent of its revenues came from Europe, a further 32 per cent from North America and the rest from India and Japan combined.¹⁶⁷

- ❖ **NEULAND ON THE GROUND - HYDERABAD AREA**

- **Neuland I (Bonthapally, Domudugu Village):** Desk research indicates that this site manufactures fluoroquinolones and other antibacterials and has been inspected by the U.S. and EU authorities inspected. The investigation team heard allegations from a Neuland employee that the company dumps chemical waste inside the site in underground containers, sealed at ground level with concrete. This is illegal, since containers are meant to be above ground in order that they can be continuously inspected for leaks. The company has covered the containers with concrete. During monsoon season the ground becomes soaked with rainwater and chemical waste reportedly seeps from the containers which are leaking underground. Apparently, this pollution, joins with the pollution from the nearby Hetero IV plant (see above) to contaminate the Nallah Punta lake.

OTHER COMPANIES OF NOTE WHICH USE PATANCHERU CETP

- **MSN LABORATORIES:** Makes APIs and finished dosages. A 2013 corporate video shows Levanol 750 packaging, which is an antibiotic containing levofloxacin.¹⁶⁸ It is unknown whether MSN provide the API for this drug or make it in finished dosages. The aforementioned corporate video also list GlaxoSmithKline, TEVA, Hospira, Sandoz (generic arm of Novartis), Mylan and Sanofi Aventis as partners.
- **LEE PHARMA LTD:** Manufactures APIs, intermediates and granules. Produces three antibiotic APIs: linezolid Form II, moxifloxacin Hcl and prulifloxacin Hcl. Also manufactures ciprofloxacin, clarithromycin and azithromycin granules.¹⁶⁹ The company lists TEVA, Dr. Reddy's, Matrix and Ranbaxy amongst its major clients.¹⁷⁰
- **GRANULES INDIA:** Makes APIs, finished dosages and intermediates including the antibiotics ciprofloxacin and rifaximin.¹⁷¹ It has three manufacturing facilities in Hyderabad and one in Jingmen, China. A fifth plant is under construction in Visakhapatnam through its joint venture partner Granules OmniChem.¹⁷² The company claims to have the world's largest capacity for producing pharmaceutical formulation intermediates through its facilities at Jeedimetla and Gagillapur, both located in Telangana. In 2015 it received three 'observations' from the U.S FDA for its Jeedimetla, facility. The FDA issues these when the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA's requirements. According to its 2014 Annual Report, Granules India has shares in Jeedimetla effluent treatment Ltd and Patancheru Envirotech Ltd.¹⁷³ Its 2005-06

Annual Report cites "Customer validations coming in from large pharmaceutical players like Pfizer, Perrigo, Ranbaxy and Sun Pharma,"¹⁷⁴ although more recent details about its customers appear to be unavailable. 32 per cent of the company's sales are in the US and 31 per cent are in Europe, with a further 11 per cent in Latin America, 10 per cent in Asia and 16 per cent in India.¹⁷⁵

- **NESTOR PHARMA:** Large antibiotics manufacturer with a bulk drug facility in Hyderabad. The company produces anti-tubercular antibiotics, penicillins, cephalosporins, tetracyclines, quinolones, and other antibiotics.¹⁷⁶ The Indian-based company has operations in India, the UK and Nigeria. Its foray into the European market began with the 2005 acquisition of Suffolk-based manufacturing unit Schering Plough, which has since been renamed Nestor UK Ltd.¹⁷⁷
- **SARACA LABORATORIES LTD:** Also part of the Virchow Group, Saraca manufactures APIs and intermediates and sells products in over 40 countries.¹⁷⁸ CSE reports that its Hyderabad unit generates about eight times the amount of hazardous waste permitted.
- **COVALENT LABORATORIES Pvt LTD.** Covalent specialises in the manufacture of cephalosporins, a class of beta-lactam antibiotics. It makes both oral and sterile types, including cefixime, cefdinir and cefpodoxime proxetil¹⁷⁹. All are bulk drugs meaning that they are sold on to bigger companies to be turned into final dose products. Covalent is part of the Virchow Group. CSE found that the Covalent unit treats its waste inappropriately. The lack of data related to the products the Covalent plant manufactures also casts doubt over

the quality of inspection by the TSPCB.

- **VIRCHOW LABORATORIES,** another member of the Virchow Group, located in Jeedimetla, claims to be the preferred supplier of the antibiotic sulfamethoxazole to GlaxoSmithKline, Hoffman La Roche, Merck Generics.... 'and various generic manufacturers worldwide'.¹⁸⁰

b. VISAKHAPATNAM AREA

The main hub of pharmaceutical activity in the Visakhapatnam area is the Jawaharlal Nehru Pharma City (JNPC), which started operating in 2008. The site comprises a Special Export Zone (SEZ) and is being touted as an "ideal destination for investors." Most of the drugs manufactured in the JNPC whether formulations, bulk drugs or intermediates are exported abroad. The SEZ plays host to numerous foreign pharmaceutical companies, including U.S. giant Mylan, Pfizer subsidiary Hospira, Japan's Eisai, Germany's Pharma Zell and India's own SMS Pharmaceuticals.¹⁸¹ Other clients apparently operating outside the SEZ include Indian companies Aurobindo, Hetero and Lupin Laboratories.¹⁸²

In the same way that the construction of the pipeline connecting the Patancheru CETP to the Amberbet Sewage Treatment plant simply shifted the pollution to a different location, rather than addressing its root causes, local environmental campaigners see the development of pharmaceutical manufacturing in Visakhapatnam as a cynical move to transfer polluting activities from Hyderabad to another area. Capt. J. Rama Rao notes in this regard that effluents [formerly] discharged into water bodies in and around land-locked Hyderabad, "can safely be discharged into sea [off the coast of Visakhapatnam] by laying a pipeline deep into sea."¹⁸³ True as this may be, with the planned expansion of pharmaceutical manufacturing in Telangana, it seems unlikely that pollution levels will drop in Hyderabad at all. In



Pipe apparently discharging effluent into village tank at Rajiyyapeta

that sense, the development of Visakhapatnam has simply opened up a new front in the fight against pharmaceutical pollution.

