

Cooperative Agreement # HRN-A-00-00-00017-00

SO/Project Title: SO2, SO3, SO4, SO5, RDM/A, LAC-1(AMI), LAC-2 (SAIDI), Africa Bureau, Cambodia, Europe & Eurasia FSA, Philippines, Russia, Madagascar & Uganda

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Grantee: United States Pharmacopeia - Drug Quality and Information Program

Sponsoring USAID operating units: Bureau for Global Health, Office of Health, Infectious Disease and Nutrition

Language: English

Date of Publication: July 31, 2006

USP Drug Quality and Information Program (USP DQI)

Third Quarter Program Report – FY 2007

April – June 2007

SO 2: Maternal Health and SO 3: Child Survival

- E. Toledo conducted a Good Manufacturing Practices (GMP) audit at Square Pharmaceuticals, Bangladesh to assess their new zinc sulfate manufacturing facility. In general, the company is in compliance with GMP, but will need to address the Corrective Action Plan (CAP) compiled for them in order to pursue pre-qualification.
- E. Toledo followed up with Shelys Tanzania on their progress related to the CAP for compliance with WHO GMP; Shelys is currently working with consultants to address USP DQI findings and conduct a gap analysis.
- J. Carpenter submitted the abstract *Zinc Adjunct in the Management of Children's Diarrhea: Ensuring Product Quality* to the 25th International Congress of Pediatrics to promote and disseminate among pediatricians the usefulness of zinc in diarrhea.
- J. Carpenter contributed to the drafting of the article *The use of chlorhexidine to reduce maternal and neonatal mortality and morbidity in low-resource settings* published in the International Journal of Gynaecology and Obstetrics in June 2007.

SO 4: HIV/AIDS

- D. Seyoum reviewed HIV/AIDS-related articles for the USP DQI website monthly update.
- D. Seyoum reviewed 40 late-breaker abstracts for the 4th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment, and Prevention to be held July 22 – 25, in Sydney, Australia.
- D. Seyoum followed up on the development of the USP/NF monographs for Nevirapine Oral Solution and Nevirapine Tablets. Both monographs have been finalized and will be official in subsequent USP/NF publications (the monograph for Nevirapine Tablets, as of August 1, 2007 and the monograph for Nevirapine Oral Solution, as of December 1, 2007).

SO 5: AMR/Infectious Diseases

- S. Phanouvong, M. Foster, D. Seyoum, M. McGinnis, and M. Ravichandran met regularly to revise the text of the Operational Guide, bringing information up to date and expanding various chapters based on suggestions from co-writers and reviewers. M. Foster and S. Phanouvong have edited text to incorporate those changes, and S. Phanouvong conducted a final technical review of the edited version.
- S. Phanouvong revised the edited version of the Rapid Assessment Tool for Quality Assurance of a Pharmaceutical Supply and Distribution System and sent it out to some 20 external reviewers for comments and suggestions.

- 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. During the International Conference on Global Health, 15 copies of the Matrix were distributed. The monthly page views of the Matrix are: April – 1,656; May – 1,531; June – 1,718 = 4,905 views for the quarter.
- A. Barojas reworked the outline and objectives for USP DQI’s E-learning course for USAID; this activity involved the participation of several USP DQI staff members. The course outline and objectives are attached.
- D. Seyoum contacted potential speakers for the upcoming FIP AMR Symposium in Beijing, China.
- D. Seyoum drafted an abridged form of the article “The Problem of Antimicrobial Drug Resistance” for publication with the International Pharmacy Journal (IPJ)
- D. Seyoum and O. Dmitrenok reviewed AMR/Infectious Diseases-related articles for the USP DQI website monthly update.
- K. Burimski traveled to Moscow, Russia to participate in the annual Man and Drug Conference and to meet with USAID/Moscow staff and local partners. USP DQI conducted a symposium “Quality of Pharmacotherapy: Medicines and Medicine Information” focused on the quality of anti-infectious therapy.
- Nauka & Zhizn (Science & Life), the oldest Russian popular science magazine (info in English available at <http://www.nkj.ru/en/about/>), published an article “Common Mistakes re Antibiotics” discussing common mistakes Russian physicians make while prescribing antibiotics to their patients and is based on the presentation of Dr. Irina Andreeva from Smolensk Medical Academy, which was given during the USP DQI Symposium at the 2007 Man and Drugs Conference. The journalist who wrote the article participated in the Symposium.
- The Smolensk team presented results of the Distance Learning Course at two conferences in Russia, including the Man and Drugs Conference in Moscow, and in an article “Distance Learning for Physicians: the Signs of the Times”¹. The article was published in Pharmaceuticheskaja Sluzba Journal established by Roszdravnadzor (Federal Health and Welfare Agency).

