

Fact Sheet: Promoting the Quality of Medicines (PQM)

June 2012



Photo: Dr. Elaine Yuan

Inspector collects medicines samples from Kampong Chan outlet for quality testing



Photo: Mr. Richard

Analysts at Oddar Meanchey sentinel site test samples using thin-layer chromatography Minilab[®] method



Photo: Staff, Economic Police

Cambodia police destroy CSMs confiscated from raids on 5 manufacturers which led to arrests of offenders.

BACKGROUND

In 2003, the prevalence of substandard and counterfeit medicines in Cambodia (and other developing countries in Asia and Africa) ranged from 10-40%, causing concern about immediate adverse effects as well as the long-term health outcome to the individual patient. Moreover, the global health care community believed that the use of substandard medicines further contributed to the escalating problem of antimicrobial resistance.

With financial support from the U.S. Agency for International Development (USAID), programs implemented by The United States Pharmacopeial Convention (USP) began working with the government of Cambodia to address these problems by helping strengthen the capacity of its national programs for sustained quality assurance and quality control of medicines. Activities in Cambodia have focused on improving detection of poor-quality anti-infective medicines through Medicines Quality Monitoring (MQM), strengthening medicines quality assurance/quality control (QA/QC) systems, improving access to medicines quality information, and raising awareness about medicines quality issues among regulators, health care professionals, and the public.

ACHIEVEMENTS

- Expanded the number of MQM sentinel sites from 4 in 2003 to 12 sites by 2008 and the types of medicines monitored from only antimalarials to include medicines for other infectious diseases as well.
- Increased the number of medicines collected from 470 samples from 7 provinces in 2005 to 3,164 samples from 12 sentinel sites in 2011.
- Decreased the failure rate from 9.4% in 2007 to 2.3% in 2011 of medicines collected that did not pass quality testing.
- Conducted a special investigation in 2011 covering 6 provinces not previously covered by MQM that showed 4.4% of 90 samples collected failed the quality testing.
- Supported creation of an Inter-Ministerial Committee for Eliminating Counterfeit Drugs and Illegal Health Care Services (IMC), the national body authorized to take enforcement actions against counterfeit and substandard medicines (CSM).
- Issued recalls for failed products identified through the MQM program –for example, recall of the failed tetracycline, azithromycin, and cloxacillin in 2011 – and detected failed



Photo: Ms. Mam Boravann

Economic police view pamphlet picturing CSMs banned by the IMC distributed to outlets, clinics and health care providers



Photo: Dr. Souly Phanouvong

NHQC Deputy Chief Sovannarith demonstrates Minilab[®] quality testing technique at POM training workshop

- Reported 100% of illegal drug outlets in the country closed by December 2011, according to the IMC Secretariat and Department of Drugs and Food (DDF).
- Provided essential laboratory equipment and supplies to National Health Products Quality Control Center (NHQC) laboratory and trained analysts in compendial test methods according to international pharmacopeial standards to improve and strengthen capacity.
- Sponsored advanced training for DDF staff and local pharmaceutical manufacturers in Good Manufacturing Practices (GMP).
- Trained DDF inspectors, QA/QC staff, and internal auditors of selected pharmaceutical manufacturer on preparing for GMP audits.
- Supported establishment of Cambodian Pharmacy Council with the objectives of professional regulation, promotion of public health, and official representation in the public sector.
- Helped establish the Cambodian Pharmacovigilance Center to raise public awareness of medicines quality and proper use of medicines.
- Supported Pharmacists' Association of Cambodia in publishing regular bulletins on issues regarding counterfeit medicines.
- Developed TV and radio spots and posters to raise public awareness about the dangers of poor-quality and counterfeit medicines among migrant populations and community villagers.

CHALLENGES AND FUTURE PLANS

- Sustaining and effectively operating all established sentinel sites after transfer of MQM program to sole DDF responsibility.
- Ensuring that construction of new NHQC building strictly follows agreed-upon action plan through Construction Oversight Committee.
- Providing provincial sites with sufficient reference standards, key reagents, and lab supplies for Minilabs[®], and equipment to control lab temperature, humidity, chemical hazardous waste, and environment safety management.
- Developing with DDF ways to regulate nationwide pharmacy practices and pharmaceutical QA/QC systems through educational program for pharmacy students and certification, registration, and licensing of professional pharmacists.
- Forming network with other countries in the Southeast Asia region to effectively take enforcement actions to fight proliferation of CSMs.
- Increasing accessibility to good-quality, affordable medicines by improving capacity of domestic pharmaceutical manufacturers for compliance with good manufacturing practices.

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