UNITED STATES PHARMACOPEIA
DRUG QUALITY & INFORMATION PROGRAM

Quarterly Report
October – December 2007

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

January 30, 2008

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USAID
FROM THE AMERICAN PEOPLE

U.S. PHARMACOPEIA
DRUG QUALITY AND 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 the successful approaches implemented 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 imparts its expertise in the field of drug quality. By working with local governments, USAID Missions, the World Health Organization (WHO), and other partners, the program helps evaluate countries' readiness and 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: Other Public Health Threats (Common Agenda)

Key Staff: All USP DQI staff

Objectives:

- Build institutional and individual skills and competencies to support the appropriate management and use of pharmaceuticals.
- Provide support to global health initiatives and organizations to assure that adequate attention is given to pharmaceutical management, quality and rational use.
- Enhance quality assurance (QA) mechanisms to improve drug quality.

Activities:

- J. Carpenter and M. McGinnis revised the *Matrix of Drug Quality Reports in USAID-assisted Countries* and disseminated it on the USP DQI website. The *Matrix* was accessed 1,916 times in October and 1,767 times in November. The *Matrix* will be included in a packet the National Alliance of State Pharmacy Associations (NASPA)/Responsible Health created for accredited continuing education for pharmacists and pharmacy technicians; was distributed at the APHA exposition; and was cited in the World Health Organization's *Survey of the quality of antiretroviral medicines circulating in selected African countries.*
- M. Welsch headed the project team for USP DQI's exhibit at the 135th Annual APHA Meeting and Exposition, held November 3-7 in Washington, DC. Approximately 50 visitors stopped by the booth each day, and about 14,000 health professionals attended the exposition. Materials distributed include copies of the brochure, *Matrix of Drug Quality Reports, Zinc Guidelines,* and USP DQI fact sheets.
- P. Lukulay met with WHO staff (Department of Medicines Policy and Standards) in Geneva to discuss procedures for USP DQI to become a collaborating partner for pre-qualification of National Quality Control Laboratories.
- P. Lukulay met with the Executive Director of Organization for Innovation, Implementation and Impact (O3i), the developer of the RAPID Pharmacovigilance program for developing countries to discuss partnership with USP DQI wherein USP DQI would provide drug quality leadership for their pharmacovigilance program. As a result of their meeting, a letter of collaboration has been drafted.
- S. Phanouvong, M. Foster, K. Burimski, D. Seyoum, and L. Krech performed a final review of the book *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide*; M. Foster created the master CD of materials which accompanies each Guide and sent the finalized version of the book for publication.

Future plans:

- Develop a training module and training materials for Drug Information Centers
- Disseminate the *Operational Guide* to collaborating partners and targeted audiences

Program: Maternal and Child Health

Key Staff: J. Carpenter, E. Toledo, M. Hajjou, P. Lukulay, N. Davydova

Objective:
- To improve child survival and child nutrition as well as maternal health and survival

Activities:
- J. Carpenter spoke about counterfeit drugs and the response from international public health practitioners at the National Alliance of State Pharmacy Associations (NASPA) meeting in Anaheim, CA. The presentation, the *Matrix of Drug Quality Reports in USAID-assisted Countries*, and the visual inspection of medicines tool will be included in a packet the National Alliance of State Pharmacy Associations (NASPA)/Responsible Health created for accredited continuing education for pharmacists and pharmacy technicians.
- J. Carpenter, M. Hajjou, and E. Toledo assessed the status of GMP-compliance in the manufacturing process for zinc sulfate tablets for Shelys Pharmaceutical Ltd. in Dar es Salaam, Tanzania. The inspection covered the air handling unit, water purification system, compressed air system, starting materials stores, production rooms, packaging area, quality control (QC) laboratory, and zinc sulfate tablets formulation.
- E. Toledo reviewed the Corrective Action Plan submitted by Square Pharmaceutical (Bangladesh).
- E. Toledo provided documents for cleaning validation and other relevant SOP templates to Shelys Pharma (Tanzania).
- E. Toledo participated in the *Reportedly Trained or Truly Trained* GMP Workshop held in Raleigh, NC December 4-5; this workshop was sponsored by FDA news.

Future Plans:
- Identify additional manufacturers of Zinc formulations and help them comply with international standards.
- Develop monographs for other formulations of Zinc such as Zinc Gluconate and Zinc Acetate.

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:
- Review HIV/AIDS-related articles for the USP DQI website monthly update.