Scientific studies have highlighted high pharmaceutical residues in the Bay of Bengal, notably of antibiotics, given their widespread use in aquaculture (in particular shrimp farming, which is a major industry in the region).¹⁸⁴ It does not take a huge stretch of the imagination to posit that the dumping of large amounts of untreated or inadequately treated pharmaceutical waste into the sea next to Visakhapatnam, a coastal city directly adjacent to the Bay of Bengal, could result in very serious consequences, mixing with the antibiotics used by the aquaculture industry to spread drug resistance in bacteria.

- **Jawaharlal Nehru Pharma City/CETP:** This huge modern industrial site, run as a joint venture between Ramky Group and the Andhra Pradesh state government, is highly securitised, bounded by perimeter walls, with checkpoints, and limited entrance/exit gates controlled by barriers. Journalists are not welcome on the site and recently media entering were pulled in for questioning on the grounds of not having prior permission, and had visa rights permanently rescinded. Outside scrutiny

is not welcome and access is therefore risky. There have been regular industrial deaths within the City. In a recent incident, in September 2015, two workers were burned to death and five others were injured following an explosion at an API plant operated by Sainor Life Sciences Ltd. At least six major fire accidents have been reported at the JNPC city in the past few years, and there are allegations that the managements of pharmaceutical companies operating at the site have not introduced adequate safety measures.¹⁸⁵ An informant described two chemical effluent lakes within the complex which discharge into nallahs⁹ flowing out of the site towards the sea, but it was not possible for the investigation team to access these.

Since the site opened, there have been steady increases in reports of adverse health effects, breathing problems, fertility issues, skin disorders, and so on, as reported in Hyderabad, and surrounding agricultural lands have reportedly been heavily contaminated in all directions by chemical effluent from the industrial area running downhill through the open nallahs which feed into local water bodies. Nallahs leading to the sea discharge chemical

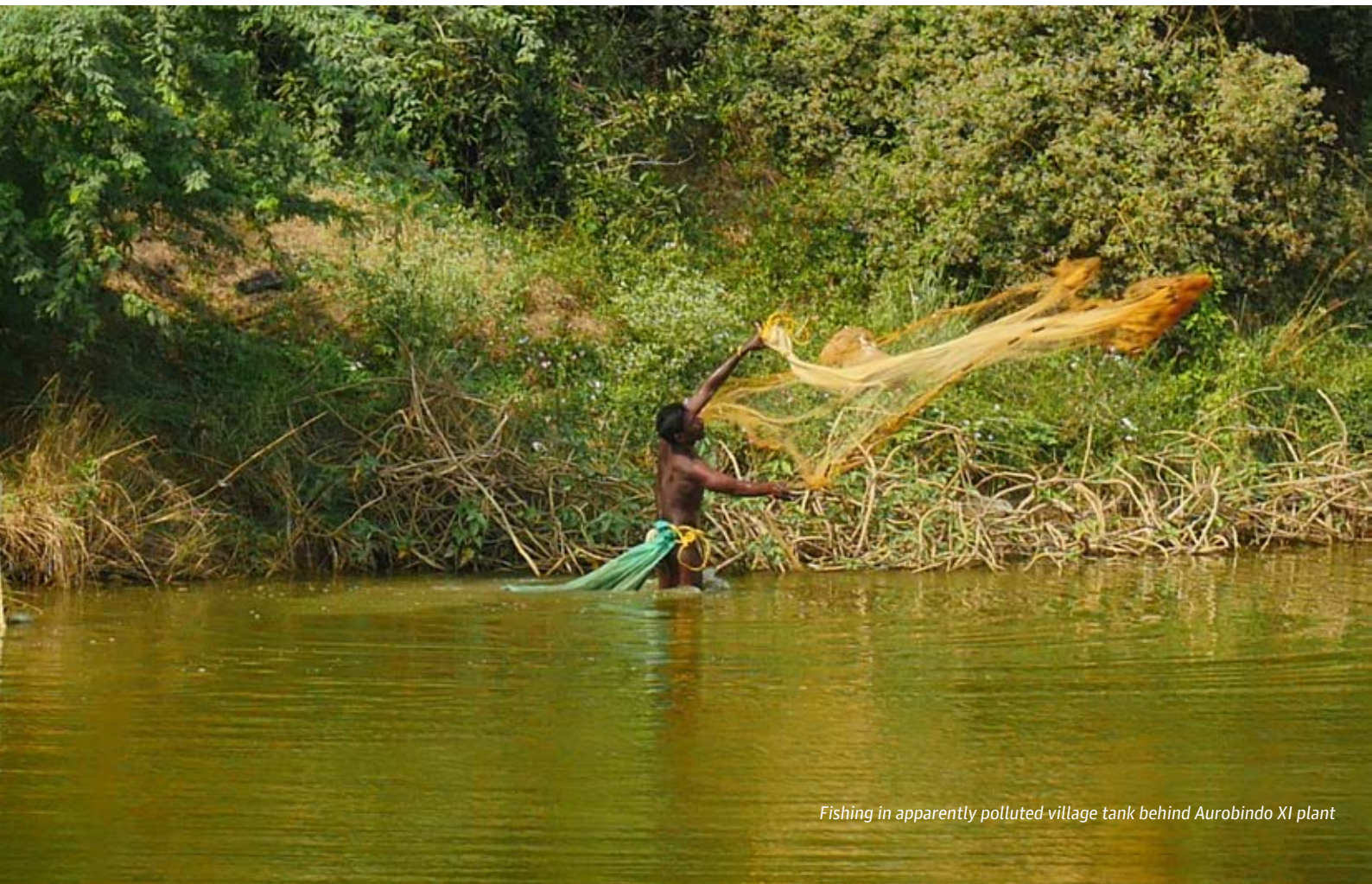
O. 'Nallahh' is an Urdu word meaning "arm of the sea" used to describe a stream, watercourse or steep narrow valley. The nallahs described here are sometimes manmade channels, sometimes following stream-type watercourses, but often with pipes connecting to them, then linking to each other, flowing into large waterbodies.

effluent affecting the fish and livelihoods of coastal villages, and discharge into the sea from the JNPC's Common Effluent Treatment Plant, which is presented as a key feature of the industrial area in marketing materials, also impacts these villages.

