



Life-Saving or Life-Threatening? India and the Drug Quality Conundrum

By Roger Bate

There are many reasons to believe that some pharmaceuticals produced in India and elsewhere in the developing world are of poorer quality than those produced in industrialized economies with rigorous attention to good manufacturing practices (GMP), even though most drugs produced in India are perfectly fine. Ranbaxy's run-in with the U.S. Food and Drug Administration (FDA) is emblematic of these quality concerns. But might there be a market for mixed-quality drugs? The developing world needs medicine, and it will seek out poorer alternatives if it cannot get high-quality Western medicines at affordable prices. Drug quality standards will rise for good when overall well-being in the developing world improves.

On a March visit to Chennai, a major city in southeastern India, I was sickened by what was probably a virus. Given the chance that it could be a nasty bacterial infection, I took ciprofloxacin, a powerful antibiotic often used for severe gastrointestinal infections. Through a friend, I had the drug—Cifran, the brand name of a drug manufactured by Ranbaxy, the largest Indian drug company—in a matter of hours. I checked the packaging and the pills as closely as a sick patient could (years of researching the dangers of substandard and counterfeit medicine has taught me to do this with any drug), and I did not hesitate to take them. I got better in a few days, probably because the virus left my system. But I have no doubt that the Cifran would have knocked out any bacteria, too.

Those who know me well might be surprised that I put trust in a Ranbaxy drug, given that I have researched and written widely about the potential dangers of Indian drugs since 2004. I was even contacted by a whistle-blower from Ranbaxy in 2005 with evidence, which later appeared to be corroborated by the FDA and the

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U.S. Department of Justice, that company officials had doctored drug stability data (see below). Yet, as I have learned over the last few years, Indian drug supply and distribution chains can be just as secure as European and U.S. ones, at least domestically. It is a question of knowing the supplier.

Empirical Research

There are many examples in the literature of illness and death being caused by poor-quality

Key points in this Outlook:

- Research shows that 8.5 percent of drugs in two Indian cities fail quality tests.
- Drugs purchased through known and trusted sources are more likely to be of satisfactory quality.
- It is understandable that developing countries want to permit drugs of mixed quality to circulate.

drugs.¹ In the past, it was generally assumed that these were counterfeits made by criminals. But studies of the drug quality problem were largely anecdotal, often relying on small sample sizes. On a global scale, there were few reliable statistics. Country-level efforts were ad hoc. The FDA's adverse event reporting system, for example, recorded any adverse drug reaction, whether caused by poorly produced or counterfeit drugs, incorrect usage, or patient-specific characteristics.

The likelihood of buying a substandard product in Delhi and Chennai is low—if one identifies a reputable pharmacist.

In 2006, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of the World Health Organization (WHO) set up an anonymous rapid-alert reporting system. But, by definition, IMPACT exclusively identified counterfeit products, and then only within the western Pacific Rim. Furthermore, IMPACT was poorly funded. Partner manufacturers in developed countries could afford to hire investigators and spur prosecutions, but they naturally focused on intellectual property infringements of their own products. And given that WHO had defined a counterfeit as a product that had been “deliberately and fraudulently mislabeled with respect to identity and/or source,” such action made sense.

WHO says that it has a more comprehensive “database on counterfeit drugs” based on information supplied by countries, but this information is not publicly available. Furthermore, it acknowledges that fewer than 5 percent of its 191 member states report any cases. Reports that are received are not validated, and some do not differentiate between substandard and counterfeit drugs.²

WHO defines substandard drugs as “genuine drug products which do not meet quality specifications set for them”—that is, products that do not contain the correct active pharmaceutical ingredient (API) in the correct quantity and formulation.³ Substandard drugs may be the result of poor (but not willfully fraudulent) manufacturing or may have degraded due to poor transportation or storage. Both counterfeit and substandard drugs can cause harm: treatment failure, wasted resources, avoidable deaths, and development of resistance, to name the main risks. From a public health perspective, the most salient question is whether the drug works. But strategies for dealing with counterfeits and substandard drugs are

obviously different: one is criminal, involving smuggling and trademark fraud; the other is a regulatory or an otherwise civil matter, in which legitimate producers and others in the supply and distribution chain fall short.

