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It's time to stop murder by counterfeit medicine

By Joel G. Breman

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It was the kind of mistake that's all too easy to make: Richard Morrow, a pioneer in international public health from Johns Hopkins University, forgot to pack antimalarial medication before traveling to the tropics in 1994. Soon after arriving at his destination in East Africa, he bought “chloroquine” at a pharmacy in the country's capital, and took the pills as recommended.

On his return to the U.S., he developed a fever, chills, and headache, and soon lapsed into the coma of [cerebral malaria](#)², a potentially deadly type of malaria. He survived with quinine treatment, but barely.

A later examination of the medication he bought showed it wasn't chloroquine despite what the package said. Instead, it was acetaminophen.

Each year, more than 250,000 children with malaria and pneumonia, common illnesses in poor countries, do not survive after treatment with fake and substandard drugs. While poor quality drugs targeting older individuals are also entering global markets, the [World Health Organization says](#)³ “it is very difficult to quantify [their] impact.”

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[The FDA, but with guns: How far should a little-known office go to track down counterfeit drugs?](#)⁴

Such useless or harmful drugs once went by the confusing designation “substandard/spurious/falsely labeled/falsified/counterfeit medical products.”

A recent [move by the WHO](#)⁵ aims to simplify this by separating them into three categories:

- **falsified medical products** deliberately misrepresent their identity and are distributed with criminal intent
- **substandard medical products** fail to meet quality standards
- **unregistered or unlicensed medical products** have not been assessed or approved

According to the WHO, [1 in 10 medical products](#)⁶ in developing countries is falsified or substandard. The personal and public health tolls are huge, as is the economic burden — up to [\\$200 billion annually](#)⁷.

Poor-quality antimicrobials are most often found in low-income countries. In addition to failing to treat infection, they also contribute to the evolution of antimicrobial resistance, which British researchers have estimated could kill up to [10 million people a year](#)⁸ by 2050. But counterfeit medications in virtually every therapeutic class, from blood pressure pills to treatments for cancer and vaccines, are made and distributed by unscrupulous criminals.

In countries with poor pharmaceutical control systems, such drugs can be made in illicit facilities inside or outside the country and enter the supply stream because no FDA-like system exists for inspection or approval. Expensive analytic equipment generally isn't available, while simple, accurate, and inexpensive testing systems for use in the field, at pharmacies, and at the point of care remain out of reach in virtually all poor countries.

To make matters worse, many countries do not have laws to define and enforce regulations addressing crimes related to counterfeit or substandard medicines, nor do they have well-defined judicial actions once criminals are suspected or identified.

[Related:](#)⁹

[Are we making progress in the fight against fake medicines?](#)⁹

High-income countries aren't exempt from this peril. In 2012, the FDA warned that [fake versions of the anticancer drug bevacizumab](#)¹⁰ (Avastin) had been distributed in the U.S. Drugs for cardiovascular and psychiatric conditions have also been counterfeited.

The internet opened a Pandora's box of opportunities for drug scams. Erectile dysfunction drugs such as sildenafil (Viagra) and vardenafil (Cialis) are the most well-known products peddled to unsuspecting clients over the internet. Approximately [35,000 online pharmacies](#)¹¹ have appeared over the last decade or so, many of them selling unapproved or counterfeit drugs. Lack of punishment for the criminals responsible for the falsified products is a major hindrance to confronting the problem.

The WHO has put in place a laudable [surveillance system](#)¹² for falsified and substandard drugs, but it relies on countries passively reporting information to an internally protected website that is regrettably not available to the general public health community. Deploying WHO experts in field-sampling methodology, drug testing, and the organization of pharmaceutical services to train individuals in countries at risk would greatly help ease the problem. In addition, data from drug quality tests should be shared widely and constructively in regular surveillance bulletins.

To help all countries stop the movement and use of counterfeit or substandard drugs, one clear objective should be that 90% or more of all drugs on a country's list of [Essential Medicines](#)¹³ meet international standards for potency and bioavailability by 2030. This 90% goal would be greatly reinforced by creating a quantifiable international [Sustainable Development Goal](#)¹⁴ that addresses preventive and curative medicines, including diagnostics

and vaccines. Many products used for regional or global health programs are “precertified” by suppliers; these also need scrutiny from factory to patient as breaching of supply chains and theft can occur.

One technology primed to address the fragmentation of multijurisdictional pharmaceutical supply chain networks is [blockchain](#)¹⁵, the technology that underpins cryptocurrencies such as bitcoin. Blockchain’s distributed ledger could be used to track and verify the movement of legitimate drugs, and thereby identify counterfeit or substandard drugs.

In some countries, it is barely illegal to manufacture or distribute poor-quality medicines. In other countries, existing laws inadequately punish those who intentionally deal in falsified or substandard medicine. The [Model Law on Medicine Crime](#)¹⁸, introduced by the University of Ottawa’s Amir Attaran, offers a template for strengthening national laws. This model is comprehensive in providing guidance on criminalization against manufacturing, trafficking, or selling falsified or substandard medicines in person or online; establishing principles for punishing perpetrators; creating tools to encourage whistleblowers to cooperate with law enforcement; and providing incentives for governments to strengthen drug regulatory capacity.

Existing international treaties protect against trafficking women and children, counterfeiting money, and transferring contraband tobacco, and also make it possible to apprehend, extradite, try, and punish the people who do this. As several colleagues and I [wrote recently](#)¹⁹ in the American Journal of Tropical Medicine and Hygiene, it’s time for a multilateral international treaty targeting counterfeit drug crime and promoting detection, apprehension, extradition, and punishment of the criminals and cartels that make, sell, and distribute fake drugs — rather than letting them off easy, as now occurs for fake and substandard drug crime.

Delays in providing technologies, protocols, and laws to guard against falsified and substandard drugs will contribute to preventable tragedies around the world as well as allowing antimicrobial resistance to increase and spread.

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