- **Hetero plant, Rajiyyapeta Village:** This plant is reported to be manufacturing antibiotics for Western export. It occupies a large site directly bordering one side of the village lake, around 2.5 km from the coast. There are no other plants in the vicinity. The lake appears to be completely polluted by chemical effluent and the water is undrinkable. Villagers originally sold the land ten years ago on the promise of jobs at the factory which never materialised - all jobs are given to outsiders.

Adjacent to the factory a large pipe mouth was observed sunk into the edge of the north east corner of the lake. Upon inspection the pipe mouth and the lake bed around had a thick layer of what looked like black chemical pollutant beginning just below ground level and going deep down under the lake. An informant confirmed that there are regularly chemical dumps which cause all of the water in the tank to turn black. The tank empties via a gully towards the sea and there is also water exchange into the surrounding area during high tides and via ground water leaching.

An informant alleged that the Andhra Pradesh Chief Minister Mr Chandra Babu Naidu is an "unofficial" shareholder in Hetero which might help explain how the company has managed to extend the site on protected forest land here to the current



plot of 2,000 acres, and also why they have not faced any prosecution over the lake contamination despite the fact there are no other factories anywhere around.

- **Aurobindo XI, Pydibhimavaram Village.** Desk research indicates that this plant manufactures APIs and has UK MHRA and FDA clearance. This ten-year-old plant is situated 80 km north-east of Visakhapatnam towards the coast and was set for expansion in 2015 according to Aurobindo.¹⁸⁶ The area has a number of manufacturing plants of different kinds but is not a concentrated hub of the sort seen elsewhere, and the site is set in amongst a number of villages, and surrounded by agricultural land. The team observed a lot of what looked like chemical effluent in standing water around the back of the plant. Although there are a couple of other factories in the vicinity, Aurobindo is the closest to the effluent observed.

Local village tanks are also in close proximity to the plant and villagers report serious pollution problems from the water. At the front of the plant is a quasi-permanent police outpost, put in place a few months ago apparently to intimidate workers who had staged a strike after many had been laid off. Gullies around the perimeter of the site at the rear were dry at the time of the investigation but clearly carrying effluent at other times since some were shored up with sandbags where there had been leaks.

In 2010 the pollution control board came to inspect the site following village demands, and found evidence of mass pollution from the Aurobindo plant, which was ordered to send its effluent to the sea 3 km away. However, this has been largely ignored: the plant continues to dump locally and the ground water is highly contaminated.

B. ON THE GROUND: INDUSTRIAL WASTE TREATMENT IN HYDERABAD AND VISAKHAPATNAM: A TALE OF SHOCKING DYSFUNCTION AND INDUSTRY CAPTURE

The bulk of pharmaceutical waste from factories around Patancheru is treated at two facilities: Patancheru Common Effluent Treatment Plant (CETP, also referred to under the acronym PETL, the name of the company that runs it)^P and Jeedimetla CETP, which were set up in the late 1980s to mid-1990s. Hazardous waste is handled at the Ramky Hazardous Waste Plant. Effluent from the Patancheru and Jeedimetla CETPs is channelled to the Amberpet Sewage Treatment Plant (STP), a major facility to the south of Hyderabad's Hussein Nagar Lake. All of these treatment plants were visited as part of the on-the-ground investigation in early 2016. The picture that emerges from the evidence gathered there and through consultation of numerous reports and documents is one of systematic dysfunction, with problems ranging from overcapacity and inappropriate processing of waste to a complete (albeit temporary) suspension of operations resulting in the discharge of untreated effluent into the local water supply over a number of days.

Local industrialists played a pivotal role in the establishment of the effluent treatment plants, and regulatory infringements there are generally treated with indulgence, not to say indifference, by the local authorities. This goes some way to explaining why they are failing today. In the case of the Jeedimetla plant, which is located roughly 20km east of the Patancheru-Bollaram cluster, it was set up by a cooperative society composed of local manufacturers. This meant that from day one, it was outside of direct state control, employing personnel appointed and paid by the polluting industries themselves. This model was subsequently replicated at the Patancheru plant, which is run by a private company owned by the manufacturers. The government and pollution control board became

P. Full name: Patancheru Enviro Tech Ltd.

mere overseers as the polluters effectively became the owners of the effluent treatment plants.¹⁸⁷

Oversight of the Patancheru CETP is the remit of the Telangana State Pollution Control Board (TSPCB). However, with the plant under the ownership of the industries that use it, and PCB officials in cahoots with companies, monitoring is poor. For example, the quality and quantity of the effluent entering the CETP should be recorded by the PCB. However, according to the Hyderabad University academic Vijay Gudavarthy, officials fail to adequately perform the required checks.¹⁸⁸ Kankana Das, Deputy Programme Manager at India's Centre for Science and Environment (CSE) paints a similar picture. She says that prior to the lifting of the 2010 moratorium on industrial expansion in Patancheru-Bollaram, PCB officials were under instructions to monitor all effluent discharge points including at the manufacturing plants themselves and the entry to the CETP. However, when the ban was lifted the PCB's responsibilities were reduced to inspecting the discharge point at Amberpet Sewage Treatment

Plant (STP), at the very end of the treatment process.¹⁸⁹

In 1997, a Supreme Court order resulted in the construction of an 18-kilometre pipeline to channel effluent from the Patancheru CETP to the STP at Amberpet, reported to be Asia's largest. From its very inception, the Amberpet pipeline project, which also receives waste from the Jeedimetla plant through Hyderabad's sewerage system, was vociferously rejected by environmental campaigners, who saw it as a way of just shifting the problem of pharmaceutical waste to another location within the Hyderabad area, and certainly not as an effective solution.¹⁹⁰ Almost twenty years on, its critics have sadly been proven right: the geography of pollution incidents has expanded to include new areas and the Musi River, which runs through the city of Hyderabad has become even more critically polluted. Furthermore, like the Patancheru CETP, the Amberpet STP does not have the capacity to remove any hazardous compounds, merely diluting the concentration levels of toxic and



Industrial effluent tanker leaving Patancheru CETP

other substances.¹⁹¹

To add to this gloomy picture, some manufacturing units are not even sending their waste to the effluent treatment plants. Illegal dumping either by tankers or through pipes that come directly from the manufacturing plants appears to be commonplace.

