



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### **Bad numbers on bad drugs**

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Chennai's massive fake medicine-labels racket is nothing new and is not confined to that city: more than half the pharmacists interviewed, there and in Delhi before the scandal broke, said relabelling expired drugs was the most popular method of counterfeiting, a new independent research shows. In Delhi, 7% of samples from intermediary wholesalers were substandard and 80% of the pharmacies sampled were providing some substandard products, twice as high as Chennai, reports A Safe Medicines Chest for the World, published last week. With 30 arrests so far, Chennai is not just the latest in a regular series of national and international headlines, the problem is endemic.

Corruption among officials suggests that even more regulations and officials would just make the problem worse. Half the pharmacists surveyed told the researchers from an international group of think-tanks that they feared drug inspectors would demand bribes and a quarter had been asked for bribes.

In December 2008, a 'thriving racket' supplying substandard drugs to government hospitals in Orissa was exposed. The inquiry said, "In most cases, spurious drugs circulation is carried out with the knowledge and connivance of officials of the drug controller, [in] Orissa, and local drug inspectors who are on the payroll of unscrupulous dealers." Nearly all of the 26 pharmacists interviewed by the researchers said they had been offered substandard drugs at cheaper prices and that they knew of the pharmacists who sold them.

Yet, the report also showed that most pharmacies are providing mainly high-quality drugs. However, a significant minority of wrongdoers are damaging the reputation of Indian pharmaceuticals and endangering patients. In Delhi, for example, nearly all the drugs with zero active ingredients (which must be counterfeits) came from the seven worst pharmacies. The two worst wholesalers provided all of the fakes from that sample. Some drugs contained chalk or talcum powder, plus a pain reliever to trick patients.

The international reputation of Indian generics is at stake. In 2008, about half of all medical products detained at European Union (EU) borders came from India—most of them seized for imitating trademarks, meaning they were fakes (separately from the few suspected patent infringements, a matter of legal dispute). Estimating the bad proportion of exported Indian drugs is difficult in a complex global supply chain. After the EU accused India in 2008 of supplying 75% of fake drugs found at its borders, shipments to Europe suddenly started showing their origin as Dubai, which produces no medicines. Without government or industry support, our independent research did not have access to a decent sample for our survey but we can cite evidence from elsewhere.

A similar team found in 2008 that 35% of the 195 anti-malarial drugs sold in shops and pharmacies in six

major African cities failed basic quality tests: a third of the samples, purportedly of Indian origin, were found to be substandard. Although counterfeiters can lie about 'Made in India' just like any other aspect of packaging, Nigeria has banned imports from certain Indian pharmaceutical firms. In November 2009, Sri Lanka banned imports from four Indian companies. A month later Kenji Toda, chairman of the Japan Pharmaceutical Manufacturers Association, said the bad reputation of Indian pharmaceuticals is a barrier to their growth in Japan.

The criminals who make counterfeits do not just undermine foreign patents, they also damage Indian producers of high-quality medicines, whose brands are a guarantee for consumers and make India the largest generics manufacturer in the world. The Confederation of Indian Industry (CII) says this piracy damages growth, with pharmaceuticals being one of the worst examples.

But a government leak in November 2009 claimed that only an incredible 0.04% of sampled medicines were 'spurious'. No actual data, however, have been disclosed and the report details several concerns about these claims and about previous surveys by the government. A government report in 2003 used unverified data from state authorities and many small samples to claim, "...the extent of substandard drugs varied from 8.19% to 10.64% and of spurious drugs varied between 0.24% to 0.47%". Discrepancies were so wide (for example, 40.4% in Haryana were substandard but only 5.3% in neighbouring Delhi) that the methodology is dubious.

The Centre must publish its full data and research methods. Its wild underestimates of substandard and counterfeit medicines only help the fraudulent manufacturers and give false assurances to patients. Counterfeiters already thrive under the lack of enforcement of existing laws and weak courts. Early this month, a Delhi court convicted a man for manufacturing counterfeit cosmetics—the case had been filed in 1987. As the CII has pointed out, it is Indian brands, not foreign ones, that have the most to gain from legal protection.

Indian companies and Indian patients need the protection of the law, with efficient, independent and fair courts—both civil and criminal. The country's prosperity and health depend on it.

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