

India's New Guinness Record: Med Pollution

World's Highest Drug Levels Entering India stream

By MARGIE MASON, AP Medical Writer AP January 26, 2009

AP – A man covers his nose to keep out the stench from the polluted Iska Vagu stream in Patancheru.

PATANCHERU, India – When researchers analyzed vials of treated wastewater taken from a plant where about 90 Indian drug factories dump their residues, they were shocked. Enough of a single, powerful antibiotic was being spewed into one stream each day to treat every person in a city of 90,000.

And it wasn't just ciprofloxacin being detected. The supposedly cleaned water was a floating medicine cabinet — a soup of 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.

Those Indian factories produce drugs for much of the world, including many Americans. The result: Some of India's poor are unwittingly consuming an array of chemicals that may be harmful, and could lead to the proliferation of drug-resistant bacteria.

"If you take a bath there, then you have all the antibiotics you need for treatment," said chemist Klaus Kuemmerer at the University of Freiburg Medical Center in Germany, an expert on drug resistance in the environment who did not participate in the research. "If you just swallow a few gasps of water, you're treated for everything. The question is for how long?"

Last year, The Associated Press reported that trace concentrations of pharmaceuticals had been found in drinking water provided to at least 46 million Americans. But the wastewater downstream from the Indian plants contained 150 times the highest levels detected in the U.S.

At first, Joakim Larsson, an environmental scientist at the University of Gothenburg in Sweden, questioned whether 100 pounds a day of ciprofloxacin could really be running into the stream. The researcher was so baffled by the unprecedented results he sent the samples to a second lab for independent analysis.

When those reports came back with similarly record-high levels, Larsson knew he was looking at a potentially serious situation. After all, some villagers fish in the stream's tributaries, while others drink from wells nearby. Livestock also depend on these watering holes.

Some locals long believed drugs were seeping into their drinking water, and new data from Larsson's study presented at a U.S. scientific conference in November confirmed their suspicions. Ciprofloxacin, the antibiotic, and the popular antihistamine cetirizine had the highest levels in the wells of six villages tested. Both drugs measured far below a human dose, but the results were still alarming.

"We don't have any other source, so we're drinking it," said R. Durgamma, a mother of four, sitting on the steps of her crude mud home in a bright flowered sari a few miles downstream from the treatment plant. High drug concentrations were recently found in her well water. "When the local leaders come, we offer them water and they won't take it."

Pharmaceutical contamination is an emerging concern worldwide. In its series of articles, AP documented the commonplace presence of minute concentrations of pharmaceuticals in U.S. drinking water supplies. The AP also found that trace concentrations of pharmaceuticals were almost ubiquitous in rivers, lakes and streams.

The medicines are excreted without being fully metabolized by people who take them, while hospitals and long-term care facilities annually flush millions of pounds of unused pills down the drain. Until Larsson's research, there had been widespread consensus among researchers that drug makers were not a source.

The consequences of the India studies are worrisome.

As the AP reported last year, 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 India — 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.

In the India research, tadpoles exposed to water from the treatment plant that had been diluted 500 times were nonetheless 40 percent smaller than those growing in clean water.

The discovery of this contamination raises two key issues for researchers and policy makers: the amount of pollution and its source. Experts say one of the biggest concerns for humans is whether the discharge from the wastewater treatment facility 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 Patancheru. "If Cipro is so widespread, it is likely that other drugs are out in the environment and getting into people's bodies."

Before Larsson's team tested the water at Patancheru Enviro Tech Ltd. plant, 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.

India's environmental protections are being met at Patancheru, says Rajeshwar Tiwari, who heads the area's pollution control board. And while he says regulations have tightened since Larsson's initial research, screening for pharmaceutical residue at the end of the treatment process is not required.

Factories in the U.S. report on releases of 22 active pharmaceutical ingredients, the AP found by analyzing EPA data. But many more drugs have been discovered in domestic drinking water.

Possibly complicating the situation, Larsson's team also found high drug concentration levels in lakes upstream from the treatment plant, indicating potential illegal dumping — an issue both Indian pollution officials and the drug industry acknowledge has been a past problem, but one they say is practiced much less now.

