Failure of Indian whistleblower scheme points to deeper woes

India's much-touted whistleblower scheme, launched this past December to burst the fake medicines racket with rewards of up to 2.5 million rupees ($55,000) for informers, has turned out to be a damp squib.

It was hoped that people would be lining up to rat out criminals and collect their due payment. But India's Health Minister Dinesh Trivedi told the national parliament on 5 March that there were only 20 tip-offs, and not a single informer "has been rewarded so far." He added that the tips have not yet led to any convictions.

The ambitious scheme, overseen by the government's Central Drugs Standard Control Organization (CDSCO), was prompted by media reports of a high prevalence—as much as 25%—of spurious drugs on the market.

The scheme's letdown does not surprise Chandra Gulhati, editor of the Monthly Index of Medical Specialties based in New Delhi and a keen observer of the pharmaceutical industry. Gulhati, a speaker at a national seminar on pharmaceutical policy, held in Kolkata in mid-February, says that the reported high incidence of spurious drugs is just media hype. He notes that substandard drugs (legitimate medicines degraded through slow delivery routes, for example) present a greater problem in India, and estimates that fake drugs represent less than 0.4% of all drugs, at most.

Under the current Indian law, counterfeit drugmakers can be sentenced to life in prison and fined up to 1 million rupees.

Industry experts have voiced skepticism about the whistleblower scheme, given a local reality: criminals use tough tactics to keep people quiet. "We tracked down a factory duplicating our tablets," a chairman of a leading Indian drug company told *Nature Medicine* on condition of anonymity. "We decided to keep quiet rather than informing the [CDSCO], as my life was threatened by the culprits, who had political connections."

And, recently, according to Gulhati, when duplicates of a popular cough remedy flooded markets in eastern India, its manufacturer quietly opted for police help, fearing that informing the CDSCO and the consequent media coverage would hurt the sale of the medicine in the rest of India. Drug control officials admitted in confidence that insiders are not coming forward for fear of retaliation.

According to Gulhati, however, there is a deliberate attempt, mostly by foreign companies, to magnify the problem in India by clubbing counterfeits and substandard drugs altogether "in order to derive advantage."

Yusuf Hamied, managing director of Cipla, India's leading generics maker, told *Nature Medicine* he is furious over attempts by the foreign corporations to treat genuine Indian generic drugs as counterfeits just because they could not patent their original products in India. "Such an interpretation means I cannot ship my generics through their ports," Hamied says. He cites a February 2009 incident in which a shipment of Cipla's HIV drugs was held up by officials in Amsterdam en route to Peru (*Nat. Med.* **15**, 350, 2009).

Amitava Guha, an organizer of the Kolkata seminar, says one key recommendation of the meeting (which was arranged in part by local industry) is that the Indian government should reject the movement led by some global groups that wish to equate 'generics' with 'counterfeits'.

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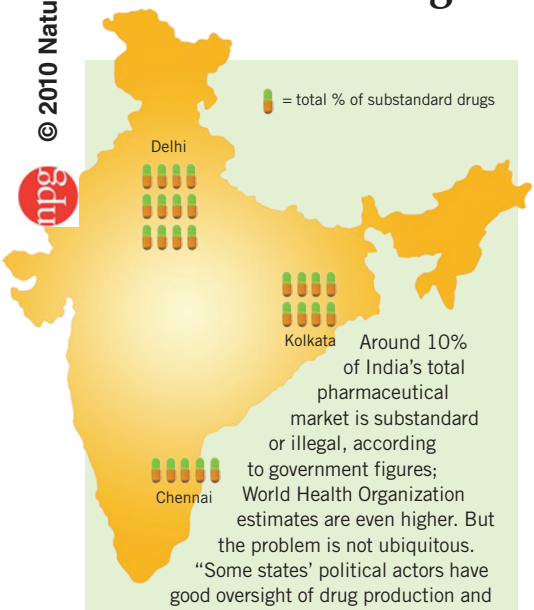
Substandard drugs overshadowed by focus on fakes



Around 10% of India's total pharmaceutical market is substandard or illegal, according to government figures; World Health Organization estimates are even higher. But the problem is not ubiquitous. "Some states' political actors have good oversight of drug production and not obviously corrupt policing; others have woeful enforcement," says Bate. Here, we show the extent of substandard antimalarial, antibiotic and antimycobacterial drugs sampled randomly from pharmacies in and around three major Indian cities.

Source: *PLoS One* **4**, e6003 (2009); Roger Bate.

International drug monitoring efforts have largely focused on catching drugs made by counterfeiters, which infringe on pharmaceutical companies' intellectual property. But for all the talk about fakes, there's another problem with drug integrity that's discussed much less frequently: medicines made and marketed by legitimate drug companies that contain compromised levels of active ingredient.

As opposed to a fake pill that sometimes contains harmful ingredients, a substandard drug simply does not produce the desired medical benefit. It effectively gets passed "through your stomach like a little pebble," says Andreas Seiter, who develops pharmaceutical policy for the World Bank in Washington, DC.

Regulators have had a tougher time cracking down on the production of substandard drugs compared to straightforward counterfeiting—a crime with clear legal ramifications. Some countries, for example, need to institute better quality standards, whereas others have strong rules on paper but require better enforcement or monitoring. "There's still a big gap in conceptualizing the problem" of substandard drugs, says Meir Pugatch, director of research at the Stockholm Network, a pan-European think tank based in London, who published a report in February calling on policymakers to address the issue and critiquing drug regulations in China, India, Brazil, Argentina and Turkey.

Although counterfeiting is the major concern in the West, "if you're talking about the poorest cities, the problem is quality," says Roger Bate, an economic health policy scholar at the American Enterprise Institute, a conservative think tank in Washington, DC. And, as more medicines are being exported from developing nations, the reach of the substandard medicines problem is rapidly growing.

Last year, Bate led a pilot study on drug quality in India that showed regional differences in the prevalence of substandard drugs (see map). A similar study in six African countries found that 35% of sampled medicines tested failed quality control—many of which were substandard rather than fake (*PLoS One* **3**, e2132, 2008).

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