Program: AMR/Infectious Diseases

Key Staff: L. Krech, S. Phanouvong, D. Seyoum, J. Carpenter

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 was interviewed by *PharmTech Magazine* regarding USP DQI's AMR activities. The article is scheduled to appear in the January issue.
- L. Krech met with WHO staff to discuss ideas for the FY 07 AMR work plan activities in Asia, Africa, and the Americas and how USP DQI can further collaborate with WHO on AMR related activities.

Future Plans:
- Review AMR/Infectious Diseases-related articles for the USP DQI website monthly update.
- Conduct quality testing of antimicrobials commonly used in the treatment of childhood infectious diseases in developing countries.
- Develop USP pharmacopeial monographs for commonly used pediatric drugs included in the WHO Essential Medicines List for Children.

Program: Tuberculosis

Key Staff: S. Phanouvong, E. Toledo, D. Seyoum

Objective:
- To reduce the spread of MDR- and XDR-TB through better access to second line anti-TB medicines
- To strengthen implementation of DOTS Expansion and enhancement through standards development and guidelines

Activities:
- D. Seyoum supplied information on the use of fluoroquinolones as second line agents in the treatment of multidrug-resistant tuberculosis (MDR-TB) to a clinician in Ethiopia, including the evidence tables he developed for review by the USP DI Expert Committee on Infectious Diseases and his poster presentation at the 2005 Annual Conference on Antimicrobial Resistance.
- S. Phanouvong and E. Toledo teleconferenced with WHO/Global TB Drug Facility (GDF), the WHO Prequalification Team, and the Green Light Committee to evaluate the applications submitted by manufacturers of second-line anti-TB medicines responding to the Expression

of Interest posted by the GDF; E. Toledo reviewed the GDF questionnaire for second-line anti-TB medicines from four companies, (Svizera Europe, Karnataka, Lupin, and Kilitch Drugs, India)
- D. Seyoum reviewed tuberculosis related articles for the USP DQI website monthly update.

Future plans:
- Review tuberculosis related articles for the USP DQI website monthly update.
- Conduct assessment visits to Karnataka and Kilitch Drugs in India from a GMP compliance and product quality perspective and identify needs for technical assistance (this activity is pending on the approval of USAID)
- Continue to coordinate with responsible departments of USP to follow up on analytical methods acquisition for pharmacopeial monographs development of rifampicin plus isoniazid FDC tablet and ethambutol plus isoniazid tablet.

Program: Malaria

Key Staff: P. Lukulay, D. Seyoum, 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)
- To Prepare country representatives for the QAMSA study through training and technical assistance

Activities:
- P. Lukulay and L. El Hadri briefed the USAID/Senegal Mission about the scope, design, and implementation plans of the study on the quality of antimalarial medicines in sub-Saharan Africa (QAMSA), explaining how the study will ultimately benefit Senegal by helping improve the overall quality of medicines in the country.
- D. Seyoum reviewed malaria-related articles for the USP DQI website monthly update.
- M. Hajjou, S. Bradby, and J. Qin performed full monograph testing on a sample of the ACT artesunate-amodiaquine from Guilin Pharma.

Future Plans:
- Review malaria-related articles for the USP DQI website monthly update.
- Conduct training of representatives from ten countries in Sub-Sahaan Africa on the use of Minilabs®

Program: RDM/A Bureau

Key Staff: S. Phanouvong, L. Krech, K. Burimski, N. Davydova, M. Hajjou, C. Raymond, E. Toledo

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Program: RDM/A – Mekong Malaria

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 revised and resubmitted a grant proposal for an antimalarial drug quality survey in Cambodia/Thailand border areas as one component of WHO's proposal to the Gates Foundation on "Artemisinin Resistance: Pilot Studies to Confirm, Characterize, and Plan for Containment." The proposal has been accepted and USP DQI is to receive $348,000 to implement the proposed survey.
- S. Phanouvong and C. Raymond presented USP DQI activities accomplished and proposed work plans at the USAID Mekong Malaria Programme Partners Meeting in Bangkok, Thailand, on October 29-31, 2007. The meeting was attended by 32 participants representing malaria core program partners which are funded, in full or in part, through the RDM-A Mission.
- S. Phanouvong, with assistance from C. Raymond and Thailand's Malaria Cluster of Vector-borne Diseases Control Department, organized and conducted a meeting, held Nov. 1-2, to plan a study on antimalarial drugs quality using randomized sampling methodology on three Cambodian and two Thai cross-border provinces in Bangkok, Thailand. Some 30 representatives from central and provincial health agencies of Thailand and Cambodia participated; C. Raymond presented sampling methodology to the meeting participants; S. Phanouvong completed the revision and addition of a new questionnaire to the study protocol and, along with C. Raymond, revised the final draft of the protocol based on the feedback received from the November planning meeting in Bangkok.
- C. Raymond met with the following during a field visit to Vientiane, Lao PDR:
  - Dr Andrew Corwin, U.S. CDC/U.S. Embassy in Vientiane to brief on USP DQI activities.

