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Growing Threat of Substandard and Counterfeit Medicines in Developing Countries Addressed by New USAID-USP Cooperative Agreement

Rockville, Md., October 26, 2009 — With substandard and counterfeit versions of medicines intended to treat life-threatening diseases such as malaria, HIV/AIDS and tuberculosis posing a growing threat throughout the developing world, the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP) will expand their joint efforts to combat this menace by launching a new program over the next five years.

The Promoting the Quality of Medicines (PQM) Program, a \$35 million cooperative agreement, will serve as a primary mechanism to help assure the quality, safety and efficacy of medicines that are essential to USAID's priority health programs. USAID is a U.S. government agency that provides economic, development and humanitarian assistance around the world in support of the foreign policy goals of the United States. USP is a nonprofit scientific organization that develops globally recognized standards for the quality of medicines.

Building on a multi-year USAID-USP partnership in this arena that assists health officials and others in 28 countries around the world, the program will increase work to address the significant public health challenge posed by substandard and counterfeit medicines. According to the U.S.-based Center for Medicines in the Public Interest, counterfeit drug sales alone will reach \$75 billion globally in 2010, an increase of more than 90 percent from 2005. Various factors contribute to the growth of substandard and counterfeit medicines, including the globalization of trade and weak regulatory capacity in developing countries.

"Substandard and counterfeit medicines represent a threat to public health worldwide but pose a particular problem in developing countries, where lack of financial, technical and other resources make it difficult to protect the drug supply chains," said Gloria Steele, USAID acting assistant administrator for global health. "Such medicines have the potential to undermine decades of investments in public health. Without good quality, safe medicines to treat diseases such as HIV/AIDS, malaria and tuberculosis, the impact of other health initiatives may be weakened. The PQM Program focuses on this critical aspect of combating these diseases."

"The lives of patients are put in serious jeopardy when they take substandard or counterfeit drugs," said Roger L. Williams, M.D., chief executive officer of USP. "Such 'medicines' have health as well as economic implications. Moreover, substandard medicines contribute to the development of drug-resistant strains of infectious diseases. Such strains are a leading challenge in the fight against malaria, HIV/AIDS and tuberculosis."

The program will help ensure the quality, safety and efficacy of medicines by: working with countries to strengthen their medicines regulatory bodies, which are responsible for protecting the supply chains; increasing the supply of good-quality medicines, which often are not available, with shortages giving health facilities no choice but to use medicines that may not have undergone rigorous quality control; combating the availability of counterfeit and substandard medicines through testing programs and other means; and conducting global advocacy to raise awareness of the dangers of substandard and counterfeit drugs.

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The PQM Program builds on the work of USAID and USP over the past decade through a predecessor program, the Drug Quality and Information (DQI) Program. Like DQI, the PQM Program will be managed by Patrick Lukulay, Ph.D., partnering with USAID's Office of Health, Infectious Diseases, and Nutrition, under the direction of Anthony Boni. Highlights of the DQI Program's work include:

- **Establishing the first large-scale continuous monitoring program for medicines quality in Africa, Asia and Latin America.** The DQI Program developed robust drug quality surveillance programs in 19 nations, leading to recalls of substandard and counterfeit medicines and closures of illicit pharmacies operating in the countries. This had never been done before in any developing region other than on an *ad hoc* basis. Monitoring is conducted largely through 107 sentinel sites that were established to perform quality testing. In July 2009, one such sentinel site in Ghana detected a counterfeit antimalarial drug that was being sold to patients as Novartis' Coartem[®]. The product, which lacked any active ingredient, was promptly seized from pharmacies in Ghana by the country's Foods and Drug Board, helping prevent further harm to patients who may be using the drug for treatment of their "uncomplicated" malaria, which is endemic in 108 countries, 45 of which are in Africa.
- **Building capacity in Asia to address gaps in medicines quality assurance.** When tested in the Greater Mekong Subregion in 2003 for identity and content, medicines failed at a significant rate, posing a serious health problem and contributing to the growth of resistant strains of malaria. DQI built capacity in national medicine regulatory agencies, assessed quality control systems in five countries, and provided equipment and training to four national laboratories, among other activities. Progress continues with work expanding beyond antimalarials to anti-retroviral, anti-tuberculosis, anti-viral and some antibiotic medicines.
- **Assisting the Global Drug Facility in efforts to increase the availability of good quality second-line anti-tuberculosis (TB) medicines at affordable prices.** A major challenge in combating tuberculosis is an inadequate number of WHO pre-qualified second-line TB medicines manufacturers—leading to an inadequate supply of products to treat patients with multi drug-resistant TB. In order to ensure quality products, United Nations procurement agencies, the Global Fund, and many international organizations mandate that only medicines prequalified by WHO (or approved by stringent regulatory agencies) are suitable for procurement. To expedite the process of pre-qualification with WHO—thereby expanding the pool of viable manufacturers—DQI provides technical assistance to companies on the preparation of drug dossiers they submit to WHO. This effort helps expand the availability of quality medicines for patients with TB.

The new PQM Program will expand on these and other activities in Asia, Eastern Europe, Latin America, and sub-Saharan Africa.

For more information about the program, please contact mediarelations@usp.org. For more information about USAID, please visit www.usaid.gov.

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The American people, through the U.S. Agency for International Development, have provided economic and humanitarian assistance worldwide for nearly 50 years.

USP—Advancing Public Health Since 1820

The United States Pharmacopeial Convention (USP) is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are recognized and used worldwide. For more information about USP visit <http://www.usp.org>. **FY1015**