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Combating dangerous medicines:

Differences in quality of medicines sold by small pharmacies and large chain pharmacies

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Summary

Evidence from numerous studies shows that emerging markets have far more poor quality drugs than western markets. There are many reasons for this, but one reason, investigated in this paper, is the possibility that smaller, often privately-owned, pharmacies take greater risks with drug procurement than larger organizations, which are often franchises or major pharmacy chains. The limited data available weakly support the hypothesis, with 14.4% of samples from smaller pharmacies failing quality control and 9.4% of samples from larger pharmacies failing. Ongoing research will hopefully provide a more robust testing of the hypothesis, as well as provide a fuller explanation.

Background

Buying a Coke in Nairobi or New York is a similar experience, for while the surroundings may be entirely different, the product is identical and often the type of seller is too. But buy an antibiotic in these cities and the experience is rather different, for only in Lusaka can you buy your medicines with the same ease as buying your Coke and often from the same seller.

All aspects of drug purchasing are more casual in emerging markets, like those of Kenya's capital Nairobi. It may be difficult to see a doctor, which certainly makes it understandable that one doesn't need a prescription to buy any drug available for sale, after all the pharmacist is often the most medically qualified person that a patient will ever see¹.

The market in Nairobi is more varied too. If you walk into ten pharmacies you might see hundreds of different brands of the same types of medicines, especially antibiotics and antimalarials. We found that prices range from under a dollar for a locally made version of an older medicine to over thirty dollars for a newer drug type made by a Western innovator. Nairobi's shoppers can compare prices far more easily than New Yorkers and probably some make decisions based on price, especially since many will be buying out of pocket, with no insurance cover.

For basic medicines like antibiotics that are required in all countries of the world, the retail price of drugs in an emerging market like Kenya is far lower than in America, but few Americans would want to buy Kenyan medicines, even at Kenyan prices because of inadequate quality assurance. While there are occasional disasters in America, such as the counterfeit heparin that probably killed 149 Americans in 2006 and 2007 ²by and large Americans have the safest medicines in the world. 3.65 billion

¹ 1 Bate, Roger, Ginger Jin, and Mathur Aparna. "Does Price Reveal Poor-Quality Drugs? Evidence from 17 countries." Journal of Health Economics. (2010): 12. doi:10.1016/j.jhealeco.2011.08.006 (accessed January 20, 2012).

² "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs." *Pew Trust Group*. (2011). http://www.prescriptionproject.org/assets/ pdfs/Pew_Heparin_Round4b_SinglePgs_b.pdf (accessed January 20, 2012).

prescriptions are filled every year³ and an unknown, but vanishingly small, number are filled with medicines of dubious quality.

But in Kenya quality medicines are less assured. A 2007 study done by World Health Organization and the University of Nairobi found 16% of the drugs assessed were substandard⁴ My own team's research found that over the period 2007-2011 at least 10% of all types of Nairobi's medicines assessed failed quality control tests⁵⁶⁷. Improving production quality of legal producers is important, as is limiting criminal activity of bogus producers and traders, but much of the improvement will have to come from the main retailers. In other words, if one wants better drug quality in cities like Nairobi, improving pharmacies will be essential. And as emerging markets develop there is the likelihood that a more safety conscious public will demand more stringent regulation. Such regulation will include demands on pharmacists to improve their practices, including limiting what they are allowed to do.

This creates opportunities for businessmen and women as well as their supporters, some of which are not for profit entities. I visited one charitable operation, overseen by the Minnesota-based Healthstore Foundation, which sells medicines to thousands of patients from over 65 of its CFW drug stores in Nairobi⁸. It runs the operation as a franchise, and like all franchises, it sets fairly strict standards and expects the entrepreneurs running single or several stores to follow the franchise-wide approach. Standards of cleanliness, store presentation, refrigeration and drug storage and security must be agreed to, in order to receive initial financing, and then demonstrated consistently if the franchise owner wants to benefit from continued support. To ensure value for money, bulk procurement is undertaken for the entire franchise from significant wholesalers or importers. It is presumed that the reputation of these larger traders is such that they will want to ensure they consistently access quality pharmaceuticals, or risk damage to their reputation.

Any pharmacist can mistakenly buy a bogus pharmaceutical of some kind (fake or substandard), but are some pharmacists particularly careless with what they order, perhaps buying from a less known trader who happens to have a good deal? Such actions are perhaps more likely in a smaller pharmacy, and less

³ Higgins, John K. "Pharma's New Prescription for CRM." TechNewsWorld - Healthcare, December 07, 2009. http://www.technewsworld.com/story/68823.html (accessed January 20, 2012).

⁴ "Antimalarial Medicines in Kenya - Availability, Quality and Registration Status." *Republic of Kenya Ministry of Health - Pharmacy & Poisons Board and Division of Malaria Control.* (2007): 9. http://apps.who.int/medicinedocs/documents/s16424e/s16424e.pdf (accessed January 20, 2012).