- FDD, MPSC, CMPE, FDQCC, FPH of Lao PDR MoH to discuss implementation of workplans, monitoring results, and facilitating more efficient systemic functioning for reporting on data generated.
- The "model hospital-based pharmacy" at Mittaphap Hospital in Vientiane to evaluate progress following equipment upgrades and training.
- Marjorie Pollack, Editor of ProMED surveillance database program, regarding USP DQI's regional activities and possible reporting mechanisms through ProMED's global network.

Future Plans:

- Finalize the RDM-A work plan and provide support to four countries in the region to implement
- Conduct a training course to resume anti-malarial medicines quality monitoring in Thailand

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

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:

- N. Davydova and S. Bradby conducted laboratory trainings on GLP and advanced methods for testing antimalarials using artesunate as a case study. Participants from Cambodia, Laos, Vietnam, and Thailand took part in the workshop, which was held at Chulalongkorn University. Chulalongkorn is now almost fully capacitated to conduct QC trainings with clients in the region without USP DQI technical assistance.
- L. Krech, S. Phanouvong, N. Davydova, and K. Burimski met with Mr. Dennis Wollersheim – IT and health informatics expert from La Trobe University, Australia – to address issues regarding the drug quality database being developed with PSyRIC.
- L. Krech and M. Hajjou finalized the logistics and curriculum of a specialized bioequivalence (BE) statistical training and software installation to be conducted by a UST CeDRES consultant for all three BE units in Vietnam.
- L. Krech, M. Hajjou, and C. Raymond assisted UST CeDRES to provide a 3-day training on bioavailability/bioequivalence in Siem Reap, Cambodia for participants from Cambodia and Vietnam. The training discussed the complexities of analyzing a fixed-dose TB drug combination and presented the results of a BE study done at UST CeDRES to register a

generic product for Rifampicin. Vietnam requested further statistical training for their three BE units and the software that UST CeDRES utilizes to conduct BE studies.

- L. Krech, N. Davydova, K. Burimski, C. Raymond, and S. Phanouvong finished reviewing the first version of the on-line database for drug quality created by PSyRIC. C. Raymond and N. Davydova met with the programmer and senior PSyRIC staff to discuss the changes that must be made before it goes public.

Future Plans:

- Conduct a training course in Thailand on sampling and testing of anti-TB drugs and commonly used antibiotics with GPHF-Minilabs®
- Commence GMP activities at Mahidol. A four-day training will be tentatively scheduled for the end of April or early May. Three days will be spent in a classroom didactic setting and the fourth day will entail visiting a pharmaceutical manufacturer to gain more practical, applied experience. Mahidol will conduct the training with USP DQI technical assistance for participants from Laos, Cambodia, and Thailand.
- The drug quality database will be online and presented at the next Mekong Malaria partners meeting.
- L. Krech and M. Hajjou will finalize the logistics and curriculum of a specialized bioequivalence statistical training and software installation to be conducted by a UST CeDRES consultant for all three BE units in Vietnam.

Program: RDM/A6-HIV/AIDS

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.
- S. Phanouvong completed the final revision of the *Rapid Assessment of QA/QC of a Medicines Supply System*.

Future Plans:

- Conduct a training course in Thailand on sampling and testing of antiretrovirals with GPHF-Minilabs®

- Finalize the RDM-A work plan, including that of HIV/AIDS and provide support to four countries in the region to implement
- Conduct a training course to expand the drug quality monitoring to cover HIV/AIDS medicines in Thailand

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Program: RDM/A7-Avian Influenza

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:
- S. Phanouvong and C. Raymond met with RDM/A, WHO Country Office/Laos, U.S. Centers for Disease Control and Prevention/Laos, and Laos Ministry of Health on sampling of oseltamivir medicines from Laos hospitals (3 central, 16 provincial) and the WHO stock house. Sampling will check the pharmaceutical quality (appearance, correct labeling and packaging, identity and content of API). USP DQI has already obtained permission from the Laos MOH for sample collection.

