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CONTACT: Theresa Laranang-Mutlu
301/816-8167; trl@usp.org

Liberian Regulatory Authority Recalls Three Counterfeit Antimalarial Medicines

Partnership with PQM Leads to Medicines Regulator's First Enforcement Action to Protect Public Health

Rockville, Md., June 16, 2011—In its first official enforcement action since its establishment in September 2010, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) has recalled three antimalarial medicines from the Liberian market. Identifying these products as counterfeit, the LMHRA has directed that the medicines be withdrawn from circulation based on testing of drug samples collected in the capital Monrovia and its suburbs. Basic screening tests showed that the three medicines contained no active pharmaceutical ingredients (APIs), rendering them ineffective and potentially exacerbating health problems for patients who use them.

Screening of the medicines samples was conducted by the LMHRA in cooperation with the Promoting the Quality of Medicines (PQM) program. Supported by the United States Agency for International Development (USAID), PQM is implemented by the U.S. Pharmacopeial Convention (USP). PQM helps to ensure the quality of medicines globally by providing technical assistance to national quality control laboratories like those of the LMHRA and by helping build local capacity in medicine quality assurance systems. PQM was also instrumental in helping to draft language for the act passed by the Liberian government in 2010 to establish the LMHRA.

The LMHRA collected 56 samples of antimalarial medicines for quality testing. Thirty two failed visual inspection or testing by a basic technique known as thin-layer chromatography (TLC). TLC tests showed that what appeared to be the three front-line antimalarial medicines—Artesunate 50 mg Tablet (Batch Number 07015FX); Colquine, quinine sulphate syrup 60 mL (Batch Number ECQ-10001); and Colquine, quinine sulphate suspension 60 mL (Batch Number ECQ-10001)—were counterfeit and contained no antimalarial ingredients. The same batch number was found on the two recalled medicines identified as Colquine, an indicator of product tampering since different dosage forms of the same drug cannot be assigned the same batch number. Batch numbers identify specific products during the manufacturing and assembly process.



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USP Headquarters

12601 Twinbrook Parkway Rockville, Maryland 20852
Tel: 301-816-8166 | Fax: 301-816-8374

Europe/Middle East/Africa
Basel, Switzerland

USP-India Private Ltd.
Hyderabad, India

USP-China
Shanghai, China

USP-Brazil
Barueri/SP, Brazil

In its recall notices, the LMHRA has directed that all pharmacies, medicines stores, hospitals, clinics and individuals that have purchased or hold stocks of the recalled medicines should return and/or report them to LMHRA's office in Monrovia. All recalled products that are returned or reported to the LMHRA will be incinerated, and failure to adhere to the recall will lead to appropriate legal actions. The LMHRA will be taking further regulatory actions on counterfeit and other substandard medicines found in the market in the course of implementing LMHRA regulatory policies.

According to Dr. Patrick Lukulay, director of PQM, "Assisting the government of Liberia in drafting medicines regulations for the LMHRA was an important part of helping to build national capacity to protect the Liberian public against counterfeit and substandard medicines. Employing fundamental screening tests like TLC and providing further training to LMHRA on this and other screening methods will augment Liberia's capabilities to identify poor-quality medicines based on effective and consistent protocols."

"Counterfeit and substandard medicines, such as the three recalled products, have the potential to create serious health threats to those counting on their medicinal properties to help combat diseases such as malaria," according to Dr. Clavenda Bright Parker, chair of the board and acting managing director of the LMHRA. "The LMHRA is committed to working diligently with all our partners in carrying out our vision, which is to establish and operate a medicines and health products regulatory authority of excellence in Liberia that protects public health."

For more information about the PQM program and its work, please email mediarelations@usp.org or visit <http://www.usp.org/worldwide/>.

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