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SO/Project Title: Common Agenda, Mainstream, SO2, SO3, SO4, SO5, RDM/A, LAC-1(AMI), LAC-2 (SAIDI), Europe & Eurasia FSA, Romania, Cambodia, Russia, & Uganda

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USP Drug Quality and Information Program (USP DQI)

First Quarter Program Report – FY 2007

October – December 2006

Common Agenda

- S. Phanouvong convened team discussions and planned for the finalization of *Improving the Quality of Medicines in Low-Income Countries: an Operational Guide*. The activities included sending out emails and postal mails to all identified experts, reviewers, and co-authors; assigning specific tasks to the responsible parties; and setting timelines for completion
- S. Phanouvong completed the first draft of a rapid assessment tool for quality assurance of a pharmaceutical supply and distribution system
- J. Carpenter and M. McGinnis revised the *Matrix of Drug Quality Reports in USAID-assisted Countries* and disseminated it on the USPDQI website. In addition, a total of 113 copies were distributed this quarter: 35 copies were sent to USAID's MAQ Mini University, 70 to the first Africa Regional Consultative Workshop on Antimalarial Drug Quality in Tanzania, 5 to John Snow, Inc., and 3 to O. Dmitrenok in Moscow
- A. Timmermans presented a poster at the 38th Annual Conference the Asia Pacific Academic Consortium for Public Health (APACPH) in Bangkok on December 5, 2006 regarding "Factors Affecting Prescribing of Anti-malaria Drugs for the Treatment of Uncomplicated Malaria Falciparum in Public Health Facilities in Kanchanaburi Province."
- A. Timmermans participated in a preparation meeting at the Thai FDA for the Cross-Border Health Meeting on Food Safety and Hygiene and Counterfeit Medicines in Phnom Penh, on December 13-14, 2006
- K. Burimski met with Tanya Soldak, Medical Director, CitiHope International and discussed a possibility of USP DQI participating in the drug information conference that CitiHope International is planning to conduct in Kyrgyzstan
- M. Foster updated the USP DQI website monthly
- M. Foster and M. McGinnis completed writing and/or updating content and structure for the new USP DQI website
- M. Welsch, M. Foster, M. Ravichandran, and K. Burimski took a one-day training course on Mastering USAID Rules and Regulations provided by the Center for Public Management
- USP DQI Marking Plan was approved by the USP Legal Department and by USAID

Mainstreaming

- N. Davydova and Imed Lassoued (Direction de Pharmacie et du Medicament – Tunisia) assessed the drug regulations, registration practices, and allocated resources to facilities of the Center for Innovation and Supply (CIS) in Azerbaijan

- N. Davydova met with CIS management to review observations during the assessment. Next steps and activities that are necessary to strengthen the drug quality control system in Azerbaijan were discussed.
- N. Davydova conducted a meeting with USAID/Azerbaijan team about the observations and suggestions for future activities to strengthen the drug quality control system in Azerbaijan
- N. Davydova and C. Wachira met with USAID and MSH-RPM Plus colleagues to discuss technical assistance activities for Azerbaijan

SO 2: Maternal Health and SO 3: Child Survival

- The revised zinc tablet monograph has been finalized and published in *USP 30*
- The document entitled *Production of Zinc Tablets and Zinc Oral Solutions: Guidelines for Programme Managers and Pharmaceutical Manufacturers* is under WHO final review, after being reviewed by J. Carpenter, A. Smine, and M. McGinnis; it is scheduled for publication by WHO in late January 2007
- J. Carpenter drafted SO2 and SO3 portfolio reviews
- J. Carpenter drafted update report of zinc activities for USAID SO3 team
- The revised USP monograph on oxytocin is under review by the USP Expert Committee
- E. Toledo and A. Smine participated in a GMP audit at Shelys Pharmaceutical in Tanzania to assess its regulatory compliance toward achieving WHO prequalification for manufacturing zinc sulfate; E. Toledo recommended a GMP corrective action plan (CAP)
- E. Toledo worked with Nutriset to follow up scheduling a visit to assess air handling unit validation
- E. Toledo worked with Square Pharmaceutical Bangladesh regarding process validation documentation for zinc tablets submitted to USPDQI and planned for the next assessment visit
- M. Hajjou, S. Bradby, and A. Smine tested zinc samples from UNICEF, Bangladesh and Tanzania