In an attempt to combat this, a rule was introduced whereby tankers are only allowed to visit the CETPs between 6am and 6pm, meaning any tankers seen on the roads outside this window are potentially dumping. Still, local reports indicate that the dumping continues, often late at night. Indeed, the investigation team heard from many informants about widespread dumping of effluent by tankers at roadsides, into open nallahs, and other water bodies. Those who bear the brunt of such pollution are the villagers and farmers living close by. Both Kankana Das and Vijay Gudavarthy report that health problems in the area are on the increase, including high rates of

miscarriage. Some pharmaceutical units attempt to distance themselves from illegal dumping, claiming no liability and instead blaming the tanker companies.¹⁹²

Patancheru Common Effluent Treatment Plant:

Companies from every stage of the production chain, including synthesis of intermediates and APIs, use the Patancheru CETP, with 200 tankers containing effluent reportedly entering the plant every day. At the plant, the investigation team encountered a high level of security, which prevented them from accessing the site. In 2007, a team of Swedish researchers alerted the international community to the possibility that the Patancheru CETP could be acting as a reservoir for the proliferation of antibiotic-resistant bacteria. They took water samples from the plant, which at the time served around 90 bulk drug manufacturers in the local area. The samples contained by far the highest concentration of pharmaceuticals reported in any effluent sampled to that point, with the presence of several broad-spectrum



Information board outside Patancheru Common Effluent Treatment Plant



antibiotics raising concerns about the development of drug-resistant bacteria. In particular, the researchers found "exceptional" concentrations of fluoroquinolones (notably ciprofloxacin), a powerful class of antibiotics reserved for the treatment of serious bacterial infections. The total discharge load was calculated as roughly 45kg of APIs per day, which is equivalent to the total amount consumed in Sweden (population 9 million) over an average 5-day period. The researchers observed that if the equivalent amount of the 11 most abundant APIs released over a 24-hour period were to be purchased as final products in a Swedish pharmacy, they would cost over 100,000 even if generic brands were selected.¹⁹³

A 2009 follow-up study found "unprecedented" contamination of surface, ground- and drinking water with pharmaceuticals in the region surrounding the Patancheru plant, and noted that "the most urgent aspect of the environmental drug contamination is that high levels of broad-spectrum antibiotics are likely to promote the development of highly antibiotic-resistant microorganisms and

possibly horizontal transfer of resistance factors to human pathogens." The use of "activated sludge" containing approximately 20% of raw human faeces, "inevitably containing pathogens", to metabolise the influent was described as an exacerbating factor in that close contact between pathogens, resistant bacteria and antibiotics can facilitate the transfer of resistance to pathogens.¹⁹⁴ Another related study published in 2009 found that a significant number of medicines available on the Swedish market contained APIs originating from Indian producers sending their effluent to PETL, implying an "international responsibility" to improve the environmental situation in Patancheru, all the more so in light of the global threat posed by the spread of AMR.¹⁹⁵

Ramky Hazardous Waste Plant: At the Ramky plant, which is the only one of its kind set up to treat hazardous waste in Hyderabad, effluent was observed to be seeping from under the perimeter wall of the plant into open land behind. According to an informant there is a major problem with the plant. The original design was intended for the final

Information board at Jeedimetla Common Effluent Treatment Plant



product sludge waste to be stored in containers, buried in synthetic-lined pits to eliminate seepage. The site was intended to last 25 years before reaching full capacity. In practice, there has been seepage on a large scale, and capacity was overshot

much earlier than 25 years, due to other regions also sending their own hazardous waste to the plant, which was not featured in the original plans.

The team was told by an informant that containers are now leaking into the ground, so that when it rains and during the monsoon season, the seepage drains out from the site underground into the water table and up into the surrounding area. The site claims it has expanded to meet the demand, but outsiders are not allowed access to inspect, and the pollution control board, which is supposed to be checking is reportedly highly corrupt.

The team observed what appeared to be chemical effluent in standing water pools in open land behind the site, starting only a couple of feet away from the perimeter wall. Also observed was what looked like a large hill inside the site, higher than the top of the perimeter wall, which the informant says is a heap additional waste now being piled up above ground level. There are high levels of security at the plant (team was forced to stop filming on the open public road outside the entrance).

A 2004 investigation by the Indian Supreme Court



Effluent flowing untreated through Amberpet Sewage Treatment Plant - closed for maintenance - directly into the Musi River

Monitoring Committee on Hazardous Wastes found that an "interesting feature of hazardous waste handling in [Hyderabad] is that a maximum percentage of it (52%) is declared "recycled", 45.4% goes for final disposal and only 2.5% is incinerable... There does not appear to be any controls over the waste once it goes for "recycling", as the example of SMS [a pharmaceutical company that has repeatedly violated basic environmental regulations] indicates. Thus, one could conclude that as far as AP [Andhra Pradesh] is concerned, one does not really know where the bulk of its hazardous waste really goes."¹⁹⁶

The report goes on to say "We had some indication of unsavory conclusions when we queried the Jeedimetla and Patancheru CETPs about what happened to effluent tankers which were turned back by the CETP managements because the effluent they carried did not meet the inlet parameters. There was no credible reply. The local citizen groups say that these effluents are then dumped into the nearest nallahs" (streams). In actual fact, tankers are rarely turned away because there are no checks on whether effluent meets these parameters."¹⁹⁷

Jeedimetla Common Effluent Treatment Plant: When the investigation team visited the Jeedimetla CETP, they encountered a heavy security presence. Tankers were observed entering and leaving the site from the public highway, and the investigators had a confrontation with security guards. There is a general air of paranoia at all the CETPs whereby any questions, photographers, video cameras are perceived as a threat and responded to with heavy-handed security and threats of police intervention.

