

A dose of reality about fakes

The problem of fake medicines cannot be ignored. A report from the European Commission found that, of 32 million medicinal products stopped by customs officials in 2007, 15% were suspected of infringing on intellectual property rights. And at the fifth Global Forum on Pharmaceutical AntiCounterfeiting in Florida this past February, Jim Thomson, chairman of the European Alliance for Access to Safe Medicines, estimated that the cost of counterfeits to the healthcare systems in the EU was at least €50 billion (\$68 billion) in 2007. Countless reports have documented that phony meds cost human lives—for example, the bogus drugs that claim the lives of children stricken with malaria. In the following pages we take a close look at the problem of counterfeit drugs and the solutions proposed to address this growing problem.

What's in a name? Lots, when it comes to counterfeits in Uganda

Throughout sub-Saharan Africa, as much as 30% of drugs in use may be counterfeit, according to groups such as the World Health Organization (WHO). The problem is less widespread in Uganda, say officials from the country's National Drug Authority (NDA). But, if so, it's only by a matter of degree; forces such as low purchasing power, corruption and consumer ignorance all combine to make the problem persist within the nation as it does throughout the region. A recently proposed law that addresses the problem directly could help, but some say it goes too far in its definition of a 'counterfeit'.

According to the NDA, most of the counterfeit drugs in Uganda are antimalarials and lifestyle drugs, especially Viagra and Cialis, that are not branded or registered. Metakelfin and chloroquine—both antimalarials that are no longer recommended by the WHO—are popular counterfeits. Metakelfin costs 4,000 Ugandan shillings (\$2) per dose and chloroquine about 500 Ugandan shillings in the private drug stores, compared to an average of 15,000 Ugandan shillings for the recommended treatment, artemisinin combination therapies (ACTs).

David Nahamya, the head of drug inspection at the NDA, told *Nature Medicine* that the WHO change of policy on ACTs, has made the antimalarials unaffordable, creating a high demand for counterfeits. "Counterfeits are profit motivated. We try to take firm measures in the formal sector but cannot control the informal sector," says Nahamya.

Counterfeiters typically tamper with the dates on packages and the pill contents, usually substituting cassava flour for active ingredients.

Presently, those arrested are charged according to the discretion of the judge. The highest conviction in Uganda has so far been 1 million Ugandan shillings, which was handed down in March 2009 for fake Metakelfin. But the counterfeits are so profitable that such penalties may not discourage the activity.

The NDA is now creating awareness and



Fatal phonies: Counterfeit malaria drugs claim the lives of children.

has joined neighboring Kenya and Tanzania to conduct joint operations. "We tell the public to look out for counterfeits and report to NDA. The message is that the repercussion of taking counterfeits is health incapacitation for rest of their lives," says Fred Ssekyana, an NDA spokesperson.

The country is also seeking to increase affordability and access to legitimate drugs.

Meanwhile, Uganda has also been considering new regulation, the Anticounterfeit Goods Bill, intended to stamp out fake goods. But how it should address counterfeit drugs is subject to debate.

Initially, the bill tasked the Uganda Bureau of Statistics to deal with the problem of counterfeits. But people in the industry have voiced concern that the bureau has neither the capacity nor the expertise to do it.

The bill mistakenly considers counterfeit drugs as a trade issue, says Moses Mulumba, a human health and rights lawyer in Kampala, Uganda's capital. "There are other laws to address these issues," Mulumba explains.

Moreover, says lawyer Naboth Muhairwe,

the bill defines counterfeits too broadly and could thereby hamper trade by limiting access to generic medicines and other products on the Ugandan market. "Intellectual property [law] is a two-edged sword; you protect investors, but people will lose access to medicine," argues Mulumba.

The bill defines counterfeits as goods that are an imitation of something else with an intent to deceive, and it includes any device used for the purposes of counterfeiting. It also sees counterfeits as goods that breach intellectual property rights, as well as goods intended to gain unfair commercial advantage over products of a similar nature.

Still, many experts say something needs to be done. They note that Uganda already has three laws dealing with intellectual property rights, but none deals with counterfeits. The NDA, for its part, is seeking increased authority.

In the meantime, the East African Community, an intergovernmental organization that includes Uganda, is drafting its own regional counterfeit bill, which may supersede national laws.

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