SO 5A: Tuberculosis

- S. Phanouvong and E. Toledo participated in discussions with WHO/Global Drug Facility and USAID on assisting WHO/GDF to improve access to second-line anti-TB drugs for the Green Light Committee Program. This activity included reviewing the draft Expression of Interest by WHO.
- At WHO’s request, D. Seyoum reviewed one article related to tuberculosis that was submitted to the Bulletin of WHO.
- D. Seyoum reviewed tuberculosis-related articles for the USP DQI website monthly update.

SO 5B: Malaria

- S. Phanouvong participated in planning for a joint study with WHO HQ on antimalarial drug quality in selected countries in Africa. This included planning for a meeting in Tanzania on July 4-5, 2007, and a review of the draft protocol for the study.
- N. Davydova made a presentation on “Drug Quality Monitoring Using Minilab Technology” for the Study of Quality of Antimalarial Medicines in Sub-Saharan Africa (QAMSA) meeting held in Dar es Salaam, Tanzania.
- D. Seyoum drafted a paper on “The Quality of Antimalarial Medicines” and submitted it for publication with the East African Network for Monitoring Antimalarial Treatment (EANMAT) Newsletter.

RDM/A1: Mekong Malaria

- S. Phanouvong revised the draft study protocol on antimalarial drug quality in the Cambodia-Thailand border areas using a randomized sampling method.

¹ Andreeva I.V. Distance Learning for Physicians: the Signs of the Times. Pharmaceuticheskaja Sluzba 2007; 4: 12-14.

RDM/A1: Mekong Malaria; RDM/A4: Mekong Expansion; RDM/A6: HIV/AIDS

- S. Phanouvong provided technical guidance to program counterparts (Food and Drugs Dept., National Lab, Malaria and other priority disease programs, and provincial sentinel sites health authorities) on the implementation of ID medicines quality monitoring in Cambodia and Laos.
- S. Phanouvong 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.

RDM/A5: Centers of Excellence

- N. Davydova conducted a meeting with Chulalongkorn University Center of Excellence partners where a time line for USP DQI – QC lab/PSyRIC FY07 activities was developed.
- N. Davydova developed training modules on HPLC and Dissolution to support and enable the Chulalongkorn QC lab to provide training on testing artesunate preparations to regional clients.
- N. Davydova collaborated with Chulalongkorn University/ PSyRIC partners on the development of a Drug Quality Information Database using regional antimalarial drug quality study data.

RDM/A6: HIV/AIDS

- S. Phanouvong participated in the Joint Training Workshop on Medicines Quality Assurances, Good Practices for the Procurement, Distribution, Storage and Dispensing of Pharmaceuticals, with focus on antiretroviral medicines held on June 25 - 29, 2007 in Savannakhet, Laos for provincial health officials, hospital pharmacists, and distributors; E. Toledo conducted a Good Storage Practices course and D. Seyoum developed a training module on Good Dispensing Practices for the workshop.

RDM/A7: Avian Influenza

- N. Davydova, S. Phanouvong, and M. Welsch followed up on the publishing of the basic testing method manual for oseltamivir with the German Pharma Health Fund. The manual was published and disseminated to selected US-based institutions and individuals.
- N. Davydova met with the Chulalongkorn University/PSyRIC partners on the Oseltamivir mapping project in Thailand; an outline and timeline for the project were drafted. N. Davydova reviewed the intermediate progress report and sent comments and recommendations for further action.
- N. Davydova attended the USAID AI Partners meeting and Regional Avian and Pandemic Influenza research meeting, in Bangkok, Thailand; N. Davydova gave a presentation “USP DQI Program Activities on Avian Influenza in South East Asia” at the AI Partners meeting.

