LMI: Promoting the Quality of Medicines in Southeast Asia

July 2012

BACKGROUND

Despite recent progress in Cambodia, Thailand and Vietnam, poor quality anti-malarial and antibiotic medicines continue to be available to the general public in Asia. The greatest dangers posed by using substandard and counterfeit medicines include death, disability and a potential increase in microbial resistance. These factors compromise treatment efficacy and patient safety and place a heavy economic burden on the health care systems. Since 2011, the President’s Malaria Initiative, a partnership between USAID and the Centers for Disease Control and Prevention (CDC), has supported national programs to address drug quality in the Lower Mekong region.

Started in 2009, through USAID the Promoting the Quality of Medicines program (PQM) implemented by the United States Pharmacopeial Convention (USP) assists countries in the Greater Mekong Sub-region—Burma, Cambodia, Laos, Thailand, Vietnam and the Yunnan province of China, to address these problems. The program addresses four persistent challenges outlined below.

- Widespread availability of poor-quality anti-malarial drugs, particularly in border areas where drug-resistant malaria has emerged.
- Inadequately trained staff in quality assurance and quality control of medicines is limiting. Staff is overextended with multiple responsibilities and are underpaid with low government salaries.
- Weak and limited information-sharing, investigation and enforcement related to substandard and counterfeit medicines.
- Low level of public awareness and understanding about substandard and counterfeit medicines.

APPROACH

The PQM program’s approach involves working with national partners to achieve the following key objectives outlined below.

Building capacity of medicines regulatory authorities to:

- Improve and expand drug registration and dossier evaluation.
- Develop supportive technical and regulatory guidelines for pharmaceutical management systems.
- Conduct Good Manufacturing Practices (GMP) inspections of manufactures, which is the measurement of production standards.
• Conduct research on medicines quality and availability, including facilities and households.
• Monitor medicines quality in the market through regional surveillance sites equipped with portable drug-testing facilities.
• Use and share information, through institutional and regional collaboration, for decision and policy making and action including shop closures and prosecution.

**Strengthen quality-control labs to meet international standards through:**

- Staff training on procedures for collecting drug samples and analytical techniques for testing them.
- Providing lab equipment and relevant training to ensure proper use and maintenance.
- Providing reference materials, reagents, and other needed chemicals to conduct drug quality testing.
- Technical assistance toward laboratory accreditation and World Health Organization Prequalification of Laboratories promoting global standards for quality drug control.

**Raise public awareness on the importance of medicinal quality through:**

- Broadcasting public service announcements and videos on the dangers of substandard and counterfeit medicines.
- Messaging campaigns advocating targeted toward consumers, drug sellers and government officials on the impacts of quality of medicines.
- Promoting articles, reports and information materials on medicine quality issues and the importance of buying medicinal drugs from approved outlets.

**IMPACTS**

Noteworthy accomplishments of the PQM program include:

- Closure of substandard pharmaceutical outlets, issued recalls, and confiscated and destroyed poor-quality medicines by country governments.
- Increased ability of official medicines control labs to test most medicines.
- National capacity in Good Manufacturing Practices in regional centers increased as well as quality assurance and quality control of medicines.
- Increased public awareness of substandard and counterfeit medicines and understanding of the concept of medicines quality.
- Reduced number of substandard and counterfeit medicines available on the market in the region.

**PARTNERS**

**Implementing Partner:** United States Pharmacopeia Convention

**Cooperating Partners:** National regulatory authorities and quality control laboratories in the Greater Mekong Sub-region, National Malaria Control Programs, Faculties of Pharmaceutical Sciences of Chulalongkorn University and Mahidol University