

**Promoting the Quality of Medicines (PQM) Program
Quarterly Reports: FY13 Activities (October 1, 2012–September 30, 2013)**

| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Common Agenda | K. Chibwe | | | | |
| Increase awareness about the importance of medicines quality | | | | | |
| Attend/present at national, regional, and int'l conferences | | <p>Four presentations were given by PQM staff:</p> <p>Dr. Lukulay presented at the AAPS lunch in Chicago, IL in Oct, the "Global Forum on Pharmaceutical Anti-Counterfeiting" in DC in Nov, and the ASTMH Meeting in Atlanta, GA in Nov.</p> <p>Dr. Chibwe presented to the Library of Congress in DC in Nov.</p> | <p>Dr. Lukulay was a member of the committee that drafted the consensus study, "Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products" published by the Institute of Medicine in February 2013.</p> | | |
| Use available media outlets to advocate need for medicines QA | | <p>Article on field-based QC tool published by Azerbaijan State Telegraph Agency; several articles documenting USP's participation in the Global Forum for Pharmaceutical Anti-counterfeiting published by media outlets; Dr. Lukulay gave an interview on counterfeits for the Care2 News Network</p> | <p>In Feb, USP issued a press release, "First Anti-TB Medicine under USAID-Supported PQM Achieves WHO Prequalification Status" and 2 media outlets published articles. USP also issued, "Handheld Device for Detecting Counterfeit and Substandard Medicines Tested by PQM" and 12 media outlets published articles. In Mar, USP issued "Medication Quality in Russia and Region Strengthened</p> | | |

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| | | | with Official Laboratory's Accreditation" and 2 media outlets published articles. | | |
| Pursue opportunities to advocate through the Voice of America | | In October, Dr. Lukulay was a panelist on the VOA TV2Africa daily magazine, In Focus, addressing public health and economic aspects of poor quality medicines. | | | |
| Produce up-to-date information about current issues in medicines quality | | | | | |
| Collect and publish reports of incidents of poor-quality medicine use | M McGinnis | 26 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 3,993 website hits | 17 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 2,664 website hits | | |
| Maintain and update PQM website | M Foster | 5 articles and 12 photos were added to the PQM website; 1 webpage was updated; 6 resources were added or updated | 10 articles and 12 photos were added to the PQM website; 1 webpage was updated; 3 resources were added | | |
| Support regional approaches and networks | | | | | |
| Contribute to NEPAD's "Institutionalization of Regulatory Training Programs in Africa using Existing Regional Structures" Technical Working Group (TWG) | | Dr. Karim Smine presented at the first meeting of the African Medicines Regulatory Harmonization TWG on Regulatory Capacity Development in Africa held Nov 2012 in South Africa. | The revised criteria for the establishment of Regional Centers of Regulatory Excellence (RCOREs) in Africa were issued. | | |
| Explore improved tools to ensure quality control or to increase the knowledge base about quality assurance | | | | | |
| Develop a field-based QC tool with increased accuracy, sensitivity, and reliability | K Chibwe | PharmaCheck prototype developed – to undergo optimization | Dr. Chibwe visited Boston University in February to observe progress on the | | |

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| | | | prototype; an oxytocin probe is also being developed. | | |
| Tuberculosis (TB) | | A. Hong | | | |
| Increase the supply of quality-assured second-line TB medicines | | | | | |
| Provide TA to mfrs of SL-ATBs identified in FY12 seeking WHO PQ | | <p>Dong-A Pharmaceutical Company was WHO prequalified in Nov 2012 for Cycloserine 250 mg capsules.</p> <p>TA continues to manufacturers in different stages of compliance with WHO PQ including Phapros, Indofarma, Dong-A, Arterium, Zhejiang Hisun Pharma, Shalina, Deurali Janta Pharma, Akrikhin, Simpex, Abbott, Sintez, and Farmasintez; Additional TA visits scheduled for next quarter: Korea United Pharma, Arterium, Phapros, Sandoz, and Indofarma</p> | <p>TA continues to manufacturers in different stages of compliance with WHO PQ, including Hisun Pharma, Arterium, HEC, Korea United Pharm, Abbott, Sintez, Phapros, and Dong-A; Additional TA visits scheduled for next quarter: Korea United Pharma, Arterium, Phapros, Sandoz, Xinhua, and Shanghai Fosun</p> | | |
| – To manufacturers currently in PQM pipeline | | <p>Currently in PQM pipeline: Concept Pharma, Macleod's, Arterium, Zhejiang Hisun, Dong-A Pharma, Varichem, Simpex Pharma, Deurali Janta Pharma, Korea United Pharma, Abbott, Lloyd</p> | <p>Currently in PQM pipeline: Hisun Pharma, DJPL, Arterium, HEC, Hizon Labs, Simpex, Korea United Pharm, Abbott, Humanwell, Sintez, Phapros, Dong-A, Shalina, Yabao Pharma, Farmasintez,</p> | | |

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| | | Labs, Hizon, Shalina, Humanwell, Sintez, Sandoz, Akrikhin, and Farmasintez | Akrikhin, Sandoz, and Unilab | | |
| – To manufacturers on preparing dossiers | | Dossier assistance is being provided to Arterium, Zhejiang Hisun, Shalina, Dong-A, Korea United Pharm, and Simpex | WHO PQ queries received for Arterium's FPP dossier in January 2013; Dossier training conducted for Korea United Pharm, EnzyChem Lifesciences; Kurgan Sintez and Shalina are compiling dossiers for submission | | |
| – With GMP audits and support until products are PQ'ed | | GMP assessment was performed for Abbott's CMO (Akorn); mock inspection was also performed at Hisun Pharma | GMP mock inspection conducted for Arterium | | |
| With GDF/WHO, conduct workshops in high burden countries; identify add'l mfrs not yet in PQM pipeline | | Decision was made to collaborate with CPHI Conferences to perform half-day seminars. CPHI Jakarta will be the first, scheduled for Mar 2013 | Manufacturers workshop conducted with CPHI in Jakarta in March | | |
| Identify/provide TA to key SL-ATB API suppliers to WHO PQ | | Zhejiang Hisun Pharma, Fuzhou Fuxing Pharma, North China Pharma, Dankang Pharma, Zhejiang Xinhua Pharma | Dong-A Pharma, Enzychem Lifescience, Zhejiang Hisun Pharma, Fuzhou Fuxing Pharma, North China Pharma, Dankang Pharma, Zhejiang Xinhua Pharma, Jinxin Pharma, HEC | | |
| – To API mfrs in PQM pipeline | | Total is now 11: Zhejiang Hisun, Shanghai Fosun, | Total is now 14: Zhejiang Hisun, Shanghai Fosun, | | |

