

Countrywide study to map fake drugs

The plan envisages sampling 50,000 drugs to identify extent and source of spurious medicines in India

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India's drug regulator is proposing a sweeping survey to collect 50,000 drug samples from across the country to directly figure out the extent and spread of fake drugs.

At the minimum, this unique survey is expected to provide an official estimate of the prevalence of fake drugs in the country. Anecdotally, there is a consensus that the problem is rampant but estimates have varied widely—from a low of 0.5% to as much as 30% of the Rs55,000 crore worth of all drugs sold in the country each year.

"The survey will give us a statistical and realistic estimate of the problem," said M. Venkateswarlu, the drug controller general of India. "The industry is being blamed locally, by the media, as well as globally, by various agencies. If there is as much wrong with the sector as is made out to be, then it has to be set straight but first, we need a true picture of the menace."

In a series of articles this year that looked at lax regulation of drug manufacturing and drug trials in India, *Mint* has highlighted the ease with which fake drugs can be obtained, just a few miles from Parliament, where a 2005 Bill to tighten regulations has been languishing, as well as the chronic delays and inaction on the part of regulators in dealing with the issue.

In response, the drug controller has proposed random checks of laboratories that do human drug trials in India. And, earlier this month, Union health minister A. Ramadoss told *Mint* that he will introduce a new Bill in the monsoon session of Parliament proposing severe penalties for makers and sellers of fake and spurious drugs.

Even the European Union (EU) has weighed in, naming India as the No. 1 source for counterfeit drugs entering the EU, ahead of the United Arab Emirates and China. A recent European Commission report found a record 2.5 million counterfeit drugs in 2006 and said over 30% of the fakes originated from India.

The drug controller's latest move to collect 50,000 random samples is also being received favourably by the industry, which has often blamed small manufacturers and lax inspections for fake versions of all major drug brands.

In a letter, the drug controller has solicited collaboration from industry bodies for the proposal, which will have to be sanctioned by the ministry of health and family welfare. Venkateswarlu declined to estimate the funds required for such a sampling effort, saying it was "too premature" to discuss the specifics of the plan.

The cooperation of the drug industry will be critical to the success of this exercise as samples collected by the drug controller will need to be compared to the genuine versions by individual pharmaceutical companies.

That's because testing by government laboratories would only reveal whether a drug meets a particular minimum safety standard or not. Typically, only the manufacturers would be able to identify fakes by comparing them with the real drugs as well as matching the packaging and other data.

"We have agreed to cooperate fully..." said Ajit Dangi, director general of the Organization of Pharmaceutical Producers of India, an industry lobby that represents all the international drug makers in India and which has already confirmed its participation in the survey. A director from

the Indian Drug Manufacturers' Association, the domestic manufacturers' lobby, also confirmed it would work with the drug controller.

Besides getting some sense of the extent of the problem, such a sampling effort could also help the government in potentially identifying makers and sellers of counterfeit drugs.

Calling such a step as "long overdue", Nicholas Piramal Ltd's director Harinder S. Sikka said: "It is a novel idea, which will give a macro view of the level of substandard and spurious drugs which harm the patients in general and tarnish the country's image in particular."

Sikka, in his personal capacity, had previously filed a public interest litigation in the Delhi high court demanding the government explain the status of the Mashelkar Report, which was the underpinning of the 2005 Bill to amend the Drugs and Cosmetics Act that governs regulations over fake drugs.

It is unclear how the health ministry will respond to the survey proposal. "The ministry might have reservations on the way the survey is done, its costing and feasibility," claimed one industry expert, who didn't want to be named.

Not everyone seems to believe India is exporting fake drugs. "Spurious and fake drugs charges are being used by international drug makers that are hurt by Indian exports, against our generic companies," claims Indian Pharmaceutical Alliance's secretary general, D.G. Shah, who too wants a scientific survey that will quantify the extent of the fake drug problem and, hopefully, set the record straight.

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