Amberpet Sewage Treatment Plant: Inputs into the Amberpet plant come from a closed pipeline direct from Patancheru CETP and the city sewage system which also apparently contains effluent waste from Jedimetla CETP.

The investigation team visited the plant, which has

a capacity of 339 million litres/day (mld). Other STPs handling domestic waste generated by the city are Attapur (51 mld), Nagul (179 mld) and Nallahcheru (30 mld), so the total capacity of all STPs is 620 mld. However the total volume of waste emanating from the city is 3,000 mld, so around 60% of the sewage waste is not being treated, and is being discharged in a raw state into the river (let alone the chemical waste which is also entering the system from Patancheru and Jedimetla CETPs and other industrial areas - see Upal below for example).

The plant has applied for expansion to be able to manage a further 120 mld but there is an issue over land so it is not clear when or if this will go through. At the time of the investigation, the plant was not operational, and all the water entering was being diverted through side channels leading towards the river. The contractor on site told the team that the entire plant was closed for four days for essential maintenance. During this time there was no treatment whatsoever. He told the team that they test for 14 parameters daily, which are to do with domestic waste only. The waste is screened for plastic objects, then filtered through grit and sand, then passed through the bioreactors.

When asked whether they test for toxicity and chemical effluent content, he said that they have no resources or money to do so, but once every couple of months the Environmental Pollution Testing Research Institute come to check whether toxicity levels have been breached. When these are found to be over the limit, instructions are issued by the institute to reduce the levels of toxic chemicals by 20-25% by mixing the toxic waste with domestic waste in order to "decompose the heavy metals." The contractor freely acknowledged that heavy metals do not decompose in biowaste and that this measure is therefore futile.

A few dozen metres from the STP is the **Golnaka Surplus Nallah I&D (Interception and Diversion)** which channels effluent into the STP from various sources. This plant is situated at the mouth of a



Effluent at Chaitanya Nagar Colony

wide nallah which leads out from the bottom of Hyderabad's Hussein Sagar lake, and is discharging large volumes of city waste directly into the river beyond the plant. A small proportion of the nallah water is being diverted through the plant, and mixed with the contents of other pipelines converging here. The investigation team observed two overhead pipelines which descend below ground at this point. They were told that one of these contains domestic waste from the Chardagard area of the city, and the other is the 18km Patancheru pipeline, and that a pipe here takes 20% of the water from the nallah and inputs into the Patancheru pipeline at this location. From here the pipe runs underground into Amberpet.

Returning to the Amberpet plant the team was told that all incoming pipes, i.e. domestic waste, other inputs and the contents of the 18km pipeline, are all mixed into one large pipe and enter the plant as one flow. When asked if they were aware that the

Since close-by available water sources are highly contaminated and in any case insufficient in volume for their requirements, the pharmaceutical companies buy up water (collected by tanker) from outlying villages - this has the knock-on effect of depriving village farmers of water for their own agricultural land, making farming increasingly unsustainable, and causing crisis for these already impoverished rural communities.

flow contains chemical effluent from Patancheru going into a domestic sewage plant unable to treat it, the operative said he was unaware and could not comment.

In Visakhapatnam, the investigation team visited the Jawaharlal Nehru Pharma City Common Effluent Treatment Plant. The pipeline from the plant originally ran to the sea overground but has now been buried, with concrete inspection manholes at intervals which enable its route to be traced for the 6-7 km it runs to the sea discharge point. Informants report that there have been leaks at various points over time. A huge thermal power plant also discharges into the sea close to the CETP pipe and contributes to the general contamination of the area.

C. ON THE GROUND: LOCAL POLLUTION IMPACTS IN HYDERABAD AND VISAKHAPATNAM AREAS

In Hyderabad, at least twenty-two villages affected by pollution lie in the immediate vicinity

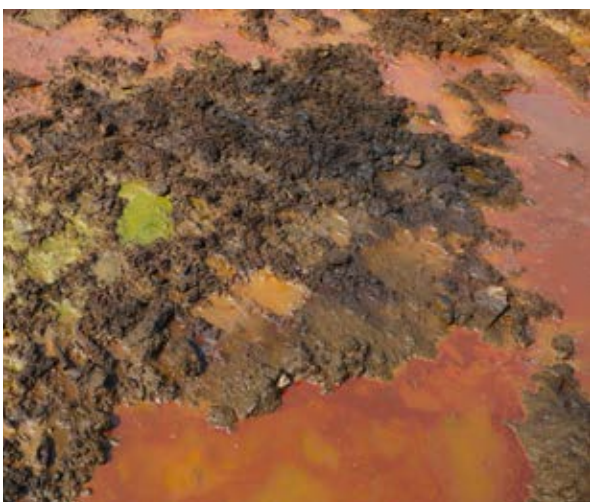
of the industrial development areas where pharmaceuticals and bulk drugs manufacturing units are located. In addition to this, twenty-three villages along the Musi River and several others



Buffalo grazing adjacent to polluted Isnapur Lake

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situated along the streams carrying pollutants, are affected.¹⁹⁸ Many of them are engaged in water-intensive activities such as the the production of rice and sugar cane, and aquaculture, so the contamination of the area's water supply poses a significant threat to their livelihoods. In Visakhapatnam, which is on the coast of Andhra Pradesh, the sea is often used as a dumping ground for industrial effluent, and the investigation team came across several instances of pipes feeding from plants or industrial areas into the sea. The impact of the pollution on local fish stocks has been dramatic, depriving local people of a key source of revenue.



Close-up of the water flowing into Isnapur Lake, Pashamylaram

a. Hyderabad and surrounding areas

At **Chinna Vagu, Chaitanya Nagar Colony**, chemical effluent was clearly observed to be pouring along an open nallah coming down from the direction of Patancheru industrial area. This is meant to be a general water/sewage nallah, however the surface of the stream was covered in heaps of thick white froth and there was an overpowering chemical smell. A small pond had collected adjacent to the main stream, and farmers were running plastic hose pipes from this highly contaminated water source into adjacent land where they were growing guava and other fruit and vegetables. There were catfish in the pond. According to our informant these are the only fish which can survive in such polluted water, and they are caught and sold for human consumption. The Chinna Vagu nallah feeds into the overall network of nallahs which form the sewage system, theoretically ultimately being treated for sewage (but not for chemical waste) at Amberpet STP before being discharged into the Musi River.

