UNITED STATES PHARMACOPEIA
DRUG QUALITY & INFORMATION PROGRAM

Quarterly Report
January – March 2008

Cooperative Agreement No.
HRN-A-00-00-00017-00

April 22, 2008

U.S. Agency for International Development
USAID/GH/HIDN/HSD
1300 Pennsylvania Avenue, NW
Room 3.07-073, 3rd Floor, RRB
Washington, DC 20523-3700
Tel: 202-712-4789
Fax: 202-216-3702
Email: aboni@usaid.gov

USAID
FROM THE AMERICAN PEOPLE

U.S. PHARMACOPEIA
DRUG QUALITY AND INFORMATION PROGRAM

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Phone: (301) 816-8162
Fax: (301) 816-8374
Email: uspdqi@usp.org
Website: www.uspdqi.org

Table of Contents

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:

- USP DQI staff conducted a technical assessment of the quality control capacity of the Ethiopian Drug Administration and Control Authority (DACA) and issued a report about needed areas for improvement and technical assistance
- *Ensuring the Quality of Medicines: an Operational Guide* was printed, the accompanying CD burned, and a dissemination plan finalized.
- M. Foster, M. McGinnis, and D. Seyoum wrote 11 articles, created 47 drug information abstracts, and added several new/revised USP DQI publications to the website.
- M. McGinnis revised the *Matrix of Drug Quality Reports Impacting USAID-assisted Countries* and disseminated it on the USP DQI website. The *Matrix* was accessed 1,558 times in January, 1,270 times in February, and 1,633 times in March. Thirty copies of the *Matrix* were disseminated to the participating QAMSA study members, and four copies were sent to relevant stakeholders who are producing the documentary film on counterfeiting.

Future plans:

- Conduct training of DACA staff in drug quality control and establish a central drug information centers at DACA and select pharmacy schools.
- Report program activities on USP DQI website; add one or more country profiles and update web pages as necessary.
- Prepare one informational flyer detailing a USP DQI project to be used as an insert in the USP DQI brochure.
- Assist in the development of the E-Learning program to meet USP DQI editorial standards and USAID marking requirements.
- Revise and disseminate the *Matrix* in July

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:

- E. Toledo, S. Bradby, and P. Lukulay visited 3 Nepalese pharmaceutical manufacturers that produce zinc. The team conducted GMP assessments and provided technical assistance on the manufacturing process. While in Nepal, the team also visited the Department of Drug Administration, the Child Health division of the Ministry of Health and Population, POUZN/PSI, and the UNICEF country office.
- E. Toledo provided a document review and other technical assistance to Nutriset and Shelys Pharmaceuticals on GMP.
- E. Toledo, S. Phanouvong, and S. Kumar (USP-India) met with the Country Director of the Academy for Educational Development (AED) to discuss collaboration regarding zinc acetate monograph procurement from local manufacturers and how USP DQI can assist with other zinc activities in India.
- DQI staff have contacted Zinc Acetate and Zinc Gluconate manufacturers in India and expressed interest in collaborating in the development of monographs.

Future Plans:

- Conduct a visit to Nutriset to:
  – Provide technical assistance on zinc sulfate tablets manufacturing standing issues, such as documentation practices and validation activities in preparation for next UNICEF audit.
  – Conduct a GMP assessment in preparation for Uganda Drug Administration inspection schedule by May 2008.
  – Learn about Zincfant registration status in France.
  – Learn about Nutriset Technology transfer to BIBCOL (India)
- Continue TA to Nepal and Tanzania manufacturers
- Continue procurement of Zinc acetate monograph in partnership with AED India

---

Program: HIV/AIDS

Key Staff: D. Seyoum

Objective:

- USP DQI will develop and disseminate technical information on prevention and reduction of HIV-1 infection

Activities:

- D. Seyoum reviewed HIV/AIDS-related articles for the USP DQI website monthly update.

Future Plans:

- Continue reviewing HIV/AIDS-related articles for the USP DQI website monthly update.

Program: AMR/Infectious Diseases

Key Staff: D. Seyoum

Objective:

- Expand regional based approaches for AMR containment, focusing on drug use practices and drug quality. Assist countries to adopt preventive strategies to help reduce antimicrobial resistance (AMR) in health care settings and in the community.

