UNITED STATES PHARMACOPEIA
DRUG QUALITY & INFORMATION PROGRAM

Quarterly Report
July – September 2007

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DRUG QUALITY AND INFORMATION PROGRAM

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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 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 over 650 USP volunteer experts.

Program: 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.

Focus for the quarter:

- Continue production of Operational Guide for Quality Assurance of Medicines.

Activities:

- Completed final technical review and proof reading of 'Ensuring the Quality of Medicines in Resource-Limited Countries: an Operational Guide.'

Outcome:

- Operational guide publication

Future plans:

- Publish and disseminate the Operational Guide.

Program: Mainstreaming

Key Staff: N Davydova

Objectives:

- Provide assessment of the drug regulations, registration practices, allocated resources, and facilities of the Azerbaijan Center for Innovation and Supply (CIS), the principal agency of the Ministry of Health responsible for the pharmaceutical sector.
- Strengthen drug registration and quality assurance system in Azerbaijan

Focus for the quarter and Activities:

- No activities planned or reported for this quarter.

Future Plans:

- Strengthen drug registration practices in the CIS; install the most recent version of SIAMED registration software, in collaboration with WHO; and train the staff on its use.
- Install the specialized program for drug import control with the SIAMED software for Medicine and Medical Devices Department, and train the staff on its use.

Based on the availability of funds, the following activities are proposed to strengthen drug quality control in Azerbaijan:

- Provide training to Drug Quality Control Laboratory staff on Good Laboratory Practices and major testing methods, such as HPLC, dissolution, and UV, according to official pharmacopeias.
- Provide technical assistance to CIS establish a pharmacovigilance program
- Provide training on GMP assessments for Inspection Department staff.

Program: SO2 (Maternal Health) and SO3 (Child Survival)

Key Staff: J Carpenter, EToledo, M Hajjou, S Bradby, L Callahan

Objective:

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

USP DQI will continue to improve procurement of good quality zinc products by UNICEF and other organizations. It will also continue to participate in the quality control/Good Manufacturing Practices assessment of zinc manufacturers for global and local supply to assist them in achieving UNICEF prequalification. USP DQI will also continue providing technical assistance to Nutriset and USAID partners and disseminate information relating to the maternal and child health issues. It will continue to provide technical assistance to USAID's chlorhexidine Working Group 's research activity involving the viability of the potential use of chlorhexidine as an infection-prevention agent for mothers and newborns.

Focus for the quarter:

- Finish testing the zinc samples from Nepal collected by Abt Associates.
- Disseminate the usefulness of zinc for children's diarrhea and the importance of good quality zinc to healthcare professionals (pediatricians).

Activities:

- USP DQI staff met with Susan Mitchell of Abt Associates and discussed potential role of USP DQI in Nepal regarding zinc product quality. Per Ms. Mitchell's request, USP DQI provided her with a slide presentation about USP DQI and the technical assistance on drug quality that it provides to the zinc scale-up activities. This presentation was delivered at her meeting with the Ministry of Health and zinc manufacturers of Nepal.
- USP DQI tested four zinc sulfate samples (100 units each) from Nepal.
- Larry Callahan updated POPPHI of PATH on the revision of the USP oxytocin injection monograph. The changes in storage conditions and the allowance for a plastic container have been approved by the USP Expert Committee. There will be no temperature information in the USP Oxytocin monograph in *USP31*.
- J. Carpenter researched for USAID information on differences in concentrations of chlorhexidine used in clinical trials.
- J. Carpenter and M. Foster drafted a presentation on USP DQI zinc activities to be included in Abt's meeting with the MoH and zinc manufacturers in Nepal in preparation for a USP DQI staff visit to provide technical assistance with GMP.

Outcome:

- Two samples of zinc sulfate failed the requirements for pharmacopeial testing.
- A poster entitled *Zinc Adjunct in the Management of Children's Diarrhea: Ensuring Product Quality* was presented at the 25th International Congress of Pediatrics in Athens, Greece on Sept 25-31, 2007.
- Because of the USP DQI presentation by Ms Mitchell of Abt Associates, USP DQI will provide technical assistance in the form of GMP assessment of one local zinc manufacturer in Nepal.

Future Plans:

- USP DQI staff will conduct a follow-up visit with a zinc manufacturer in Tanzania to prepare them to pass the UNICEF audit and become prequalified. USP DQI staff will also meet with the Tanzania Food and Drug Administration to follow up on the zinc registration in the country.
- USP DQI will meet with Ms. Mitchell of Abt for a debriefing regarding her trip to Nepal and discuss the potential role that USP DQI will play in Nepal regarding zinc.

Program: SO 4 – HIV/AIDS

Key Staff: D Seyoum

Objective:

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

USP DQI will continue its efforts in the development of monographs for the Nevirapine Tablet and Nevirapine Oral Suspension. ARVs are now widely used in a number of countries with limited resources. However, the quality of these medicines may be questionable. The development and dissemination of monographs for all available ARVs provides unbiased standards crucial to ensure the quality of these products. USP DQI will continue to disseminate drug information on ARVs and their monographs.