At least in principle, anticounterfeiting efforts are not highly politicized: they focus on establishing and enforcing sensible laws. After all, who wants to defend someone passing off paint as a life-saving drug? Even near-perfect counterfeits raise the ire of many people who rightly argue that they undermine incentives for innovation. But substandard drugs are politically more difficult to tackle because they often involve embarrassing and expensive issues in developing countries: inconsistent and often woeful oversight of manufacturing, poorly educated drug traders and dispensers, wretched transportation systems, and unreliable electricity for climate-controlled storage. Developing countries prefer to improve such matters quietly and without public scrutiny, it seems, and so regulatory authorities have collaborated with corporations, the police, and even academics primarily to eliminate counterfeiting, rather than improve the practices that create substandard drugs—even though substandards arguably affect millions more people than counterfeits. There are some exceptions to this trend—the FDA, for example, recently opened a satellite office in Beijing and has partnered with Peking University and the nonprofit International Society for Pharmaceutical Engineering to conduct training programs in GMP, inspection practices, and testing methods. Given China's growing role as a supplier of low-cost pharmaceuticals and API, many bound for the lucrative U.S. market, both countries see this as in their interest.⁴ But on the international stage, counterfeits still receive much of the enforcement resources and attention.

One has to go back more than a decade to find rigorous research that deals with substandard drugs as distinct from counterfeit products. In 1997, researchers from Robert Gordon University and the Hospital for Tropical Diseases in the United Kingdom sought to quantify and qualify bad drugs and, in particular, distinguish between counterfeit and substandard drugs.⁵ In this study, local collaborators in Nigeria and Thailand bought chloroquine, then the standard treatment for malaria, and several popular antibacterials from pharmacies and other retail outlets. The researchers concluded that there was some evidence of decomposition due to poor storage or transportation, but poor—not fraudulent—manufacturing was the predominant cause of poor quality in 36.5 percent of sampled drugs.⁶ The tested drugs were labeled as

originating in India, Italy, Nigeria, Pakistan, Thailand, and the United Kingdom, with no appreciable difference in the quality of product from country to country.

So, while counterfeiting is undoubtedly a growing problem—even in well-regulated countries, a bad product may occasionally slip through; tainted heparin in the United States in 2007–2008 contributed to the deaths of nearly one hundred Americans⁷—it may be that poor, not willfully fraudulent, production and inefficient distribution pose the greatest hazard. Publicly available data in countries that distinguished clearly between counterfeit and substandard medicine appear to support this point: the Indian government, for example, reports that less than half of 1 percent of drugs sold in the country were, on average, counterfeit from 1995 to 2003, whereas less than 10 percent were substandard.⁸ (In a less precise description, WHO has reported that Indian manufacturers estimate that 20 percent of drugs in major Indian markets are “fake.”⁹)

To generate more data, a team of researchers and I collected antimalarial drugs from six major African cities in late 2007. We assessed only whether the main API was present in the right quantity, not whether the drug was counterfeit. We found that roughly a third of the drugs failed basic quality-control tests, including 31 percent of the drugs allegedly produced in India.¹⁰ (Not all of these drugs were necessarily manufactured in India. In June 2009, for example, Nigeria’s National Agency for Food and Drug Administration and Control [NAFDAC] announced that a large consignment of fake generic antimalarials labeled “made in India” was in fact produced in China.¹¹)

Our research team wondered whether the failures owed to poor manufacturing, poor transportation conditions, or poor conditions of final storage in Africa. We launched another research project in spring 2008, aiming to test the quality of the same antimalarials sold in pharmacies in two major Indian cities: Chennai and Delhi. Almost none of the Indian brands found in Africa were even for sale in Delhi and Chennai, however, partly because a different strain of malaria from that in Africa predominates in the subcontinent, and a different first-line therapy is used. It was impossible to assess the quality of direct exports to Africa because such drugs could not be procured publicly except in large volumes—too expensive for an academic study.

We decided to broaden our scope, then, from antimalarials to other essential medicines. We collected 541 samples of five essential drugs from fifty-two pharmacies.

