Commentary

Combating a Global Pandemic of Weak, Adulterated, and Fake Drugs

Menghis Bairu
is founder and CEO of Serenus Biotherapeutics. He also served as Elan's General Manager, was the head of Elan International, and has broad international experience in the United States, Europe, Latin America, South East Asia, the Middle East, and Africa. Prior to that, he worked for several leading biopharmaceutical companies including Genentech, Johnson & Johnson, and served on the board of OneWorld Health, a not-for-profit pharmaceutical company funded by the Bill and Melinda Gates Foundation. Dr. Bairu is also an author and lectures widely on global health and biopharmaceutical issues, particularly in emerging markets.

ABSTRACT

Whether it's willful counterfeiting, sloppy manufacturing processes, or neglectful handing of drugs in the global supply chain, recent studies suggest the problem of weakened, adulterated, and fake drugs is a growing global issue with deadly consequences. In Africa, the lack of access to innovative drugs makes the population vulnerable to counterfeits and inefficacious copies of medicines that are much needed. This humanitarian crisis rests on policymakers' steadfastness in each country to ensure the authenticity of the drug supply. Among the steps that should be taken is the restriction of the sale of drugs to pharmacies and hospitals and the prohibition of their sale through street vendors and open markets. There is also an urgent need for post-importation testing to ensure drugs actually contain their active ingredients in adequate strength before they are sold. These are necessary parts of a needed comprehensive approach to combating the importation of counterfeit, weakened, and adulterated drugs. Countries have it within their power to protect their populations, ensure the integrity of medications, and restore trust in their healthcare systems.

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In Sub-Saharan Africa, the deaths of an estimated 122,350 children under the age of five in 2013 involved the use of poor-quality drugs to treat malaria. That represents a small part of the global toll from pharmaceutical products that are not what they appear to be.

Whether it's willful counterfeiting, sloppy manufacturing processes, or neglectful handing of drugs in the global supply chain, recent studies suggest the problem of weakened, adulterated, and fake drugs is a growing global issue with deadly consequences. Beyond the harm they do to the patients who use them, these so-called "falsified medicines" as dubbed by a recent special journal supplement by The American Journal of Tropical Medicine and Hygiene, undermine trust of the health system and carry an economic toll as well.

It's difficult to quantify the problem because falsified drugs often go undetected due to weak or absent regulatory systems in some parts of the world, or assumptions by doctors that when a treatment fails it was merely not the right drug for the particular patient rather than questioning whether the drug used by the patient was of the formulation and strength assumed. An introduction to the journal's special supplement[1] estimates criminals generate $75 billion in annual illegal revenue through the sale of falsified drugs. Seven quality studies covered in the supplement examined 16,800 samples of drugs to treat malaria, tuberculosis, bacterial infections, and leishmaniasis that were tested for quality. Those various studies found between 9 percent and 41 percent failed to meet quality specifications. Quality issues are a serious problem even among World Health Organization accredited drug manufacturers.

Similar studies have produced similar results. In 2012, the U.S. National Institutes of Health found that more than one-third of the malaria drugs in 21 Sub-Saharan African countries failed a chemical analysis test

Correspondence:
Menghis Bairu, Serenus Biotherapeutics, US. Email: mbairu@serenusbio.com

1 http://www.ajtmh.org/content/92/6_Suppl/2.full.pdf+html?sid=4d17bcce-0181-41d6-bd72-24e02af9d689

because they were either expired or poorly made. Some 20 percent of the drugs were outright counterfeits.

This is a problem that is by no means limited to Africa. Of the more than 11,700 incidents of counterfeit drugs globally in 2014 examined by the Pharmaceutical Security Institute, a non-profit established by international drugmakers, it found the highest incidence were in China, India, Pakistan, the United States, and Japan. But in low- and middle-income countries the problem is particularly concerning because it threatens to undo progress made against deadly diseases such as malaria, AIDS, and tuberculosis. The use of adulterated antibiotics also threatens to worsen the problem of resistant bacteria, thereby broadening the toll from substandard drugs beyond the people who use them.

The U.N. Office on Drugs and Crime notes that criminal groups take advantage of gaps in the legal and regulatory frameworks, weaknesses in capacity, and the lack of enforcement. "The prospect of the comparatively low risk of detection and prosecution in relation to the potential income make the production and trafficking in fraudulent medicines an attractive commodity to criminal groups, who conduct their activities with little regard to the physical and financial detriment, if not the exploitation, of others," the organization says. Jim Thomson, co-founder of the European Alliance for Access to Safe Medicines in 2009 told the London newspaper The Daily Star that "major league" narcotics dealers were turning to counterfeit pharmaceuticals because they carried greater profits with far smaller risks. He said a kilo of the active ingredient for Viagra yielded about 2,000 times more profit than cocaine.

With an increasingly complex global supply chain, the problem requires a broad and coordinated effort to combat. This includes public education efforts, increased surveillance, the use of technology to track and trace the chain of custody, as well as verify the authenticity of products. It is also essential that tougher legislation is enacted and enforced to make the penalties against counterfeiting fit the seriousness of the crime. "Where existing laws are not enforced crime is perpetuated as criminals are not afraid of being arrested and prosecuted," says the World Health Organization. "Lenient punishments for offences tend to encourage criminal activities such as medicines' counterfeiting, particularly when the penalties for counterfeiting non-medicinal products are more severe."

In Africa, the lack of access to innovative drugs makes the population vulnerable to counterfeits and inefficacious copies of medicines that are much needed. This humanitarian crisis rests on policymakers' steadfastness in each country to ensure the authenticity of the drug supply. It is incumbent on them to implement regulations to put a halt to it.

Of the 191 member states of the WHO, about 20 percent have well developed drug regulation. Of the remaining member states, about half implement drug regulation at varying levels of development and operational capacity, the organization says. The remaining 30 percent have no drug regulation in place or a very limited capacity that hardly functions. "Inadequate, ineffective or weak drug regulatory control could promote unregulated importation, manufacture, and distribution of drugs, leading to the proliferation of counterfeit drugs in the national market," WHO says.

Among the steps that should be taken is the restriction of the sale of drugs to pharmacies and hospitals and the prohibition of their sale through street vendors and open markets. Registered distributors should be the only source of supply to pharmacies and hospitals, and these distributors should be monitored and inspected by regulatory authorities.

In Africa, there is an urgent need for public-private partnership to work with ministry of health authorities to implement an effective Good Laboratory Practices so samples of drugs coming into a country can be tested. Post-importation testing should be conducted to ensure drugs actually contain their active ingredients in adequate strength before they are sold.

These are necessary parts of a needed comprehensive approach to combating the importation of counterfeit, weakened, and adulterated drugs. It is not financially prohibitive, but requires political will, and the right equipment and training. Countries have it within their power to protect their populations, ensure the integrity of medications, and restore trust in their healthcare systems.