Makers of shoddy medicines should be put on notice

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Some drugs that the World Health Organization (WHO) has approved for distribution to the world's poor are of inferior quality — shoddy products that hurt people who urgently need medicine — and some of the manufacturers, predominantly Chinese and Indian firms, may be knowingly producing them. This is the conclusion of my research teams' studies, published this week in the journal Research and Reports in Tropical Medicine.

We purchased, off the shelf from local pharmacies, about 2,600 drugs to treat malaria, tuberculosis and bacterial infections in low- and middle-income countries, including Ghana, Nigeria, Turkey, India and China. We then tested these drugs to see how much active pharmaceutical ingredient — the chemical that performs the drug's lifesaving function — they contained.

Drugs made by Chinese and, to a lesser extent, Indian manufacturers performed quite badly — sometimes a fifth of them failed basic quality-control tests. Most worryingly, more than 15 percent of the Chinese drugs approved by the WHO failed to include adequate amounts of active pharmaceutical ingredient.

To add insult to injury, some of the drugs we tested had been bought through Western donor programs, funded by taxpayers, and steered through aid programs to African markets.

Some of these drugs were likely outright fakes. Others were real but badly manufactured, perhaps to cut corners.

How do we know? Poor-quality drugs can have either too little or too much of the active pharmaceutical ingredient. We tested many different batches of the same drug produced by the same manufacturer and found that a few were consistently under-dosed. We didn't find any drugs with too much of the active ingredient.

By exposing people to insufficient doses of the active ingredient, the drugs may also accelerate drug resistance and cause tremendous harm to whole populations in the long run. Here's how:

When a person takes a drug containing too little of the active ingredient, some of the parasites or bacteria are killed. But the strongest germs survive, mutating and evolving into more resilient strains. Drug resistance is already making it difficult — in rare cases, impossible — to treat malaria and tuberculosis, diseases that kill millions of people each year. And our governments, which spend billions on aid programs designed to stop them, may inadvertently be causing harm by increasing access to substandard treatments.

To be clear, these donors did not knowingly buy bad medicine. As a rule, they purchase only drugs approved by a respected regulator, such as the U.S. Food and Drug Administration, or the WHO. But testing the actual drugs sold on the market, as we did in our studies, is a rare exercise.

In the United States, the President's Malaria Initiative conducts some testing, but many other donors don't. Bernard Nahlen, deputy coordinator of the initiative, said it had bought drugs for distribution but sent them back to the manufacturers because of quality issues. "There need to be checkpoints throughout that system," he said.

However, regulators in poor countries such as Angola or Kenya — where we found many substandard drugs — have few resources to pick up the slack.

The reality is that once a manufacturer gets the green light to sell its drugs in Africa — sometimes through the lucrative donor programs —

there are often no consequences for failing to maintain a high standard of quality.

The Chinese and Indian manufacturers making substandard drugs are often significant producers, certainly capable of making high-quality products — they did so to obtain WHO approval. But given available, albeit limited, data, they are not doing so consistently.

With little or no oversight, these companies may be cutting corners in the manufacturing process — or worse, watering down the active ingredient in their drugs, perhaps when the price of the raw material spikes and supply becomes harder to obtain. The drug most often with too low a dose in our samplings, for instance, involved the hard-to-getartemisinin, a key antimalarial ingredient.

The WHO has launched an investigation into the product failures we've reported, but it lacks the resources to do much more. Even if Beijing tries to bring the hammer down on its lucrative pharmaceutical industry, it is unlikely to properly address the corner-cutting found in so much of Chinese production. So the burden must fall on Western governments. After all, their citizens' tax dollars — and the lives of millions they purport to help — are on the line.

Donor governments should urgently step up post-market surveillance and increase penalties for repeat offenders. If three product failures occur from the same manufacturer in a given year, that company should lose approval status with the WHO — and across all of its registered products.

If donor governments took drug quality as seriously in Africa as they do in their own countries, they could save lives and increase the impact of the public health programs taxpayers fund.

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