



Novartis (Sandoz): Pharmaceutical waste causing resistant superbugs and health risks

By outsourcing pharmaceutical production to countries with weak anti-pollution legislation companies like Sandoz, a subsidiary of the Swiss Novartis, contribute to the emergence of bacterial ‘superbugs’, blamed for 700,000 deaths every year.

Problem Analysis

Next to climate change, the international spread of multiresistant bacteria is one of today’s biggest catastrophes. “About 700,000 deaths every year worldwide are linked to common antimicrobial therapies becoming ineffective against these superbugs.”¹ It has been estimated that total global deaths caused by antibiotic-resistant infections could reach 10 million per year by 2050². Water sources in and around major pharmaceutical production hubs often contain excessively high levels of drug residue because sewage and industrial emissions from bulk drug production are often dumped untreated or only partially treated in the environment. Local bacteria then become resistant to those drugs, becoming the so-called superbugs, which have created a global public health emergency.³

Many pharmaceutical majors, including Novartis, outsource their production to emerging markets where labour is cheap, workforces skilled and environmental standards weak. As a result, places like Hyderabad where Novartis subcontractor Mylan Laboratories is based, come to depend on the economic benefits provided by the sector. The contamination will continue until pharmaceutical companies and major buyers of antibiotics take their responsibility for their entire supply chain.

Company

Main Company: Novartis International AG

Head office: Basel, Switzerland

Subsidiary: Sandoz, Germany

Other company involved: Mylan Laboratories Ltd, Hyderabad (India)

Sandoz claims to be the the “largest generic antibiotic

manufacturer in the world, with 300 million packs of antibiotics produced annually” and “the 3rd largest maker of antibiotics globally and we produce the active pharmaceutical ingredients (API) for other leading companies.”⁴

Company background

CEO of company: Joseph Jimenez (Novartis)

Total compensation: 11,989,448 CHF⁵

Company’s annual net PROFIT: US\$ 6.7 billion (2016)⁶

Company’s annual TURNOVER: US\$ 48.5 billion (2016)⁷

Countries in which main company is present: Novartis products are available in 155 countries⁸

Number of employees: 123,000 employees worldwide⁹

Company activity

Company activity: Pharmaceuticals

Business sector: Antibiotic production

Country and location in which the violation occurred

India, Hyderabad

Summary of the case

India is in the grip of a severe water pollution crisis of which industrial pollution is a leading cause. This is in particular due to its bulk drug production sector, which has a major hub in the southern Indian city of Hyderabad, where around 170 pharmaceutical companies are located.¹⁰ During the last 40 years the sector has become more and more economically important to the area. Many pharmaceutical majors, based in the US and Europe, outsource their production to emerging markets where labour is cheap, workforces skilled, and environmental standards weak.¹¹ The production plants in Hyderabad supply almost all of the world’s major drug companies. As such Mylan Laboratories Ltd, one of India’s top ten pharmaceutical exporters and one of the major

polluters, supplies Germany's Sandoz (the generics arm of Switzerland's Novartis).¹² Despite this concentration of drug manufacturing very little attention has been paid to the impact of pharmaceutical production on the environment and the inhabitants living in proximity to factories and industrial parks.¹³

In Hyderabad, sewage and industrial emissions from drug manufacturing are often dumped untreated or partially treated into the environment. Scientific studies have found excessively high levels of drug residue (antibiotic and antifungal) in water sources in and around a major production hub in Hyderabad, as well as high levels of bacteria and fungi resistant to drugs. This results in the creation of superbugs, as the microbes living there build up resistance to the ingredients in the medicines that are supposed to kill them. These superbugs travel easily and have multiplied in massive numbers all over the world; the result is a public health emergency that is already killing hundreds of thousands of people a year.^{14,15}

International bodies, such as the World Health Organization, say the governments of the countries where the drugs are made are the ones responsible for stopping the pollution – but studies show that domestic legislation is having little impact on the ground.¹⁶ The Hyderabad-based state pollution control board said they did not find antibiotics in their studies of the water in the area and that the situation has improved. However, despite several requests from media outlets they did not share a copy of their report.¹⁷ A study of this issue prepared for Nordea by Changing Markets and Ecostorm¹⁸ attracted media attention, but neither Indian authorities nor the companies responded. Hyderabad heavily depends on the economic benefits that come from the bulk drug production sector. It's up to the home states of pharmaceutical companies, and the major buyers of antibiotics, to ensure they take their responsibility for the impacts of their entire supply chain.