⁵ Bate, Roger, Philip Coticelli, Richard Tren, and Attaran Amir. "Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa – A Six Country Study." *PLoS ONE.* 3. no. 5. http://www.plosone.org/article/info:doi/10.1371/journal.pone.0002132 (accessed January 20, 2012).

⁶ Bate, Roger, Kimberly Hess, and Lorraine Mooney. "Antimalarial medicine diversion: stock-outs and other public health problems." *Research and Reports in Tropical Medicine - Dove Press Journal* 1 (2010). http://www.dovepress.com/antimalarial-medicine-diversion-stock-outs-and-other-public-health-pro-peer-reviewed-article-RRTM (accessed January 20, 2012).

⁷ Bate, Roger, Lorraine Mooney, and Julissa Milligan. "The Danger of Substandard Drugs in Emerging Markets: An Assessment of Basic Product Quality." *Pharmacologia*. 3. no. 2 (2011). http://docsdrive.com/pdfs/pharmacologia/2012/46-51.pdf (accessed January 20, 2012).

⁸ Bate, Roger. "What Works in Africa." *The American Magazine*, February 2007. http://www.american.com/archive/2007/january-february-magazine-contents/what-works-in-africa/ (accessed January 20, 2012).

likely for example, in Nairobi's 65 CFW Shops, or the <u>Apollo</u> pharmacy chain, which operates over 1000 shops across India.

Given the reputational concerns of such large organizations, it is assumed that they are more likely to have systems in place to prevent poor ordering practices, and hence have demonstrably better quality products. In order to test this hypothesis I compared drug quality by pharmacy type – pharmacies were either recorded as small or large (either a substantial stand alone organization or more likely, part of a larger chain).

Methods

From previous research study over 1,000 drug samples were tested from 19 cities in 17 countries. Drug quality was assessed using a variety of techniques as established in the literature ⁹¹⁰. Assessing those previous records, samples were identified by the type of pharmacy they were procured from – small local pharmacies or larger chain pharmacies.

Results

221 samples could be positively identified as being procured at small pharmacies, and 265 from larger chain pharmacies. Of the total 486 samples, 57 samples failed quality control (11.7%). Of those failures 32 were from smaller pharmacies (14.4%) and 25 from larger pharmacies (9.4%). As established in a previous working paper¹¹, it is not always possible to identify the causes of the failures, whether the products were fake or substandard. And that is the case with many of the 57 failures sampled here, where only 26 can definitely be identified as fake.

There are far fewer failures with zero active pharmaceutical ingredient (the most obvious type of fake drug) in the large pharmacies (4 failures) than in the smaller pharmacies (13 failures).

Discussion

The hypothesis is weakly supported since considerably more products fail from smaller pharmacies than larger chain pharmacies and franchises. The difference isn't vast -14.4% versus 9.4% - and more data would be required before strongly confirming the hypothesis. What is perhaps more interesting is that the relative failure rate due to identifiable fake products is considerably higher in the small pharmacies (13/212, 5.9%) than larger pharmacies (4/265, 1.5%). If these data were replicated in larger samples it

⁹ Bate, Roger, Kimberly Hess, and Lorraine Mooney. "Antimalarial medicine diversion: stock-outs and other public health problems." *Research and Reports in Tropical Medicine – Dove Press Journal* 1 (2010). http://www.dovepress.com/antimalarial-medicine-diversion-stock-outs-and-other-public-health-pro-peer-reviewed-article-RRTM (accessed January 20, 2012).

¹⁰ Bate, Roger, Ginger Zhe Jin, and Aparna Mathur. "Does Price Reveal Poor-Quality Drugs? Evidence from 17 countries." *Journal of Health Economics*. (2010). http://www.aei.org/files/2011/08/18/Does-Price-Reveal-Poor-Quality-Drugs.pdf (accessed January 20, 2012).

¹¹ Bate, Roger. "The market for inferior medicines: Comparing the price of falsified and substandard products with the legitimate medicines in emerging markets." American Enterprise Institute. (2011): 7. http://www.aei.org/files/2011/12/14/-the-market-for-inferior-quality-medicines_122143586079.pdf (accessed January 20, 2012).

could explain the reason for the only marginal differences in overall failure rates. Since larger pharmacies are presumably buying drugs from better known wholesalers, the chances of procuring fake products are also presumably lower. It is quite possible, however, that substandard drugs, made poorly by legal producers, will not be intercepted and removed by legitimate wholesalers, and hence would find their way into larger pharmacies. And if the ratio of substandards is similar in products sold by large and small firms, overall failure rates would be similar, with the discrepancy made up largely by more fake drug failures in smaller pharmacies. However, the sample sizes really are too small to draw this conclusion strongly, but it does provide source for future research

Conclusion

Smaller pharmacies have slightly more lower quality drugs in them than larger chain pharmacies, and considerably more fake drugs. Sample sizes are too small to draw the firm conclusion that larger pharmacies procure better drugs, but the data point in that direction. Only further research will determine the strength of this finding.