



SIDE ROAD: A billboard for Abbott in Mumbai. The American pharmaceutical company and hundreds of other firms in India are selling drugs that have been approved by a state but not by the central government. REUTERS/Danish Siddiqui

## *Broken Health*

# As combination drugs engulf India, an American pharmaceutical giant profits

By [Krista Mahr](#) and [Zeba Siddiqui](#) | Filed Dec. 15, 2015, 1:07 p.m. GMT

Part 3: A unit of Abbott Laboratories is marketing a drug in India that doesn't have New Delhi's approval – or that of the U.S. drug authorities. Experts say the misuse of combination

## drugs risks boosting antibiotic resistance, turning India into an incubator of “superbugs.”

MUMBAI – Prabhu Dayal arrived at a clinic on the outskirts of Mumbai on a muggy afternoon in July to see the doctor about a cold and cough. The 75-year-old had been feeling unwell for a few days and hoped to get something to treat his symptoms.

He did. But the prescription Dayal left with that day wasn't for any regular cold medicine.

It was for a powerful antibiotic cocktail marketed in India by a unit of U.S. pharmaceutical giant Abbott Laboratories. It is not approved for sale in major markets such as the United States, United Kingdom, Germany, France, Japan and Australia. Medical experts say it doesn't make sense to prescribe the cocktail for cold symptoms. And a government-appointed panel in India recommended to the Health Ministry last year that it not be approved for sale here, citing lack of safety and efficacy data and a high potential for “misuse.”

In fact, the drug has not been approved by the central government, as required by the Drugs Controller General of India (DCGI), the regulator responsible for approving new drugs.

Under India's complex drug-approval regime, many pharmaceutical manufacturers have obtained permission from a single state to make new fixed-dose combination drugs, or FDCs, like the Abbott one - and are selling them in other parts of the country without the approval of the central government. FDCs combine two or more drugs in a single pill.

India's top drug regulator is trying to shut down this avenue. “The first clearance of new drugs which anyone wants to market in India, that has to be given by the national regulatory authority,” G.N. Singh, the Drugs Controller General of India, told Reuters.

But inconsistent enforcement of the drug laws means that hundreds of FDC drugs are being sold in India without the approval of the central government. Policymakers have also now given pharmaceutical companies a chance to retroactively prove the safety and efficacy of these drugs, including the Abbott one. They are currently under review in New Delhi.

Doctors and public health experts both in India and abroad say the proliferation and misuse of antibiotic combinations here may be contributing to antibiotic resistance, making India a

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who travelled from India to the United States, Britain and other countries.

The drug prescribed to Dayal was Zimnic AZ, which combines two antibiotics in a single pill. Last year, the Illinois-based Abbott's India units had sales of more than \$1 billion. Its revenue in India from combination drugs in 2014 was 24.62 billion rupees (\$367 million), according to IMS Health, a Connecticut-based firm that provides data on the healthcare industry.

In interviews, former and current medical representatives for Abbott said Zimnic AZ has been promoted and administered as a treatment for a wide variety of illnesses, including colds, fevers, urinary tract infections, drug-resistant typhoid and sexually transmitted diseases. Reuters visited chemists who were also selling the drug for respiratory ailments and to prevent post-operative infection. The doctor who prescribed Zimnic AZ for Dayal said the elderly patient seemed to be suffering from a respiratory tract infection.

Combining cefixime and azithromycin - the two antibiotics that make up Zimnic AZ - is risky, said Ramanan Laxminarayan, director of the Center for Disease Dynamics, Economics & Policy, a think tank with offices in Washington and New Delhi. By administering these two drugs in a single dose, "you'd be creating strains (of bacteria) resistant to both these antibiotics," said Laxminarayan, who lectures on public health at Princeton University.



OVERKILL: Patients like Prabhu Dayal, a 75-year-old watchman in Mumbai, are being prescribed powerful antibiotic combinations for common cold symptoms. REUTERS/Danish Siddiqui

“Drug resistant strains spread globally,” he said. “They already have. It’s very hard to regulate the movement of people.”

The fact that Abbott and hundreds of other companies in India are able to sell drugs like Zinnic AZ without the central government’s approval is evidence of a health system in disarray. This year, Reuters has documented how the training of doctors in India – the world’s largest exporter of physicians – was riddled with fraud and unprofessional teaching practices. A second article revealed how an Indian doctor facing corruption charges is next

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Nearly half the drugs on the market in India last year were combinations. These include medications consisting of three different drugs apiece, doctors said. In the United States, combinations made up 13.9 percent of drugs on the market, while in China the number was 14.4 percent, according to IMS Health. Last year, about 78 percent of combination drugs in India were sold by local firms, with multinationals making up the rest, the health data provider said.

Abbott declined to answer questions from Reuters about why it was selling a drug in India without the approval of the central government.

The manufacture and marketing of Zimnic AZ in India “is aligned with local regulations,” said Varsha Chainani, director of public affairs for Abbott in India. Chainani noted that more than 15 other companies in India are also manufacturing and marketing the same combination under different brand names.

Abbott didn’t respond to questions about whether it was appropriate to prescribe Zimnic AZ for patients like Dayal with cold symptoms. The company wouldn’t say for which specific indications the drug had been approved in India and what marketing instructions have been given to its medical representatives. Abbott declined to say what it was doing to address concerns that combinations like Zimnic AZ may be contributing to antibiotic resistance.

“It would be inappropriate to comment in view of the pending evaluation,” said Chainani, referring to the drug review currently being conducted by the Drugs Controller General of India. “Abbott will abide by the final outcome of the proceedings in this regard.”

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