Bulk Dug Industry Spewing highest Drug Levels into Water Bodies around Hyderabad and into Bay of Bengal?

Why Andhra Pradesh (India) a Bulk Drug Hub?

The developed countries have set strict limits and enforce them ruthlessly, on more than 30 chemical compounds and their toxicity in the effluents discharged by the industries making Bulk Drugs, technically known as “active pharmaceutical ingredients”: raw materials for pills, capsules, etc. When it comes to the cost of patented prescription drugs in the United States, the sky's the limit. But in the global bulk-drug market, low cost is the name of the game.

The polluting industries like Bulk Drug/Drug Intermediates are moved from developed to developing countries, being environmentally dirtier process. Because of laxity in enforcement, instead of monitoring various chemical compounds and their toxicity in the effluents, only the total quantity of pollutants is tracked, with almost no information on specific toxic compounds. It is serious, because some of the drug industry's solvents, byproducts, and ingredients can harm people even at low concentrations. As market competition is fierce in bulk drug industry, corner cutting on waste treatment is rampant.

Magnitude of Pattancheru Pollution

The seriousness of the pollution problem from bulk drug industries at Pattancheru near Hyderabad is highlighted in 2007, by Joakim Larsson, an environmental scientist at the University of Gothenburg in Sweden. When he analyzed vials of treated wastewater taken from CETP Pattancheru (PETL), where about 90 bulk-drug industries dump their residues, he found the discharge load of Ciprofloxacin, corresponding to approx 45 kg of active ingredient per day. This is equivalent to the total amount of Ciprofloxacin consumed in Sweden (population 9 Million) over an average 5 day period.

And it wasn't just ciprofloxacin being detected. The supposedly treated wastewater of PETL has 21 different active pharmaceutical ingredients, used in generics for treatment of hypertension, heart disease, chronic liver ailments, depression, gonorrhea, ulcers and other ailments. Half of the drugs measured at the highest levels of pharmaceuticals ever detected in the environment, researchers say.

In economical terms, if the equivalent amount of the 11 most abundant active substances released by PETL during 24 hrs were to be purchased as final products in a Swedish pharmacy, they would cost over 100,000 British Pounds.

The Associated Press (AP) reported that the so called treated wastewater from PETL contained 150 times the highest levels detected in the U.S. Before Larsson's study detected such large concentrations of ciprofloxacin and other drugs in the treated wastewater, the levels of pharmaceuticals detected in the environment and drinking water worldwide were minute, well below a human dose.

Adverse Impacts of Pharmaceutical Contamination

The pharmaceutical contamination is an emerging concern worldwide. The medicines are excreted without being fully metabolized by people who take them, while hospitals & health-care facilities annually flush millions of Kgs of unused/expired pills down the drain. Until Larsson's research, there had been widespread consensus among researchers that bulk-drug makers were not a source.

As the AP reported, researchers are finding that human cells fail to grow normally in the laboratory when exposed to trace concentrations of certain pharmaceuticals. Some waterborne drugs also promote antibiotic-resistant germs, especially when- as in PETL- they are mixed with bacteria in human sewage. Even extremely diluted concentrations of drug residues harm the reproductive systems of fish, frogs and other aquatic species in the wild. Experts say one of the biggest concerns for humans is whether the discharges from PETL is spawning drug resistance.

"Not only is there the danger of antibiotic-resistant bacteria evolving; the entire biological food web could be affected," said Stan Cox, senior scientist at the Land Institute, a nonprofit agriculture research center in Salina, Kan. Cox has studied and written about pharmaceutical pollution in Pattancheru. "If Cipro is so widespread, it is likely that other drugs are out in the environment and getting into people's bodies."

The more bacteria is exposed to a drug, the more likely that bacteria will mutate in a way that renders the drug ineffective. Such resistant bacteria can then possibly infect others who spread the bugs as they travel. Ciprofloxacin was once considered a powerful antibiotic of last resort, used to treat especially tenacious infections. But in recent years many bacteria have developed resistance to the drug, leaving it significantly less effective.

Regulation & Control of Contamination

Before Larsson's team tested the treated water at PETL, researchers largely attributed the source of drugs in water to their use, rather than their manufacture. In the U.S., the EPA says there are "well defined and controlled" limits to the amount of pharmaceutical waste emitted by drug makers.

But in AP State, the Regulator (APPCB) & the Bulk-Drug Industry are invariably in a denial mode. They say standards have now been tightened & are being met and hence the screening for the residues & their toxicity at the end of the treatment process is not required, as per the Schedule-I (S.No.55) of the Environment (Protection) Rules, 1986

There is no incentive to Bulk-Drug industry in India, to minimize the release of certain drugs into waste waters, requiring substantial investments, because of high profit margin- high value of final product compared to much lower production cost of bulk-drugs.