Activities:

- D. Seyoum reviewed AMR/Infectious Diseases-related articles for the USP DQI website monthly update.
- D. Seyoum revised the FIP draft statement on AMR based on comments received from the members of the FIP's Board of Pharmaceutical Sciences.

Future Plans:

- Continue reviewing AMR/Infectious Diseases-related articles for the USP DQI website monthly update.
- Finalize the revised FIP draft statement on AMR for adoption at this year's FIP Congress in Basel, Switzerland.

Program: Tuberculosis

Key Staff: P. Lukulay

Objective:

- 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:

- S. Phanouvong, E. Toledo, and S. Kumar (USP-India) completed two GMP audits of two pharmaceutical manufacturers in India (Kilitch Drugs in Paonta Sahib of Himachal Pradesh State; and Karnataka Antibiotics and Pharmaceuticals in Bangalore of Karnataka State) and assessed their needs for technical assistance to prepare for the WHO-Prequalification scheme for second-line antituberculosis drugs.
- D. Seyoum reviewed TB related articles for the USP DQI website monthly update.

Future plans:

- Continue reviewing TB-related articles for the USP DQI website monthly update.

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:
- M. Hajjou and N. Davydova, with the help of L. El Hadri, conducted a training course February 10-15 in Ethiopia on basic tests for the QAMSA study. Twenty trainees from ten countries attended the training.
- DQI staff developed sampling protocols and result tables for the QAMSA study. and shared with country representatives from ten countries
- D. Seyoum reviewed Malaria-related articles for the USP DQI website monthly update.

Future Plans:
- Validate the sampling in USP DQI and MSH-sponsored countries including Madagascar, Senegal, Uganda, and Malawi.
- Validate Minilab testing and select samples for confirmatory testing.
- Carry out confirmatory testing at USP laboratory
- Continue reviewing Malaria-related articles for the USP DQI website monthly update.

Program: Avian Influenza

Key Staff: N. Davydova

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

Activities:
- S. Phanouvong developed an outline of guidelines on how to maintain the quality of oseltamivir from acquisition to use. The document was distributed to participating authors from WHO and relevant partners.

Future Plans:
- Develop guidelines in collaboration with WHO and other relevant partners.

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:

- S. Phanouvong finalized a study protocol for the antimalarial drug quality survey in Cambodia/Thailand border areas for the Bill & Melinda Gates Foundation grant under "Artemisinin Resistance: Pilot Studies to Confirm, Characterize, and Plan for Containment."
- S. Phanouvong and C. Raymond presented updates on USP DQI anti-infective medicines quality monitoring and the protocol of the antimalarial drugs quality study at Cambodian-Thai cross-border provinces at the WHO Mekong Malaria Programme's Planning Meeting on February 9-10.
- S. Phanouvong and C. Raymond participated in an *Informal Consultation to Define Strategies to Eliminate P. falciparum Parasites with Altered Response to Artemisinins on Cambodia-Thailand border provinces* on February 13-14.
- S. Phanouvong finalized USP DQI's RDM-A FY08 workplan and obtained approval on February 11 from the RDM-A Mission (Dr. J. MacArthur).
- S. Phanouvong, L. Straker, and M. Welsch worked with the Legal Department regarding BMGF's Technical Service Agreement through WHO HQ providing $348,000 for the antimalarial drug quality survey in Cambodia/Thailand border areas; the agreement was signed by USP's senior management.

Future Plans:

- Participate in USAID midterm review of FY07 Mekong Malaria Program in Thailand
- Conduct a training workshop on establishing anti-infective medicines quality monitoring in Thailand

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:

- L. Krech, S. Phanouvong, N. Davydova, and K. Burimski updated the Centers of Excellence work plan and sent it to John McArthur for official approval.
- L. Krech, N. Davydova, C. Raymond, K. Burimski, and S. Phanouvong finished the first version of the drug quality monitoring database (created in collaboration with PSyRIC) and drafted a plan to test it among a selected group of partners for their feedback. This online database contains searchable information on antimalarials sampled and tested in Cambodia, Lao PDR, Vietnam, China (Yunnan), and Thailand.