Our research—to be published on June 23 in *PLoS One*¹²—found that 8.5 percent of drugs failed quality tests, including 5 percent in Chennai and 12 percent in Delhi. These data mirror the Indian government’s statistics. (The Delhi rate may be higher owing to the city’s proximity to major counterfeit and substandard drug operations in Delhi, Agra, and Aligarh.) Most interestingly, there was marked heterogeneity in the quality of pharmacies in both cities. Nearly half of the pharmacies assessed (twenty-one out of fifty-two) had zero failures, and only a handful had more than 20 percent. The majority of pharmacies fell somewhere in between, with 8–20 percent failure rates.

This suggests either that some pharmacists are complicit in the sale of substandard products or that they rely on different wholesalers or manufacturers, some of which trade in substandard products. To assess fairly the quality of drugs supplied by manufacturers, one would need to obtain randomly selected samples, which cannot be easily done without raising suspicion and thereby biasing results. At the wholesale level, ongoing research seems to indicate a heterogeneous quality pattern, which may explain some or most of the heterogeneity observed at the pharmacy level.

But I have little doubt that at least some pharmacists are responsible for distributing substandard drugs. In informal surveys conducted after the quality assessment, a strong majority (nineteen out of twenty-six) of the pharmacists told researchers that many of their colleagues were complicit in the sale of substandard drugs. Many pharmacists knowingly peddled such drugs to enrich themselves, the pharmacists said.

Speaking with middle-class Indians in Delhi and Chennai, I concluded they are far more wedded to a single distribution chain than many Americans are. Americans may have a favorite pharmacy, but I imagine few of us would think twice before using a different one if it were more convenient or more cost-effective. As a resident of the District of Columbia, I have used four pharmacies in the past five years to fill prescriptions. I assume, after all, that each pharmacy supplies high-quality products.

In India, however, middle-class Indians find it important to establish a relationship with a pharmacist; one must return to the same store and see the same pharmacist or else end up with poorer service, including potentially poorer-quality products. When we initially designed the survey, we assigned drug collectors from the same city but not the same neighborhood of collection, thinking this would minimize bias. But given that customers

who do not know their pharmacist may receive poorer-quality drugs, this protocol may actually overstate the share of substandard drugs in the market. To test properly for this effect in future studies, we would need to identify enough buyers who were known at each of the previously sampled pharmacies and ask them to buy the same set of sampled drugs.

It is clear that the likelihood of buying a substandard product in Delhi and Chennai is low—if one identifies a reputable pharmacist. The same thing may not be true, however, for exports to places where such personal relationships obviously do not exist.

The Ranbaxy Saga

In 2004 and 2005, I analyzed the drug approval system at WHO and found it wanting.¹³ WHO approved copies of branded HIV drugs but did not establish that these drugs were true “generics”—that is, bioequivalent to the brand originals. (Other stringent drug regulatory authorities like the FDA and the European Medicines Agency demand evidence of bioequivalence before approving generics for their markets.¹⁴) Since that time, the deficiencies in WHO’s approval system have probably been resolved.

As a result of this initial analysis and subsequent publications, a whistle-blower from Ranbaxy contacted me with allegations that the company was falsifying data on stability, thinking I would expose such bad practice. GMP dictates, among other things, that companies record the degradation of a product over time in order to show that a product works when it is first made and throughout its approved shelf life. The documents I was given showed identical degradation data for HIV products examined after nine months and twelve months. Given that the readings were to several decimal places—and products inevitably degrade over a three-month period—the data were almost certainly incorrect. Indeed, internal Ranbaxy emails also shown to me revealed staff concern that such data would be a red flag to inspectors, lowering the chance that Ranbaxy would win a procurement order for HIV medicines from UNICEF. Had a small data transfer error occurred, or was the entire production line compromised? Were some of the managers at this Ranbaxy plant just a bit incompetent, or were they cutting corners on a wide scale, resulting in potentially dangerous products coming off the line?

I realized the significance of the data and tried to meet with the whistle-blower, but he claimed to be scared for his life. Without a face-to-face meeting, I was

concerned that I was being misled. Instead of writing about the subject, I forwarded the data to WHO and the FDA in late 2005 and to the Department of Justice in mid-2008, with the expectation that they would act. The FDA closely examined Ranbaxy’s production. In a June 2006 warning letter to Ranbaxy, the FDA recommended “withholding approval” of new drugs and API manufactured at the company’s Paonta Sahib plant until certain deficiencies were corrected.¹⁵ Nearly a year later, Ranbaxy’s counsel admitted “that it had not yet addressed all of [the FDA’s] concerns.”¹⁶ Nonetheless, the FDA did not hesitate to approve eighteen new drug applications from Ranbaxy, suggesting that the problem was likely one of record-keeping rather than quality.¹⁷

While cutting corners has risks for patients in terms of efficacy and safety and for the broader population in terms of increased resistance risks, there may be conditions under which it is warranted.

