Inferior medicines post a major health risk

By Roger Bate

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Global health agencies and western donors have made great efforts in recent years to subsidise and improve the supply of medicines for diseases affecting the world's poorest people, particularly malaria, tuberculosis (TB) and other deadly infections.

It is, therefore, a serious cause for concern that a significant proportion of drugs for these diseases fail basic quality tests, potentially undermining these efforts and posing a grave threat to public health.

This week, my team of researchers publishes one of the world's biggest studies into drug quality. Over the past four years, we purchased 2652 samples of antimalarials, antibiotics and TB drugs from pharmacies in 19 cities across 17 developing and middle-income countries. The results are alarming: up to 15% of all drugs tested in African cities and 7% in Indian cities failed basic quality testing. A more detailed study of malaria drugs also just released found up to 40% of those bought in the two largest West African cities have insufficient active ingredient.

If a drug used to treat these diseases is not made to the highest standards, this means the sick patient is unlikely to recover and it increases the chance of malaria parasites or TB bacteria developing resistance to the treatment. This has the potential to render entire classes of medicines useless, making malaria or TB untreatable with currently available medicines. Given that 8,8-million people contracted TB in 2010, and at least 240million malaria, the public health consequences are unthinkable.

Some of the substandard drugs we identified were most likely counterfeits.

But many more were made by local African, Indian or Chinese companies, but without the proper oversight of a competent government drug regulatory authority. Up to 25% of such drugs manufactured in Africa, 16% of those made in China and 4% of Indian drugs failed our testing, compared with 1,7% of those made in the European Union and the US.

More disturbingly, a small but significant number of poor quality drugs we found had been quality-assured by the World Health Organisation (WHO), which has the responsibility for ensuring medicine standards in developing countries. While drugs approved by the WHO are generally high quality, there appears to be a problem with such products, especially antimalarials, manufactured in China. Nearly 18% of the WHO-approved Chinese products we tested did not reach required standards, contrasting with a still worrying 2,4% failure rate of Indian-made WHO-approved products.

There are several reasons this may be happening. The most acute problem is with artemisinin combination therapies, a modern class of malaria drug.

One explanation is that recent global shortages of artemisinin (the main natural ingredient in the drug, derived from the sweet wormwood plant) have led to supply problems, which has resulted in many companies being forced to cut corners in order to deliver their medicines to agreed timetables. Another explanation is more sinister. It may well be that certain Chinese (and to a lesser extent Indian) drug manufacturers are boosting profits by cutting corners in the manufacturing process of drugs they supply to Africa. As the drug regulatory failures in India and China are well known, this is not so difficult for unscrupulous manufacturers to get away with.

In April, the Indian drug regulator was heavily criticised by the Indian parliament for colluding with drug manufacturers. Chinese authorities do not allow proper access to inspectors from overseas, resulting in audit reports indicating that more than a third of Chinese ingredients come from unknown sources.

Many African countries do not have the expertise or money to monitor properly the quality of drugs in their own markets and the WHO does not have the budget or ability to monitor the drugs it has approved once they have made it onto the market.

International pressure therefore must be placed on Beijing and New Delhi to put their regulatory houses in order. Part of this pressure should come from international donors, who pay for many of these Chinese and Indian drugs on behalf of the poor in Africa. Donors should expose and combat the double standard of companies exploiting weak oversight to sell poor-quality products to lower-income markets. In the face of such a threat to public health, inaction is not an option.

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ABOUT THE AUTHOR

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