Isnapur Lake, Pashamitaram is a large tract of water adjacent to one side of the Patancheru industrial area. It is traditionally rain-fed, so

would be completely dry at the time of year the investigation took place. However, there was a substantial amount of water in the lake, all of which derived from waste flowing in through open nallahs from the industrial area. What appeared to be chemical effluent was observed to be flowing into the lake, forming thick crusts in some places, and in others appearing to be bubbling with chemical reactions occurring under the surface.

The lake bed was thickly coated in a black tarry sediment which appeared to go down to a considerable depth. An informant who herds cattle at the lakeside (some animals were entering the water) said that he brings around 60 buffalo each year to the area to graze the common land grass here for various owners in surrounding area. He said that half of the herd fall sick and die each year, from drinking the water or eating the grass - the buffalo are milked and the milk is consumed by

owners/purchasers. The animals then go to the slaughterhouse and enter the food chain as meat. He told the team that the pharmaceutical industry association pays compensation to the owners each time, and they use it to buy replacement animals. Farmers are bringing animals here to graze despite the risks since their former agricultural land is all being bought up, often forcibly, for development. This means that they have shrinking areas of public grazing space and have to resort to whatever is available, even if it is contaminated.

Gaddapotharam: Nallahs flowing downhill from Gaddapotharam industrial area, which contains many pharmaceutical companies and has no on-site CETP, enter into an existing irrigation system which traditionally watered the entire valley, and enabled a drought-prone region to achieve two crops per year for 400 years.



Close-up of chemical pools in lakebed at Kazipally

The gullies from many factories on the site all connect in a large network. In one direction they lead towards a vast lakebed, now completely dry but smelling strongly of chemicals and with what looks like chemical salt crusting its surface. In the other direction the gullies converge and feed into an open concrete well, built around 2005, about 25 feet deep, filled to the brim with effluent.

Since a large volume of effluent is constantly pouring in from the whole Gaddapotharam industrial area, the overflow is diverted through a side channel which leads off towards the edge of the hill and from there runs in a strong steady flow down an open nallah into the wide valley below. An informant told the team that this well was constructed officially, under the auspices of an organisation called the Model Industry Association^Q even though it is illegal to collect untreated chemical effluent in open tanks. In the rainy season the well overflows and more of the effluent inside joins the existing open flow heading out and down towards the valley. The original intention had been to regularly empty this well and transport the contents by tanker to a Common Effluent Treatment Plant, but the informant says this has rarely, if ever, been known to happen.

The system is constructed of interlinked canals and water tanks controlled by gates, the first of which is at **Kazipally village**. The tank there was completely dry when the investigation team visited. The villagers keep all the gates permanently open now, which means that no water can collect within the system any more, and the lake bed was crusted with what looked like concentrated chemical salts. Rings of what appeared to be rust-coloured chemical deposits were visible on granite boulders dotted across the lakebed. Digging with a stick below the surface crust revealed thick black tarry sediment, which our informant told us has been measured and goes down to a depth of 200 feet.

The entire irrigation system, and the surrounding water table and fields is completely contaminated

with industrial effluent on a huge scale and has been for decades. The growth of the pharmaceutical industry in the area greatly exacerbated the problem. Villagers can no longer drink from the lake, from their wells or even from the bore well which was provided for safe drinking water. They have very limited weekly access via tap to a pipeline connected to municipal water sourced from the Manjeera river but this is intended for urban Hyderabad, is already under great pressure, and cannot be spared in any great volume.

Herds of buffalo and goats graze the surrounding land, but very little can be grown since the soil is so toxic. An informant told the team of an incident (undated) when a large chemical dump had entered the lake, and buffalo who were in the water emerged with their skin hanging from their bodies. It should be noted that the area was deemed "critically polluted" on the Central Environment Pollution Index (CEPI) assessed by the Central Pollution Control Board (CPCB) up until the early 2000's, then was de-notified around 2009 when its overall score fell below 70, then re-notified when the score rose in 2013 to 76 at a time when pharmaceutical pollution was greatly increasing in the industrial area.



Apparent effluent pollution on the Musi River

Q. Information on the Model Industry Association is hard to come by. However, it would appear that Aurobindo is a member.



Effluent at Upal gully

Village informants reported to the team many serious health issues, including women having miscarriages, skin disorders, cancers, and intestinal problems. The livestock suffer from the same issues, for example goats have frequent miscarriages from eating the contaminated grass. The investigation team was told that nothing can be grown for human consumption in Kazipally village.

Bonthapalle, Domudugu Village: Village people avoid eating the food they grow here, which is mostly sold elsewhere, and there are many health problems linked to the high pollution levels, including miscarriage, cancers, deaths of livestock etc. The village well is contaminated and

unusable, and they have had to dig a bore well a long way from the village for their drinking water. No locals are employed in the Hetero factory here despite assurances they would be at the time of land purchase. The plant has informers within the village, and villagers who complain are threatened by local police who are complicit with the plant owners. Between 50-100 tankers enter the plant each day, each carrying approximately 5,000 litres of water. Yet only 1-2 tankers leave the site per month carrying wastewater for treatment at the CETP. This is a large discrepancy, by no means fully accounted for by evaporation processes. A source told the investigation team that between Hetero I and another plant called Horner Labs is a tract of privately owned land, into which effluent pollution leaks from both sites. The landowner will reportedly not act against the companies as he is involved in a business arrangement with them.



Downstream of Amberpet Sewage Treatment Plant: The investigation team visited locations downstream from the discharge point of the Amberpet STP on the Musi River to gauge the impact of the pollution on local communities.

