UNITED STATES PHARMACOPEIA
DRUG QUALITY & INFORMATION PROGRAM

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Introduction

USP's Drug Quality and Information (USP DQI) program, a cooperative agreement with the United States Agency for International Development (USAID), was a five-year contract initiated in October 2000. During this period, USP DQI gained a better understanding of the health care needs of people in developing countries, and its successful approaches resulted in a five-year extension of this program. The USP DQI program, thus far, has established a presence in USAID-priority countries in four continents, advancing strategies to improve drug quality and the appropriate use of drugs.

Ensuring Drug Quality: USP DQI works with local governments, USAID Missions, the World Health Organization (WHO), and other partners to help evaluate a country's capacity to provide necessary drug quality assurance. Trained pharmaceutical scientists perform assessments, identify weaknesses, and provide available tools and trainings to national drug regulatory authorities, procurement organizations, manufacturers, and distributors in order to improve drug quality assurance in both the public and private sectors.

Providing Continuing Education: USP DQI provides training for physicians, pharmacists, and nurses in drug information and pharmacovigilance to help improve drug dispensing practices and ensure competence and accountability.

Developing and Disseminating Evidence-based Drug and Therapeutic Information: Drawing upon the authoritative expertise of its scientific volunteers, USP DQI develops targeted drug and therapeutic information materials for health care providers based on specific needs. In addition, the program offers assistance in establishing and equipping local drug information centers by working with local academic, government, nongovernmental, and professional institutions.

Furnishing Technical Leadership toward Regional and International Cooperation: USP has a long tradition of convening and facilitating policy discussion through the organization's system of open conferences, internet–based communications, and regular publications. The USP DQI staff who implement the program activities include internationally trained doctors, scientists, chemists, drug and medical information specialists, and GMP experts with access to state-of-the-art laboratory technology and hundreds of USP volunteer experts.

Program: OPHT (Common Agenda)

Key Staff: P. Lukulay

Objectives:
- Conduct assessment of DACA and NQCL and develop work plan for TA (Ethiopia)
- Update USP DQI brochure on core activities and issues of relevance for USAID programs
- Continue to provide up-to-date information about drug quality and raise awareness about sub-standard and counterfeit products
- Enhance quality assurance (QA) mechanisms to improve drug quality.

Activities:
- E-learning draft was revised internally and by USAID, with minor modifications pending; course is expected to be complete in late fall 200808/early winter 2009.
- *Matrix on Drug Quality Reports Affecting USAID-supported Countries* updated and disseminated on USP DQI website; there were 4,648 hits this quarter. Copies were distributed at World Bank meetings.
- Eleven articles, 15 abstracts, and 5 resources were added to the USP DQI website.
- Sixty copies of *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide* were distributed to MRAs designated as "low-income" by World Bank.
- The USP DQI brochure was distributed at work plan meetings in Benin and Mali and at the DQM launch in Ethiopia.

Program: Maternal and Child Health

Key Staff: E. Toledo

Objectives:
- Increase availability of quality zinc products for program implementation by providing technical assistance to Zinc manufacturers
- Develop monographs to assess the quality of Zinc products

Activities:
- Zinc gluconate tablets monograph acquired; draft will be validated prior to the review process. Samples of zinc acetate oral solution were procured by AED and sent to USP to be used in monograph development.
- Continued support was given to Tanzania and Nepal manufacturers; helped Shelys address European GMP inspection findings.
- Six samples from UNICEF 2008 Zinc Tender were tested and the report was sent.

Program: Tuberculosis

Key Staff: P. Lukulay

Objectives:
- Reduce the spread of MDR- and XDR-TB through access to quality second line anti-TB medicines
- Strengthen implementation of DOTS Expansion and enhancement through standards development and guidelines
- Conduct GMP assessment and provide TA to 2nd line TB drug manufacturers for WHO pre-qualification

Activities:
- TA now includes assistance for dossier preparation. USP DQI has developed a concept paper to collaborate with GDF and WHO to provide TA to prepare dossiers and accelerate the progress of manufacturers toward pre-qualification.

