

To,
President of the European Commission
Jean-Claude Juncker
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels
Belgium

CC in:

Member of Cabinet with responsibility for environment:
Telmo Baltazar

and:

Member of Cabinet with responsibility for health and food safety:
Léon Delvaux

Dear President Juncker,

On behalf of our fellow Indian citizens, we are writing to urge you to take action and address the grave environmental and human health crisis currently unfolding in India linked to the production of pharmaceuticals for global markets, including the European Union (EU). Specifically, we call on you to address pollution from drug manufacturing in the upcoming EU strategic approach on pharmaceuticals in the environment (PiE) by extending Good Manufacturing Practices (GMP) to also include environmental criteria, as this would provide an opportunity to oblige pharmaceutical companies to tackle polluting practices throughout their supply chains, including in third countries such as India.

The devastating environmental and human health impacts from the manufacturing of pharmaceuticals are well documented. India's Environment Ministry classifies pharmaceutical manufacturing as a "red category" activity owing to the hazardous waste it produces. However, Active Pharmaceutical Ingredient (API) discharges from factories are currently not regulated, and enforcement of existing pollution norms is extremely inadequate, as demonstrated by several studies and media stories.¹

As a result of this, the lives of many people living in India's pharmaceutical manufacturing hubs, such as Hyderabad, the capital of the southern Indian state of Telangana, Baddi Barotiwala Nalagarh Industrial town in the foothills of Himachal Pradesh, SIPCOT Cuddalore in Tamil Nadu have been blighted by rampant pollution. Successive studies have shown that air, water and soil in Hyderabad are significantly contaminated by toxic chemicals and pharmaceutical APIs, notably from the production of antimicrobial drugs such as antibiotics.

¹ Down to Earth, Newer, not better, 18.07.17, <http://www.downtoearth.org.in/news/newer-not-better-58292>; First Post, NGT's reluctance to hold big pharma accountable for polluting Telangana waters unfortunate, 17.11.2017, <https://www.firstpost.com/india/ngts-reluctance-to-hold-big-pharma-accountable-for-polluting-telangana-waters-unfortunate-body-is-simply-passing-the-buck-4214063.html>

In 2007, Swedish researchers first revealed the true extent of the impacts from pollution at drug manufacturing sites in Hyderabad when they found "exceptional" concentrations of fluoroquinolones, a powerful class of antibiotics reserved for the treatment of serious bacterial infections in wastewater from the Patancheru industrial area. 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.²

In the intervening decade, the situation has only got worse. A landmark study published in March 2017 by scientists from the University of Leipzig investigating companies supplying the German market showed that insufficient wastewater management by drug manufacturing facilities in India is leading to "unprecedented" contamination of water resources with antimicrobial pharmaceuticals.³ The researchers found concentrations of antibiotics and antifungal substances that were several hundred times, or even several thousand times, higher than the levels predicted to select for resistance. In addition, 95 per cent of all samples tested positively for multi drug-resistant bacteria.

India has a huge AMR problem: every year, 58,000 babies die in India as a result of contracting a multi-drug resistant infection.⁴ However, expanding international trade and tourism mean that the consequences of this problem are not confined to India. For instance, a 2010 study by Swedish researchers showed that seven out of eight travellers to India returned to Sweden carrying drug-resistant bacteria in their gut.⁵

With several huge pharmaceutical manufacturing hubs distributed around the country, India is one of the world's largest manufacturers of pharmaceuticals and the EU one of its key export markets. Multinational drug companies have flocked here in pursuit of cheap production and numerous Indian manufacturers are also exporting medicines under their own label. This is why the EU cannot turn a blind eye to this problem. The communities affected by pollution have already tried legal avenues and won several landmark court cases, but this has not led to an improvement in the situation on the ground.⁶ Pharmaceutical companies keep on polluting in impunity, because they are allowed to do so by their customers in the EU and US.