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| | | Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Shenxue Dachen Pharma, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem | Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem, HEC, Suzhou Kaiyuan Minsheng, Dandong Beiqi, Zhejiang Excel Pharma | | |
| – To new mfrs on dossiers | | Zhejiang Xinhua Pharma | Xinhua Pharma, Fuzhou Fuxin, Dong-A | | |
| – With GMP audits and support until products are PQ'ed | | EnzyChem, Zhejiang Hisun Pharma, NCPC Huasheng, Hebei Shengxue Dacheng' | Enzychem, Zhejiang Hisun Pharma, NCPC Huasheng | | |
| Participate in GDF and WHO meetings with mfrs to discuss PQ | | Attended meeting with WHO PQ team in Geneva | No meetings attended | | |
| Complete development of Minilab [®] test methods for SL-ATBs | | Developed and published methods for Clarithromycin, Kanamycin, and Ofloxacin | No new methods developed | | |
| Obtain comparator products and assist select mfrs with funding for BE studies/capital investments | | Reference standards were provided to Shanghai Hefeng Pharma and Simpex; Comparator products were provided to KUP (Avelox), Farminguinhos (Trecator), and Simpex (Levaquin) | Comparator products provided to Hisun (Tarivid); Hefeng (Kanamycin); Shalina (Levaquin) | | |
| Reduce the prevalence of substandard and counterfeit SL-ATB medicines | | | | | |

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| Develop USP monographs for Prothionamide and Terizidone | | In progress | In progress | | |
| Conduct quality monitoring for SL-ATBs | | In progress | In progress | | |
| Develop the API bank concept and engage FPP manufacturers | | | | | |
| Develop the API Bank concept; identify/engage FPP producers to manufacture FPPs for GDF | | Two FPP contract manufacturers have been identified and meetings were held to discuss potential development for Capreomycin and Kanamycin. FPP prices have been negotiated to support GDF. | This is currently on hold; legal matters are under review | | |
| Malaria | P Lukulay | | | | |
| Conduct studies to assess the diversion of antimalarial medicines from public to private sector | | | | | |
| Adapt study protocols for antimalarial MQM study in new countries | | Protocol developed | Completed | | |
| Conduct four new studies | | One antimalarial monitoring study is underway in Congo Brazzaville. | Two studies completed in Congo Brazzaville. | | |
| Develop reports and disseminate results | | | Reports completed. | | |
| Conduct follow-on studies | | | One follow-up study completed in Congo Brazzaville. | | |
| Conduct follow-on study of Liberian market for prevalence of artemisinin-based monotherapies | | | | | |
| Select two countries to conduct survey for monotherapies | | Liberia was selected; the second country is still in discussion | Study in Liberia underway. | | |

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| Develop sampling strategy and protocol; identify locations | | Study protocol has been finalized and partners as well as USAID/Liberia have approved it; study will begin on January 28. | Study protocol is under review by NMCP and USAID. | | |
| Travel to sites and conduct survey | | | Plans are being made to travel to sites to conduct studies, along with partners. | | |
| Procure samples and generate reports | | | | | |
| Develop monograph for Dihydroartemesinin-Piperaquine FDC | | | | | |
| Verify analytical methods | | | Analytical methods developed and verified. | | |
| Conduct method validation | | | Method validation completed. | | |
| Characterize API and include in USP MC | | PQM has identified the Italian company that is the innovator for DH/PP and obtained their approval to provide background analytical method information as well as API to be characterized by USP for the purpose of developing reference standards. | API has been characterized, and MC monographs are in development. | | |
| Develop Minilab[®] methods for Dihydroartemesinin-Piperaquine FDC | | | | | |
| Develop screening method | | In progress. API has been obtained for analytical methods development. | Methods are being developed and are nearing completion. | | |
| Validate analytical methods | | | | | |
| Publish method in | | | | | |

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| manual | | | | | |
| Conduct quality control tests on antimalarials from developing countries | | | | | |
| Obtain samples of medicines at request of PMI team and test | | No samples have been requested for testing. | Testing is underway on Ghana artesunate samples being sent by USAID/Ghana to USP. | | |
| Maternal Health and Child Survival E Toledo | | | | | |
| Support selected United Nations Commission medicine manufacturers | | | | | |
| Conduct GMP baseline assessment of selected mfrs; present findings to USAID, stakeholders | | GMP TA visit to Lomus Pharmaceutical (chlorhexidine manufacturer) in Nepal scheduled for Jan 2013 | Visited Lomus in Jan 2013; conducted GMP assessment and issued report Visits to manufacturers in Madagascar scheduled for Q3 (PATH-funded activity) | | |
| Provide TA to mfrs of promise to improve GMP compliance | | TA will begin for Nepal manufacturer in Q2, following assessment | Started providing TA to Nepal manufacturer. EOI for CHX manufacturers will be issued in Nigeria during Q3 | | |
| Conduct quality testing of select UN commission medicines | | Chlorhexidine samples were procured from manufacturers in Nepal and India; will be tested in Q2 | Chlorhexidine samples for Nepal and India manufacturers were collected and tested; report was disseminated | | |
| Support selected zinc manufacturers for local procurement | | | | | |
| Conduct QC/GMP assessments of zinc salt mfrs | | Conducted GMP assessment at Medicamen, India; continued support to 2 manufacturers in Ghana and 1 in Kenya toward GMP compliance | Continued support to 2 manufacturers in Ghana and 1 in Kenya toward GMP compliance. Prepared EOI for zinc manufacturers in Nigeria to be disseminated early Q3; GMP assessments | | |

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| | | | will occur late Q3 | | |
| Conduct quality testing of zinc medicines sent by UNICEF, USAID, and other partners | | Tested 4 samples from Ghana, India, and Kenya manufacturers and submitted report | 2 samples from Ghana received at the end of Q2; will be tested in Q3 | | |
| SUB-SAHARAN AFRICA | | | | | |
| Burundi | M Hajjou | | | | |
| Develop interventions to ensure the quality of antimalarial medicines | | | | | |
| Conduct a gap analysis of the country's medicine quality assurance system | | Discussions were held with USAID-PMI in Burundi to prepare for the gap analysis, scheduled for Jan 2013; background information was gathered to facilitate the visit to the country. | Gap analysis conducted and report shared with stakeholders. A workplan was developed based on the results of the analysis and the funding available. | | |
| Assist National Malaria Control Program in developing a quality assurance policy for antimalarial medicines and diagnostics | | | Information gathered to develop a quality assurance policy for the national malaria control program. | | |
| Develop an implementation plan to strengthen QC lab capacity | | | In collaboration with the head of the QC lab, information was gathered to develop an implementation plan to bring the National Institute of Public Health lab to international standards. | | |
| Support developing a strong pharmaceutical law suited to the country's needs | | | Review of the draft law is underway. Comments and recommendations will be communicated in May. | | |
| Ethiopia | Eshetu W. | | | | |