Program: Malaria

Key Staff: M. Hajjou

Objective:
- To work jointly with WHO to develop the protocol and study design for QAMSA (Quality of Antimalarial drugs in sub-Saharan Africa) in ten sub-Saharan African countries.
- Train country representatives from the national quality control laboratories on the use of Minilabs® in the QAMSA study

Activities:
- Sample testing is underway in the ten QAMSA countries.

Program: Avian Influenza

Key Staff: S. Phanouvong

Objectives:
- Develop guidelines in collaboration with WHO et al. on how to maintain the quality of oseltamivir from acquisition to use.

Activities:
- The text of the Quality Control of Oseltamivir section of the guidelines has been added. A literature review is underway to draft a section on "objective information" and instructions for effective use of the product.

Program: RDM/A – Mekong Malaria

Key Staff: S. Phanouvong

Objectives:

- Obtain data on antimalarial drug quality through a regional monitoring program in Cambodia, Laos, Vietnam, and Thailand for two rounds
- Utilize data under Objective 1 for national and regional efforts to respond rapidly to antimalarial drugs quality problems. This includes raising awareness among the public and relevant parties, and supporting regulatory action taking against substandard and counterfeit drugs.
- Strengthen capacity of national drug quality control laboratories of Laos and Cambodia, enabling them to perform analyses reliably on all essential antimalarial medicines.
- Obtain objective estimate of prevalence of poor-quality AMLs using random sampling in Thailand-Cambodia cross-border provinces to learn more about drug quality-drug resistance association.

Activities:

- During FY08, 578 antimalarial samples were collected and tested (9 provinces in Vietnam, 12 in Laos, and 10 in Cambodia).
- Data on poor quality antimalarials received in 2007-2008 will be presented at the USAID/RDM-A Mekong Malaria Partners meeting on Oct 7-8, 2008 in Bangkok.
- Vietnam focal point reported all substandard and suspected counterfeit antimalarials to the Drug Administration of Vietnam, which is investigating all the cases.
- Data on specific problematic drug samples were provided to WHO/WPRO and INTERPOL under “Operation Storm.”
- Country and provincial investigators completed mapping the sampling locations.
- Samples are being collected and basic testing on the samples is ongoing in both Cambodia and Thailand for the cross-border project. Cambodia reported that 207 samples were collected; Thai counterpart is compiling data on the number of samples collected. The health facility and household survey (part of the data collection) is completed in all provinces in Cambodia.
- Two representatives paid supervisory visits to Chanthabury province (Thailand side) and Pailin, Battambang, and Odda Meanchey provinces (Cambodia side) to provide TA and M&E.
- The translation of WHO Guidelines on Good Practices for NPCL are under review.

Program: RDM/A OPHT – Mekong Expansion and Centers of Excellence in Quality Assurance of Medicines (ANEQAM)

Key Staff: L. Krech

Objectives:

- Document the quality of selected anti-TB medicines and commonly used antibiotics and assist national and regional regulatory systems/authorities to initiate rapid responses to quality problems.
- Further strengthen ANEQAM to enable the Centers of Excellence to provide technical assistance in drug quality to clients in the region. The three institutions that are part of the Centers of Excellence are: Chulalongkorn University Drug Quality Control lab and Pharmaceutical System Research and Intelligence (PSyRIC); University of Santo Tomas Center for Drug Research, Evaluation and Studies (UST CeDRES); and Mahidol University Faculty of Pharmacy

Activities:

- During FY08, 1491 antibiotic, anti-TB, and anti-HIV/AIDS samples were collected and tested (9 provinces in Vietnam, 12 in Laos, and 10 in Cambodia).
- USP staff visited the national lab of Cambodia and determined that there is no need for a QA/QC expert to visit at this time; there are basics in QA that the lab needs to implement before a scheduled visit.
- Funding was transferred for the water purification system for Mahidol University.
- A final report was received from Chulalongkorn University/PSyRIC on the creation of the drug quality database. Since all funding for Centers of Excellence activities was eliminated for FY09, the planned test run was cancelled and all efforts are being devoted to entering in the rest of the medicine quality data from 2005-2008.