LAC-1-Amazon Malaria Initiative

- V. Pribluda participated in a debriefing session on AMI to Admiral Tim Ziemer, Coordinator, President's Malaria Initiative, as part of an external evaluation commissioned by USAID. A. Barojas and V. Pribluda supported external evaluators by providing documentation of USP DQI activities for both AMI and SAIDI, reviewing evaluators' documents, and participating in meetings and debriefings to USAID officials.
- A. Barojas and V. Pribluda organized the Drug Quality Conference for all AMI and SAIDI participating countries to be held in September in Lima, Peru.

LAC-2- South American Infectious Diseases Initiative

- V. Pribluda assessed Paraguay's drug regulatory agency (DNVS), installed SIAMED registration software, and trained personnel
- A. Barojas attended and participated in the SAIDI panel presentation at the International Conference on Global Health. The SAIDI presentation emphasized the success of the approach of international and national partners working together in developing and implementing effective and sustainable interventions to contain anti-microbial resistance.

- A. Barojas and V. Pribluda attended the SAIDI Steering Committee Meeting, gave presentations, and participated in the evaluation of current activities and preparation for next year's programs.
- A. Barojas coordinated sampling rounds of antibiotics and anti-tuberculosis medicines with the regulatory agencies and official medicines control laboratories of Bolivia, Paraguay, and Peru.

Africa Bureau

- D. Seyoum and S. Phanouvong worked with the Pharmacovigilance Department of the Pharmacy and Poison Board (PPB) in supporting the Pharmacovigilance system in Kenya by proposing a training on the use of Minilabs[®] for identifying counterfeit and substandard antimalarial drugs at the two pharmacovigilance reporting sites in collaboration with the PPB, National Drug Quality Laboratory, and the Department of Malaria Control (this training is subject to USAID approval).
- D. Seyoum continued working with the Kenyatta National Hospital (KNH) Drug Information Center (DIC) in Nairobi, Kenya. The KNH is in the process of setting up a financial system for the DIC; once this is done, USP DQI will transfer funds for the purchase of computers and office equipment.

Cambodia

- S. Phanouvong and E. Toledo continued to provide technical and managerial guidance on the expansion of anti-infective medicines quality monitoring in Cambodia.
- S. Phanouvong and E. Toledo worked closely with the Admin team to prepare the training workshop materials for "Establishing anti-infective drug quality monitoring mechanisms in 10 provinces in Cambodia."
- S. Phanouvong followed up on the progress of the testing of samples collected from Utopian Company in Cambodia with Bureau of Drugs and Narcotics in Thailand, USP, and National Lab in Cambodia. This involved regularly checking how many of the tests had already been completed as well as discussing and addressing any technical issues that may have hampered progress.

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

Moldova DIC of the National Institute of Pharmacy:

- Answered 387 requests from pharmacists, physicians, nurses, and patients.
- Developed and prepared "Drug Bulletin" for publication. Selected topics include: "Top 10" Drug Errors and How to Prevent Them, Information from the USP DQI Symposium at Man and Drug Conference 2007.
- Sent 2 adverse drug reactions reports to the Republic Adverse Drug Reactions Center.
- Conducted a presentation on DIC objectives and drug information strategies for pharmacists and nurses in postgraduate courses.

Madagascar

- M. Hajjou prepared a training module on Bacterial Endotoxins testing to be delivered July 16-20, 2007; also provided Drug Quality Control Lab (DQCL) with lab supplies needed for the training workshop.
- M. Hajjou provided the Pharmacovigilance team with reference books as requested.
- M. Hajjou provided additional lab supplies and USP reference standards to DQCL; also transferred funds to purchase reagents and non-USP reference standards needed for the Drug Quality Monitoring Program.

Philippines

- J Carpenter and M. Hajjou drafted the project description for the Anti-TB Quality Monitoring program and sent it to the Ministry of Health for review.
- M. Welsch and M. Hajjou sent reference standards to UST CeDRES, as requested. These standards will help CeDRES develop the required methodology to validate bioanalytical procedures and fulfill its mandate to assure the quality of medicines by requiring bioequivalence testing before a generic product

can be registered and marketed. The protocol validation is necessary for USP CeDRES to be able to support BFAD.