Focus for the quarter:

- Develop and disseminate technical information on "ARV Drug Interactions" and "ARV Drug Resistance"

Activities:

- D. Seyoum reviewed HIV/AIDS-related articles for the USP DQI website monthly update.
- D. Seyoum received acknowledgement for reviewing abstracts for the 4th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment, and Prevention that was held July 22–25 in Sydney, Australia.
- D. Seyoum reviewed two articles related to mother to child transmission of HIV-1 infection that were submitted to the journal *AIDS.*

Outcomes:

- Reviewed 28 HIV/AIDS related articles for the USP DQI website.
- Reviewed 40 late breaker abstracts for the 4th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment, and Prevention held in Sydney, Australia (July 22-25, 2007).
- Followed up on development of Monographs for the following:
  Nevirapine Tablets – First published in Pharmacopeial Forum Volume No. 32(3) Page 807 and then became official in USP30–NF25 Supplement No.1 Page 3820
  Nevirapine Oral Solution – First published in Pharmacopeial Forum Volume No. 32(4) Page 1090 and subsequently balloted to become official in USP30–NF25 Supplement No.2 Page 4116

Future Plan:

- Continue to review tuberculosis, malaria, HIV/AIDS, and AMR/infectious diseases related articles for the USP DQI website monthly update

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Program: SO 5 – AMR/Infectious Diseases

Key Staff: L Krech, S Phanouvong, D Seyoum, J Carpenter and M McGinnis

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.

Focus for the quarter:

- To finalize AMR related publications and preparation for distribution in the next quarter.
- Participate in the International Pharmaceutical Federation (FIP)conference in Beijing, China. USP DQI leads a Working Group of the FIP that examines the causes and the magnitude of AMR from a regional and global perspective, helping define the roles of pharmacists and professional health organizations in setting strategies and measures to reduce AMR, and identifying information resources on the appropriate use of antimicrobials.

Activities:

- For the Rapid Assessment Tool for Quality Assurance of a Pharmaceutical Supply and Distribution System, S. Phanouvong followed up with all external reviewers for their comments/suggestions and received comments from 6 reviewers, which were incorporated into the final version of the document.
- J Carpenter and M. McGinnis added 21 new reports to the *Matrix of Drug Quality Reports in USAID-assisted Countries* and disseminated it on the USP DQI website
- N. Blum and D. Seyoum participated in the International Pharmaceutical Federation (FIP) 67th World Congress of Pharmacy and Pharmaceutical Sciences in Beijing, China.
- D. Seyoum and O. Dmitrenok reviewed AMR/Infectious Diseases-related articles for the USP DQI website monthly update.

Outcomes:

- At the FIP, D. Seyoum presented on "Antimicrobial drug resistance: The next pandemic" at a symposium he led on the topic. D. Seyoum also co-facilitated the session on "Antimicrobial Drug Resistance–the role of the pharmacy profession in tackling this emerging global health problem."
- The Rapid Assessment Tool for Quality Assurance of a Pharmaceutical Supply was cleared by legal and is ready for final editing.
- Updates on USP DQI AMR activities were posted on the USP DQI website.
- AMR FY 06 funding was fully spent.

Issues:

- New program manager for AMR arrived in July 2007.

Future Plans:

- With the commencement of FY 07, a new draft work plan has been circulated involving activities such as: 1) conducting quality testing of antimicrobials commonly used in the treatment of childhood pneumonia in developing countries, and 2) Providing GMP technical assistance to those manufacturers who want to obtain WHO/UNICEF prequalification for medicines on the new WHO List of Essential Medicines for Children. This workplan is under review by the CTO.

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Program: SO 5A – Tuberculosis

Key Staff: S Phanouvong

Objective:

- Expand regional-based approaches for AMR containment, focusing on drug use practices and drug quality.
- Strengthen QA for the procurement, distribution, and storage of anti-TB medicines in selected high-TB-burden countries in Southeast Asia to enhance the DOTS. implementation

Activities:

- Revised the EOI questionnaire with E. Toledo and P. Lukalay for WHO/Global TB Drug Facility to scale up the access to reliable manufacturers of anti-TB medicines.

Outcome:

- Revised EOI questionnaire sent back to the WHO/Global TB Drug Facility for circulation to TB manufacturers

Future plan:

- Review EOI questionnaires completed by interested TB manufacturers and identify and recommend TB manufacturers to WHO/Global TB Drug Facility that will require USP DQI's GMP technical assistance

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Program: SO 5B – Malaria

Key Staff: P Lukulay

Objective:

- To work jointly with WHO to develop the protocol and study design for QAMSA (Quality of Antimalarial drugs in sub-Saharan Africa)

- To establish the extent of the problem of substandard and counterfeit ACTs and SPs in selected sub-Saharan African countries and to provide evidence-based data for subsequent action by the respective drug regulatory agencies. The current study is a follow-up to an earlier study by WHO in 1999 where only Chloroquine and SP were evaluated. ACTs were not included in the previous study because they were not available. The current study is designed to address the shortcomings of the previous study and to include the more widely recommended ACTs as well as SP which is widely used in intermittent preventive treatment. Previous WHO study identified the prevalence of substandard SP in the distribution chain in seven sub-Saharan African countries.