SO 4: HIV/AIDS

- D. Seyoum followed up on the process of development of a USP/NF monograph for Nevirapine Oral Solution and Nevirapine Tablet; Both monographs are under public review The monograph for Nevirapine Oral Solution was published in Pharmacopeial Forum (PF) 32(4), and the monograph for Nevirapine tablets was published in PF 32(3).
- D. Seyoum worked on the development of information on antiretroviral drug interactions
- D. Seyoum reviewed HIV/AIDS related articles for the USP DQI website monthly update

SO 5: AMR/Infectious Diseases

- D. Seyoum researched clinical information on antimicrobial drug resistance in support of the information being developed for the FIP position statement on AMR
- D. Seyoum and O. Dmitrenok reviewed AMR/Infectious Diseases related articles for the USP DQI website monthly update
- O. Dmitrenok and K. Burimski started preparation for the USP DQI symposium at “Man and Drug” conference in Moscow in April 2007. Presentations, speakers, invitees, etc. were discussed and partially selected
- Eight students in Russia completed the Distance Learning Continuing Education Course provided by the Smolensk Medical Academy; 54 students are currently enrolled. Four students completed the Distance Learning Continuing Education Course provided by secondary Distance Learning Continuing Education Centers and 35 are currently enrolled. In total, 277 students from Russia and the NIS have completed the course, including 22 students trained by secondary Centers
- The Smolensk team presented results of the Distance Learning Course at seven conferences in Russia, Belarus, Ukraine, and at Eighth International Congress on Drug Therapy in HIV Infection in Glasgow
- On the www.antibiotic.ru website, 54 new topics were added, including eight devoted to HIV infection, five to TB, and seven to AMR. Titles of selected topics include: “Treatment for adult HIV infection: 2006 recommendations of the International AIDS Society-USA panel”, “A multicenter observational

study of the potential benefits of initiating combination antiretroviral therapy during acute HIV infection”, “Survival rate and risk factors of mortality among HIV/tuberculosis-coinfected patients with and without antiretroviral therapy”, “Improving antibiotic selection: a systematic review and quantitative analysis of quality improvement strategies”

- 13 electronic drug bulletins from www.antibiotic.ru were e-mailed to 2582 subscribers
- The Smolensk team moderated antimicrobial therapy forums for health care professionals on the www.antibiotic.ru site
- The Smolensk team updated information (Russian and English versions) of the map of antimicrobial resistance in Russia, including new data on *Mycobacterium tuberculosis* (<http://www.antibiotic.ru/map/rus/>, <http://www.antibiotic.ru/map/eng/>).
- The online version of the Infectious Diseases Textbook was visited 104,670 times during this quarter, bringing the total number of visits to 3,476,084
- The on-line version of the Guide to Infection Control in the Hospital was visited 9,446 times this quarter, bringing the total number of visits to 226,898
- V. Rafalski and I. Andreeva from Smolensk team presented a poster and published the abstract “Possible role of distance education for improvement of physicians' knowledge concerning antiretrovirals and HIV/AIDS therapy and prevention in resource-poor settings” at the Eighth International Congress on Drug Therapy in HIV Infection. 12-16 November 2006, Glasgow
- O. Dmitrenok wrote and published an article on the rational treatment of vaginal candidiasis, including recommendations for HIV patients, in Russian medical journal “Pharmateca”

Vladivostok DIC staff: (detailed activities report-Appendix 1)

Novgorod DIC staff: (detailed activities report-Appendix 1)

Ryazan Central Oblast Hospital DIC staff: (detailed activities report-Appendix 1)

Ryazan State Medical University DIC staff: (detailed activities report-Appendix 1)

SO 5A: Tuberculosis

- D. Seyoum participated in the 37th Union World Conference on Lung Health of the International Union Against Tuberculosis and Lung Disease (IUATLD) between October 31 and November 4, in Paris, France. At a satellite symposium, D. Seyoum gave a PowerPoint presentation on “Antituberculosis drug resistance and multidrug-resistant tuberculosis (MDR-TB).”
- D. Seyoum reviewed tuberculosis related articles for the USP DQI website monthly update

SO 5B: Malaria

- A. Smine and C. Wachira, in collaboration with RPM Plus, organized the first “Africa Regional Consultative Workshop on Antimalarial Drug Quality”, which convened on November 14-16, 2006, in Dar es Salaam, Tanzania; A. Smine gave three presentations during the workshop, facilitated discussions, and responded to technical questions about pharmacopeial issues
- A. Smine, in collaboration with WHO and the Pharmacovigilance Center in Morocco, prepared for the pharmacovigilance workshop scheduled to take place in Morocco in February 2007. All Francophone African countries will participate
- D. Seyoum and C. Wachira conducted an assessment of the Kenyatta National Hospital (KNH) Drug Information Center between November 18 and December 2, 2006 in Nairobi, Kenya
- A. Timmermans assisted the USP laboratory with the procurement of primaquine samples from GPO Thailand for monograph development