For this reason, we are urging you to take action and include environmental criteria in GMP. This solution has been supported by scientists, NGOs and progressive

² Larsson, D.G.J., de Pedro, C., Paxeus, N., 2007. Effluent from drug manufactures contains extremely high levels of pharmaceuticals. *J. Hazard. Mater.* 148, 751–755. <http://dx.doi.org/10.1016/j.jhazmat.2007.07.008>

³ Study: <http://link.springer.com/article/10.1007%2Fs15010-017-1007-2>

⁴ New York Times, 'Superbugs' Kill India's Babies and Pose an Overseas Threat, 03.12.2014,

<https://www.nytimes.com/2014/12/04/world/asia/superbugs-kill-indias-babies-and-pose-an-overseas-threat.html>

⁵ Bloomberg, 19.01.2017, Indian Travel Boom Is Sending Tourists Home With Superbugs

<https://www.bloomberg.com/news/articles/2017-01-19/superbug-stowaways-india-travel-boom-spreads-dangerous-microbes>

⁶ Changing Markets Foundation, Impacts of pharmaceutical pollution on communities and environment in India, February 2016, p16-17, <http://changingmarkets.org/wp-content/uploads/2016/12/Impacts-of-pharmaceutical-pollution-on-communities-and-environment-in-India-WEB-light.pdf>;

The New Indian Express, NGT Notice to Drug Producer, 12.11.2013, <https://www.pressreader.com/india/the-new-indian-express/20131112/281694022545697>;

India Environmental Portal, Judgement of the National Green Tribunal regarding pollution caused by the industrial units in Patancheru and Bollaram, Medak District, Telangana, 24.10.2017,

<http://www.indiaenvironmentportal.org.in/content/448690/judgement-of-the-national-green-tribunal-regarding-pollution-caused-by-the-industrial-units-in-patancheru-and-bollaram-medak-district-telangana-24102017/>

governments.⁷ We believe that it should be included in your upcoming impact assessment and legislative considerations.

Thank you for your attention and we remain at your disposal for any questions.

Signed:

Panchayats (Village Councils) in Hyderabad and outskirts affected by pollution from pharmaceutical manufacturing activities:

Mr Batte Sankar

President,
Edulabad Panchayat (Village Council)

Mrs Aleti Nagamani Venkatesh

President,
Makthala Anantharam Panchayat (Village Council)

Mr Jaligam Venkatsh

President,
China Raavarla Panchayat (Village Council)

Mr Palle Yadireddy

President,
Palligudem Panchayat (Village Council)

Public Health Professionals/Groups/Activists:

Dr Sree Karuna Murthy Kolli

President, Indian Public Health Association (IPHA) Andhra Pradesh State and Vice President South IPHA National.

Dr. Veena Shatrugna

Former Deputy Director & Head, Clinical Division,
National Institute of Nutrition,
Hyderabad.

Dr. Smarjit Jana

Medical Doctor and Public Health Specialists,
Former National Advisor to India's Ministry of Health and Family Welfare's National AIDS Control program

Dr. Ravikant Singh

President, Doctors For You, India

⁷ Swedish Medical Products Agency, Swedish initiative for green medicine production, 04.07.2011, <https://lakemedelsverket.se/english/All-news/NYHETER-2011/Swedish-initiative-for-green-medicine-production/>; European Public Health Alliance, Joint Statement: Europe must align policies to tackle Pharmaceuticals in the Environment and Antimicrobial Resistance, 17.05.2018, <https://epha.org/joint-statement-europe-must-align-policies-to-tackle-pharmaceuticals-in-the-environment-and-antimicrobial-resistance/>

The Bhopal Medical Appeal

Unit 2, The Foundry,
St. George's Mews,
Brighton.
BN1 4EU

Dr Adithya Pradyumna,
Public Health Researcher, India

Dr Manan Ganguli,
MBBS (Kolkata), MSc (London)

Dr. S.V. Nadkarni,
Ex. Dean L.T.M. Med. College,
Sion, Mumbai,

South India AIDS Action Program, Chennai

Dr Shyamala Nataraj,
Chennai

Dr. P Chandra
D. ArulSelvi Community Based Rehabilitation
Brindavanam, Periyakasinayakanpatti
Tirupattur. Vellore District
Tamilnadu, India

Anupam Bhattacharjee
Public Health Professional

Jagannath Chatterjee
Public Health Professional

Sindhu Nilla
Public Health Professional

Dr Ravindra Khaiwal, MRSC, FHEA
Additional Professor of Environment Health,
School of Public Health
PGIMER, Chandigarh
160012, India

Rosamma Thomas,
Pune

Veena Johari,
Legal Practitioner, Public Health

Sudha N,
Independent researcher & Health Activist, Bangalore

Jagdish Patel,
Occupational Health Specialist,
Peoples Training and Research Centre, Gujarat.