Focus for the quarter:

- Finalize the study design and protocol and make preparations for training of country representatives on the use of Minilab.
- Finalize the location for the training and obtain Government clearance for training.
- Obtain necessary materials including Minilabs, additional reagents and other accessories required for training

Activities:

- P. Lukulay and N. Davydova attended a meeting in Dar es Salaam, Tanzania, along with representatives from WHO and participating countries from July 3rd-5th.
- P. Lukulay gave a presentation on the capabilities and weaknesses of Minilab technology for quality control testing and fielded questions from participants
- Timeline for the study was established

Outcome:

- A study design and protocol for QAMSA was developed
- Country representatives appointed national focal persons to lead efforts in collecting drug samples from markets in various countries.
- Country representatives obtained budget needed to conduct the study in their respective countries.

Issues:

- Issues in getting Government clearance to conduct the training in Ethiopia.
- Training delayed from anticipated date of November 2007 to January 2008
- Purchase of minilabs was delayed due to waiver issues
- Budget to support the three countries that USP DQI is supporting needs to be obtained with buy-in from local missions in Senegal, Madagascar and Uganda.

Future Plans:

- Work with WHO to ensure that the current timeline for the training is met.
- Obtain minilabs and/or additional reagents for Uganda, Madagascar and Senegal
- Conduct training of country representatives on the use of minilabs in Ethiopia
- Oversee the collection of samples and analyses using minilab followed by confirmatory tests in a quality control laboratory.
- Disseminate information about the results obtained in the QAMSA study

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Program: RDM/A Bureau

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

Activities affecting all RDM/A programs:

- S. Phanouvong successfully recruited C. Raymond as a consultant, based in Bangkok, to coordinate USP DQI activities in South-East Asia.
- C. Raymond re-established USP DQI office in Kenan Institute Asia (Bangkok) and completed orientation to BAAM and KIAsia.
- S. Phanouvong led the SEA team (L. Krech, K. Burimski, N. Davydova, N. Blum) to develop the FY08 work plan for RDM/A FY07 funding and submitted by the deadline of September 1, 2007.

Program: RDM/A1 – Mekong Malaria

Objectives:

- Collect and test the quality of antimalarial drug samples in five countries for two rounds in FY07.
- Increase and expand the antimalarial drug quality monitoring at the Thai/Cambodian border.
- Provide GMP technical assistance to one or two selected ACT manufacturers in the Mekong region.

Focus for the quarter:

- Obtain the formality clearance for USP DQI to continue to provide support to Vietnam and Thailand relative to quality monitoring activities for anti-infective medicines.
- Continue collection and testing of ARVs, anti-TB medicines, and commonly used antibiotics in Laos and Cambodia.

- Present evidence-based data obtained from countries and propose possible policy revisions or system-strengthening to address drug quality problems.

Activities:

- S. Phanouvong, in cooperation with the USP DQI admin staff, editors, and K. Burimski, successfully obtained formal clearance from relevant authorities allowing USP DQI to continue to provide technical support to Vietnam and Thailand in the effort to improve the quality of their medicines.
- S. Phanouvong completed a final revision of the study protocol on antimalarial drugs quality using randomized sampling methodology on Cambodia and Thai cross-border areas and sent it to country collaborators.
- S. Phanouvong and K. Burimski followed up on the formality clearance for USP DQI to continue to provide support to Vietnam and Thailand relative to anti-infective medicines quality monitoring activities
- S. Phanouvong, E. Toledo, and S. Bradby traveled to Laos, Cambodia, and Thailand and conducted trainings on minilab, Good Storage Practices, Good Dispensing Practices, and Good Laboratory Practices..
- S. Phanouvong and C. Raymond traveled to Vietnam to conduct a training course on "Establishing Anti-Infective Drugs Quality Monitoring Using Basic Tests, Sampling Procedures, and Drug Quality Data Management" In Vietnam. The training was attended by 20 participants from nine provincial sites, including five new sites which previously had been supplied with Minilabs by Global Fund.
- C. Raymond met with Dr. John MacArthur (RDM/A) and Dr. Chantha Chak (USAID/Cambodia) concerning current USPDQI regional projects.
- C. Raymond met with Jim Hopkins (BAAM) and Kenan Institute regarding the collaboration with USP DQI on antimalarial drug resistance monitoring in Thailand border areas and to develop the work plan for upcoming fiscal year activities.
- C. Raymond met with representatives from the Bureau of Vector-Borne Diseases at the MoH, Thailand concerning formal clearance and MoU with USPDQI for upcoming monitoring and training project (including regional and cross-border surveillance with Cambodia).
- C. Raymond met with representatives of Family Health International (FHI) Bangkok concerning collaboration with upcoming possible grant award for RDM/A malaria project in Pailin, Cambodia
- C. Raymond attended the "Informal consultation on monitoring *P. falciparum* and *P. vivax* resistance to antimalarial drugs in the Greater Mekong Subregion (GMS)" organized by the WHO Mekong Malaria Programme; participated in the planning meeting on efficacy trials for GMS and discussed re-initiating monitoring project in Yunnan, China, with WHO.
- S. Phanouvong organized a meeting with Vietnamese partners meeting (MOH; Drug Administration of Vietnam; National Institute of Drug Quality Control; HIV/AIDS, TB and STDs programs; National Institute of Malariology, Parasitology and Entomology; MSH/Strengthening Pharmaceutical Systems; WHO Country Office; and PEPFAR-Vietnam/CDC) to update, discuss and agree on the implementation of anti-infective drugs quality monitoring in Vietnam in FY08.