At **Upal**, a municipality located to the east of Hyderabad, high levels of what looked like chemical effluent were observed being discharged from

a stream into an open nallah which heads down towards Amberpet STP. This effluent emanates from other industrial areas at Nacharam and Mallapur, and joins with the waste coming from Jeedimetla and the pipeline, entering the STP, and ultimately being discharged into the Musi. It is supposed to be treated before joining the main sewage network, but the nearby treatment plant is only designed for sewage treatment, not chemical effluent. The pollution control board have insisted that the effluent is domestic detergent but informants report that the white foam on the surface has been seen to reach 30 feet high at midnight on some occasions, which is an unusual time for domestic waste discharge or detergent to appear. The nallah flows down into the Hussein Sagar lake then nallahs lead out from the bottom of the lake towards the Amberpet plant and the river. Much of the flow actually bypasses Amberpet and is discharged directly into the Musi.

Next to the Marriott Hotel, adjacent to the bottom of the Hussein Sagar lake, construction work was underway at an intersection where water flowing from the lake joins an open nallah again heading towards the Musi. At this point the flow is joined by an underground pipe, the contents of which look very much like chemical effluent, with black tarry sediment. Once again, chemicals from industrial areas are apparently being mixed in the open with the domestic sewage system and flowing untreated either into the Amberpet STP or being discharged

directly into the river.

Edulabad Village is approximately 20 km downstream, and since the plant was opened villagers have faced enormous pollution and destruction of livelihoods both fishing and farming, as well as major health problems. Fish in the village tank regularly die when chemical effluent flows into the water body.

The Musi River historically was seasonal and rain-fed, and irrigated approximately 24,000 hectares of adjacent farmland, but now due to the massive increase in waste water volume (up 80% to 700 million gallons/day) being added to the flow by Hyderabad city and the STP, it has become a perennial river, irrigating 150,000 hectares, so most farmers have turned their crops over to rice paddy which is deemed more lucrative.

A farmer interviewed for the investigation said that buffalo no longer mate naturally, and have to be artificially inseminated to produce young - this is very costly for the farmers as it may take 3-4 attempts to be successful. The milk produced by the animals fetches a very low price as it smells bad,

Women working in paddy irrigated by the polluted Musi River



and animals often give as little as 3 litres (the norm is 10 litres). Other livestock also face health issues due to contaminated water and feed.

Children have eyesight problems, old and young people have joint pains and skin diseases, people and animals have frequent diarrhoea. Rice yields may increase (due to fertiliser and pesticide contamination) but the weight of the rice is down by 50% and the quality is very poor. The investigation team crossed the Musi River downstream, and observed a new bridge under construction approximately 40 feet (12 metres) higher than the existing one. This is being built because at certain times the piles of white foam chemical pollutant visible on the river surface mount up 10-20 feet (3-6 metres) higher than the river, obscuring the existing road bridge - drivers are unable to see the road and have driven off into the river, resulting in fatalities.

Pedhagudam Village is 12 km further downstream, local informants spoke of (and showed) skin conditions caused by working in the water in their paddy fields. The water table is totally contaminated and all crops are affected: rice is blackish in colour and spoils very fast (if cooked in the morning it will be bad by the afternoon). The village has to have drinking water delivered by tanker and has to pay for it. One informant has paddy fields on the river bank. He says he regularly observes tankers coming down from the industrial areas illegally dumping straight into the river (i.e. bypassing the CETP). Once, some of the farmers apprehended a group of tanker drivers who were dumping and brought them before the police. Nothing was done, they were released and the farmers themselves were threatened by the police.

In addition to the pollution entering the sewage system, many informants report widespread dumping by tankers at roadsides, into open nallahs, and other water bodies, and a doctor told the team of many cases he personally treated that were directly linked to chemical pollution. These include

menstrual problems, miscarriages, low fertility, birth abnormalities, organ failures, skin problems, high levels of heavy metals present in breast milk of mothers, fluoride poisoning causing bone defects and many other illnesses.

b. Visakhapatnam and surrounding areas

Uracheruvu lake, Tanam Village: A nallah from the Jawaharlal Nehru Pharma City feeds into this village water supply and has apparently completely contaminated it. In addition to this, tankers from the city have reportedly dumped illegally directly into the lake and onto surrounding land and nallahs. The water is now poisoned - initially after much campaigning by local activists the companies delivered free tanker water, but this contribution (and admission of responsibility) faded once media attention moved on and now the villagers have to buy most of their water at a cost of Rs. 20 for 20 litres. An informant told the team that buffalo are poisoned and produce low levels of milk which tastes and smells bad, so they have problems selling it. The animals stop yielding completely very early compared to the norm. Villagers also report the same health problems reported by the other communities the team visited.

Mutyalammalem Village: This village is situated at the southern end of a small coastal bay. Around the centre of this bay, the Jawaharlal Nehru Pharma City CETP pipeline discharges into the sea. The pipe of the thermal power station discharges at the northern end of the bay. The nallah from the Pharma City also ultimately discharges in this area, having been joined by 6 other nallahs along its route down to the sea.

The community is dependent on fishing, men fish at sea on small boats, and women dry and sell the fish at the market. The team was told that the villagers' livelihoods have been devastated by ongoing chemical pollution of the coastal waters over the last ten years. The fish stock has decreased dramatically, and the quality of fish caught has

also deteriorated. One fisherwoman told the team that the fish catch was often blackish in colour and smells and tastes bad, so that it is very difficult to sell - and frequently the entire catch has to be thrown away to rot since nobody will purchase it. They themselves still eat the fish as they have no other option and there are health issues throughout the village.

Tikkavanipalem: The team observed the area of bay where the CETP pipeline discharges. Although the pipe is buried underground until it is out to sea, its route is indicated with concrete blocks used to weigh it down. The opening of the pipe lies several metres out in the bay and is visible during very low tides around October. An informant told the team that there are often chemical dumps through the pipe on a Monday evening, because traditionally fishermen do not fish on a Tuesday as they attend the market, so will not be out at sea to observe the yellow effluent and the immediate effect on fish; by the time they commence fishing again on Wednesday the effluent has diluted into the sea. It is also common, reportedly, for dumps to be made under the cover of cyclone and other adverse weather conditions during the year.

