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Counterfeit Antimalarial Drug Discovered in Ghana with Aid of USP Drug Quality and Information Program

Product Lacked Any Active Ingredient

Rockville, Md., July 22, 2009 — Quantities of a prescription medication used throughout the world for treating malaria have been identified as lacking any active ingredient and presumably counterfeit. These are being removed from the market in Ghana, where they were discovered recently and confirmed as fake last Friday. The discovery was made by a vigilant citizen who contacted the Medicines Quality Monitoring program set up by the U.S. Agency for International Development (USAID)-supported Drug Quality and Information (DQI) Program, implemented by the U.S. Pharmacopeial (USP) Convention. USP is a nonprofit scientific organization that develops globally recognized standards for the quality of medicines. Through the DQI Program, USP works in developing countries to help verify, assure and improve the quality of medicines intended to treat life-threatening neglected diseases such as malaria, HIV/AIDS and tuberculosis, as well as advance the appropriate use of these medicines.

The fake drug found in Ghana did not contain the active pharmaceutical ingredients of the Novartis Coartem® product it was being sold as, posing a significant health threat to patients relying on the medication. This drug is an artemisinin-based combination therapy recommended by the World Health Organization (WHO) for treating “uncomplicated” malaria, which is endemic in 108 countries, 45 in Africa. A major barrier in combating malaria throughout much of the developing world is the widespread presence of counterfeit and adulterated drugs, which undermines the public health. Not only do these drugs fail to deliver the appropriate treatment to individual patients—putting their lives at risk—but they contribute to the growth of drug-resistant strains of malaria, one of the greatest challenges to malaria control today.

In this case, a local citizen brought a suspicious sample of “Coartem®” to one of five sentinel sites set up in the country to monitor and test medicine quality. After failing initial testing at the site, further testing by Ghana Foods and Drug Board (FDB) confirmed the medicine was indeed counterfeit. The USP DQI Program established the sentinel sites in coordination with the FDB and other partners with funding from USAID/Ghana under the President’s Malaria Initiative.

“This episode illustrates that the system the DQI Program established to improve drug quality by removing counterfeits is working,” said Rev. Jonahan Martey, head of the FDB’s Quality Control Laboratory. “Our joint efforts have only just begun to improve the public health situation here in Ghana, which has been continually challenged by the overwhelming presence of poor quality medicines. I look forward to continuing our work together to address malaria and other neglected diseases in the country—among the biggest threats to the citizens of Ghana.”

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The FDB is currently seizing the drugs from wholesale and retail pharmacies as well as from licensed chemical sellers and is warning patients about the presence of the counterfeit Coartem[®] tablets.

“We are pleased to see this compelling example of how the Medicines Quality Monitoring program established by the USP DQI Program is directly and positively impacting the health of patients in Ghana,” said Patrick Lukulay, Ph.D., director of the program. “In this case, a local citizen brought the questionable medicine to one of the sentinel sites, which demonstrates one of the key ways we hoped the sites would work—by becoming an integrated part of the local community that citizens would feel comfortable and confident going to with concerns.”

The USP DQI Program is a cooperative agreement first awarded to USP by USAID in 2000 and renewed in 2005. Through the program, USP works in countries throughout Asia, Eastern Europe, Latin America and sub-Saharan Africa. Explaining the program, Lukulay notes that, “Every citizen deserves access to good quality medicines, and helping to make this a reality is our mandate.”

For more information about the DQI Program and its work, please email mediarelations@usp.org or visit www.uspdqi.org.

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