In July 2008, the FDA and the Department of Justice made their concerns public, announcing that they were investigating Ranbaxy for fabricating bioequivalence and stability data to support applications to market new generic drugs in the United States and to sell drugs to the President’s Emergency Plan for AIDS Relief. “Allegations from reliable sources and supporting documents indicate a pattern of systemic fraudulent conduct,” the Justice Department wrote in its July 3 brief. “Evidence suggests that Ranbaxy uses API from unapproved sources, blends unapproved API with approved API, and uses less API in its drug than had been approved by the FDA.”¹⁸ In September 2008, the FDA issued an import ban on more than thirty generic Ranbaxy products.¹⁹

Ranbaxy claimed that “except for issues that have already been fully aired with the [U.S.] government, [it knew] of no evidence to support” the allegations.²⁰ It pointed out that the FDA collected more than two hundred samples of Ranbaxy products and believed that the “FDA’s testing of these samples did not uncover any product failures.”²¹

In September 2008, the Department of Justice dropped its case after Ranbaxy provided it with a tranche of requested documents. But the import ban remained, and in February 2009, the FDA announced Ranbaxy had

indeed falsified laboratory tests for drugs approved for sale in the United States. In mid-May, company CEO Malvinder Singh announced his resignation, and the FDA received a “corrective action plan” from the company.²²

What can be learned from the Ranbaxy saga? Despite the media furor over the issue, it should be noted that FDA inspections of manufacturing plants—both foreign and domestic—routinely identify GMP shortcomings similar to those alleged to have occurred in the Ranbaxy plant. The FDA often takes punitive action, including halting all new drug approvals, even when there is no evidence that a product is actually dangerous. (The FDA did not issue a recall for any of Ranbaxy’s products.) The FDA can and should act proactively because Americans can afford—and demand—the highest level of quality compliance when it comes to their pharmaceuticals.

But not all countries will make the same choice. During the period that Ranbaxy was being investigated by the FDA, WHO also inspected Ranbaxy’s Paonta Sahib plant several times and took a decidedly different view. In May 2007, it concluded that the plant was operating at an “acceptable level of GMP,” although noncompliance with WHO guidelines “needed to be addressed by the manufacturer and verified.”²³ In November 2008, WHO commissioned a special inspection team composed of itself, the Therapeutic Goods Administration (Australia), the Medicines and Healthcare products Regulatory Agency (United Kingdom), and Health Canada, which concluded that Ranbaxy was “operating at an acceptable level of compliance with WHO GMP guidelines.”²⁴

Back in Chennai in March, I adopted a similar tack. Ranbaxy had cut corners, yes. But assuming a low probability that the product was substandard and a higher probability that I had a bacterial infection, I happily took the pills.

The Ranbaxy affair puts into perspective issues about drug quality for developing countries. There can be no doubt that it is expensive for companies to keep products registered with various authorities. In April 2007, Ranbaxy voluntarily withdrew four of its HIV/AIDS drugs—eleven formulations, including one manufactured in its Paonta Sahib plant—saying that “the demand generated through WHO PQ Status” had “been minimal and not commensurate with the concomitant administrative mechanism required to sustain it.”²⁵ And while cutting corners has risks for patients in terms of efficacy and safety and for the broader population in terms of increased resistance risks, there may be conditions under which it is warranted.

Is There a Market for Products of Differing Quality?

Most health activists have argued for the past decade that Indian generic drugs are safe, cheap, and more readily available than generics produced outside of India. *Médecins Sans Frontières* (MSF) says: “Because generics are in general a lot cheaper than patented products, they have played a huge role in making sure people actually have access to essential medicines in the developing world. MSF relies overwhelmingly on quality Indian generics for its antiretrovirals to treat HIV/AIDS, for example.”²⁶ However, there seems to be a tacit assumption made by groups like MSF that all Indian copy drugs are true bioequivalent generic drugs. While I believe that high-quality generic drugs, many of which are produced in India, can significantly increase access to drugs, I have generally taken the other side of this debate. It was manifestly obvious that many producers in developing countries, including India, did not make sufficiently high-quality products. Furthermore, innovators deserve to be rewarded for continuing to develop safe and effective new products.