In addition, before Larsson's study detected such large concentrations of ciprofloxacin and other drugs in the treated wastewater, levels of pharmaceuticals detected in the environment and drinking water worldwide were minute, well below a human dose.

"I'll tell you, I've never seen concentrations this high before. And they definitely ... are having some biological impact, at least in the effluent," said Dan Schlenk, an ecotoxicologist from the University of California, Riverside, who was not involved in the India research.

And even though the levels recently found in Indian village wells were much lower than the wastewater readings, someone drinking regularly from the worst-affected reservoirs would receive more than two full doses of an antihistamine in a year.

"Who has a responsibility for a polluted environment when the Third World produces drugs for our well being?" Larsson asked scientists at a recent environmental research conference.

M. Narayana Reddy, president of India's Bulk Drug Manufacturers Association, disputes Larsson's initial results: "I have challenged it," he said. "It is the wrong information provided by some research person."

Reddy acknowledged the region is polluted, but said that the contamination came from untreated human excrement and past industry abuses. He and pollution control officials also say villagers are supposed to drink clean water piped in from the city or hauled in by tankers — water a court ordered industry to provide. But locals complain of insufficient supplies and some say they are forced to use wells.

Larsson's research has created a stir among environmental experts, and his findings are widely accepted in the scientific community.

"That's really quite an incredible and disturbing level," said Renee Sharp, senior analyst at the Washington-based Environmental Working Group. "It's absolutely the last thing you would ever want to see when you're talking about the rise of antibiotic bacterial resistance in the world."

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.

"We are using these drugs, and the disease is not being cured — there is resistance going on there," said Dr. A. Kishan Rao, a medical doctor and environmental activist who has treated people for more than 30 years near the drug factories. He says he worries most about the long-term effects on his patients potentially being exposed to constant low levels of drugs. And then there's the variety, the mixture of drugs that aren't supposed to interact. No one knows what effects that could cause.

"It's a global concern," he said. "European countries and the U.S. are protecting their environment and importing the drugs at the cost of the people in developing countries."

While the human risks are disconcerting, Sharp said the environmental damage is potentially even worse.

"People might say, 'Oh sure, that's just a dirty river in India,' but we live on a small planet, everything is connected. The water in a river in India could be the rain coming down in your town in a few weeks," she said.

Patancheru became a hub for largely unregulated chemical and drug factories in the 1980s, creating what one local newspaper has termed an "ecological sacrifice zone" with its waste. Since then, India has become one of the world's leading exporters of pharmaceuticals, and the U.S. — which spent \$1.4 billion on Indian-made drugs in 2007 — is its largest customer.

A spokesman for the Pharmaceutical Research and Manufacturers of America, representing major U.S. drugmakers, said they could not comment about the Indian pollution because the Patancheru plants are making generic drugs and their members are branded. A spokesman for the Generic Pharmaceutical Association said the issues of Indian factory pollution are "not within the scope of the activities" of their group.

Drug factories in the U.S. and Europe have strictly enforced waste treatment processes. At the Patancheru water treatment plant, the process is outdated, with wastewater from the 90 bulk drug makers trucked to the plant and poured into a cistern. Solids are filtered out, then raw sewage is added to biologically break down the chemicals. The wastewater, which has been clarified but is still contaminated, is dumped into the Isakavagu stream that runs into the Nakkavagu and Manjira, and eventually into the Godawari River.

In India, villagers near this treatment plant have a long history of fighting pollution from various industries and allege their air, water and crops have been poisoned for decades by factories making everything from tires to paints and textiles. Some lakes brim with filmy, acrid water that burns the nostrils when inhaled and causes the eyes to tear.

"I'm frustrated. We have told them so many times about this problem, but nobody does anything," said Syed Bashir Ahmed, 80, casting a makeshift fishing pole while crouched in tall grass along the river bank near the bulk drug factories. "The poor are helpless. What can we do?"

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AP National Writer Martha Mendoza contributed to this report from California.