Because of laxity in enforcement of rules and standards, the non-compliance has become a high-profit business. The contamination can only be prevented, when non-compliance is made high-risk business by heavy penalties and stringent & speedy penal action. The other aspect is restriction on the use of water, being liberally used for dilution and charging the water reasonably high, like any other solvent used by the bulk-drug industry.

Shifting the Problem from PETL (18Km Pipeline)

The Minister of State for Environment & Forests, Govt. of India, is reported to have complimented APPCB &PETL for commissioning 18 KM pipeline for transferring PETL treated effluents to surface-water standards to Amberpet STP & discharging into Musi. He is also reported to have stated that this will minimize water pollution at Pattancheru.

The following remain unanswered regarding the performance of PETL & Pollution Loads:

a) The Swedish Environmental Scientist pointed out that the process of water treatment plant of PETL is outdated and the treated water, though free from suspended solids and clarified, is still contaminated. How is it ensured that the discharges from PETL into 18 km pipeline are free from traces of toxic pharmaceutical ingredients and conform to inland -surface water standards?

b) If the outlet standards, applicable for discharge into inland surface waters, are being met by PETL, why not the treated effluents from PETL, be utilized by the member industrial units in Pattancheru Area? What is the need to use the 18 Km pipeline, to convey treated effluents, suitable for discharge into inland surface waters, all the way to STP at Amberpet, incurring considerable recurring expenditure for pumping etc?

c) The very fact that commissioning of 18 KM pipeline will minimize water pollution at Pattancheru, as reported to have been stated by the Minister, does it amount to shifting the pollution problem from Nakka Vagu to Musi River, for diluting the pollution concentration levels (pollution load remains the same) and the accountability, that too cleverly camouflaged in a pipeline ?

d) How does 18 KM pipeline & STP Amberpet help to prevent the load of 11 most abundant active pharmaceutical substances discharged from PETL and accumulating down stream of Musi, which is not a perennial river?

e) As the waterborne drugs promote antibiotic-resistant germs, especially when they are mixed with bacteria in human sewage, how does STP Amberpet get over the problem?

Bay of Bengal Provides new Dumping Place

As the villagers downstream of Musi are agitating against the discharge of effluents through pipelines, the pollution problem of Pattancheru & Industrial areas around Hyderabad is being shifted to north coastal districts of AP in the name of industrial development.

The justification given is, that effluents generated by these units, containing predominantly dissolved inorganic salts**,** which are being discharged into water bodies in and around land locked Hyderabad, can safely be discharged into sea by laying a pipeline deep into sea. The Parwada Pharma City and many Bulk Drug and Chemical units set up along the coast are already discharging the supposedly treated effluents into Bay of Bengal.

There is no guarantee that traces of toxic pharmaceutical ingredients, the persistent, bioaccumulative and toxic wastes from the bulk drug units, which found their way into surface and ground water sources in and around Hyderabad, are not being discharged into sea**,** particularly when the detection is going to take much longer and becomes much more difficult.

The discharge of toxic effluents into sea, even though they are diluted to some extent, is bound to have an adverse impact on the aquatic life in the years to come, as the total pollution load being discharged remains the same. This is going to hamper the fish stock availability, affecting the livelihood of the large fishermen community in the area apart from health hazards for people consuming contaminated fish.

The ecosystems and resources of the land-sea interface and the communities dependent on coastal resources are going to be adversely affected, by permitting discharge of toxic effluents from bulk drug units into sea, as it cannot be pushed beyond its limit to absorb wastes.

What is the Responsibility of Developed World?

. Is it not the responsibility of European Countries and the U.S for the environmental damage and the human risks in the Third World Countries producing drugs for the well being of the developed countries?"

The developed countries may think that they are protecting their environment by importing the drugs at the cost of the environment & people in the developing countries. But it is going to raise antibiotic bacterial resistance in the world, making it a Global Concern. People might say, that's just a dirty River in India or Bay of Bengal, but we live on a small Planet, everything is interconnected. The water in a River in India/ Bay of Bengal could be the rain coming down in a Town in Europe or USA in a few weeks.

US Responsibility?

What is the responsibility of U.S. — which spent $1.4 billion on Indian-made drugs in 2007 – the largest customer?

The Current Good Manufacturing Practice (cGMP) Regulations enforced by the US Food and Drug Administration (FDA). provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities

If a bulk-drug company is not complying with cGMP regulations, any drug it makes is considered “adulterated” under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug..

Even if the drugs are not defective, FDA can bring a seizure or injunction case in court to address cGMP violations. When FDA brings an injunction case, FDA asks the court to order a company to stop violating cGMPs. Both seizure and injunction cases often lead to court orders that require companies to take many steps to correct cGMP violations. FDA can also bring criminal cases because of cGMP violations, seeking fines and jail time.

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