Program: RDM/A-HIV/AIDS

Key Staff: S. Phanouvong

Objectives:

- Obtain data on HIV/AIDS medicines quality through a regional monitoring program in Cambodia, Laos, Vietnam, and Thailand for two rounds
- Utilize data under Objective 1 for national and regional efforts to respond rapidly to HIV/AIDS medicines quality problems. This includes raising awareness among the public and relevant parties, and supporting regulatory action taking against substandard and counterfeit drugs.
- Strengthen capacity of national drug quality control laboratories of Laos and Cambodia, enabling them to perform analyses reliably on all essential HIV/AIDS medicines.

Activities:

- During FY08, 243 HIV/AIDS medicine samples were collected and tested (9 provinces in Vietnam, 12 in Laos, and 10 in Cambodia).
- Two training courses on the "Quality, Safety, and Rational Use of HIV/AIDS Medicines" were given for a total of 49 pharmacists from Vietnam (35) and Laos (14).

Program: RDM/A-Avian Influenza

Key Staff: S. Phanouvong

Objectives:

- Establish oseltamivir quality monitoring program in the RDM/A region
- Obtain comprehensive information on all suppliers and distribution networks of oseltamivir in the region
- Improve the quality of stockpiled and circulated oseltamivir through good procurement, distribution, and storage practices
- Maintain the quality of stockpiled and circulated oseltamivir in the Mekong subregion

Activities:

- Fifteen Tamiflu capsule samples were collected from 14 provincial government health facilities and one major hospital in Laos. Samples were tested using Minilab protocol. A draft report was received from Laos on the 15 samples, and USP DQI will present the data at the USAID/RDM-A AI partners meeting on Oct 13-24, 2008.

Program: Cambodia

Key Staff: L. Krech

Objectives:

- Improve detection of poor quality anti-infective medicines in the Cambodian market
- Strengthen existing drug quality assurance systems
- Raise awareness about drug quality issues and disseminate information among regulators, health care professionals, and patients
- Improve access to and use of objective up-to-date information about medicines

Activities:

- USP DQI staff visited Phnom Penh and one of the cross-border sites to determine how all parties that are collecting and testing medicine samples can work best together to maximize funding and activity efficiency.
- Two MOH staff members and one USP employee were selected for a WPRO/WHO pharmacovigilance training; the USP staff worked closely with the Cambodian team to create

a concrete action plan for next year's PV activities and visited the PV center which is starting activities.
- Updated and nearly finalized versions of the PSAs were distributed to USAID staff and shown to DDF and PAC. USP DQI worked with Khmer Mekong Films to record the Khmer voiceover.
- The interview with Yim Yann (in Khmer with English subtitles) was distributed to USAID staff and shown to DDF and PAC.

Program: Philippines

Key Staff: L. Krech

Objectives:
- Strengthen technical capacity of the University of Santo Tomas Center for Drug Research, Evaluation, and Studies (UST CeDRES) to provide assistance to regional, national, and local institutions, especially the Bureau of Food and Drugs (BFAD)
- Strengthen BFAD's activities in post-marketing surveillance for drug quality, particularly for infectious disease treatments

Activities:
- BFAD/DOH hired a local focal point to work solely on the sampling and testing project; the focal point will begin work in FY09 Q1.
- USP, BFAD, and DOH staff visited two of the six sentinel sites and provided TA for sampling and testing. DOH/BFAD are still in the process of finalizing the sampling protocol specifically concerning outlet randomization. The first official round of sampling and testing should occur in FY09 Q1.