- USP DQI staff contributed to writing and revision of an article, “A forensic epidemiological investigation into the criminal fake artesunate trade: an international collaboration between police, scientists, and health workers,” in collaboration with WellcomeTrust/Laos, WHO, Interpol, and others; submitted it to a peer review journal (PLoSMedicine) for publication.

Outcome:

- The formality clearance for USP DQI to continue to provide support to Vietnam and Thailand relative to anti-infective medicines quality monitoring activities was obtained
- New consultant was hired, office re-established, general administrative requirements completed, and routine reporting procedures instituted.
- Study protocol was finalized
- Various trainings on minilab, Good Storage Practices, Good Dispensing Practices, and Good Laboratory Practices were conducted

Issues:

- USP was required to obtain formal clearance from the countries’ governments in the region, which took more time than initially anticipated
- The waiver from USAID to provide Minilabs to Thailand has not been received yet

Future Plans:

- Pending receiving the USAID waiver, conduct a workshop on ‘Establishing Anti-Infective Drugs Quality Monitoring Using Basic Tests, Sampling Procedures, and Drug Quality Data Management’ in Thailand
- Continue collecting and testing selected antiTB medicines, ARVs, and commonly used antibiotics.

Program: RDM/A3 – AMR Survey

Key Staff: S Phanouvong, K Burimski

Objectives:

- Determine operational strategy toward better understanding and containment of ACT resistance in Mekong region.

Focus for the quarter and Activities: Funding has been expended.

Program: RDM/A4 – Mekong Expansion

Key Staff: S Phanouvong, K Burimski

Objective:

- Increase surveillance capacity by including selected antituberculosis (anti-TB) agents, antiretrovirals (ARVs), and commonly used antibiotics
- Document the quality of selected anti-TB agents, ARVs and commonly used antibiotics

Focus for the quarter:

- Obtain the formality clearance for USP DQI to continue to provide support to Vietnam and Thailand relative to quality monitoring activities for anti-infective medicines.
- Continue collection and testing of ARVs, anti-TB medicines, and commonly used antibiotics in Laos and Cambodia.
- Present evidence-based data obtained from countries and propose possible policy revisions or system-strengthening to address drug quality problems.

Activities:

- S. Phanouvong, in cooperation with the USP DQI admin staff, editors, and K. Burimski, successfully obtained formal clearance from relevant authorities that allows USP DQI to continue to provide technical support to Vietnam and Thailand in the effort to improve the quality of their medicines.
- C. Raymond was hired as a consultant, based in Bangkok.
- S. Phanouvong, E. Toledo, and S. Bradby traveled to Laos, Cambodia, and Thailand to conduct trainings on minilabs and Good Laboratory, Dispensing, Storage Practices
- S. Phanouvong and C. Raymond conducted a training course on "Establishing Anti-Infective Drugs Quality Monitoring Using Basic Tests, Sampling Procedures, and Drug Quality Data Management" In Vietnam The training was attended by 20 participants from nine provincial sites, including five new sites which previously had been supplied with Minilabs by Global Fund.
- C. Raymond participated in the Steering Committee meeting organized by NIMPE and USP-DQI to plan for the upcoming sampling rounds of anti-infective medicines monitoring in nine Vietnam provinces.
- C. Raymond met with a film production team and advertising agency to finalize budget proposal, project proposal (targets, etc.) and develop 3-D Animatrix story boards for two PSAs to be produced as part of public relations campaign to increase visibility of USP DQI programs regionally and to provide public education regarding counterfeit medicines.
- S. Phanouvong organized a meeting with Vietnamese partners meeting (MOH; Drug Administration of Vietnam; National Institute of Drug Quality Control; HIV/AIDS, TB and STDs programs; National Institute of Malariology, Parasitology and Entomology; MSH/Strengthening Pharmaceutical Systems; WHO Country Office; and PEPFAR-Vietnam/CDC) to update, discuss and agree on the implementation of anti-infective drugs quality monitoring in Vietnam in FY08.
- Collection of samples were done in Cambodia and Laos.

Outcome:

- The formality clearance for USP DQI to continue to provide support to Vietnam and Thailand relative to anti-infective medicines quality monitoring activities was obtained
- New consultant was hired

- Sample were collected and tested in Cambodia and Laos. Test results should be available in the next quarter.

Issues:

- USP was required to obtain formal clearance from the countries' governments in the region, which took more time than initially anticipated
- The waiver from USAID to provide Minilabs to Thailand has not been received yet

Future Plans:

- Pending receiving the USAID waiver, conduct a workshop on 'Establishing Anti-Infective Drugs Quality Monitoring Using Basic Tests, Sampling Procedures, and Drug Quality Data Management' in Thailand
- Continue collecting and testing selected antiTB medicines, ARVs, and commonly used antibiotics
- Results of the sample testing from Cambodia and Laos will become available.