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| Strengthen FMHACA's management capacity based on findings from the gap analysis | | | | | |
| Support FMHACA in addressing gaps found, especially critical gaps | | Guidance for undercover study of leakage of "Food By Prescription" products drafted and submitted to USAID; SOW for consultant(s) who will assess the current and future operational costs of FMHACA submitted to USAID; concept paper supporting the establishment of technical committees for registration and licensing of foods and medical products is being developed. | Prepared paper recommending the establishment of external expert committees to carry out assessments of safety, efficacy, and quality data for marketing authorization of medicines; submitted to FMHACA. Submitted technical and audit reports on USP/PQM Ethiopia office activities to the Charities and Societies Agency of the Government of Ethiopia. | | |
| Strengthen FMHACA's registration and licensing system | | | | | |
| Identify critical areas where PQM can provide TA to Product Registration & Licensing Directorate | | Developed GMP inspection service fee direct payment procedure for FMHACA; completed training material preparations and developed basic GMP principles for FMHACA staff. | Training on basic GMP held in Bishoftu in Jan-Feb; 40 participants from FMHACA and local pharmaceutical industry attended. Training for FMHACA staff on basic dossier assessments held in Bishoftu in March; 32 participants from Ministry of Agriculture and FMHACA attended. | | |
| Recommend solutions to gaps w/timelines & | | | | | |

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| expected outcomes | | | | | |
| Support the establishment of a centralized FMHACA information/ knowledge management system | | | | | |
| Provide TA to establish a central data system for registration, licensing, import/export control, inspection, enforcement | | Concept paper for the data management system partially complete. | | | |
| FMHACA to determine directorate to manage the system | | | | | |
| Support physico-chemical lab to maintain and expand the accreditation to other test methods | | | | | |
| Develop a detailed implementation plan with timelines and expected outcomes | | Surveillance quality audit of the PQAD lab was performed; helped PQAD participate in PT dissolution testing at EDQM lab; assisted in purchasing lab supplies for the microbiology lab. | <p>USP signed a tripartite agreement in March to move the PQAD lab to the new site.</p> <p>One PQAD staff sent to India for training on lab equipment maintenance Mar-May 2013.</p> <p>Lab equipment, chemicals, and reference standards purchased and supplied to FMHACA laboratory.</p> <p>Assisted PQAD to participate in proficiency testing for 3 tests; supplied reference standards and other laboratory supplies.</p> | | |
| Support FMHACA condom lab to become ISO 17025 accredited and WHO prequalified | | | | | |
| Develop a detailed | | Condom testing lab will | Revised five SOPs; | | |

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| implementation plan with timelines and expected outcomes | | participate in PT by Enersol Australia; PQAD condom analysts were trained at FHI360 lab in Thailand. | training on ISO 17025 and ISO 4074 is planned for Q3. | | |
| Strengthen two FMHACA branch offices, enabling them to carry out post-marketing surveillance inspection activities | | | | | |
| Identify two branch offices to be supported | | Provided financial support | Installed lab equipment and trained the analysts of FMHACA's eastern branch. | | |
| Identify critical areas of needed support | | | | | |
| Develop a detailed implementation plan, timelines, expected outcomes | | | | | |
| Support post-marketing surveillance of antimalarial medicines | | | | | |
| PQM, ISD and FMOH Malaria Program to revise protocol | | Collected samples from one sentinel site | | | |
| Select sentinel areas, identify activities, set timelines | | Purchase of lab supplies initiated | | | |
| Conduct PMS | | | Collected antimalarial samples from three sentinel sites and provided lab supplies for testing; initiated testing | | |
| Write report based on information gathered and data generated | | | | | |
| Support local OI medicines manufacturers to become GMP compliant and their OI products WHO prequalified | | | | | |
| PQM & PRLD will identify potential local OI medicines mfrs | | Feedback on the GMP compliance report received for three manufacturers; CAPA | With the working group, prepared a first draft of the roadmap of local pharmaceutical | | |

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| | | report for remaining manufacturer under discussion. A team made up of partner representatives was established to develop the GMP roadmap. A confidentiality agreement for the direct support of Cadila Pharmaceutical (Ethiopia) for WHO PQ was signed | manufacturing | | |
| Identify activities to be supported, set timelines and expected outcomes | | | | | |
| Improve capacity and skills of local OI medicines manufacturers to ensure that their products and manufacturing sites comply with GMP | | | | | |
| Use results of GMP audit to identify gaps of local mfrs in compliance | | | | | |
| Select gaps most easily addressed w/PQM TA | | | | | |
| Provide TA to address select gaps & promote GMP compliance | | | | | |
| Monitor and evaluate program implementation | | | | | |
| Develop monitoring & evaluation tool | | | | | |
| Conduct monitoring & evaluation of program implementation | | | | | |
| Ghana | R. Okafor | | | | |
| Support post-marketing surveillance of antimalarials at existing sentinel sites, establish two additional sites, and encourage FDB to take enforcement actions based on the results | | | | | |

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| Select and supply two new sentinel sites | | Requested quote for 2 Minilabs for 2 new sites; Discussed sites with FDB | Two Minilabs were ordered, shipped, and received by the FDA. | | |
| Conduct two rounds of MQM at selected sites for testing | | | Contract for MQM money transfer submitted. | | |
| Conduct confirmatory testing at FDB lab and CePAT | | | Planned for Q3 | | |
| Conduct onsite evaluations of selected sentinel sites | | | Planned for Q3 | | |
| Promote enforcement actions based on data | | | Planned for Q3 | | |
| Strengthen the capacity of the FDB national QC lab and assist toward ISO 17025 accreditation | | | | | |
| Facilitate qualification, validation of equipment in new facilities | | FDB move to the new facility is pending minor repainting of floor; move to occur in Q2 | Painting of FDA lab to be completed in April; the move was delayed again. | | |
| Procure equipment and supplies necessary for ISO accreditation | | Provided standards for equipment qualification/maintenance; provided list of key equipment procured and at site | Provided supplies for the lab – reference standards for qualification of dissolution tablet, certificate of analysis, lab consumables with proper certificate. | | |
| Train staff on new equipment as needed in lab and at CePAT | | Training planned for Q2 | Lab move has delayed training; training scheduled for May 2013. | | |
| Facilitate assessment audit and provide TA with CAPAs | | | Provided TA via e-mail and teleconferences. | | |
| Collaborate with FDB and other stakeholders in the local pharmaceutical industry to build capacity for GMP improvement | | | | | |

