

Substandard and counterfeit antimalarial drugs discovered in Ghana

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Substandard and counterfeit versions of thirteen key antimalarial medicines were uncovered in multiple locations across Ghana by the Medicines Quality Monitoring surveillance program. Set up by the Ghana Food and Drugs Board (FDB) in collaboration with the U.S. Pharmacopeial Convention (USP) and the U.S. Agency for International Development (USAID), the program samples antimalarials across the public and private sectors. It was established in 2008 and is implemented by USP's Promoting the Quality of Medicines (PQM) initiative. USP is a scientific nonprofit organization that develops globally recognized standards for the quality of medicines. Through the PQM program, USP works in developing countries to help verify and improve the quality of medications intended to treat life-threatening neglected diseases such as malaria, HIV/AIDS and tuberculosis.

"Few people fully realize the devastation that distribution of substandard or counterfeit medications can wreak on vulnerable populations," said Stephen Opuni, M.D., <u>chief executive officer</u> of the FDB. "In this case some of the drugs discovered contained no active pharmaceutical ingredient, while others failed to meet required quality standards. This causes great harm in two ways: the individual patients taking the drugs get no relief, and drug-resistant strains of <u>malaria</u> may grow stronger. In addition, people lose confidence in the efficacy of medicines and may be reluctant to seek medical help when they need it. I'm very pleased with the outcomes we're seeing from the Medicines <u>Quality Monitoring</u> program."



In 2009 the same program uncovered a counterfeit version of Novartis' Coartem®, another widely used antimalarial. In that case an alert citizen notified the authorities after suspecting the drug he bought might be fake. "Last year's seizure of counterfeit drugs showed the importance of public education," said Patrick Lukulay, Ph.D., director of the PQM program. "In the current case, rigorous surveillance worked very well. The fact that the fake and poor quality drugs were so widespread—found in many areas across Ghana, and in many types of outlets—underscores the need not only for continuing surveillance but also for active enforcement of anti-counterfeiting laws."

The discovery of the counterfeits—tragically, in use at a government-run hospital and private clinic, and being distributed through many pharmacies—has resulted in a nationwide recall of all thirteen drugs, including publicizing the names of the outlets where they were found. This is intended as a strong deterrent, making pharmacy and hospital procurement personnel more vigilant about their suppliers. Manufacturers of some of the recalled medications will be required to meet with the FDB for required regulatory sanctions. Noted Dr. Lukulay, "It's important to keep in mind that all these fake and substandard medicines were found just in one round of post-market surveillance, just of antimalarials. The existence of many more substandard and counterfeit medications for other types of medicines and in other locations and facilities must be assumed. Public education and official collaborations between public and private sectors are both essential to protecting public health here in Ghana and in many other developing nations."

Provided by US Pharmacopeia

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