Program: RDM/A5 – Centers of Excellence in Quality Assurance of Medicines (ANEQAM)

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

Objective:

- 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

Focus for the quarter:

- Introduce new program manager and new project coordinator based in Bangkok
- Facilitate organization of a bioavailability/bioequivalence training in Cambodia for Vietnamese and Cambodian participants,to be taught by UST CeDRES
- Provide guidance to PSyRIC on the oseltamivir mapping project and the design of an on-line database that contains drug quality data collected from the sentinel sites in Cambodia, Thailand, Vietnam, and Laos

Activities:

- S. Phanouvong, S. Bradby, and E. Toledo visited PSyRIC to see the initial design of the drug quality database layout, contents, and navigational features. The team also visited Mahidol University to check on the status of installing a water purification system in order for USP DQI to conduct a future GMP training.
- USP DQI provided technical assistance to the QC laboratory of Chulalongkorn University with Good Laboratory Practices (GLP), Dissolution, and High Performance

Liquid Chromatography (HPLC) training modules and lab supplies to become a training site for ANEQAM in artesunate testing

- N. Davydova attended the Avian Influenza Partner's Meeting in Bangkok, Thailand and during this time met with the staff from Chulalongkorn QC laboratory to prepare for their first training as a Center of Excellence for 15 participants from Laos, Cambodia, Vietnam, and Thailand which will occur in December 2007
- N. Davydova met with PSyRIC to discuss the progress of the oseltamivir project to map suppliers and distributors in the region in order to determine the availability and quality of oseltamivir. The project will begin with Thailand and will include three other countries in the region: Cambodia, Laos, and Vietnam
- UST CeDRES developed a comprehensive curriculum with statistical, analytical, and clinical components for a previously developed validated bioequivalence method for rifampicin containing fixed dose combinations
- UST CeDRES provided a 3-day BA/BE training in Siem Reap, Cambodia for 24 participants from Cambodia (Department of Drugs and Food, National Institute of Public Health, and the National Laboratory for Drug Quality Control) and 8 participants from Vietnam (Drug Administration of Vietnam, National Institute for Drug Quality Control, and Danang Drug and Cosmetic Department). The training discussed the complexities of analyzed 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
- C. Raymond met with members of SEAMEO-Tropmed network and the Dean of Tropical Medicine for Mahidol University.
- S. Phanouvong participated in the series of discussions with L. Krech, N. Davydova, M. Hajjou and ANEQAM counterparts (Chulalongkorn University Faculty of Pharmacy and PSyRIC, and CeDRES of UST) on securing the MoUs on agreed activities with each of these institutions.

Outcome:

- BA/BE training successfully completed in Siem Reap and further activities with UST CeDRES as a Center of Excellence were discussed
- Drug quality database is now online with USP DQI and PSyRIC staff testing its functionality
- Oseltamivir mapping project in progress

Issues:

- At Mahidol, the purchase and installation of a new water purification system has taken longer than expected and will be accomplished by Q1 of FY08. In addition, a work plan will be put in place for Mahidol to continue to provide GMP expertise to regional clients

Future Plans:

- Once the water purification unit is installed, USP DQI will provide a GMP training to Mahidol, who in turn, as part of ANEQAM, will organize a GMP training course at their facility for participants from Thailand, Laos, Cambodia, and Vietnam

- The Chulalongkorn QC laboratory, with the technical assistance of USP DQI, will give their first training as a Center of Excellence on artesunate testing to 15 participants from Laos, Cambodia, Vietnam, and Thailand in December 2007
- Leasing and installation of specialized BE software from UST CeDRES to the National Institute for Drug Quality Control in Vietnam by December 2007

Program: RDM/A6-HIV/AIDS

Key Staff: S Phanouvong

Objectives:

- Strengthen good distribution, dispensing and storage practices in two Mekong countries as related to DQ in national HIV/AIDS programs.
- Dissemination of technical information on quality of ARVs to improve national procurement processes.
- Document and disseminate the information on quality, suppliers, costs of HIV/AIDS, and ARVs in the region based mainly on data obtained from drug quality surveillance project
- Collect and test samples of selected ARVs in four Mekong countries as part of the quality surveillance activities (RDM/A 4)

Focus for the quarter:

- Prepare for ARV sampling activity in four Mekong countries.

Activities:

- Completed and submitted to RDM/A Mission the portfolio review of FY07 RDM/A HIV/AIDS activities.
- Conducted in collaboration with National Institute of Malariology, Parasitology and Entomology, Ministry of Health of Vietnam a training workshop on 'Establishing anti-infective drugs quality monitoring' on Sept, 18-22, 2007 in Hanoi, Vietnam, for 19 participants from 9 selected provincial sites.