But as I have traveled in Africa and worked on recent drug projects, I have noticed that it is often the Indian and Chinese companies whose drugs penetrate private markets, where most Africans get their drugs. The products of Western companies such as Glaxo-SmithKline, Merck, and Pfizer are often absent because these markets are relatively insignificant for their companies. They often supply large orders (often heavily discounted or donated) of treatments for high-profile diseases to African ministries of health, but their products are not typically sold in as many private markets. Novartis’s anti-malarial is one of the more available products, but it is still found in far fewer private pharmacies than a wide variety of Indian drugs. The choice for an African consumer is often an Indian product, a Chinese product, or no medicine at all. Is taking nothing the best option?

The top Indian companies—including Ranbaxy, Cipla, Piramal India, Dr. Reddy, and others—consistently make high-quality products. I have seen at least thirty Indian antimalarial brands from another ten or more companies during my quality-assessment research; many of these failed basic quality tests. (A few of the top companies’ products failed as well, but this was likely due to poor storage.) The FDA is right to refuse entry of such products because Americans demand the best products possible with as low a risk as is economically sensible.

Developed-world companies want the very best standards adopted globally. In the long run, this makes sense, as it prevents the emergence of dangerous drug resistance and ensures that all people are treated with high-quality products. And for diseases that require consistent treatment for many months or years (tuberculosis and HIV/AIDS, in particular), such worries about substandard products leading to resistance may mean that only the very best drugs should be supplied.

It is certainly arguable and perhaps even testable, however, that poor countries benefit from having laxer standards in the short run if it means that generally good drugs are available. If one can guard against the lowest-quality products, perhaps by using basic thin-layer chromatography testing (although this does not assess bioavailability) or spectrometry, this option is better than nothing. Dora Akunyili, Nigeria's minister of information and communications and former director general of NAFDAC, told me that it is better to have access to no drugs than access to counterfeit drugs. But she also has studiously avoided discussing Nigeria's own producers, some of which make products that are legal there but fail quality-control tests.²⁷

Governments in Africa indirectly condone substandard drugs. Kenya's *Daily Nation* reported in January 2009 that an unpublished Ministry of Health report confirmed "what had always been known to be the biggest obstacle to a successful anti-malaria campaign—well-entrenched cartels of drug manufacturers and distributors working in cahoots with corrupt Health ministry officials to supply their own drugs."²⁸ The *Daily Nation* shared a copy of the report with me, and it was alarming: more than half of all 187 malaria drugs the report evaluated in the country were not registered, and 16 percent of the drugs, many of which were produced locally, failed quality tests.²⁹

Still, these countries may be right to tacitly condone mixed drug quality. As people become wealthier, they will demand better products, and the worst ones will be driven from the market by market forces and by increasingly stringent regulation. Of course, there is the danger that substandard suppliers, which can often sell at lower prices, may corner the drug markets and dominate political decision-making, making subsequent improvement less likely. (This is a topic I will examine in future *Health Policy Outlooks*.) At worst, condoning such behavior could even encourage firms currently making good products to cut corners, possibly lowering overall quality.

Evidence from countries like India and Brazil, however, suggests that markets with mixed-quality products tend to improve over time. Since 2003, the administration of Brazilian president Luiz Inácio Lula da Silva has worked to improve the quality of medicines on the market there. But Brazil retains a three-category system, which permits the sale of innovator products; bioequivalent generics; and *similares*, or nonbioequivalent, locally manufactured branded copies. The Brazilian consumer advocacy agency has discussed the production and marketing of such products and whether the government should take any action to make them illegal before 2013, when bioequivalence testing will become mandatory for all pharmaceuticals. Even if the Brazilian authority takes no action, however, industry-watchers believe that growth in the generics market—fueled by growing profit prospects, the changing consumer preferences of a more affluent public, and government support—will eventually drive them from the market.³⁰

Until such a time, which could be many decades for Africa's poorest countries, a messy world of mixed-quality drugs is what we have, even if no one really wants to admit it.

Notes

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