Satya Sivaraman,
Journalist, India

Public Health Professionals from Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Pondicherry:

Dr. Vishvaja Sambath
Dr. Surbhi Tripathi
Dr. Veena Babu
Mr. Britzer Paul
Mr. Arul Prakash
Ms. Rajeswari
Ms. Durga Swarupa
Dr. Ranjana R
Dr. Deepak Azad
Ms. Margaret Elsy
Mr. Balachandar
Dr. Manisha Khemani
Dr. Jaswant Kumar
Dr. Arin Nandi
Dr. Anupama Verma
Ms. Pushpa Mins

Consumer Rights and Community Groups:

Shweta Narayan
Community Environmental Monitoring, A program of The Other Media
Chennai

Anil Dayakar
GAMANA, Hyderabad

Rachna Dhingra
Bhopal Group for Information and Action

Children Against Dow - Carbide, Bhopal

Bhopal Gas Peedit Mahila Stationery Karmchari Sangh

Bhopal gas Peedit Mahila Purush Sangharsh Morcha

Devraj Chowdary

Ex-Pardhan

Saned Panchayat (Baddi Barotiwala Nalagarh Industrial Area, Himachal Pradesh)

Sanjeev Kaushal,

Himparivesh, Himachal Pradesh

Sumit Mahar,

Himdhara Collective, Himachal Pradesh

Sipcot Area Community Environmental Monitoring SACEM- Cuddalore.

Consumer Fedration Tamilnadu (CONFET)- Cuddalore.

Tamil Nadu Environment Council (TNEC)- Dindugal.

Women Consumer Protection Association - Madurai.

Indian River Network -Tamil Nadu

EMPOWER-Tuticorin.

Center for Consumer Human Resource & Environment Protection -The Nilgiris.

Exnora- The Nilgiris.

Tirupr Taluk Consumer Centre - Tirupr

Consumer Rights Protection Association -Gudalur -Theni District.

Tamilnadu Consumer Education and Development Foundation(TAMCED)

Vadalur Consumer Rights and Environment Protection Organisation -Vadalur.

District Environmental Protection Organisation for Right Tackling (DEPORT) - Cuddalore.

Tamil Nadu Private Sugar Mill Can Growers Association.

Cuddalore District Farmers Federation.

Citizens Voice Coimbatore.

Consumer and Environment Protection Organisation Semmankuppam- Cuddalore District.

District Women's Rights and Consumer Protection Organisation -Cuddalore.

Vellore District Environment Monitoring Committee- Ambur

WASIDA - Cuddalore.

Human Rights and Consumer Protection Society (HRCPS)- Puducherry

**Annai National Farmer's Development Project (Organic Farmer Organisation)
Tamil Nadu.**

Eachankadu Consumer Protection Organisation- SPICOT Cuddalore.

**SPICOT Area Community Environment and Consumer Protection Trust -
Songolikuppam- SIPCOT Cuddalore.**

**Tamilndu Consumer Protection Environment Protection and People Rights
Organisation- Cuddalore.**

Cuddalore District Consumer and People Rights Protection Centre - Neyveli.

Poonamallee North Consumer Rights Protection Centre - Thiruvallur District.

Bharathiyar Makkal Nalvalvu Sangam (BMNS) -Salem.

Kauvari Environment Protection Society - Nagappatinam.

Consumer and People Rights Organisation - Cuddalore old town

+++++

For further correspondence please contact:

Shweta Narayan (shweta.n@icloud.com)

or

Anil Dayakar (anildayakar@gmail.com)

+++++END+++++