Future Plans:

- Mahidol University faculty from the School of Pharmacy will conduct Good Manufacturing Practices (GMP) training for 10 drug manufacturers from Thailand. USP DQI staff will be on hand to provide technical assistance since this is the first GMP training Mahidol will provide as a Center of Excellence.
- Mahidol University will install a water purification system partially paid for by USP DQI to improve future GMP trainings for medicine manufacturers in the region.
- PSyRIC will launch the online drug quality database to a selected group of partners in the region for feedback. This launching will only include antimalarial drug quality data, but over the next few months, other drug quality data for HIV/AIDS, TB, and other antibiotics medicines will be added.
- At the Thai Bureau for Drugs and Narcotics, a Minilab® training to monitor the quality of antimalarials, antibiotics, anti-TB and HIV/AIDS medicines, and oseltamivir will be conducted. Monitoring activities will be expanded to 12 sentinel sites. This activity is shared among RDM-A Mekong Malaria, HIV/AIDS, and Mekong Expansion.

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:
- S. Phanouvong coordinated with K.I. Asia and RDM/A to procure six GPHF-Minilabs® for establishing anti-infective drugs quality monitoring in Thailand, and reviewed the quote submitted by Technologie Transfer Marburg e.V. in Germany. (This activity is a combined effort with Mekong Malaria and Mekong Expansion)

Future Plans:
- Conduct a training workshop on establishing drug quality monitoring, including HIV/AIDS medicines, as part of the anti-infective drugs quality monitoring in Thailand
- Coordinate with collaborators and USP Expert Committee to develop training materials for certification of selected pharmacists in Vietnam and Laos on HIV/AIDS medications information, safety, and quality.

Program: RDM/A-Avian Influenza

Key Staff: N. Davydova

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:
- N. Davydova created and C. Raymond presented a poster *Simple, Rapid Basic Tests for Evaluation of Quality of Oseltamivir* at the Bangkok International Conference on Avian Influenza 2008. The poster discussed a new field manual – jointly developed by USP DQI and the Global Pharma Health Fund – that outlines simple, inexpensive techniques that

resource-limited countries can utilize as part of their routine drug quality monitoring system. The poster, which received positive feedback from Roche Pharmaceuticals and other stakeholders, was also disseminated on both USP DQI's and GPHF's websites.
- N. Davydova prepared a poster related to USP DQI FY08 Avian Influenza activities in Southeast Asia. The poster was presented by C. Raymond at the USAID Avian Influenza Partners Meeting, March 25-27 in Bangkok, Thailand.
- N. Davydova reviewed a draft of the PSyRIC report on Mapping Supply of Avian Influenza Medicines in Thailand.
- N. Davydova drafted sampling instructions applicable to the survey of the quality of stockpiled and circulated oseltamivir products in Laos.

Future Plans:
- Provide refresher training for Minilab® users on how to analyze anti-infective medicines and oseltamivir
- Start to collect and test oseltamivir samples using basic testing methods in Laos, Thailand, and Cambodia

---

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:
- L. Krech, C. Raymond, and P. Lukulay met with the Vice-President and other staff members of the University Research Company (URC) to discuss specific projects in Cambodia for collaboration. One potential project will consist of sampling and testing medicines collected from retail pharmacies in the provinces of Battambang, Oddar Meanchey, Beantey Meanchey and Pailin. URC will be a new partner for USP DQI.
- L. Krech reviewed the budget, adjusted the work plan, and sent the updated work plan to USAID Cambodia requesting approval.
- L. Krech and M. Hajjou drafted a proposal for the USAID Cambodia Mission and the Department of Food and Drugs to hold a three-day workshop to plan activities for establishing a national pharmacovigilance program.
- At the request of the Mission, L. Krech composed a brief on the counterfeit medicines situation in Cambodia to discuss with members of the FBI who were visiting Phnom Penh.
- L. Krech, S. Phanouvong, C. Raymond, and M. Foster reviewed and made adjustments to the script for four public service announcements about the dangers of counterfeit medicines which will be available in four languages: Thai, Lao, Khmer and Vietnamese.