Program: LAC-1 – Amazon Malaria Initiative

Key Staff: V. Pribluda

Objectives:
- Provide technical assistance to malaria control programs in the Amazon Basin sub-region to substantially incorporate selected best practices.
- Address Quality Assurance/Quality Control (QA/QC) issues related to malaria medicines at the central level, including Drug Regulatory Agencies (DRAs) and Official Medicines Control Laboratories (OMCLs) and at sentinel sites using Minilabs®

Activities:
- Staff attended the Steering Committee Meeting in Washington DC, where FY08 updates and FY09 work plans were presented. The Master Plan was presented during the meeting (based on USAID comments, a new version was prepared and sent in Oct.2008).

- A training on GLP and lab techniques was given in August to 27 participants (Ecuador: 19, Brazil: 1, Colombia: 1, Honduras: 2, Guatemala: 2 and Panama: 2).
- MSH-SPS and USP DQI finalized the Terms of Reference for the Malaria Medicines at Informal Sites study; search for countries' consultant initiated.
- Headspace apparatus delivered and installed in INVIMA (Colombia) and CNCC (Peru).
- Interns from Colombia (INVIMA) and Peru (CNCC) completed 3 month internships at USP on September 15. The report on their activities at USP and action plans for their countries' OMCLs will be prepared during FY09 Q1.

Program: LAC-2 – South American Infectious Diseases Initiative

Key Staff: A. Barojas

Objectives:
- Improve systems to prevent development and dissemination of antimicrobial resistance
- USP DQI activities address QA/QC issues related to antibiotics and tuberculosis (TB) medicines at the central level, working mostly with Drug Regulatory Agencies (DRA) and Official Medicines Control Laboratories (OMCL)

Activities:
- Bolivia finalized the 3rd round protocol and began sampling.
- Peru analyzed 48 samples and sent the report to USP DQI for review.
- Report on activities, status, and recommendations for DIGEMID (a USP DQI consultant assessed DIGEMID's status on June 18-20, 2008) was distributed in July. Development of electronic modules for decentralized post-marketing surveillance is recommended; a chronogram of development was provided by DIGEMID.
- Profiles for the Country Profiles Report were received from Bolivia and Peru and were reviewed for QA/QC content.
- Staff attended the Steering Committee Meeting in Washington DC, where FY08 updates and FY09 work plans were presented. The Master Plan was presented during the meeting (based on USAID comments, a new version was prepared and sent in Oct.2008).

Program: Madagascar

Key Staff: M. Hajjou

Objectives:
- Strengthen the drug quality control system
- Strengthen post-marketing drug quality and safety monitoring

Activities:
- 222 samples were tested under the malarial quality monitoring program. Following confirmatory testing, the country decided to withdraw 2 lots.

- 30 adverse drug event reports were submitted to the WHO Collaborating Center.
- The PV Center is coordinating a DIC staff training and purchasing equipment. USP DQI provided resources for the training.
- Testing of the 120 samples collected under QAMSA is complete, and confirmatory testing is planned.

Program: Senegal

Key Staff: L. Elhadri

Objectives:
- Support the malaria quality monitoring program
- Complete the QAMSA study
- Support implementation of a national pharmacovigilance program

Activities:
- Testing of the 141 samples collected under QAMSA is complete, and confirmatory testing is planned.

Program: Uganda

Key Staff: M. Hajjou

Objectives:
- Strengthen drug quality control system
- Strengthen the drug regulatory functions of National Drug Authority (NDA)
- Provide TA to local manufacturers of antimalarial medicines

Activities:
- Sampling at the sentinel sites completed; testing is ongoing.

Notes on additional activities

In FY08 Q4, several activities were conducted in countries for which USP DQI will receive funding in FY09. In Benin and Mali, staff conducted assessments of drug quality labs. In Ethiopia, an assessment of drug quality assurance was conducted and a drug quality surveillance program was established. USP DQI also provided lab training for 27 people on sampling and basic tests.