GoodRx Health

Why Substandard and Counterfeit Medications Are a Danger to Global Public Health


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Key takeaways:

- Substandard and counterfeit medicines are those that do not meet quality control standards and specifications. This can either be due to poor manufacturing or mal intent.
- Most developed countries have strong systems in place to prevent these products from entering the drug supply chain. But, it is still a major problem globally.
- The USP-USAID partnership is an example of an organization that has been working to address the issue by strengthening regulatory systems. And in Nigeria, they did so by helping quality control labs get fully accredited to international standards.

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When you get a prescription filled at a U.S. pharmacy, you can feel confident there are strong systems in place that make sure the medicine listed on the bottle is contained within each dosage form.

Manufacturers must adhere to Current Good Manufacturing Practices. Also, systems are in place to issue and quickly communicate recalls to pharmacies and laws to protect the supply chain.

In other parts of the world, however, counterfeit and substandard medications remain a serious threat to the public's health. Here, we'll explore the issue of substandard and counterfeit medications, what they are, and what is being done to address this global problem.

What are substandard and counterfeit medications?

Both substandard and counterfeit medicines, also called substandard and falsified medicines, are products that will not provide the patient with the prescribed therapy.

The World Health Organization (WHO) defines substandard as an out-of-specification medicine. This means the medicine did not meet quality control standards or specifications.

Counterfeit medicines, on the other hand, are deliberately misrepresented as something they are not. They may have the wrong active ingredient, no active ingredient, or the wrong amount of an active ingredient.

Both can not only fail to meet the patient's care needs, but they can also be toxic. They might have toxic inactive ingredients, like mercury, arsenic, cement, and rat poison.

Also, high doses of active ingredients are sometimes found in both counterfeit and substandard medicines. And it might lead to toxicity. An example is the case of a Class 1 recall, the most serious kind, on Digitek in the U.S. in 2008.

How do they end up in the drug supply chain?

The primary reason these products can end up in the drug supply chain is poor regulatory and enforcement mechanisms.

In the U.S. and other developed nations, when a manufacturer produces a medication that fails to meet quality standards, recalls are issued to limit the harm to the public. But in many low- and middle-income countries, strong systems are not in place to prevent, find, and remove these products from the market.

In fact, the WHO estimates that about 10% of all medicines sold in low- and middle-income countries are substandard or falsified.

What can a health system do to address the issue?

A 2015 literature review of the issue found three major categories of actions countries can take:

- Regulatory
- Technology
- Quality control and vigilance

In the regulatory domain, countries can make sure manufacturers, distributors, importers, and pharmacies are licensed and that robust laws are in place.

For technology, product authentication and tracking can confirm products are authenticated from the point of manufacture to when it is dispensed. Some examples include the U.S. Drug Supply Chain Security Act (DSCSA) or the E.U. Falsified Medicines Directive (FMD).

In the quality control and vigilance domain, countries can implement inspections of manufacturers and distributors, conduct pharmacovigilance, and improve awareness and communication between all stakeholders.

A key part of awareness and communication is public education. As the WHO notes, many falsified products can be identified by features that are not found on genuine products.

Some examples include:

- Spelling mistakes on the packaging
- Websites offering low prices or medicines without a prescription
- Lack of a verification logo or certificate

The WHO also maintains the Global Surveillance and Monitoring System. This system offers an avenue for countries to report any substandard or counterfeit medicines in their country. Plus, the WHO can respond by giving technical support and sending out alerts to other countries in the region. The system offers data that can be used for research and surveillance, too.

Taking action: Promoting the Quality of Medicines (PQM)

Promoting the Quality of Medicines (PQM) is a partnership between the United States Pharmacopeia (USP) and the United States Agency for International Development (USAID). It began in 1992 as a joint effort to improve medication information and quality and gradually grew in size and scope.

Today, the program works to improve the quality of essential medicines in low- and middle- income countries. They do this by:

- Helping to strengthen regulatory systems
- Supporting both legislation and regulatory agencies
- Providing evidence-based information to all involved parties
- Helping manufacturers create high-quality medicine

One of their success stories was improving Nigeria's capacity for quality control testing. To do so, PQM worked with five laboratories: three national quality control laboratories, the National Control Laboratory for Vaccines and Biologicals, and the National Institute for Pharmaceutical Research and Development.

Ultimately, all five laboratories achieved ISO/IEC 17025 accreditation, which is the primary accreditation to give the public confidence in the testing, sampling, or calibration results of the laboratory.

In the first stages, the PQM team took most of the cost to develop the facilities and staff. But after accreditation, the laboratories could become more financially stable. This is because the accreditation allowed them to charge for their services.

So, by the time the laboratories were due for re-accreditation, NAFDAC (Nigeria's FDA equivalent) was able to pay the full cost and show the program's sustainability.

Obtaining accreditation for quality control laboratories is an important step towards strengthening the drug supply chain. It allows regulators and those tasked with enforcing legislation the ability to confirm a sample is substandard or counterfeit.

The bottom line

Substandard and counterfeit medications pose a serious threat to global health. These medications end up in the drug supply chain because of financial incentive to cut costs. Combined with poor regulatory systems, nations find it hard to catch any medications that don't meet standards.

But by strengthening manufacturing, quality control and testing, and the drug supply chain, health systems can address this problem and save lives.

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