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| Conduct baseline GMP assessment of local manufacturers | | | | | |
| Conduct basic GMP training for local manufacturers | | | | | |
| Support inclusion of FDB data in the PQM MQDB, analyze trends to provide a basis for informed decision-making | | | | | |
| Support data entry and develop statistics using MQM data | | To be entered in Q3 upon completion of MQM | | | |
| Sensitize the public to the dangers of substandard and counterfeit medicines through IEC activities | | | | | |
| Facilitate dissemination workshop for media, public re CSM findings | | | | | |
| Provide FDB with resources to produce awareness-raising materials | | | | | |
| Kenya | L El Hadri | | | | |
| Continue strengthening medicines quality monitoring beyond sentinel sites | | | | | |
| Conduct fourth round of MQM; provide training on Minilab, sampling strategies, and reporting to the new staff and refresher training to team leaders | | MQM planning activities are ongoing; Minilab supplies will be delivered by Feb 2013. | Minilab training scheduled for April 2013. | | |
| Conduct supervisory and M&E visits to sentinel sites | | | | | |
| Confirm validated samples at NQCL | | | | | |
| Provide TA to NQCL on using pharmacopeial methods to test failed samples, samples with | | | | | |

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| reported ADEs, and any sample collected from refugee camps | | | | | |
| Continue to promote regulatory actions by sharing MQM data | | | | | |
| Promote efforts to support enforcement actions by PPB based on data | | | | | |
| Share data w/PPB, DOMC, and other stakeholders to raise awareness | | <p>NQCL completed confirmatory testing on nine quinine sulfate products; two failed and the results were submitted to DOMC and PPB for action.</p> <p>A report on the second and third rounds of MQM activities will be shared at a stakeholders' meeting in Q2.</p> | Report on third round drafted and will be shared with stakeholders in Q3. | | |
| Strengthen NQCL's capacity and assist the lab toward ISO 17025 accreditation | | | | | |
| Improve NQCL staff's technical capacity and facilitate participation of NQCL in NOMCOL inter-laboratory proficiency testing (ILP) | | NOMCOL charter was established; Ciproflaxin was the molecule agreed upon to be tested in ILP. | Resources provided to start ILP testing of Ciproflaxin. | | |
| Review data of the ILP and provide guidance to improve testing techniques | | | ILP is ongoing. | | |
| NQCL senior staff will participate in NOMCOL meeting | | PQM facilitated the participation of the NQCL deputy director in | | | |

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| | | a NOMCOL directors meeting. | | | |
| Accompany the lab toward ISO 17025 accreditation | | | | | |
| Assist NQCL in submitting their ISO 17025 application to SANAS | | First part of the ISO 17025 application submitted to SANAS | | | |
| Review NQCL QMS documentation and quality manual | | NQCL quality manual revised and corrections / suggestions for improvements submitted to NQCL | | | |
| Assist NQCL in starting the process of SANAS pre-audit | | | Provided guidance and reviewed application forms to start ISO 17025 accreditation with SANAS. | | |
| Assist NQCL in addressing the major and minor findings | | | | | |
| Liberia | L El Hadri | | | | |
| Continue building the capacity of the Quality Control Laboratory | | | | | |
| Provide lab supplies and reagents needed to conduct Minilab and compendial testing on antimalarial, ARV, and OI medicines | | Needed supplies will be delivered in Q2 | Lab supplies procured and delivered to the lab. | | |
| Provide step-by-step training in compendial methods and Good Laboratory Practices, according to international standards | | Training is scheduled for Feb 2013 | Lab training provided for 5 staff; additional training on USP General Chapters and General Notices was also provided. | | |
| Assist the lab staff in conducting confirmatory | | PQM assisted the lab to test antimalarials | Using compendial methods, 3 ARVs and 7 | | |

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| testing on samples that failed Minilab testing | | (monotherapy and FDC) and selected ARVs; results will be submitted Jan 2013 | antimalarials were tested; the ARVs all passed, but two antimalarials failed. | | |
| Procure a power stabilizer, fuel, and lubricants for the generator procured by LMRHA | | | | | |
| Assist the lab in repairing the water purification system | | Lab supplies procured to repair the system will be delivered in January 2013; installation will be completed in Feb 2013 Other lab supplies procured for the lab include: Minilab RS to test Ciprofloxacin 250mg Sulfamethoxazole/Trimet hoprime 100/20mg and parts to repair the UV Vis and HPLC | Assisted in cleaning, sanitizing, and installing new filters. | | |
| Secure a contract for maintenance service to repair non-working lab equipment | | PQM provided TA to troubleshoot some lab equipment | | | |
| Continue assisting LMHRA in strengthening its regulatory capacity | | | | | |
| Strengthen LMHRA inspection functions | | | | | |
| Strengthen LMHRA medicines registration system | | | | | |
| Support NDS, LMHRA, and major health programs in monitoring the quality of essential medicines and promote regulatory actions | | | | | |
| Develop MQM protocol for sampling strategies, list of meds; define | | | Plans made to establish the MQM program | | |

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| | | Q1 | Q2 | Q3 | Q4 |
| roles, responsibilities | | | | | |
| Select sampling sites in 1-2 counties | | | | | |
| Conduct one round of sampling and testing of essential medicines | | | | | |
| Provide Minilab [®] supplies & reagents; NQCL supplies & RS | | | Supplies provided to the lab | | |
| Conduct M&E visit to sentinel site, NQCL | | | | | |
| Draft and share reports with stakeholders | | | | | |
| Promote LMHRA taking enforcement actions based on MQM data | | | | | |
| Mozambique | R. Okafor | | | | |
| Strengthen the capacity of the National Laboratory for Medicines Quality Control | | | | | |
| Strengthen quality management capacity by training the staff | | Staff trained on Karl Fischer and received refresher training on basic HPLC | Staff provided with exercises to assess proficiency following training; reports were submitted by the lab for PQM review Provided TA via e-mail and telephone on HPLC issues | | |
| Procure and install equipment and supplies | | Procured and shipped reagents, lab supplies, and reference standards; ordered International Pharmacopeia; obtained quotes for major | Procured and shipped lab consumables and equipment; ordered major equipment which is en route to Maputo | | |

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | equipment | | | |
| Assist LNCQM to refine strategic plan for ISO accreditation/WHO PQ | | Strategic plan for ISO written; will be discussed with the head of the PD and new director of LNCQM | Meeting scheduled for April 2013 | | |
| Sensitize the public to the a dangers of counterfeit and substandard medicines by publicizing LNCQM and DF activities | | | | | |
| Assist LNCQM to develop quarterly Q&A sessions w/local media to highlight activities | | To be performed Q2-Q3 | Meeting to happen in Q3 after MQM round 1 has been initiated in April | | |
| Establish an IEC campaign to inform public about CSMs | | To be performed Q2-Q4 | | | |
| Coordinate activities between LNCQM and ARV manufacturer | | Discussion meeting planned with head of PD, USAID, and SMM | | | |
| Support the MQM program | | | | | |
| Extend MQM to 2 new sites; conduct 2 rounds MQM sampling, testing | | Sites identified; first round to start in March | 2 sites selected; Minilabs have been purchased and shipped | | |
| Supply new sites; train provincial staff and DF inspectors | | Minilabs ordered for new sites; provincial staff identified; approval letter sent to minister for training; training arranged for February 2013 at LNCQM | Training re-scheduled for April 2013; wire transfer issues delayed initiation of training. | | |
| Support DF efforts on enforcement actions based on MQM data | | Proposal to the head of the PD to be discussed during visit in February | Meeting scheduled for April. | | |
| Senegal | L El Hadri | | | | |
| Continue to support monitoring the quality of medicines at the nine established sentinel sites, encourage DPM to take enforcement actions based on the results of MQM data, and monitor the Minilab® activities at the sites | | | | | |
| Conduct supervised round of monitoring the quality of essential | | Round 2012: Sample collection and testing using basic tests | The majority of confirmatory testing has been completed. | | |