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

- M. McGinnis submitted an article to the USAID Health, Infectious Diseases, and Nutrition (HIDN) Newsletter about the recent success of the Moldova DIC, which is now self-sustaining

Moldova DIC of the National Institute of Pharmacy:

- Answered 191 requests from pharmacists, physicians, and nurses
- Developed, published, and distributed among health care professionals 3500 copies of Drug Bulletin devoted to rational drug use
- Sent 3 adverse drug reactions reports to the Republic Adverse Drug Reactions Center
- Conducted two presentations on DIC objectives and drug information strategies for physicians, pharmacists, and nurses in postgraduate courses and in out-patient settings of Chisinau

E&E-2: SEED

- Cluj, Romania DIC quarterly report attached

M. McGinnis submitted an article to the USAID Health, Infectious Diseases, and Nutrition (HIDN) Newsletter about the recent success of the Romania DIC, which is now self-sustaining

RDM/A1 and 4: Mekong and Mekong Expansion

- S. Phanouvong provided technical guidance on management (i.e., implement, supervise, coordinate, follow-up, and report) of ID drugs quality monitoring in Cambodia, Laos, and Vietnam
- S. Phanouvong presented “Antimalarial Drug Quality Monitoring in Mekong Region – Lessons Learned” in a WHO Regional Workshop for Malaria Control Program managers, organized by WPRO in Manila on October 3-7, 2007. The Workshop had approximately 80 representatives from 12 countries in WPRO and SEARO
- S. Phanouvong compiled a list of laboratory equipment, supplies, and chemical reagents and reference substances that USP DQI has provided to strengthen the national regulatory authorities and their drug quality control labs in the Mekong Region for RDM/A
- S. Phanouvong prepared a response to Malaria Obligation Reporting Application System with information that RDMA requested
- J. Carpenter participated in the WHO Regional Workshop for Malaria Control Program Managers that was organized by WHO/WPRO and held October 3-7, 2006, in Manila, Philippines; while there, J. Carpenter and S. Phanouvong met with the USAID Regional Mission and other partners
- A. Timmermans assisted USP DQI team members in follow-up (monitoring and supervision) to make sure that the project activities in Asia are implemented successfully
- A. Timmermans attended the follow-up meeting (to last month's meeting in Ubon Ratchathani) with development partners on the Cross-Border Health project (Thai/Lao and Thai/Cambodian border) at the Ministry of Public Health of Thailand in Bangkok on October 5, 2006
- A. Timmermans coordinated with Dr. Saowanit Vijaykadga, Technical Officer in the Malaria Cluster (Bureau of Vector-Borne Diseases-BVBD), MOPH Thailand regarding current and future drug quality monitoring activities by the BVBD. She went on a 2-day field trip in Kanchanaburi Province, Thailand on November 20-21 to meet with staff involved in sampling and basic testing of antimalarials
- A. Timmermans, in collaboration with the USP DQI team, prepared a USP DQI webpage on the new website of the Kenan Institute of Asia
- A. Timmermans assisted Dr. Saowanit Vijaykadga with document review for a movie and a poster on the National Malaria Control Program, both developed by the Bureau of Vector-Borne Diseases
- A. Timmermans attended and participated in a workshop entitled “Review of The Recent Malaria Control Program Strategy in Thailand and Recommendations for a New Five-Year Strategy”, organized by the Ministry of Public Health, during 4-6 November 2006, at the Orchid Hotel in Chiang Mai Province
- A. Timmermans attended and participated in the USAID Regional Partners Malaria Strategy Review and Planning Workshop during November 7-8 2006, at the Orchid Hotel in Chiang Mai Province

RDM/A-5: Centers of Excellence in Quality Assurance of Medicines

- A. Timmermans assisted Mahidol University with the procurement of a water purification system (identifying and contacting suppliers, assisting with requests for quotations, regular follow-up). Three quotations have been obtained
- E. Toledo developed GMP modules for Mahidol School of Pharmacy
- E. Toledo worked with Mahidol to acquire a water purification system in compliance with WHO GMP

RDM/A-6: HIV/AIDS

- USP DQI staff worked with Vietnamese and other international partners to prepare a draft proposal for activities intended to expand the role of pharmacists in the management and treatment of HIV/AIDS in Ho Chi Minh City

