Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

FOR IMMEDIATE RELEASE

CONTACT: Nils Hagen-Frederiksen
301-816-8268; nhf@usp.org

Field Testing for Rapid Counterfeit Drug Screening Tool Begins in Africa

Initial testing targets ability to identify fake & poor quality malaria medicines

Rockville, Md., June 4, 2014 — Field testing for a new screening tool intended to help quickly detect counterfeit and poor quality medicines has begun at the U.S. Pharmacopeial Convention's (USP) Center for Pharmaceutical Advancement and Training (CePAT), located in Ghana.

The new screening device, called CD-3+, was launched by the U.S. Food and Drug Administration in April 2013 (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm349195.htm).

"CD-3+ is, rapid, portable device that requires little training for effective use, potentially changing the way counterfeit and poor quality products are detected and resulting in substantial cost savings over more expensive alternatives," says Patrick Lukulay, Ph.D., vice president of Global Health Impact Programs at USP and director of the Promoting the Quality of Medicines program (PQM). "The testing now underway in Ghana will provide a side-by-side comparison of CD-3+ with other existing screening devices to assess the capability to discriminate between authentic and substandard medicines."

Specifically, the tests conducted in the field and at CePAT will evaluate CD-3+ in the screening of two malaria treatments commonly used in Sub-Saharan Africa. A total of 200 test samples are being collected from sites across Ghana through a collaborative partnership between USP and the Ghana's Food and Drug Authority. Results from the first field study are expected in September 2014.

"Field tests such as these will not only help us determine complementary advantages of the tools under evaluation, but will also help identify potential design improvements to CD-3+ to enable the development of a more robust, more portable and even easier to use tool," says Leigh Verbois, director, Asia Pacific Office, Office of International Programs at U.S. FDA.

The U.S. FDA was responsible for training personnel on how to properly use CD-3+ at CePAT and other test sites.

Testing is being conducted under an agreement between FDA and the U.S. Agency for International Development (USAID), which funds PQM, operated by USP. Funding for the activity has been provided by the Skoll Global Threats Fund. Other partners include the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

"As a development agency, USAID is well-positioned for in-country capacity building such as this," says Anthony Boni, who leads PQM on USAID's side through its Office of Health Systems in the Bureau for Global Health. "The presence of infrastructure as well as established relationships with the Ghana FDA provided an excellent platform for the field-testing of CD-3+ in Ghana."

Since 2008, USAID, through the U.S. President's Malaria Initiative (PMI) Ghana, has provided USP with US$1,470,000, specifically to strengthen the capacity of the Ghana FDA for the quality assurance of medicines in Ghana.

The tests being conducted in Ghana will evaluate CD-3+ in complementing GPHF's Minilab™ (thin-layer chromatography) and Thermo Scientific's TruScan™ (hand-held Raman spectrometer), evaluating counterfeit detection for two commonly used artemisinin-based combination therapies (ACTs) for malaria treatment in Sub-Saharan Africa: artemether + lumefantrine (AR-LU) and artesunate + amodiaquine (AS-AQ).

For more information, contact mediarelations@usp.org.

###

The Promoting the Quality of Medicines (PQM) program is made possible by the generosity of the American people through the United States Agency for International Development (USAID).

USP – Global Expertise, Trusted Standards, Improved Health

The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are used worldwide. For more information about USP visit http://www.usp.org.

.