Beef up international cooperation on counterfeits

Marv Shepherd


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Counterfeit drugs are a menacing and deadly problem worldwide. The proliferation of fake drugs is astounding, with over 100 countries reporting incidents of fake drugs, according to a 2008 report from the Pharmaceutical Security Institute. And incidents of drug counterfeiting show no evidence of declining: some industry insiders suggest that the number of counterfeit medicines on the market has increased as much as 25% each year over the past several years.

There are many reasons for the growth of this fraudulent activity, but one major cause is the globalization of pharmaceutical manufacturing and distribution. The worldwide demand for inexpensive and innovative medicines kindles the drug counterfeiting trade. Additionally, companies are setting up manufacturing and research facilities in far-flung regions around the globe, creating new regulatory and enforcement challenges never experienced before.

This means that drug counterfeiters take advantage of countries where regulation and enforcement is limited and weak. As recently noted in the media, the US Food and Drug Administration (FDA) has only two drug manufacturing inspectors in China (*Nat. Med.* **16**, 139, 2010). Similarly, European authorities only inspected 18 facilities in China in 2008, and they only visit facilities with a reported problem.

The regulatory and enforcement agencies of many countries are chronically underfunded—and understaffed. What's more, nations typically lack laws and penalties tough enough to deter counterfeiters.

In many countries, there are insufficient licensure requirements for manufacturing, distributing, importing and exporting drug products. This creates a situation where the quality control of drugs made for export is lax—thus facilitating the production of fake drugs. As one China government official told me at a Beijing conference two years ago, "drug exports are not our problem, they are your [US] problem." It is no surprise that China has topped some lists as the world's largest producer of counterfeit drugs.

Controlling the entry of fake drugs into a country can be done, but it is a technological and human resource challenge. The current trend in getting substandard or counterfeit medications to US homes is through the internet. Rogue websites use deception and fraud to facilitate the sale of fake drugs. Some sites do not even require a prescription; all you need is a credit card number. A common tactic is to create a website with a false company address. People think they are patronizing a legitimate, licensed pharmacy and are receiving an authentic drug from the designated country, but in reality they receive a fake or substandard product from a foreign source.

Renewed international understanding and cooperation is essential if we aim to control the fake drug problem. This will not be accomplished with just another international conference to discuss the issue.

We need multilateral agreements that have real strength and utility. These should foster cooperation among inspectors and law enforcement agencies to share information on a slew of components: counterfeit drug manufacturing, fake drug distribution networks, repacking and labeling facilities and wholesalers, plus those involved in financing the operations such as brokers and trading houses.

These agreements should also involve legitimate drug manufacturers and distribution network operators. One step in this direction was the formation of IMPACT, the International Medical Products Anti-Counterfeiting Taskforce by the World Health Organization (WHO) in 2006. The task force aims "to build coordinated networks across and between countries" to stop drug counterfeiting.

For global cooperation to work, however, we need international agreement on what constitutes a 'counterfeit drug', as opposed to a 'substandard drug' or a 'generic drug'. Currently, many countries cannot agree upon these definitions and confuse the terms. Without universally agreed upon definitions, troubles can arise. The problem is that some countries will make generic drugs for brand-name products that are still under patent protection. They may be 'legal' products within that country but may infringe on patent protection when the product is shipped outside of the country.

In some places the pendulum has swung very far in the direction of intellectual property protection. Just this past March, Kenya's Constitutional Court heard arguments that the country's Anti-Counterfeit Act of 2008 fails to specifically exempt generic drugs (made after patents on the initial brand-name version expire)—potentially limiting access to legitimate essential medicines. Broadly speaking, the law bans the manufacture and packaging of medicines "without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods."

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There is an urgent need to avoid confusion. The WHO definition of counterfeits, agreed upon in 1992, represented a step in the right direction. It stated that "a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

But disagreement over this WHO definition lingers, with some saying it is too broad, and others too narrow. There should be a concerted effort for countries to compromise and hammer out a version that they can readily apply domestically.

Fraud, deception and counterfeit drugs are a growing problem. Solutions lie in the harmonization of international cooperation among government, law enforcement and pharmaceutical entities. In other words, we need cooperation from "all sides of the border."

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