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 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| medicines at nine sites | | completed in the remaining 4 sentinel sites; prelim report submitted to major stakeholders; confirmatory testing of 2012 round will be completed by Jan 2013. Round 2013: Initiated planning for one round of MQM activities | Budget and plans made to start 2013 round. | | |
| Monitor and evaluate MQM activities at selected sentinel sites and share pharmacovigilance tools with the MCR of each region | | | | | |
| Present MQM results and promote DPM regulatory actions | | MQM results (2011 and 2012) will be presented at a meeting with relevant stakeholders and MCRs in Q2 | Meeting postponed until Q3. | | |
| Strengthen the capacity of DPM and support enforcement of its regulatory actions | | | | | |
| Procure and install a new server for DPM to improve data mgmt | | Specifications of the server finalized; process of procuring and shipping the server to Senegal/DPM ongoing | Server for storing data from the newly established registration software was procured and delivered to DPM. | | |
| Organize workshop for DPM and customs on enforcing regulations | | Change of the Minister of Interior resulted in change of the general directors of the customs and judiciary police. PQM will plan the workshop once the new directors are appointed | Plans made and tentative agenda shared with the director of customs operations for his review. | | |

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|--|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Continue strengthening the capacity of LNCM and guide the lab toward ISO 17025 accreditation | | | | | |
| Assist LNCM in participating in NOMCOL inter-laboratory proficiency (ILP) testing | | NOMCOL charter established; Ciproflaxin was the molecule agreed upon to be tested in ILP. | Resources provided to start the ILP testing. | | |
| Present the results of PQM QMS and lab audit to LNCM staff | | Results of QMS and lab audit presented to LNCM staff and action plan established to correct minor and major deficiencies. | | | |
| Develop implementation plan; conduct site visit to review progress toward ISO 17025 accreditation | | Implementation plan developed and presented to lab staff; site visit to review implementation progress is scheduled for March 2013. | Follow up visit to the lab postponed until Q3. | | |
| Review the SOPs drafted by LNCM staff | | Using SOP template provided by PQM, LNCM submitted 20 SOPs, which are under review by PQM. | 10 SOPs reviewed. | | |
| Assist LNCM in finalizing managerial and technical documents | | Planned for Q2 | Technical (section 4) and managerial documents (section 5) of ISO 17025 requirements are under review. | | |
| Assist the lab in selecting accrediting bodies for testing, calibration, and proficiency testing (PT) and submitting the accreditation | | With PQM assistance, LNCM selected TUNAC as their accrediting body for testing; PQM and LNCM initiated the process of submitting the application to | | | |

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| applications | | TUNAC and for selecting the accrediting bodies for calibration and PT | | | |
| Assist LNCM to prepare additional SOPs and train staff in analytical tests | | | Guidance provided to draft new SOPs and training provided to 11 staff on Karl Fisher titration, LOD, pH meter, and GDP according to ISO 17025 accreditation requirements | | |
| ASIA | | | | | |
| RDM-A Mekong Malaria S. Phanouvong | | | | | |
| Support medicines quality surveillance by maintaining the sub-regional MQM to obtain evidence-based data to support policy decision-making and enforcement action | | | | | |
| Adapt existing MQM & special investigation protocols to improve strategies & techniques | | In discussions with MRAs in GMS to adapt protocol | Further discussions with country partners and USAID-PMI team planned for April 3-5, 2013 at the PMI partners meeting and CAP-Malaria Cross-border Working Group meetings in Yangon. | | |
| Help GMS partners conduct 2 MQM rounds in hot-spot border areas using new protocols | | Planned for Q3 | Planned for Q4 | | |
| Build the capacity of NQCLs in pharmaceutical analysis toward compliance with ISO 17025 and/or WHO prequalification for both pre- and post-marketing surveillance of medicines quality, with support provided by ANEQAM and BREMERE | | | | | |
| Assess documentation, procedures of Laos and Thailand NQCLs; provide TA on CAPAs | | Assessment agenda completed; to be implemented in Q2 | Assessment completed in February and CAPA recommendations provided to each of the labs; regular reports were requested. | | |
| Train Mahidol GMP- | | Planned for Q4 | Initial discussions were | | |

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 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| compliance faculty on WHO PQ process | | | held with Mahidol team re: training schedule and logistics | | |
| Support Chula PTSC to conduct a regional workshop on analysis of DHA/PIP, AVQ/PGN | | Planned for Q4 | Initial discussions were held with Mahidol team re: training schedule and logistics | | |
| Support regional and in-country coordination for effective enforcement through BREMERE and, possibly, WHO SSFFC mechanism | | | | | |
| Support BREMERE quarterly meetings to share information, and coordinate enforcement | | Implementation meeting scheduled for Feb 2013 in Cambodia | Implementation meeting held in Feb. An action plan was developed and disseminated among the BREMERE countries. | | |
| Support investigations on timely reporting and enforcement with WHO-INTERPOL | | Planned for Q4, after obtaining the results of the comparative study of AML quality | | | |
| Disseminate findings of investigations and report data to MQDB | | Planned for Q4 | | | |
| Participate and present data at relevant mtgs | | Presented at Annual Consciousness on CSMs in the Philippines in Nov and at the 2012 Malaria Conference in Australia in Oct/Nov | Data from MQDB was presented at the BREMERE meeting in Siem Reap, Cambodia | | |
| Support the pharmacy schools to improve last-year pharmacy student curriculum on medicines policy, quality assurance and regulations to prepare them for real-world experiences with different types of pharmaceutical practices | | | | | |
| Develop review methodology and tools; meet with key parties to recommend changes | | Ongoing at two Cambodian Faculties of Pharmacy | Ongoing | | |
| Submit final curriculum for ratification by responsible agency | | Planned for Q3 | | | |
| Field-test the new curriculum at two | | Planned for Q4 | | | |