Endnotes

- 1 "Swiss Tourists Carried Superbugs From India", Asian Scientist, 28 July 2016, at <http://www.asianscientist.com/2016/07/health/travelers-import-drug-resistant-superbugs-colistin-india> (accessed at 23-11-2017)
- 2 Akram Ahmad et al., "Pharmaceutical waste and antimicrobial resistance", *The Lancet*, June 2017, <http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2817%2930268-2/fulltext>, (accessed at 23-11-2017)
- 3 Christoph Lübbert et al., "Environmental pollution with antimicrobial agents from bulk drug manufacturing industries in Hyderabad, South India, is associated with dissemination of extended-spectrum beta-lactamase and carbapenemase-producing pathogens" 26 April 2017, *Infection*, Volume 45, Issue 4, pp 479–491. at <https://link.springer.com/article/10.1007/s15010-017-1007-2> (accessed at 23-11-2017)
- 4 See Sandoz company website at <https://www.sandoz.com/our-work/disease-areas/anti-infectives> (accessed at 13-11-2017)
- 5 Novartis, Annual Report 2016, <https://www.novartis.com/sites/www.novartis.com/files/novartis-annual-report-2016-en.pdf> (accessed at 23-11-2017)
- 6 Ibid., Gross profit from continuing operations
- 7 Ibid., Operating income from continuing operations
- 8 Ibid., p. 8
- 9 Ibid., p. 8
- 10 Madlen Davies, "Big pharma's pollution is creating deadly superbugs while the world looks the other way," *The Bureau of Investigative Journalism*, 6 May 2017 at <https://www.thebureauinvestigates.com/stories/2017-05-06/big-pharmas-pollution-is-creating-deadly-superbugs-while-the-world-looks-the-other-way>
- 11 "Impacts of pharmaceutical pollution on communities and environment in India," Nordea, February 2016 at https://www.nordea.com/Images/33-107450/2016%2004_Nordea%20report_final_web_single%20page%20small.pdf (accessed at 4-12-2017)
- 12 Ibid.
- 13 Ibid.
- 14 Madlen Davies, "Big pharma's pollution is creating deadly superbugs while the world looks the other way," *The Bureau of Investigative Journalism*, 6 May 2017 at <https://www.thebureauinvestigates.com/stories/2017-05-06/big-pharmas-pollution-is-creating-deadly-superbugs-while-the-world-looks-the-other-way> (accessed at 4-12-2017)
- 15 Zedda Siddiqui, "The cost of cheap drugs? Toxic Indian lake is 'superbug hotspot'," *Reuters*, 29 September 2016 at <http://uk.reuters.com/article/us-health-superbugs-india-insight/the-cost-of-cheap-drugs-toxic-indian-lake-is-superbug-hotspot-idUKKCN11Y35G> (accessed at 4-12-2017)
- 16 Madlen Davies, "Big pharma's industrial pollution goes unchecked, breeds superbug crisis," *EcoWatch*, 13 May 2017 at <https://www.ecowatch.com/big-pharma-pollution-superbugs-2398355351.html> (accessed at 4-12-2017)
- 17 Zedda Siddiqui, "The cost of cheap drugs? Toxic Indian lake is 'superbug hotspot'," *Reuters*, 29 September 2016 at <http://uk.reuters.com/article/us-health-superbugs-india-insight/the-cost-of-cheap-drugs-toxic-indian-lake-is-superbug-hotspot-idUKKCN11Y35G> (accessed at 4-12-2017)
- 18 "Impacts of pharmaceutical pollution on communities and environment in India," Nordea, February 2016 at <https://www.nordea.com/Images/35-107206/impacts%201-20.pdf> (accessed at 09-12-2017)