RDM/A-7: Avian Influenza

- S. Phanouvong contributed to the development of basic testing methods by the German Pharma Health Fund on oseltamivir capsules
- M. Hajjou, S. Bradby, and A. Smine tested the suitability of German Pharma Health Fund basic methods for testing oseltamivir preparations

Cambodia

- S. Phanouvong coordinated, with S. Bradby and L. Straker, the purchase of one spectrofluorometer for the National Laboratory for Drug Quality Control of Cambodia. The equipment was installed in December; familiarization training to operate the equipment was conducted by the supplier, and the equipment is being used by the lab professionals
- S. Phanouvong assisted the Ministry of Health and Department of Food and Drug of Cambodia to organize an Inter-Ministerial Committee for Eliminating Counterfeit and Substandard Medicines, and Illegal Health Care Services for Poverty Alleviation workshop in Phnom Penh on October 9-10, 2006. The workshop had some 90 representatives from 8 ministries and organizations. A. Timmermans, J. Murphy, and S. Phanouvong participated in the meeting
- S. Phanouvong, upon the request of USAID Mission in Cambodia, collected information and documented the list of locally produced ARVs and the registration status of ARVs in Cambodia
- A. Timmermans assisted A. Smine with a technical visit to Cambodia between December 5-13, 2006 to meet with the USAID Mission, FDD, NLDQC, CNM, and the GFATM. A. Timmermans also conducted a 2-day field visit to Battambang Province to collect basic information for the planned antimalarial drug quality study along the Thai-Cambodia border in 2007
- A. Timmermans coordinated with MEDiCAM and WHO in Cambodia regarding USP DQI's presentation on Counterfeit Medicines at the 4Ms meeting in Phnom Penh, Cambodia on January 19th, 2007
- A. Smine worked with CNM, DDF, and USAID on the best strategy to assist the Cambodian DDF address the issues of substandard and counterfeit drugs
- A. Smine facilitated communication between NLDQC and the Global Fund Second Generation Surveillance (SGS) lab on analytical methods for mefloquine and artesunate

LAC-1-Amazon Malaria Initiative

- A. Smine and V. Pribluda participated in the Steering Committee Meeting in Washington D.C.
- V. Pribluda collaborated with PAHO in the preparation and translation of documents for sampling methodology for antimalarial drugs in sentinel sites
- A. Barojas and M. Hajjou trained the QC lab of Guyana (FDD) on USP-NF General Notices, GLP, HPLC, Dissolution, and UV

- A. Barojas and M. Hajjou conducted a workshop on basic tests and use of Minilabs in Guyana for Guyana and Suriname
- V. Pribluda met with DINAMED and Malaria Program personnel in Bolivia to discuss work in progress and future activities
- V. Pribluda prepared Operation Plans for FY07 and FY08

LAC-2- South American Infectious Diseases Initiative

- A. Barojas, A. Smine, and V. Pribluda participated in the Steering Committee Meeting in Virginia
- A. Barojas and V. Pribluda prepared, with Links Media, the Communication Grid for Bolivia, Peru, and Paraguay
- A. Barojas and V. Pribluda coordinated with Paraguay and Peru the implementation of the second round of sampling of antibiotics and TB medicines
- A. Barojas and V. Pribluda assisted the QC laboratory in Peru on ISO 17025 implementation
- A. Barojas and N. Davydova purchased and coordinated the shipment of HPLC equipment to CONCAMYT, Bolivia
- V. Pribluda prepared Operation Plans for FY07 and FY08

Russia

- Agreement regarding development of the Third Edition of the Infectious Diseases Textbook was signed with the Interregional Association for Clinical Microbiology and Antimicrobial Chemotherapy (IACMAC). The updated edition will include monographs on newly introduced antimicrobials, quality of antimicrobial drugs, and avian influenza
- O. Dmitrenok and K. Burimski monitored the development of the Third Edition of the Infectious Diseases Textbook. All drug information monographs have been updated. The following monographs have been completed: nosocomial infections, infections of face and neck, anti-infectious therapy in pregnancy and lactation

Uganda

- N. Davydova and S. Bradby provided technical assistance to the National Drug Quality Control Laboratory in Uganda regarding testing of ITNs
- N. Davydova attended a post-summit briefing "White House Summit on Malaria: Mobilizing to Fight Malaria Now" December 15, 2006, Washington D.C.

