



# 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 polluted<sup>1</sup>. 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.<sup>2</sup> 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)<sup>A</sup> 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.

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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 species<sup>3</sup> to the feminisation of fish<sup>4</sup> 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."<sup>19</sup> 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.<sup>20</sup>

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.<sup>B</sup>

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*"<sup>C</sup>

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."<sup>D</sup>

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B. CDDEP, 2015, State of the World's Antibiotics 2015, [http://cddep.org/publications/state\\_worlds\\_antibiotics\\_2015#sthash.BmYsUzGz.dpbs](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](http://ec.europa.eu/health/files/environment/study_environment.pdf)  
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*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 20<sup>TH</sup> 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 economy<sup>8</sup> and has experienced rapid and sustained expansion since the second half of the 20<sup>th</sup> Century.<sup>9</sup> A 2010 report by McKinsey and Company predicted high growth rates in the sector, with turnover increasing from \$12.6 billion in 2009<sup>10</sup> to a projected \$55 billion by 2020, with the potential to reach \$70 billion in an "aggressive" growth scenario.<sup>11</sup> 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.<sup>13</sup>

From the 1970s onwards, changes to the country's patent laws to make medicines affordable to the poor,<sup>14</sup> 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.<sup>15</sup>

Today, India is one of the world's leading suppliers of generic drugs, which account for approximately 75 per cent of its market by volume<sup>16</sup> and revenues of \$15 billion in 2014.<sup>17</sup> The country is responsible for around one-fifth of the world's production of

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

**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.<sup>22</sup> These APIs, manufactured at very low cost in China<sup>23</sup>, 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.<sup>E</sup>, 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

<sup>E</sup> 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."<sup>24</sup> 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.<sup>25</sup> Antibiotic APIs are among the products for which India is dependent on Chinese imports.<sup>26</sup> 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.<sup>27</sup>

## 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.<sup>28</sup> 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.<sup>29</sup> The city of Hyderabad in Telangana state, which was part of Andhra Pradesh until its division into two separate states in 2014,<sup>30</sup> 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."<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup>

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.<sup>34</sup> 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.<sup>35</sup> The city's Patancheru-Bollaram cluster, which is part of the Medak District, is home to a variety of industries<sup>36</sup> 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.<sup>37</sup> Several studies, including a detailed survey by Greenpeace in 2004<sup>38</sup> 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.<sup>39</sup>

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.<sup>40</sup> 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.<sup>41</sup>

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; Maithri Laboratories; Yag Mag Labs Pvt Ltd; South Whale Chemicals; Eshwar Pharmaceuticals; KRR Drugs & Intermediates Pvt Ltd; Vayajayanthi 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; Sritha 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](http://cpcb.nic.in/Newspaper_Advt_Online_Monitoring.pdf)]

players, partly by making its patent regime more amenable to foreign firms in the mid-2000s<sup>42</sup> 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.<sup>43</sup> Abbott Laboratories, Pfizer and GlaxoSmithKline are identified as key international players in India.<sup>44</sup> 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.<sup>45</sup>

### 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).<sup>46</sup> 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)".<sup>47</sup> 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.<sup>48</sup> This made it considerably more difficult for Indian companies to copycat new drugs and make "new" generics.<sup>49</sup> 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.<sup>50</sup>

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 antibiotics<sup>6</sup> 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.<sup>51</sup> 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.<sup>52</sup> 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.<sup>53</sup> 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.<sup>54</sup>

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.<sup>55</sup> and Dr Reddy's Laboratories.<sup>56</sup>

Over half of India's pharmaceutical exports are to highly regulated markets such as the U.S. and the EU.<sup>57</sup> 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.<sup>58</sup> 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 FDA<sup>59</sup> and the EU introduced a ban on 700 generic drugs supplied by Indian companies.<sup>60</sup>

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.<sup>61</sup> 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.<sup>62</sup>

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.<sup>63</sup> Under the trade partner 'World', antibiotic trade value for India is \$858,827,114 with a total net weight of 11,041,080 kg.<sup>64</sup>

#### 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 Ltd<sup>95</sup>**

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.<sup>66</sup> 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.<sup>67</sup> This has generated "significant costs for local populations in terms of loss of assets, health, natural resources and quality of the environment."<sup>68</sup>



*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"<sup>69</sup> 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,<sup>70</sup> 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.<sup>71</sup>

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."<sup>72</sup>

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.<sup>73</sup>

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<sup>H</sup> and the case is still being heard at the time of writing.<sup>74</sup>

## 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."<sup>75</sup>

**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.<sup>76</sup>

**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.<sup>77</sup>

**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.<sup>78</sup>

**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.<sup>79</sup>

**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.<sup>80</sup>) 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/](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.<sup>81</sup>

**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*"<sup>82</sup>) 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 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.

Bonthapalle

BANJARA HILLS  
Hyderabad

# 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