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Indian drug talk – a different language, similar problems

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Delhi – In the Fall of 2008, my Indian colleagues, led by expert survey consultant Sujat Khan, undertook an informal survey of pharmacy staff across Delhi in an attempt to understand some of the problems Indian pharmacies were facing[1]. In particular we were interested in how much pharmacy staff knew about falsified medicines, whether they thought they had been exposed to such products, and what they did to prevent their procurement.

The surveys were initiated as a result of findings from a pilot study that discovered a small but significant proportion of drugs purchased from retailers in Delhi failed basic quality control[2]. Subsequent analysis showed that the profile of pharmacies selling low quality drugs was similar across the cities sampled (and incidentally similar to pharmacies sampled in some African cities[1]); a few sold a high percentage of fakes, and most sold none. The worst performing pharmacies were also responsible for selling products with zero active ingredient content, which we can only assume were purposefully faked. Most of these pharmacies did not meet high/western pharmacy management standards (ensuring climate control, storage of medicines elevated from the floor and out of direct sunlight, clean facilities, electronic stock management to ensure first-in first-out, etc.); although pharmacy chains, such as those run by the Apollo Group of companies, an Indian healthcare conglomerate that runs hospitals, pharmacies and other businesses, were obviously held to a far higher standard.

Most Indian pharmacists surveyed acknowledged having been offered fake drugs, and interestingly, far more pharmacists in India than in Africa reported having been approached by drug salesmen and offered counterfeit products. However it is important to note that in India, counterfeits are not necessarily seen as a bad thing. In fact, often they are considered the preferred product to purchase since not only are

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they cheaper, but the money doesn't go into the pockets of large corporations (especially foreign corporations).

Pharmacists (or pharmacy staff) were also asked how they would define a good quality medicine versus a low quality medicine; however, in retrospect, we neglected to ask specifically about the quality of medicines their pharmacy sold. As the answers were replicated across the vast majority of pharmacies surveyed, it was assumed the answers given implied detailed knowledge, when in fact they were simply the more obvious manifestations of quality. Essentially, pharmacists like Ravinder Singh, who manages his own small pharmacy in Delhi, reported that the "packaging material should contain the right information about the product (product name, manufacture and expiry dates, batch numbers, and any local registration numbers required by state or federal government)". However like the assumption made about "counterfeit" drugs, it was probably dangerous to assume that the pharmacists were aware of what they were selling and what constituted a problem product. After all, every pharmacy insisted they always sold "medicine of good quality", and when asked about problems they faced, none said "lack of quality assurance of medicines".

I've personally met several Indian pharmacists, all of whom appeared well trained and some of whom had Master's degrees from the US or Europe. They understand the problems with poor production methods and inferior quality ingredients, and the risks of bogus products passed off as genuine. They know that some manufacturers do actually make poor quality products, some by mistake, others intentionally. But that knowledge stands against their near universal working assumption that Indian manufacturers making products they procure, actually follow good clinical practices. Additionally, while the pharmacists are knowledgeable, that doesn't prevent them (or more likely their non-pharmacologically trained staff) from placing new labels with new expiry dates on out-of-date medicines. This practice is so widespread in fact that there is an entire cottage industry creating labels with manufacture and expiry dates for different products.

Pharmacies engage in such practices because there are "inadequacies in drug testing, severe shortage of regulatory inspectors, corruption and lack of law enforcement," says Dr. Azhar Yaqoob Khan of the Jamia Hamdard University, School of Pharmacy, New Delhi. His comment about corruption is particularly interesting in the context of pharmacies. Most Indian pharmacists surveyed were concerned

that government regulators were extracting bribes in order to stay in business (and perhaps some to turn a blind eye to illegal activity, such as selling fake drugs), which led to some pessimism about the helpfulness of stricter regulation, and better enforcement.

Five years after these initial surveys were conducted we repeated the surveys with pharmacies in Delhi (including ten that were sampled before), and found similar results, with one notable exception. Fewer of the pharmacy staff were willing to speak to our surveyors and insisted we speak with the pharmacist himself. Pharmacists also appeared far more knowledgeable about the terms; reporting that they had not been offered 'spurious' products. They also reported being comfortable providing "cheap medicines", and didn't care, as one put it, "if the medicines were deceptively similar to a well known [trademarked western] product". Perhaps linked was the fact that many pharmacists insisted none of their products were poor quality, and therefore who cared if a property right was breached.

It appeared to our team that pharmacists had become far more "political". The phrase "deceptively similar" has been used by India's generic industry associations; a phrase I've heard a dozen times in various meetings by DG Shah of the Indian Pharmaceutical Alliance – one of the most effective Indian generic lobby groups. IPA argues that as long as the product copied is not "identically similar" to a copied product, but has obvious differences (to the eye upon close inspection), then merely slightly misleading buyers is acceptable.

It doesn't appear that Indian pharmacists are directly aware of the international fights on trademarks, but rather believe that "western interests" are out to get them. Indian pharmacists opinions appear to have become both more nationalistic and certain since 2008, and could be summed up this way – our products are safe, only westerners claim we sell poor quality medicines, and they do that to damage our industry because we sell safe, cheap medicines that outcompete them.

Surveys were also conducted of customers leaving pharmacies, who appeared to have purchased medicines, in an effort to understand their knowledge about medicine problems in India. We suspected that Indian consumers would underestimate the dangers of low quality medicines.

We found that the vast majority of customers had even stronger views about counterfeit medicines than pharmacists. When asked whether they were concerned they might have just bought counterfeit or substandard medicines, over 90% said

they were not. Most of them thought such medicines would be cheaper and probably just as effective, especially the counterfeit medicines, since many had similar opinions to one customer who stated that "brands just mean higher prices, and I don't want to give my money to corporates [big business]".

When it was explained to them that lying about provenance could mean weaker production quality or even the wrong ingredients, and that such medicines could well fall into the Indian category of medicines known as "spurious," over a third still thought the medicine would work, just more slowly, or not quite as effectively. At least half of the survey respondents were indignant, and a few were very annoyed, at the suggestion that the drugs they had just bought might be spurious.

Although the focus was on Indian cities throughout these investigations, due to ease of operation rather than a desire to ignore rural communities, my colleagues did interview 21 customers in rural areas outside of the town of Aligarh who had recently bought pharmaceuticals. Aligarh is a known location of falsified medicine production, so we thought knowledge of such products would be as high in these rural areas as anywhere. But the answers were similar to the results in Delhi. There was, predictably perhaps, even less knowledge of pharmacological problems with medicines in these areas than in Delhi. Or perhaps there was even greater fatalism among buyers; as one 23 year old mother stated, "we buy what we can afford".

N.B. The next discussion paper will focus on India's standing in medicine production and how its producers and regulators are viewed inside and outside of India.

References

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[2] Bate R, Tren R, Mooney L, Hess K, Mitra B, Debroy B, Attaran A (2009) Pilot study of essential drug quality in two major cities in India. *PLoS ONE* 4(6): e6003. doi:10.1371/journal.pone.0006003.