- C. Raymond produced a short film outlining the use of the Minilab® in USP DQI sentinel surveillance (filmed in rural Pailin)(This activity is a combined activity with Mekong Malaria)

Future Plans:
- In April, filming of Public Services Announcements alerting the public to the dangers of counterfeit medicines will begin.
- In May, a pharmacovigilance workshop will be held to commence activities for a national pharmacovigilance program and to train the staff responsible. WHO and the Department of Food and Drugs are participating with USP DQI to organize this workshop.

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:
- L. Krech and M. Hajjou revised and updated the project description *Monitoring the Quality of Anti-tuberculosis Drugs in Selected Sites in the Philippines* for the Bureau of Food and Drugs (BFAD), the Department of Health (DOH), and the USAID Philippines Mission.
- L. Krech reviewed the budget, adjusted the work plan, and sent the updated work plan through October 2009 to the Mission for approval. The plan was approved and funding secured for FY 08 and FY 09 activities.
- L. Krech and M. Hajjou sent a proposal to USAID-Philippines, BFAD, and DOH regarding selection of an in-country focal point to help manage the anti-TB drug quality monitoring program and communication between partners.
- L. Krech purchased 8 Minilabs® for the training to be held in May in Manila and has been in close communication with the Department of Health, Bureau of International Health Cooperation, USAID, BFAD, and the manufacturers of the Minilabs® to ensure customs clearance.

Future Plans:
- A Minilab® training to monitor the quality of tuberculosis medicines in six sentinel sites will occur in May for 24 participants from the Bureau of Food and Drugs and the Department of Health.
- L. Krech, M. Hajjou, and C. Raymond will meet with relevant partners in Manila during and after the Minilab® training.

Program: Russia

Key Staff: K. Burimski

Objectives:
- Improve access to and understanding of information relating to the appropriate prescribing of antimicrobial agents
- Contribute to slowing the spread of antimicrobial resistance

Activities:
- 3,828 copies of the Infectious Diseases Textbook were disseminated this quarter; 1,400 of those were sold. 13,731 copies have been disseminated in total; 3,041 of those were sold. The online version was visited 802,741 times, bringing the total number of visits to 5,639,274.

Future Plans:
- Continue dissemination of the Textbook

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:
- Planned, along with PAHO and MSH SPS, the Regional Workshop to Improve the Management of Supply and Quality Assurance Systems for Malaria to be held in Bogotá, Colombia the week of May 12-16.
- Identified candidates from Colombia's and Peru's OMCLs for three month internships at USP laboratories. (Note: Participants will start internships during third quarter)

Future Plans:
- Attend Annual AMI/RAVREDA and AMI Steering Committee Meeting in Peru April 7-11.
- Redesign AMI Work Plan and the corresponding budget.
- Finalize, in conjuncture with MSH and PAHO, the Master Plan for a "Strategic Approach to Antimalarial Medicines Access and Use for the Amazon Malaria Initiative (2008-2010)."
- Review additional drug quality data received by National Malaria Control Program's MiniLab® activities at sentinel sites from Bolivia, Brazil, Colombia, Guyana, and Suriname. (Note: USP DQI will create a report and possibly an article of all the compiled data)

- V. Pribluda and A. Barojas will participate in the Regional Workshop to Improve the Management of Supply and Quality Assurance Systems for Malaria to be held in Bogotá, Colombia the week of May 12-16. (Note: USP DQI will chair the session on Quality Assurance/Quality Control (QA/QC) of malaria medicines).
- Procure, ship, and install a Head Space Apparatus for Colombia.
- Procure, ship, and install a Head Space Apparatus for Peru.
- One representative from INVIMA-Colombia and one from CNCC-Peru will begin three month internships at USP laboratories and will be trained on USP's laboratory workflow, standard operational procedures, and quality management system.