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 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Pharmacy schools | | | | | |
| Maintain the momentum of awareness-raising about the danger of using CSMs in the GMS through existing and proven means and tools | | | | | |
| Disseminate copies of "Pharmacide: The Mekong" documentary; produce trailer for use on YouTube and media | | Finalization has been delayed by 3-4 months due to clearance issues in some countries | The film was finalized in Feb and disseminated; was also played at the BREMERE mtg and the Awareness Campaign in Kamponchamp by the French Fonds de Solidarité Prioritaire and the Cambodia Economic Police team. | | |
| Adapt and disseminate BCC/IEC materials to raise awareness in high-risk areas | | Leaflets, brochures, and play scripts were developed in collaboration with CAP-Malaria in Cambodia for schoolchildren and communities in remote areas; awareness-raising activities for pharmacy retailers were conducted in Laos in collaboration with MOH/FDD and the U.S. Embassy's PR Unit. | Leaflets on basic knowledge of counterfeit medicines were printed and distributed to pharmacy outlets in all 24 provinces in Cambodia through DDF/MoH-PHDs channel and to community villagers through URC-CAP Malaria and other partners. In collaboration with URC-CAP Malaria project, PQM produced and presented a poster in elementary schools to educate children about counterfeit antimalarials. Printing production is planned for Q3. A preliminary report of the survey on | | |

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 Quarterly Reports: FY13 Activities

| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | awareness of retail pharmacists was presented by the MOH/FDD and the Embassy. Interventions have been introduced and evaluation is planned for Q4. | | |
| Burma S. Phanouvong | | | | | |
| Establish a formal presence in Burma through an MOC with Ministry of Health or Food and Drug Administration and hire a country consultant to help operationalize PQM activities | | | | | |
| Consult with relevant partners for pragmatic advice on establishing an MOC with MOH | | No tangible progress made due to political sensitivities and restrictions. An office space in Yangon will be established under an agreement with CAP-Malaria. | Awaiting clearance and authorization from PMI-USAID Washington. A draft Project Agreement Letter between USP and Burma MOH was submitted to PMI-USAID/RDMA and Burma Missions for suggestions before its submission to the AOTR for review and authorization to extend the letter to the MOH. | | |
| Recruit a country consultant | | Recruitment of a country consultant reached final stages, but the candidate was hired by another NGO; recruitment has to start from scratch again. | A part-time consultant has been contracted and he will assume the position from May 1, 2013. | | |
| Support the FDA Nay Pyi Taw QC lab to perform compendial monograph testing of key antimalarials and fixed-dose combination products | | | | | |
| Procure dissolution tester, install, calibrate | | Specifications established and supplier identified, waiting for clearance. | Awaiting authorization from USAID Washington | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Train lab staff to test A/L , DHAP/PIP FDCs | | Planned for Q2-3 | Postponed to Q4 | | |
| Conduct program implementation review and develop a strategic document for improving the quality of essential medicines for Burma | | | | | |
| Hold national mtg to present MQM data; document strategy for proposed improvement | | Planned for Q4 | | | |
| Cambodia E. Yuan | | | | | |
| Improve detection of poor-quality medicines, sustaining activities in 12 established sentinel sites while transitioning program ownership to the Cambodian government | | | | | |
| With DDF begin pilot in four sites to form, train teams to oversee transition process | | Held initial discussions with DDF-MoH on MQM phase-out project to seek their cooperation in jointly developing ways to keep existing operations sustainable. PQM will visit Cambodia in Feb to meet with DDF-MoH to discuss strategies. | Dr. Phanouvong met with H.E. Chou Yin Sim, Dr. Heng Bunkiet, and their deputies to clarify PQM's role and discuss MQM sustainability issues. | | |
| Coordinate with GFATM, JPMA, WHO to streamline PMS; identify other funding | | After approaching JPMA and WHO in Cambodia, there is no progress. | Attempts were made with no progress | | |
| Maintain essential PMS activities at 12 sites during transition | | MQM activities were temporarily held off because funding from GFR6 is on hold. Confirmatory testing is ongoing; preliminary results were released showing there were no failed samples out of 72 tested. | No activity this quarter | | |
| Focus efforts on non-MQM regions of | | In Oct, PQM, in collaboration with local | Sampling and testing within 9 non-MQM sites | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| growing AMR & borders with Thailand, Vietnam | | partners, conducted training in Vietnam on sampling methods for comparative studies; participants came from MRAs, QC labs, and national malaria control programs of Cambodia, Laos, Thailand, and Vietnam. | is ongoing. A study team is ready to start the comparative study after funding is allocated and a protocol is in place. | | |
| Strengthen authorities for timely reporting; share data with key stakeholders | | Several meetings and conference calls were conducted to expand current MQDB to make it more useful for country health authorities and national QC labs. | Improvements continue to be made to MQDB. | | |
| Establish/strengthen tie between MQM and enforcement actions | | Continuous collaboration with IMC/DDF/MoH to support inspections of the sentinel sites and promote appropriate enforcement actions. | IMC/MOH/DDF were actively involved in the BREMERE initiative and hosted the implementation meeting in Siem Reap in February. The DDF Director was selected to lead BREMERE for the next two years. | | |
| Continue strengthening PQM/IMC efforts on enforcement actions | | Supported annual IMC meeting held in Dec. | PQM and IMC have closer collaboration through BREMERE. | | |
| Strengthen medicines quality assurance and quality control systems by building up the capacity of DDF and NHQC | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Continue TA to NHQC; ensure new lab is built to WHO/ISO standards | | A teleconference was conducted in Oct with PQM and its consultants including arc2lab architect and the World Bank (WB) lab experts; a face- to-face meeting among arc2lab, the WB, HSSP2-MoH, NHQC, and the local design company will take place in January 2013. | Face- to-face meeting among USP’s consultant (arc2lab), the World Bank and its lab technical officials, HSSP2-MoH, NHQC management and technical staff, and local engineer designers took place in Jan to clarify roles for supporting the NHQC construction and necessary TA. PQM and NHQC held a teleconference in Feb with arc2lab to discuss the status of lab construction and some technical issues. | | |
| Work w/NHQC mgmt & staff to implement ISO accreditation roadmap | | The agenda for reviewing NHQC lab’s QMS has been drafted; PQM plans to visit NHQC in Q2 | PQM QMS manager visited NHQC in Feb to perform an assessment of the NHQC lab, evaluate ISO 17025 preparations, review training & documentation records, and schedule further discussions with the QA manager and deputies on ISO accreditation. | | |
| Enhance the capacity of NHQC to conduct confirmatory testing | | PQM has proposed inviting one senior scientist from NHQC, via USP’s visiting scientist program, to come to USP for 2-4 weeks of | PQM in-country consultant collaborating with NHQC management on logistics of training. | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | hands-on training. | | | |
| Strategically introduce “systematic steps” to strengthen DFF QA/QC | | Provided TA to DDF/MoH to develop National Guideline for Pharmacy Practitioners | Guideline for Good Pharmacy Practices was developed and approved by the MoH; English version was reviewed by PQM, edited, and sent back to DDF/MOH | | |
| Develop local expertise in QA/QC, medicines regs by expanding pharmacy curriculum | | <p>Local consultant met with the Dean of Faculty of Pharmacy of Int'l Univ to ask for permission to conduct an evaluation of the medicines QA/QC and regulation syllabus; a meeting with the Univ of Health Sciences is planned for Q2.</p> <p>Questionnaires are being developed to survey final-year pharmacy students on their QA/QC knowledge.</p> <p>After BREMERE's inauguration, PQM has collaborated with DDF/MOH to prepare for the Feb meeting to be held in Cambodia; Cambodia is co-chair.</p> | No progress | | |
| Raise awareness about medicines quality issues and disseminate information among regulators, health care professionals, and the public | | | | | |
| With partners, develop & disseminate BCC/IEC materials at grass roots levels | | | Leaflets on basic knowledge of counterfeit medicines were printed and distributed to drug | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | <p>outlets in all 24 provinces through DDF/MoH-PHDs channel and to community villagers through implementation partners).</p> <p>In collaboration with URC-CAP Malaria project, PQM produced and presented a poster in elementary schools to educate children about counterfeit antimalarials. Pre-testing with students was conducted in March at Pa'hee Elementary School in Pailin province. Printing production is planned for Q3.</p> | | |
| Collaborate with PAC to publish bulletins, news-letter and conduct educational workshops | | | No progress | | |
| Introduce BREMERE; move countries toward timely reporting and enforcement actions | | In collaboration with PQM, DDF-MoH will host the meeting to kick off the BREMERE action plan in Feb 2013. | The BREMERE implementation meeting was held in February in Siem Reap, Cambodia. There were 32 participants from Cambodia, Laos, Vietnam, Thailand, and South Korea, and other partners such as FSP. Dr. Heng Bunkiet, DDF Director, was selected to | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | be BREMERE's Chair for the next two years. | | |
| Indonesia S Phanouvong | | | | | |
| Maintain existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines | | | | | |
| Support first-line ATB mfrs (Indofarma, Phapros, Kimiafarma) toward WHO PQ | | <p>Provided TA to Phapros and Indofarma while Kimiafarma dropped out due to lack of commitment to address critical observations found during a facility inspection. A private company, Sandoz Indonesia, has recently begun working with PQM.</p> <p>Phapros has completed about 90% of CAPA items recommended, invested in upgrading some manufacturing equipment, and renovated the solid dosage form production plant which is ready for PQM inspection. The equipment and process validation and dissolution profiling of its reformulated products (2 FDC (RH) and 4 FDC (RHZE) have been completed. A pilot BE</p> | <p>Phapros: in March, PQM staff conducted a site inspection at the Semarang plant following renovation and facility upgrades. During Q2 they prepared the pilot biobatch for 4FDC; the dossier will be recompiled & submitted to PQM in April.</p> <p>Indofarma: approval for new construction was sent for NA-DFC review in Q1, BPOM will give final decision in Q3. Indofarma submitted new facility blueprints to PQM for review. Following construction, PQ process will be reinitiated at new site.</p> <p>Sandoz: submitted questionnaire to PQM; PQM evaluated stability data (incomplete) on 2FDC, 3FDC, and 4FDC adult and pediatric</p> | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | <p>study for 4FDC has started at Equilab</p> <p>Indofarma decided to build a new facility. A preliminary design will be sent to PQM for review.</p> <p>PQM and USAID arranged a high level visit of the MOH's delegate, Professor Dr. Tjandra Yoga Aditima, to USP HQ in Dec 2012 to discuss next steps; action items were agreed upon.</p> | <p>formulations and conducted a baseline survey of the manufacturing facility in South Jakarta. PQM met with the Country Director and the Regional QC Manager who committed to achieving WHO PQ; Sandoz will form a PQ team for this purpose.</p> <p>Kimia Farma: following a PQ Coordination meeting at the NTP with NA-DFC, NTP, and state-owned manufacturers, Kimia expressed that it would like to be reconsidered for receiving TA for PQ. They submitted their CAPA report to PQM team, and PQM will re-engage with them beginning in Q3.</p> <p>Phapros, Indofarma, and other manufacturers attended the CPhI WHO PQ Seminar, co-hosted by PQM in Jakarta in March.</p> | | |
| Encourage mfrs of levofloxacin tabs and kanamycin powder toward WHO PQP | | No progress | Sanbe Farma, based in Bandung, Java, expressed interest in receiving TA from PQM for two products: | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | <p>kanamycin 1g powder for injection and levofloxacin 500mg tablets. PQM conducted a baseline survey of the manufacturing facilities in Bandung. PQM will conduct a full inspection in Q3. The team met with the Owner-Director and senior management who all expressed commitment to achieving WHO PQ.</p> <p>Sanbe attended the CPhI WHO PQ Seminar, co-hosted by PQM in Jakarta in March 2013.</p> | | |
| Support implementation of MQM for anti-TB medicines at five pilot sentinel sites that completed training in June 2012 | | | | | |
| Procure equipment, provide training, and establish MQM sentinel sites for TB and selected antibiotics | | <p>5 Minilabs were provided and training conducted; additional RS and supplies were purchased and shipped.</p> <p>In Oct 2012, an action plan to implement MQM activities was agreed upon among PQM and implementing partners. Delays have occurred due to bureaucratic hurdles, especially regarding opening a bank account in Indonesia and transferring money from</p> | <p>Minilabs were deployed to the 5 provincial sentinel sites. One round of sampling was completed in Q2, and testing with Minilabs is ongoing. Confirmatory testing and a second round of sampling will take place in Q3.</p> <p>PQM conducted a monitoring site visit to Makassar (a Minilab site) together with the NQCL-DF Director and staff, including sampling, site visits to a provincial</p> | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | USP. | hospital, city warehouse, and the provincial QC lab where testing is taking place. | | |
| Open a PQM office in Jakarta; recruit GMP technical staff | | Potential local partners (Indonesia Univ. and Bali Expat Services) identified to assist in this regard. | Signed a contract with Bali Expat Services as a local service provider for work permits and visas, as well as for securing a country office. PQM contracted with consultant Chris Raymond to serve as Chief of Party for the Indonesia program, based in Jakarta. A new country office will be opened in April, following assessment of at least 12 potential locations in Jakarta. | | |
| Continue to assist two local contract research organizations (CROs) toward compliance with Good Clinical Practices (GCP) for bioequivalence studies of ATB medicines | | | | | |
| Provide TA to Equilab Int'l and San Clin EQ Lab to complete CAPA | | Equilab CAPA implementation report received. | Equilab CAPA implementation is nearly complete as of the end of Q2. San Clin EQ is in the process of implementing PQM recommendations to comply with GLP/GCP guidelines. | | |
| Follow up inspections and support two to conduct BE studies | | A WHO consultant conducted an inspection as part of educational audit training of NA-DFC | Equilab BE study protocol for Phapros 2FDC was reviewed by PQM and the WHO PQP | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | staff in BA/BE in Nov 2012 and found a few minor observations which Equilab has already addressed. Equilab drafted BE study protocols for 2 and 4 FDCs and submitted to PQM for review. The review of the 4 FDC will be complete in Jan 2013 | team. PQM submitted a report to Equilab, who will be ready to conduct the 4FDC BE study for Phapros, starting in Q3. PQM visited the San Clin EQ facility in Bandung to follow up on recent renovations and adjustments made towards compliance with GLP/GCP. | | |
| Strengthen regulatory systems and measures of Ministry of Health and National Agency for Drug and Food Control to better control and regulate ATB medicines, particularly 2nd-line ATBs, in the market to support the MDR-TB program | | | | | |
| Review requirements on ATB MAs and licensing systems for clinics, pharmacies | | Preliminary discussions and consultations with relevant stakeholders were held. | This activity is planned for Q3-Q4. | | |
| Assess the availability, quality and main source of all first- and second-line ATB medicines in the main supply chains | | | | | |
| Develop assessment protocols | | Under consultation with relevant partners | Protocol is being developed | | |
| Train investigators on sampling protocols | | Planned for Q2-Q3 | Planned for Q3-Q4 | | |
| Collect and test samples at NQCL-DF/ regional reference lab | | Planned for Q2-Q3 | Planned for Q3-Q4 | | |
| Analyze data and report recommendations | | Planned for Q4 | Planned for Q3-Q4 | | |
| Assist NA-DFC and DG-PPD to sample and test (lot-based) for quality ATBs in the main warehouses of Jakarta and main cities prior to distribution | | | | | |
| Adapt existing sampling and testing protocols | | Further discussion among key stakeholders is necessary. | Further discussion among key stakeholders is necessary. | | |
| Set up sampling team | | Planned for Q3 | Planned for Q3 | | |
| Conduct testing | | Planned for Q4 | Planned for Q4 | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Write a report, disseminate to stakeholders | | Planned for Q4 | Planned for Q4 | | |
| Encourage NTP and NA-DFC to take action on failed ATBs | | Will be on a case-by-case basis. | Will be on a case-by-case basis. | | |
| Expand MQM systems to cover antimalarial (AML) and antiretroviral (ARV) medicines | | | | | |
| Train staff of NQCL-DF & provincial QCLs on Minilab [®] , compendial test methods for select AMLs and ARVs | | | Planned for Q3 | | |
| Purchase reference products, solvents and reagents for Minilabs [®] | | Planned for Q2 | Planned for Q3 | | |
| Add 150 AMLs, 100 ARVs to ATB sampling & testing in field | | Planned for Q3-Q4 | Planned for Q3-Q4 | | |
| Conduct confirmatory tests at NQCL-DF | | Planned for Q4 | Planned for Q4 | | |
| Produce a combined report for ATB, AML, and ARV data | | Planned for Q4 and FY14 Q1 | Planned for Q4 and FY14 Q1 | | |
| Encourage NA-DFC and NTP to take enforcement actions | | ongoing | ongoing | | |
| Provide technical support to NQCL-DF toward renewing ISO 17025 accreditation with better, product-based scope | | | | | |
| Conduct ISO 1705 assessment; propose changes to scope and quality system | | Discussions initiated with the NQCL-DF management who have agreed to change the scope | During a national workshop for the NQCL-DF provincial QC labs in Palembang, Sumatra, PQM met with the national Director and senior staff to discuss timelines; planned for Q3 with a week-long, on-site training and assessment | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Produce assessment report and CAPA recommendations | | Planned for Q2 | Planned for Q3 | | |
| Philippines E. Yuan | | | | | |
| Sustain the MQM activities in established sentinel sites | | | | | |
| Continue to support MQM at 6 existing sites plus 2 newly established sites on first line TB medicines quality checking through Minilab replenishment, site visits, training and refresher training, and database updates. | | Communicated with the sites re: supplies, RS; processed Minilab orders for two new labs; supplied FDA satellite lab Davao with USP-NF, FCC; visited Davao and Malolos sites in Oct; attended meetings for Minilab updates. | Replenished Minilab supplies and reagents; Collected expired medicine samples for proper disposal at FDA. | | |
| Expand MQM to include SL-ATB Ciprofloxacin | | Planned for Q2 | Used Minilab test procedures to analyze the new products; Consultant performed confirmatory testing at FDA for Ciprofloxacin. | | |
| Expand MQM to include antibiotics Amoxicillin and Cefalexin | | Planned for Q2 | Used GPHF-Minilab test procedures to analyze the new products; Consultant performed confirmatory testing at FDA for Amoxicillin and Cefalexin. | | |
| Strengthen FDA capacity and its QC Lab to enhance the medicine regulatory system in drug registration and post-marketing surveillance | | | | | |
| Finalize inventory of TB mfrs, importers, and distributors on sources, supply chains, products. Determine improved sampling points; | | Received the tentative list; will finalize in Q2. PQM team met with local pharmaceutical mfrs in Nov to follow up with those interested in | Planned for Q3. Hizon and Lloyd Laboratories submitted their accomplished questionnaire for WHO PQ. | | |

