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The Counterfeit Drugs Issue Deserves More Attention

As reported recently in GFO, the Global Fund's Office of the Inspector General (OIG) is investigating allegations that malaria drugs funded through Global Fund-supported programmes are being stolen and then sold in the private sector for profit. (See "Report Renews Concerns About Stolen Malaria Medicines" in GFO 131.) There is no indication yet that this a widespread problem. However, the use of counterfeit medicines, which is linked to the sale of stolen medicines, is definitely a widespread problem, affecting numerous countries on at least three continents (Asia, Africa and Europe).

Just how big a problem is it? What are the repercussions? How does it affect the Global Fund? Can or should the Global Fund do anything about it?

"Nobody knows the full scope of the crime, although the World Health Organization (WHO) estimates that counterfeit drugs are associated with up to 20 percent of the one million malaria deaths worldwide each year," wrote Andrew Marshall in the magazine Smithsonian in October 2009. "Reliable statistics … are hard to come by, partly because the damage seldom arouses suspicion and because victims tend to be poor people who receive inadequate medical treatment to begin with."

"Rich countries have long employed expensive methods, like tracking systems or sophisticated equipment, to verify whether drugs are authentic," but countries in Africa can't afford these methods, wrote Maria Cheng of the Associated Press in 2010. Studies by the WHO and other agencies have shown that a significant percentage of medicines in Africa are counterfeit or substandard (30% or higher in some parts of Africa).

According to Cheng, "Fake drugs can infiltrate shipments even when it's the United Nations or the Global Fund to Fight AIDS, Tuberculosis and Malaria that is the sender. Last year, malaria medicines dispatched to Ghana by the Global Fund mysteriously went missing. Once the drugs arrived in the country, they were

replaced by counterfeits, leading Ghanaian authorities to investigate allegations a cartel was replacing real drugs with fake ones."

In a report on an audit conducted in 2009 on programmes supported by the Global Fund in Cambodia, the OIG said that "Cambodia has a high prevalence of counterfeit and substandard drugs," included artemisinin–based combination therapies (ACT) and drugs for opportunistic infections (OIs). The OIG cited a University of the South Pacific report from June 2009 showing that 27% of artesunate (a drug that is part of the artemisinin group) being distributed in Cambodia was counterfeit. The OIG said that a similarly high percentage was reported for some OI drugs. "The laws that would help curb the proliferation of counterfeit and substandard drugs were in place but law enforcement was weak," the OIG said. "Urgent action is needed to address this problem."

According to Marshall, between 1999 and 2003, medical researchers conducted two surveys in which they randomly purchased artesunate from pharmacies in Cambodia, Myanmar, Laos, Thailand and Vietnam. The volume of fake pills was 38% percent in the earlier survey and 53% in the later survey.

Counterfeit drugs – which are often mostly flour or sawdust or baby powder – end up killing people. Malaria is a deadly infectious disease, but it usually is curable if treated early with appropriate drugs. Patients who think they are taking the right medicines, but who are actually taking counterfeit medicines, will likely die from the disease.

And that's not the only problem. Fake medicines speed up drug resistance. "If a drug contains some but not enough of the active ingredient, it won't kill the disease's virus or bacteria, but gives it a chance to mutate into a deadlier form instead," Cheng said.

The WHO says that clinical trials conducted in 2007-2008 confirmed the emergence of artemisinin resistance along the Thai-Cambodian border. "This is extremely serious because resistance to a number of formerly-effective malaria drugs originated from the Thai-Cambodian border and then spread west to South Asia, then Africa – where most malaria deaths occur," the WHO says. "If this were to occur with artemisinin, millions of lives could be at risk. It would also be a huge setback to intense international efforts over recent years to combat the threat of malaria globally."

The problem affects Global Fund grants because they are funding treatment to save lives. The presence of counterfeit drugs, the existence of drug resistance, and the threat of even higher drug resistance negatively impact the ability of grant recipients to meet their targets.

Should the Global Fund do anything about it? In accordance with the core Global Fund principle of country ownership, shouldn't the onus be on countries to address this problem in their proposals? Perhaps; and, indeed, some countries are doing so – for example, a Round 6 malaria proposal from Laos was devoted almost entirely to reducing the use of counterfeit medicines. However, the Global Fund has actively supported the development of programmes to address other problems – for example, gender inequalities, human rights abuses, and mother-to-child transmission of HIV; and it has promoted interventions to strengthen health systems and community systems. Why not also promote interventions to address the counterfeiting problem?

At a minimum, the Global Fund could produce an information note outlining the problem and describing different interventions currently being used by international agencies and individual countries to combat the problem. It may also be possible to produce some "best practice" case studies to help countries learn from each other's experiences.

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; and “Battling Drug Resistance Along the Thai-Cambodian Border,” WHO, online at www.who.int/malaria/diagnosis_treatment/arcp/faq/en. The article by Maria Cheng describes how text messages are being used in Kenya to help people check if their medicines are genuine.

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