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:
- V. Pribluda attended the Steering Committee Meeting: Prioritizations of FY08 Work Plan and FY09 Follow-up Activities.
- A. Barojas conducted a training course on Good Laboratory Practices and Water Determination by Karl Fischer at CONCAMYT in Bolivia for 15 participants.
- A. Barojas met with representatives of UNIMED (Bolivia's NDA) to ensure non-conforming drug quality results obtained from sampling and analysis of selected antibiotic and anti-tuberculosis medicines will result in appropriate corrective actions.
- A. Barojas and S. Bradby conducted a training course on Good Laboratory Practices, Quality Management System, HPLC, and Water Determination by Karl Fischer at CEMIT in Paraguay for 18 participants.
- A. Barojas met with the new director of DNVS and his staff (Paraguay's NDA) to discuss USP DQI activities in Paraguay and to reach mutual agreements regarding each stakeholder's commitments. Commitments were made to ensure non-conforming DQ results obtained from sampling and analysis of selected antibiotic and anti-tuberculosis medicines will result in appropriate corrective actions. (Note: Due to results of presidential election, the new director of DNVS and other SAIDI stakeholders in Paraguay may be replaced)
- The second round of sampling of selected antibiotic and anti-TB medicines in DISA Callao, Lima, Peru was finalized and analysis has begun.

Future Plans:
- Perform third round of sampling and analysis in Paraguay. This round will be centralized in Asuncion and will be focused on non-conforming antibiotic medicines from the second round. This round will also serve to reintegrate CEMIT as the responsible laboratory for

performing QC analysis of the sampled medicines. (Note: Sampling for this activity has already been finalized (11 samples) and analysis has begun).
- Perform third round of sampling and analysis in Bolivia; this round will be centralized in La Paz.
- W. Monterroso (USP DQI consultant) will travel to Peru to assist DIGEMID (Peru's NDA) in the integration of decentralized post-marketing surveillance activities into the NDA centralized information system (SI DIGEMID).
- Strengthen DNVS' registration procedures by updating current software or migrating to SIAMED and purchasing and installing equipment for IT infrastructure. (Note: Due to results of presidential election this activity may not be feasible)
- Perform fourth round of sampling and analysis in Paraguay. This round will be centralized in the Alta Paraná Region (border with Brazil). (Note: Due to results of presidential election this activity may not be feasible)

Program: Madagascar

Key Staff: M. Hajjou

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

Activities:
- M. Hajjou provided the national laboratory with reagents, reference standards, and laboratory supplies to complete confirmatory testing and carry out basic tests at sentinel sites.
- M. Hajjou provided recommendations for the budgeting of activities relating to pharmacovigilance.

Future Plans:
- Supervise training of regional trainers in pharmacovigilance.
- Analyze and compile data from drug quality monitoring program and provide recommendations for future rounds.

Program: Uganda

Key Staff: N. Davydova

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:
- N. Davydova purchased a GC column for analysis of insecticides.

- N. Davydova and L. Straker purchased five Minilabs® for Uganda.
- N. Davydova prepared for the training to be held in May in Kampala and has been in close communication with NDA – Uganda.

Future Plans:
- Provide a training workshop on sampling of antimalarial medications and the proper use of the Minilab® testing kit.
- Start to monitor the quality of antimalarial drugs.

Other Activities

- L. Krech and C. Raymond created a presentation for an Interpol training workshop for Operation Storm – a follow-up plan of action building on the successes of Operation Jupiter – to tackle counterfeit medicines in SE Asia. L. Krech tabulated the latest USP DQI data on counterfeit and substandard medicines in Lao PDR, Vietnam, Cambodia, and Thailand. C. Raymond presented the information March 14 in Bangkok, Thailand; Interpol was interested in seeing which products were most frequently counterfeited and in what locations. Also presented were USP DQI's regional activities and an introduction to the use of Minilabs® in sentinel site surveillance. Most of the participants were customs officials, police, and Interpol country representatives. Interpol has formally requested USP DQI to participate in Operation Storm.
- S. Phanouvong, L. Straker, and M. Welsch worked with relevant USP departments to get the technical service agreement with the World Health Organization (WHO)/Bill and Melinda Gates Foundation (BMGF) grant signed; the grant will fund a Cambodian-Thai cross-border study on antimalarial drugs quality to compliment the USAID/RDM-A funded activities.
- C. Raymond conducted a Thai-Cambodia cross-border site visit and coordination trip overland from Phnom Penh to Pursat, Battambang, and Pailin [Cambodia], and Chanthaburi and Trat [Thailand] from March 16-23, 2008. This activity relates to the WHO/BMGF grant.