Program: RDM/A7-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

Focus for the quarter:

- Attended the USAID Avian Influenza Program Workplan Development Meeting, September 19-21, 2007, Bangkok, Thailand

Activities:

- N. Davydova met with representatives of Pharmaceutical System Research and Intelligence Center (PSyRIC), a participating Institution of Asian Network of Excellence on Quality Assurance of medicines (ANEQAM), and discussed the status of the oseltamivir mapping project
- N. Davydova attended the USAID Avian Influenza Program Workplan Development Meeting and made a presentation about the USP DQI Avian Influenza program in South East Asia, September 19-21, 2007, Bangkok, Thailand

Outcomes:

- PSyRIC will send a final report on all oseltamivir manufacturers and distribution networks in Thailand by the end of October to USP DQI
- Dr. Sauwakon Ratanawijitrasin will develop training material on oseltamivir mapping methodology and will deliver a training to three countries: Cambodia, Laos, and Vietnam

Future Plans:

- USP DQI will identify institutions in Vietnam, Cambodia, and Laos who will be able to identify and map all oseltamivir manufacturers and distributors in the countries, using experience gained from Thailand
- USP DQI will support PSyRIC in delivering training to three countries: Cambodia, Laos, and Vietnam

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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

Focus for the quarter:

- Expand anti-infective medicine testing sites for early detection of poor drug quality.
- Collecting anti-infective medicine samples at the sentinel sites to detect poor drug quality; sending samples that fail for confirmatory testing.
- Introduce new program manager based in Rockville, Maryland, USA, and new project coordinator based in Bangkok, Thailand.

Activities:

- Organized and facilitated a training course on "Establishing Anti-Infective Drugs Quality Monitoring Using Basic Tests, Sampling Procedures, and Drug Quality Data Management." The training was attended by 20 participants from 10 provincial sites in Cambodia, including three new sites which share borders with Vietnam and Laos. ITN Channel 4 News, China Correspondence, filmed the training and interviewed USP DQI trainers (S. Phanouvong, E. Toledo and S. Bradby) about the problem of substandard/counterfeit medicines and the USP DQI program in Southeast Asia.
- Tested 20 samples of anti-infective medicines from the Thai pharmaceutical company Utopian by the Bureau of Drugs and Narcotics of Thailand due to quality concerns in Cambodia. The testing was carried out by the USP reference lab, Thai National Lab, and Cambodian National lab; received results on July 10, 2007.
- Provided essential laboratory equipment to the NLDQC and training for proper use and maintenance
- USP DQI staff met with partners from USAID, DDF, Pharmacists Association of Cambodia, WHO, PATH, and MSH in July and September to discuss new activities and to monitor the progress of existing projects.
- Facilitated training seminar/workshop on Bioavailability/Bioequivalence in conjunction with UST CeDRES, DDF Cambodia, USAID, and ANEQAM on September 26-28 in Siem Reap.
- Set up USP DQI/partner meetings in Phnom Penh for first week of October 2007.
- Visited Kampong Cham province to meet with PHD of K. Cham, FHI, BTC, and other partners.

Outcome:

- Training course successfully conducted.
- All Utopian samples passed at the USP reference lab and a report was generated.
- New activities were planned for FY 07 with partners during visits in July and September

Issues:

- Timeliness by the National Lab to perform sample confirmation from the sentinel sites and to release the results
- Timeliness by the DDF to release the data from the National Lab and lack of action to use this data to tackle counterfeit drugs

Future Plans:

- Maintain drug quality monitoring activities with the DDF at 10 sentinel sites. The USP DQI project coordinator and one DDF staff member will go on supervisory visits to the sentinel sites in 2008 to improve sample data collection and filling out the reports with the test results
- USAID Cambodia and USP DQI want the project coordinator to become more actively involved in all Cambodia activities, and he will visit frequently to meet with partners to monitor progress and/or challenges
- Collaborate on a follow-up article in Health Messenger on counterfeit drugs and how communities can use and learn from WHO's Dealers in Death VCD. USP DQI will support mass distribution of the VCD to all Health Messenger recipients (roughly 20,000 people)

- Collaborate with PATH and the Pharmacists Association of Cambodia to develop a drug quality and counterfeit/substandard drug module in Khmer to add to the existing curriculum provided to pharmacists
- Circulate a Public Service Announcement and other accompanying print materials on counterfeit medicines in Khmer
- Establish a medicines information center/unit in the DDF with two full time staff that will provide objective, accurate, and up-to-date information about medicines and their use. The center will also contribute to the fight against substandard and counterfeit drugs

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Program: Philippines

Key Staff: L Krech, M Hajjou

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

Focus for the quarter:

- To commence the project entitled, "Antituberculosis Drug Quality Monitoring" in 3 to 4 pilot sites with the Department of Health
- Plan and monitor activities with UST CeDRES
- Introduce new program manager

Activities:

- Monitor progress of UST CeDRES in the finalization of bioanalytical validation methods for selected fixed-dose combinations of anti-tuberculosis medicines requiring bioavailability/bioequivalence (BA/BE) studies according to the B-list of BFAD

Outcome:

- At UST CeDRES 5 reference standards are being used for bioanalytical methods validation

Issues:

- The project entitled "Antituberculosis Drug Quality Monitoring" should have begun last quarter. USP DQI staff repeatedly contacted our focal point at the Department of Health to begin this activity and also requested USAID/Philippines to intervene on our behalf to facilitate communication. No official response from the DOH was received until October of 2007, after Q4 ended, however, the proposal is now officially approved and activities will begin in conjunction with BFAD in Q1-Q2 of the next fiscal year.