Pydibhimavaram Village: Villagers are using the lakes for fishing and washing. To the side of the Aurobindo Unit XI plant is a wide rain-fed river basin, currently dry but full during the monsoon. An informant said that in the monsoon the river becomes full of chemical effluent leaching from the plant, that local villagers are suffering with major health problems including blood disorders of children, weakness and anaemia, that livelihoods have been destroyed by the pollution, and that the plant ignores all representations from the community.

An additional concern expressed was that a nuclear plant has been approved for construction 2 km away and will come on-stream in 1-2 years. It is feared that pollution discharge from that plant might combine underground with chemical pollution

from this site to create further toxic and dangerous compounds. Although there have been some small localised studies of health impacts, there has been no systematic wide-scale sampling and testing in this area.

Rajiyyapeta Village: The villagers suffer with the usual severe health problems. There has been a marked increase in cancer incidence over the ten-year period. All surrounding ground water is contaminated and village wells are undrinkable. The villagers used to fish in the lake but all the fish have died. A nallah flows into the lake from the west, and is itself already polluted, reportedly by illegal tanker dumping of effluent upstream. Villagers report frequent illegal dumping by company tankers in the surrounding areas.

PART 3 - Conclusion

The overall picture in the valleys and agricultural lands surrounding industrial areas in Hyderabad is a bleak one, of communities which have been blighted by pollution for thirty plus years, since Indira Gandhi's first welcoming in of heavy industry to the area. There is no doubt that the pharmaceutical industry has played its role in the mounting pollution crisis, confirmed by pollution index readings which have steadily risen over the last 10-15 years, during which the bulk drug industry has boomed in the region. The picture in Visakhapatnam is very similar although the polluting industries are of more recent vintage, and problems mostly started in the early 2000s. In the entire area visited, the team did not see one single village which actually had its own safe drinking water supply - all of them had to buy water from tankers or other sources. This also has a knock-on impact on agriculture, especially as food production is competing with the pharmaceutical industry for water and land.

The pharmaceutical companies appear to act with more or less total impunity. The investigation team was told time and again of specific examples where companies had clearly polluted, communities tried to take action and were ignored, and their claims denied. Even when the Pollution Control Board itself took action (a rare occurrence since all information suggests that it is highly connected to the industry it is intended to police), then their prosecutions and fines did not act in any way as a deterrent, given that the companies in question paid the (usually derisory) fines and continued to pollute in the same manner.

Activists have tried to bring numerous cases before India's Supreme Court and Green Tribunal, but face enormous problems since these cases drag on for years and have to be personally funded, to avoid accusations from the industry of 'bias.' Of particular concern to many of our interlocutors was the deepening of the nexus between politicians and the industry since Prime Minister Narendra Modi's accession to power. Under a mantra of "ease of

doing business" Modi has been heavily promoting India as a location for outsourcing of polluting industries which the West would prefer not to host within their borders, and all regulatory bodies have had their teeth drawn, either by having pressure applied from above, or by being 'bought' by the industry.

Heedless of their citizens' distress, the state governments of Telangana and Andhra Pradesh are keen to promote further industrial development in the region. A huge 11,000 acre industrial park dedicated to pharmaceutical manufacturing, the 'Hyderabad Pharma City', is planned in the city's Rangareddy District.¹⁹⁹ Local inhabitants and campaigners have expressed profound disquiet about the plans, not least because 6,000 acres of the area are currently forested.²⁰⁰ At a roundtable on 'Pharmacy Implications on Environment' in October 2015, distinguished Supreme Court lawyer M.C. Mehta stated his opposition to the project, explaining that the new development had the potential to become "another Patancheru." Mr Mehta further claimed that "foreign companies were cleverly exploiting Indian resources and polluting the water and land [in India] while keeping their lands safe and clean."²⁰¹ The Bulk Drug Manufacturers Association is also urging the government of Andhra Pradesh to allot between 6,000 and 10,000 acres for the establishment of two industrial states between Visakhapatnam and Kakinada and Naidupeta near Nellore exclusively for pharmaceutical units.²⁰²

There is little space for dissenting voices within institutions, and the political space for public debate is being closed down. Local NGOs working on environmental issues face problems if they communicate with internationals, and risk having their assets frozen if they are deemed to be challenging government/industry interests. The industries themselves operate private security firms (as experienced directly by the investigation team) and intimidate and threaten local villagers who attempt to call them to account for polluting

activities. The police also seem to be complicit with the industry, as backed up by several first-hand accounts.

The overall impression gained from interlocutors was a pessimistic one. It is felt that the government intends to continue to pursue a pro-industry line regardless of human, social or environmental costs, and will turn a blind eye to the manipulation or overriding of regulatory legislation by industry, in the service of profit-driven production.



Aurobindo is one of India's largest vertically integrated pharmaceutical companies. Based in Hyderabad, it exports to over 150 countries around the world and more than 86% of its revenues are derived from its international activities. Aurobindo supplies antibiotics to the U.S. and UK market and has operations in several EU Member States."



Aurobindo supplies antibiotics to NorthStar Rx, a U.S.-based generic drug company which is a subsidiary of McKesson.



In 2009, Pfizer licenced a selection of generic drugs from Aurobindo as part of the U.S. company's "grand plan" to expand into generics with lower manufacturing costs. The deal failed when the U.S. FDA suspended imports from Aurobindo's Unit VI in Hyderabad



India's place in the global pharmaceutical supply chain

Dr Reddy's supplies antibiotics to the U.S. and UK market



Teva is listed by Lee Pharma and MSN Laboratories as being a client. Both companies operate factories in the Patancheru-Bollaram cluster

Aurobindo has imported APIs from polluting factories in China run by CSPC, NCPC, Harbin Pharmaceutical Group and Sinopharm. It has a 10% stake in Sinopharm's Datong facility.



Jawaharlal Nehru Pharma City



Aurobindo and Hetero have subsidiaries in Malta. Aurobindo describes Malta as a "gateway" to the European market

Jawaharlal Nehru Pharma City (JNPC) lists U.S. giant Mylan, Pfizer subsidiary Hospira, Japan's Eisai, Germany's Pharma Zell and India's own SMS Pharmaceuticals as operating in its 'Special Economic Zone' (SEZ). Other clients include Aurobindo, Hetero and Lupin Laboratories.

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