Future Plans:
- Develop sampling methodology applicable for oseltamivir
- Collect and test oseltamivir samples, using basic testing methods, at identified sentinel monitoring sites in the region
- Support PSyRIC to deliver training to three countries, Cambodia, Laos, and Vietnam on mapping all oseltamivir manufacturers and distributors in the region.
- Identify and map all oseltamivir manufacturers and distributors in Cambodia, Laos, and Vietnam, using Thailand experience.

Program: Cambodia

Key Staff: L. Krech, C. Raymond, M. Hajjou

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 wrote *Investigating Medicine Quality of the Manufacturer Utopian* which was reviewed by M. Hajjou, S. Bradby, S. Phanouvong, K. Burimski, C. Raymond and the Cambodian Department of Food and Drugs (DDF). The report reviewed the testing results of Utopian medicine samples collected by the DDF and the Pharmacists Association of Cambodia in 3 provinces. The medicines were tested by the Bureau of Drugs and Narcotics of Thailand and USP's Research and Drug Laboratory Lab (S. Bradby and J. Qin).
- S. Phanouvong reviewed testing results of investigative samples of Utopian collected from Cambodia by the Bureau of Drugs and Narcotics of Thailand and USP's Research and Drug Laboratory RDL Lab and handed over the case to L. Krech to follow-up with the DDF.
- C. Raymond continued development of a public relations campaign for USP DQI using public service announcements and photo-journalism to increase visibility of USP DQI programs regionally and to provide public education regarding counterfeit medicines.
- L. Krech and senior USP DQI staff members sent the DDF a proposal to set up a Pharmacovigilance/Drug Information Center in Cambodia.
- L. Krech sent USP DQI training materials to PATH to begin collaboration on a drug quality component of the trainings that PATH provides to over 600 pharmacists.
- L. Krech, C. Raymond, S. Phanouvong, and Health Messenger wrote the article "VCD Dealers in Death: *Watch the Dealers in Death VCD and Learn What You Can Do To Stop the Circulation of Counterfeit Drugs*" with input from WHO (Cambodia), USAID, CNM (National Center for Parasitology, Entomology and Malariology Control Program), DDF, and the Pharmacists Association of Cambodia (PAC). The article and the VCD were distributed to over 20,000 health professionals in Cambodia.

Future Plans:

- Conduct a workshop in Phnom Penh with all partners who will be involved with the Pharmacovigilance/Drug Information Center. The purpose is to clearly define what activities the PV/DIC will undertake and what are the roles and responsibilities of each of the partners.
- Conduct supervisory visits to selected sentinel sites to improve data collection and reporting.

Program: Philippines

Key Staff: L. Krech, M. Hajjou

Objectives:

- Support and 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 completed laboratory safety training so that she will be able to receive further training (provided by M. Hajjou and S. Bradby) on how to conduct TLC tests using Minilabs®.

Future Plans:

- Establish an Anti-TB drug quality program –
  - Provide training on sampling and testing of anti-TB drugs at the sentinel sites
  - Review the first progress report and provide comments and suggestions for improvement.
  - In April, the TB drug quality monitoring project – in partnership with BFAD, the Department of Health, and the USAID Mission – will commence in six selected sites. M. Hajjou and L. Krech will provide a Minilab® training to over 30 participants from BFAD and DOH.

Program: Russia

Key Staff: K. Burimski

Objective:

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

Activities:

- 1,701 copies of the Textbook were disseminated this quarter. The online version was visited 682,152 times, bringing the total number of visits to 4,836,533.

Future Plans:

- Continue dissemination of the Textbook

Program: LAC-1 – Amazon Malaria Initiative

Key Staff: A. Barojas, V. Pribluda

Objectives:

- Malaria control programs in the Amazon Basin sub-region to substantially incorporate selected best practices
- USP DQI activities 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:

- Together with partners, V. Pribluda and A. Barojas developed drafts of 1-, 3-, and 5-year strategic plans for AMI.
- V. Pribluda and A. Barojas met with National Malaria Control Program personnel in Peru regarding the status of activities monitoring the quality of antimalarials at sentinel sites; MiniLabs® in the Amazon region of Iquitos and Yurimagua received approval for use of

controlled reagents and MiniLabs® in Tumbez and Piura coordinated with the clinical lab from the Regional Health Authority (DIRESA) for the use of controlled reagents.
- V. Pribluda and A. Barojas sent invitation letters to the official medicines control laboratories (OMCL) in Colombia (INVIMA) and Peru (CNCC-INS) for participation in internships at USP.