Future Plans:

- USP DQI will provide a training on Good Laboratory Practices and proper use and maintenance of CeDRES' lab equipment and instruments.
- The program manager and chemist will start planning activities for the Antituberculosis Drug Quality Monitoring project and visit Manila early in 2008.
- UST CeDRES and USP DQI will provide technical assistance to BFAD to streamline the registration process.

Program: E&E-1 – Freedom Support Act/Moldova/NIS

Key Staff: K Burimski

Objective:
- Provide current and unbiased drug information to health practitioners.

Focus for the quarter:
- Answer drug information requests; disseminate drug bulletin

Activities:
- Moldova Drug Information Center (DIC) answered 272 requests from pharmacists, physicians, nurses, and patients
- Published a drug bulletin. Among the topics:
  - What is new in medications for asthma?
  - Drug Interactions: what you should know
  - About influenza vaccination
- Conducted a presentation on DIC objectives and drug information strategies for nurses in postgraduate courses
- Presented a poster on the DIC at the international conference MoldMEDIZIN & MoldDENT, September 11-14, 2007
- Participated in several medical conferences, including Role of Physician and Pharmacist in Rational Drug Use; Medicine and Life; Modern Issues of Etiology, Prophylactic, Diagnosis and Treatment of Tuberculosis; and others

Outcome:
- 272 drug information requests were answered
- Drug bulletin published

Future Plans:
- Continue to provide objective current unbiased drug information to health practitioners
- Publish next issue of drug information bulletin

Program: Russia

Key Staff: K Burimski, O Dmitrenok

Objective:

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

Focus for the quarter:

- Continue dissemination of the Infectious Diseases Textbook which was developed and printed in Q3

Activities/Outcomes:

- 2,962 copies of the Textbook were disseminated, including 2050 that were sold. The online version of the Textbook was visited 469,182 times during this quarter, bringing the total number of visits to 4,154,381. The third edition of the Textbook was presented at several medical conferences, including Pulmonology Congress in Kazan, Anesthesiology Conference in Saint Petersburg, and others

Issues:

- Many health care practitioners and medical and pharmacy schools staff take vacations during summer months, so the number of disseminated copies of the Textbook is expected to increase in the next quarter

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

Focus for the quarter:

- Assess progress of FY 07 activities and develop work plans for FY 08

Activities:

- Work plans for FY08 finalized
- Participation at Steering Committee Meeting in Washington, DC

Outcome:

- Partners work plans evaluated at the Steering Committee Meeting and suggestions and recommendations for proposed activities discussed
- 1, 3 and 5 Master Plan will be developed by partners
    - USP DQI is member of the Case Management, Drug Access and Use, and the Malaria Vector Control, Monitoring and Evaluation working groups
- Partners' work plans will be aligned with the 1, 3 and 5 year Master Plan that is in development

Future Plans:

- Complete 1, 3 and 5 year Master Plan
- Develop, with MSH and PAHO, a Concept Paper and Preliminary Agenda for a workshop on Quality Management in the Medicines Supply Chain, for AMI and SAIDI countries
- Develop Template Table for reporting MiniLab results
- Finalize timetables and identify, engage, and develop resources for FY 08 activities
- Trip to Peru to assess difficulties encountered with MiniLabs use (SAIDI related meetings planned during this trip)

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)

Focus for the quarter:

- Assess progress of FY 07 activities and develop work plans for FY 08
- Continue coordination of post-marketing quality surveillance of antibiotics and TB medicines with countries' DRAs

Focus for the quarter:

- Assess progress of FY 07 activities and develop work plans for FY 08
- Continue coordination of post-marketing quality surveillance of antibiotics and TB medicines with countries' DRAs

Activities:

- Work plans FY08 finalized
- Participation at Steering Committee Meeting

- Second round of antibiotics and TB medicines in La Paz, Bolivia, completed and analyzed (21 samples)
- First (re-sampling) round of antibiotics and TB medicines in Asunción, Paraguay, completed and analyzed (33 samples)

Outcome:

- Partners work plans evaluated at the Steering Committee Meeting and suggestions and recommendations for proposed activities discussed and/or incorporated
- 1, 3 and 5 Master Plan will be developed by partners
- Partners' work plans will be aligned with the 1, 3 and 5 year Master Plan that is in development
- Bolivia and Paraguay have data on the quality of antibiotics and TB medicines
    - Sub-standard medicines identified
    - Follow up actions implemented

Issues:

- There have been delays in the response from Peru's DRA (DIGEMID) and OMCL for the sampling and analysis of antibiotics and TB medicines, due in part to a lack of coordination and communication between these two institutions. The person responsible at DIGEMID for the sampling left in October, and two new representatives have been assigned for this activity. These and other related issues will be addressed during the coming trip to Peru.

