

## Promoting the Quality of Medicines (PQM) Program in Southeast Asia

February 2014



Photo: Christopher Raymond

*Sentinel site staff visually inspect medicines collected from outlet in Thailand border*



Photo: Sanya Sookkam

*Survey investigator interviews local citizen on his knowledge about SCMs at Thai-Cambodia border*



Photo: Myat Phone Kyaw

*Burma trainees test quality of antimalarial medicine using Minilab®*

### BACKGROUND

Despite improvements, poor-quality medicines continue to be available to the general public in Southeast Asia. The greatest dangers posed by using substandard and counterfeit medicines (SCMs) include death and potential increase in microbial resistance, all of which compromise treatment efficacy and patient safety and place a heavy economic burden on the health care systems.

With financial support from USAID and the President's Malaria Initiative (PMI), the PQM program, implemented by the United States Pharmacopeial Convention (USP), has been assisting countries in the Greater Mekong Subregion (GMS), Indonesia, and the Philippines to address these problems, yet some challenges and constraints persist:

- Concerns continue about the presence of SCMs.
- Limited number of staff is adequately trained in quality assurance and quality control (QA/QC) of medicines, and many are overextended with multiple responsibilities.
- Cooperation, collaboration, and coordination of information-sharing, investigation, and enforcement related to SCMs found in the region remains weak and limited.
- Public awareness about SCMs is limited, yet neither a regional education campaign nor an effective rapid alert system has been put in place.

### APPROACH

#### Build capacity of medicines regulatory authorities (MRAs)

- Work with MRAs to establish dynamic post-marketing surveillance.
- Provide technical support in medicine registration & dossier evaluation.
- Help manufacturers meet current Good Manufacturing Practices (GMP) standards and achieve WHO Prequalification status.
- Train inspectorate in GMP and supply chain and distribution inspection.
- Establish regional centers of excellence network in medicines QA.

#### Strengthen QC labs to meet international standards of practices

- Train lab staff in analytical techniques and quality control procedures.
- Provide lab equipment and train in its proper use and maintenance.
- Provide reference materials, reagents, and other needed chemicals.
- Provide technical assistance toward ISO 17025 accreditation and WHO Prequalification of laboratories.

#### Conduct operational research on medicines quality

- Conduct studies on medicines quality in public & private health facilities.
- Investigate quality of high-priority essential medicines in border areas.



Photo: Mam Boravann

Cambodia officials incinerate confiscated medicines found through MQM program



Photo: Souly Phanouvong

Counterfeit and illegal medicines found in the Mekong Subregion on display at BREMERE meeting in February 2013 in Siem Reap, Cambodia



Photo: Christopher Raymond

Training of Trainers on testing anti-TBs and antimalarials, October 2013 in Jakarta,

**Contact:**

Patrick Lukulay, Ph.D.  
 Director  
[phl@usp.org](mailto:phl@usp.org)

Souly Phanouvong, Pharm.D., Ph.D.  
 Manager, Asia Programs  
[xsp@usp.org](mailto:xsp@usp.org)

Elaine Yuan, MD  
 Program Manager, Southeast Asia  
[exy@usp.org](mailto:exy@usp.org)

Promoting the Quality of Medicines  
 U. S. Pharmacopeial Convention  
 12601 Twinbrook Parkway  
 Rockville, MD 20852, USA

**Monitor medicines quality and use data to support enforcement**

- Help establish regional surveillance sites and equip with Minilabs® to obtain evidence-based data to support enforcement actions.
- Train site staff in sampling techniques, test methods, and data reporting.
- Facilitate regional network to act on SCMs detected.

**Raise awareness about how medicines quality affects public health**

- Create public service announcements and films on the dangers of SCMs.
- Conduct communication campaigns advocating medicines quality.
- Publish articles, reports, and promotional materials on medicines quality issues and importance of buying from approved outlets.

**ACCOMPLISHMENTS AND IMPACTS**

Since the inception of the program in the region in 2003, surveillance activities have documented a marked decrease in product quality failure rates for antimalarials and other essential medicines collected from the surveillance sites. In 2005, the overall failure rate was 3.3% for all medicine samples collected and tested. In 2009 and 2012 this figure dropped to 2.3% and 0.4% respectively. For antimalarials, the failure rate remains relatively high at 6.1% in 2012.

- Using data obtained via MQM, country governments have closed medicines outlets, issued recalls, and confiscated/destroyed SCMs found.
- Through PQM laboratory training and technical assistance, all participating official medicines control laboratories are able to test most essential medicines with increased test performance and reliability.
- Two national quality control laboratories (Vietnam and Thailand) achieved WHO prequalification status. National QC lab of Indonesia achieved recognition by the GFATM, Philippines and Laos QC labs achieved ISO-17025 accreditation.
- Awareness of SCMs and the concept of medicines quality has increased among health care professionals and the general public.
- Fewer SCMs circulated on the markets in the region.

**NEW INITIATIVES**

Recently, PQM has launched Building Regional Expertise in Medicines Regulation, Information Sharing, Joint Investigation, and Enforcement (BREMERE), a new component of ANEQAM to enhance regional cooperation and collaboration among law enforcement agencies with access to experts and information on CSMs for timely investigation and enforcement. USP has also recently launched the Network of Official Medicines Control Laboratories for Asia and the Pacific (NOMCOL – Asia Pacific) and Technical Assistance Program (TAP) to promote South-South cooperation in QC expertise and to increase the exchange of technical skills among labs to strengthen their technical and procedural capacity toward achieving and maintaining international standards.

**KEY PARTNERS**

Medicines regulatory authorities (Thailand, Burma and Philippines FDAs, Cambodia DDF, Laos FDD, Vietnam DAV, Indonesia NA-FDC); National Malaria Control Programs; K.I. Asia; Faculties of Pharmaceutical Sciences of Chulalongkorn Univ. and Mahidol Univ.; WHO; URC; WWARN; National QC labs (Laos FDQCC, Thailand BDN, Vietnam NIDQC, Cambodia NHQC, Myanmar and Philippines FDA Labs, Indonesia NQCL-DF); WHO regional and country offices; the INTERPOL and ASEAN.