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USP Helps Expand Worldwide Access to Key Tuberculosis Drugs

Promoting the Quality of Medicines (PQM) program helps attain WHO approval for treatment of drug resistant TB

Rockville, Md., Tuesday, June 10, 2014 – The US Pharmacopeial Convention (USP) is pleased to announce that with the assistance of the U.S. Agency for International Development (USAID) funded Promoting the Quality of Medicines (PQM) program, the first Active Pharmaceutical Ingredient (API) for injectables used in the treatment of multi-drug resistant tuberculosis has been assessed by the World Health Organization and given prequalification status. The prequalification of Capreomycin, the first "second line" anti-tuberculosis API for injectables to achieve this status, is a significant development in the global fight against one of the world's most prevalent and deadly diseases.

Drug quality is central in the fight against tuberculosis, AIDS and malaria because it is one of the key factors driving multi-drug resistance. Just as not finishing a full course of antibiotics can engender resistance, taking a full course of a substandard drug can have the same effect.

"The dramatic growth of counterfeit and substandard medicines has made multi-drug resistant TB (MDR-TB) a growing threat to public health," explained Dr. Patrick Lukulay, vice president of global health impact programs at USP and director of the PQM program. "Although the rate of new TB cases has been falling worldwide, in 2012, the number of people diagnosed with multi-drug resistant TB doubled. So, the availability of a quality-assured second line medication will fill a critical need and should make these medicines more affordable."

Currently, treatment regimens for MDR-TB can be up to 20 times more expensive than drug-susceptible TB. The treatment regimen for MDR-TB is also over twice as long, typically 20 months, and success rates are low. Only 34% of MDR-TB patients are successfully treated – more than half die, fail treatment or stop taking treatment.

The United Nations prequalification program is managed by the World Health Organization (WHO) in cooperation with regulatory agencies to make quality priority medicines available for the benefit of those in need and to build national capacity for sustainable manufacturing and monitoring of quality medicines. It is also a useful tool to help ensure that groups contributing to the global effort to fight tuberculosis and other diseases know which manufacturers they can rely on to provide high quality products that will enhance and not hinder their efforts.

Since 2009, USAID and USP through the PQM program have been actively providing technical and professional assistance to manufacturers and regulatory agencies in countries around the world to strengthen quality assurance systems for medicines; guide manufacturers toward compliance with WHO good manufacturing practices; and help manufacturers prepare product dossiers for submission to the WHO Prequalification program.

As a result, the PQM program has helped three key drugs achieve prequalification status: Cycloserine, 250 capsule, produced by Korea-based Dong-A Pharmaceutical Co. Ltd. – an anti-tuberculosis medicine;

ZinCfant 20 mg dispersible tablet, produced by France-based Nutriset/Laboratoire - a zinc product for managing diarrhea in children; and now Capreomycin, produced by Zhejiang Hisun Pharmaceutical Co Ltd - the first second line anti-tuberculosis API for injectables prequalified by WHO and also the first API obtained directly from fermentation. All technical assistance was provided by PQM at no cost to the manufacturers as part of the USAID funded program.

"The PQM program is making significant contributions to global health by expanding access to quality-assured medicines and improving quality assurance systems and good manufacturing practices," said Anthony Boni, who leads PQM on USAID's side through its Office of Health Systems in the Bureau for Global Health. "This reinforces USAID's conviction that extending support for the PQM program through 2019 will foster continued success in the fight against counterfeit and substandard medicines."

For more information, contact mediarelations@usp.org.

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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).

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