Planned for Next Quarter

- Participate in the Cambodia National Anti-malaria Drug Policy Workshop on January 24-26, 2007
- Participate in WHO Informal Consultation Workshop on containment of antimalarial multi-drug resistance on Cambodia-Thailand border areas, in Phnom Penh Jan 29-30, 2007
- Finalize the FY07 work plans assigned and plan to execute them according to the set time frame
- Continue to review and, where appropriate, incorporate comments received into the final version of the Operational guide
- Revise and disseminate *Matrix of Drug Quality Reports in USAID-assisted Countries*
- Finalize the oxytocin monograph
- Participate in the pharmacovigilance workshop in Africa
- Continue working with the Drug Information Center at the Kenyatta National Hospital (KNH) in Nairobi, Kenya. As indicated in the initial proposal, the next steps for strengthening the DIC at the KNH will include: supplying necessary equipment, computer software, medical and pharmaceutical literature, and printed reference materials, as well as training staff.
- Finalize and disseminate the information developed on antiretroviral drug interactions

- Continue to review tuberculosis, malaria, HIV/AIDS, and AMR/infectious diseases related articles for the USP DQI website monthly update
- Assist the USP DQI team with the preparation of the presentation on Counterfeit Medicines at the MEDiCAM 4Ms meeting in Phnom Penh on January 19, 2007
- Finalize study design and sampling protocol for anti-malarial drug survey along Thai-Cambodia border with relevant partners
- Collect information about oseltamivir distribution in Thailand
- Participate in the Cambodia National Anti-malaria Drug Policy Workshop organized by the National Center for Parasitology, Entomology and Malaria Control, Cambodia, in collaboration with WHO on January 24-26, 2007
- Participate in Cambodia-Thailand Consultation on Containment of Malaria Multi-Drug resistance, organized by WHO in Phnom Penh, on January 29-30, 2007
- Assist UST/CeDRES, Mahidol University, Chulalongkorn University with the implementation of ANEQAM activities as mentioned in the work plan
- Continue monitoring the development of the Third Edition of the Infectious Diseases Textbook
- Per USAID's approval, finalize the preparation for the USP DQI symposium and deliver a presentation at the "Man and Drug" conference in Moscow in April 2007

Appendix 1

Vladivostok DIC staff:

- Answered 403 requests from health care professionals, including 277 requests on antimicrobials (about 70% of total amount)
- Senior clinical pharmacologist of Primorski Region, Dr. Olga Danilchenko, participated in a regional TV program devoted to counterfeit drugs
- Prepared information at the request of health care professionals from the Primorski Region on monitoring drugs for restricted use
- Participated in the work of Central Regional Hospital and territorial Formulary Committees. Peer-reviewed data and prepared expert opinion on 5 drugs proposed for inclusion/exclusion from Territorial Formulary, conducted expertise of the list of drugs proposed for tendering for Central Regional Hospital of Primorski Region, and developed a list of essential drugs for emergency in cardiovascular events
- Conducted DUR on use of painkillers in Central Regional Hospital of Primorski Region, developed and tested questionnaire for prescribers on use of painkillers
- Analyzed rationality of prescribing narcotic, psychotropic and other drugs for restricted use (33 case reports), monitored drug use in out-patients departments in Vladivostok (256 case reports), provided expert assessment of drug therapy in four serious cases, including two lethal cases
- Participated in multi-center Russian study “Infection control measures in hospitals”
- Sent 31 reports about serious or unexpected adverse drug reactions not listed in the drug package insert to Federal Adverse Reaction Center

Novgorod DIC staff:

- Participated in the development of new Oblast Formulary List for centralized medicines purchases
- Maya Sviridenko from Novgorod DIC developed new presentation “Adverse drug reactions on antibiotics” and delivered this presentation at regional conference “Contemporary antibacterial therapy.” Presentation was delivered for 180 physicians
- Organized seven regional conferences for physicians and pharmacists of Novgorod and Novgorod Oblast, and delivered 2 workshops as invited lecturers in postgraduate courses at Novgorod Medical University. Titles of presentations included “Rational therapy of respiratory infections”, “Antibacterial therapy of STD and urinary infections”, “Sepsis protocol”

Ryazan Central Oblast Hospital DIC staff:

- Answered 486 drug information requests and prepared 124 brief reports for physicians of Ryazan Oblast Hospital
- Sent 8 adverse drug reactions reports to the Federal Adverse Drug Reactions Center, 2 of them on antibiotics

Ryazan State Medical University DIC staff:

- Organized and delivered 3 conferences and 4 workshops for prescribers, pharmacists, and medical students on different issues of rational drug use, including antimicrobial therapy of respiratory tract infections, and STDs
- Revised and updated training materials for medical students on formulary system and drug information