Future Plans:
- Attend Annual AMI/RAVREDA meeting in Lima, Peru in March 2008
- Review DQ Data from AMI countries presented at Annual AMI/RAVREDA meeting
- Finalize "Drug Access and Use" Master Plan Document with PAHO & MSH
- Start internships at USP laboratories for OMCL participants from Colombia & Peru
- Procure headspace apparatus's for Colombia, Guatemala, and Peru's OMCLs
- Finalize AMI/SAIDI DQ Workshop objectives, date and location with PAHO & MSH
- Initiate assessment of QA/QC status of insecticides in AMI countries

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Program: LAC-2 – South American Infectious Diseases Initiative

Key Staff: A. Barojas, V. Pribluda

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:
- Together with partners, V. Pribluda and A. Barojas developed drafts of1-, 3-, and 5-year strategic plans for SAIDI.
- V. Pribluda and A. Barojas assessed Peru's OMCL (CNCC) for advancement towards ISO 17025:2005 accreditation and suggested ways to improve understanding of audit procedures
- V. Pribluda and A. Barojas worked with Peru's Regulatory Agency (DIGEMID) to refine the sampling and testing protocol for selected antibiotic and anti-tuberculosis medicines found in the market in DISA Callao.
- V. Pribluda and A. Barojas assessed development status of DIGEMID's Data Integration System (SI DIGEMID)

Future Plans:
- Finalize AMI/SAIDI DQ Workshop objectives, date and location with PAHO & MSH
- Install and train Bolivia's OMCL on the proper use of a donated KF instrument
- Train Paraguay's OMCL in GLP compliance and analytical laboratory techniques (KF and HPLC)
- Continue to provide TA and support Peru's OMCL to obtain ISO 17025:2005 accreditation

- Coordinate with local partners the second round of sampling and analysis of selected AB & TB medicines in Peru and Paraguay
- Coordinate with local partners the third round of sampling and analysis of selected AB & TB medicines in Bolivia
- Assist development of SI DIGEMID to include decentralized post marketing surveillance activities
- Coordinate with Paraguay's Regulatory Agency (DNVS) installation and implementation of SIAMED

Program: Africa Bureau

Key Staff: D. Seyoum, P. Lukalay

Objectives:
- Strengthen technical capacity of the of the Kenyan PPB Pharmacovigilance Department's activities in post-marketing surveillance for ADR of pharmaceuticals, especially infectious disease medicines.
- Strengthen technical capacity of the of the QCL in key functions related to pharmaceutical analysis for product registration and laboratory management practices

Activities:
- D. Seyoum and M. Welsch purchased and shipped books for the Kenyatta National Hospital Drug Information Center in Nairobi, Kenya.
- D. Seyoum and M. Welsch purchased and shipped books for the Thika District Hospital DIC in Thika, Kenya.

Future Plans:
- Facilitate the purchase of computers and equipment for the Kenyatta National Hospital Drug Information Center in Nairobi, Kenya and Thika District Hospital DIC in Thika, Kenya.

Program: Madagascar

Key Staff: M. Hajjou, P. Lukulay and L. El Hadri

Objectives:
- Strengthen drug quality assurance system
- Raise awareness about drug quality and safety and disseminate information among regulators, health care professionals, and general public
- Improve access to and the use of objective up-to-date information about medicines

Activities:

- M. Hajjou reviewed the second semester progress report on drug quality monitoring and discussed with the chief of national drug quality control laboratory (NDQCL) the confirmatory testing and the planning for next round. The data revealed an increase of failed samples. Confirmatory testing is underway.
- M. Hajjou and NDQCL chief prepared the budget for the next round of sampling and testing of anti-malarial drugs.

Future Plans:

- Establish a drug information center in Antananarivo.
- Assess the reporting system used to collect pharmacovigilance data and identify opportunities for improvement.
- Review all the progress reports on drug quality monitoring and prepare an article based on the results obtained from this program.
- Expand pharmacovigilance activities to other districts

Program: Senegal

Key Staff: M. Hajjou, P. Lukulay and L. El Hadri

Objectives:

- Strengthen drug quality assurance system
- Raise awareness about drug quality and safety and disseminate information among regulators, health care professionals, and general public

Activities:
None

Future Plans:

- Facilitate the establishment of a national pharmacovigilance program with representatives from the University, the national drug authority, and the malaria control program
- Expand the number of sentinel sites across the country

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:

- None

Future Plans:

- Purchase 4 MiniLabs® and provide a training workshop on sampling of antimalarial medications and the proper use of the MiniLab® testing kit
- Monitor quality of antimalarial drugs at the central and the periphery levels.
- In collaboration with WHO, install verification software which was developed particularly for NDA in order to improve registration and importation functions of NDA, and provide training for all identified users on the proper use of SIAMED and its applications.