Future Plans:

- Complete 1, 3 and 5 year Master Plan
- Develop with MSH and PAHO a Concept Paper and Preliminary Agenda for a workshop on Quality Management in the Medicines Supply Chain, for AMI and SAIDI countries
- Finalize sampling for second round for antibiotics and TB medicines in Peru
- Finalize sampling for second round for antibiotics and TB medicines in Paraguay
- Trip to Peru to plan, discuss, and coordinate activities at the OMCL and DRA for FY 08 (AMI meetings planned during this trip)

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

Focus for the quarter:

- Obtaining authorization to conduct a training for DIC pharmacists in post-marketing surveillance for ADR of pharmaceuticals

Activities:
- Coordinated dates with KNH Partners.

Issues:
- Delayed due to issue of waiver required for GPHF-Minilabs® and scope of training.

Program: Madagascar

Key Staff: M Hajjou, PLukulay and L Elhadri

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 use of objective up-to-date information about medicines

Focus for the quarter:
- Support the national drug quality control laboratory (NDQCL) and expand its expertise to microbiological testing.
- Sampling and testing drugs available in the market

Activities:
- Organized and provide training on "Bacterial endotoxins testing using Gel-Clot technique.' The training was attended by all the five staff of NDQCL.
- A total of 226 samples were collected and tested at the sentinel sites. Confirmatory testing of 89 samples is underway at NDQCL.
- Supervisory visit was made to 2 sentinel sites to monitor the progress of drug sampling and testing.
- Review of the progress made in reporting drug adverse reaction.

Outcome:
- Training workshop successfully conducted. Bacterial endotoxins testing can be carried out at NDQCL instead of subcontracting this testing to an outside-country laboratory.
- Advice was provided to improve drug testing at the sentinel sites.
- New ideas were discussed to expand the expertise of Pharmacovigilance Center of Madagascar to include active reporting of drug adverse reaction.

Issues:
- The site for a first drug information center in Madagascar was identified. The establishment of this DIC is underway. This activity was not completely achieved and need to be pursued during FY08.

Program: Senegal

Key Staff: M Hajjou, P Lukulay and L Elhadri

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

Focus for the quarter:
- Support the drug quality monitoring program at the sentinel sites.

Activities:
- Review the progress report on anti-malarial drug monitoring at the sentinel sites.
- Budget a new round of drug sampling and testing.

Outcome:
- New round of drug sampling and testing focusing on anti-malarial drugs is underway.
- National drug quality control laboratory (NDQCL) completed the confirmatory testing of failed samples from previous rounds.

Issues:
- Slow coordination between the National Malaria Program (PNLP), NDQCL and the University of Dakar (UCAD) delayed the confirmatory testing of failed samples identified at the sentinel sites.
- Fund allocated to USP DQI for 2007 has not been obligated.

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

Focus for the quarter:
- Attended the President's Malaria Initiative (PMI) Stakeholders Meeting
- Attended the PMI partners progress review meeting
- Met with NDA to discuss the proposed USP DQI work plan for the PMI program's third year

Activities:

- N. Davydova met with NDA representatives to discuss proposed USP DQI year 3 (2008) activities in Uganda within PMI
- N. Davydova; Mr. Apollo Muhairwe, NDA Executive Secretary; and Dr. Anthonia Nakamia, the Head of NDQCL, met with USAID representatives Mr. Richard Greene Director, Office of Health, Infectious Diseases and Nutrition, USAID/ Washington, and Dr. Gunawardena Dissanayake, Senior Malaria Technical Advisor, USAID/Uganda at the NDQCL. Mr. Muhairwe informed the visitors how the NDA is organized and operates. Dr. Nakamia described the laboratory procedures for quality control and quality assurance of antimalarial medicines and related health products. N. Davydova and Dr. Nakamia outlined the year 1 (2006) activities that had been accomplished by USP DQI and NDQCL since NDA received financial support from PMI. Dr. Davydova described upcoming USP DQI activities on strengthening antimalarial drug quality control system in Uganda by establishing post-marketing surveillance activities in four selected provinces and in Kampala, which can reduce the prevalence of poor quality medicines circulating in the pharmaceutical market. N. Davydova also outlined the proposed year 3 (2008) work plan within PMI. Dr. Davydova, Mr. Nakamia, and Ms. Muhairwe answered questions that had been raised by Mr. Greene and Dr. Dissanayake. Dr. Nakamia then conducted a laboratory tour for the visitors
- N. Davydova attended the U. S. President's Malaria Initiative Stakeholders Meeting, which brought together various stakeholders involved in PMI to hear an update of the progress of implementation of PMI activities and to discuss the proposed plan for year 3
- N. Davydova attended the PMI partners progress review meeting and made a presentation about the USP DQI program, its accomplishments, and proposed activities within PMI

Outcome:

- The draft of the proposed USP DQI year 3 (FY 08) work plan within PMI was developed and will be sent to the USAID Uganda mission for future consideration
- Trip report on Uganda visit, July 9-13, 2007, was written and distributed

Future Plans:

- PMI FY 07 funds were allocated to USP DQI at the end of September, 2007. We have to wait for a waiver from USAID Washington to purchase 4 Minilabs for Uganda. As soon as the waiver is granted, 4 Minilabs will be purchased and delivered to Uganda, and time for a training workshop on the sampling of antimalarial medications and the proper use of the Minilab testing kit will be determined