- M. Hajjou purchased and sent LC-MS HPLC supplies to UST CeDRES, as requested. These materials are necessary in order to upgrade their capabilities to support BFAD.
- M. Hajjou provided BFAD with a complementary copy of USP 30 NF 25.

Russia

- The third edition of the Infectious Diseases Textbook was published and presented during the joint Congress of the Interregional Association for Clinical Microbiology and Antimicrobial Chemotherapy (IACMAC) and British Society for Antimicrobial Chemotherapy (BSAC) in Moscow May 30 – June 1. K. Burimski traveled to Russia to participate in the presentation. 5,240 copies of the Textbook were disseminated, including: USAID/Russia - 100 copies, WHO/Russia TB program - 70 copies, University Research Centers/Moscow - 400 copies, AIHA/Moscow - 400 copies, Moscow Medical Academy - 550 copies, Moscow University of Peoples Friendship - 100 copies, Novgorod DIC - 300 copies, Vladivostok DIC - 420 copies, two Ryazan DICs - 100 copies each, PHARMEDINFO – 400 copies. Approximately 1500 copies were disseminated via conferences, including 800 at the joint IACMAC and BSAC Congress. 200 copies were sent to individuals via online requests (shipping and handling was paid by requestors). 600 copies were sold, including 100 to individuals, and 500 to the pharmaceutical company LEC. The price of the Textbook is 480 rubles (approximately \$19), plus shipping and handling. The on-line version of the Infectious Diseases Textbook was visited 102,432 times during this quarter, bringing the total number of visits to 3,685,199. The Chairman, Department of Pharmacology, School of Pharmaceutical Sciences of the Moscow Medical Academy sent a letter to USP DQI thanking the program for providing the Textbook. It is recommended by the Department as tuition materials for the Curriculum theme: Medicines for Anti-infection Therapy. The Textbook is recommended for third and fourth year students for all tuition forms, including tuition by correspondence.

Uganda

- N. Davydova made a presentation on “Strengthening Drug Quality Control Systems in Uganda under the President’s Malaria Initiative” for the PMI Stakeholders Meeting, Kampala, Uganda.

Other Activities

- J. Carpenter and K. Burimski hosted visitors from Addis Ababa University (AAU) and Drug Administration and Control Authority of Ethiopia and colleagues from Howard University. Howard University is in the process of establishing a twinning partnership with the AAU School of Pharmacy, lending its expertise in strengthening the education and training of the pharmacy profession in Ethiopia. This partnership is being organized under the American International Health Alliance's Twinning Against HIV/AIDS Program. USP DQI staff gave a short overview on its activities, focusing on experience in establishing and sustaining DICs in Romania, Moldova, and other low-income countries.

Planned for Next Quarter

- Follow up to obtain formality clearance from the relevant authorities in Vietnam and Thailand so that USP DQI will be able to continue to support the two countries’ activities.
- Publish the final version of the *Operational Guide*.
- Publish the revised USP DQI brochure.
- Incorporate comments to the final version of the Rapid Assessment Tool for Quality Assurance of a Pharmaceutical Supply and Distribution System.
- Continue working with the Drug Information Center at the Kenyatta National Hospital (KNH) in Nairobi, Kenya to set a date for the training of DIC staff at KNH and Thika District Hospital.
- Pending USAID approval, participate in the joint workshop on “Principles of good laboratory practices, basic tests, sampling procedures, and data documentation and reporting for medicine quality” in Nairobi,

Kenya to support drug quality testing of ACTs, and building local capacity for peripheral testing of antimalarials.

- Participate at the upcoming 67th FIP Congress in Beijing, China and act as the congress chair at the FIP AMR Symposium.
- Continue to review tuberculosis, malaria, HIV/AIDS, and AMR/infectious diseases related articles for the USP DQI website monthly update.
- Coordinate dissemination of the third edition of the Infectious Diseases Textbook.
- Participate at the QAMSA study meeting in Tanzania
- Make a presentation on zinc for diarrhea at the International Congress of Pediatrics