Promoting the Quality of Medicines (PQM Program)
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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| provide TA in the pharmaceutical mgmt system (PMS) and QA/QC system. | | WHO PQ, with the focus on 2 nd -line ATB manufacturers. | | | |
| Provide training on areas identified through gap analysis and request from FDA. | | <p>Held hands-on training on Compendia Analysis of ATB Meds and Intro to GLP in Oct in Davao Sat Lab, Tagum City for 5 Davao staff, 2 Cebu staff, 3 Central lab staff, and several observers</p> <p>Held Pharmaceutical Process Validation training in Nov in Alabang Muntinlupa City with 26 participants and several observers.</p> | Follow-on training will be in-line with the previous PV training that was given to 25 FDA regulatory staff; training is planned for Q4, and topics are TBD. | | |
| Sponsor two visiting scientists from FDA central office coming to USP to receive training on BA/BE | | Met with USP's VSP coordinator to discuss logistics. | <p>Selected 1 regulatory officer and 1 lab tech for a 12-week training course at USP HQ; training topics TBD.</p> <p>Alternatively: The BA/BE training might be offered in the Philippines to benefit local stakeholders more.</p> | | |
| Provide training opportunity through USP's International Training Program (ITP) to the scientists and staff from FDA satellite labs | | Met with ITP coordinator to discuss training topics | Selected 2 participants from FDA Davao Sat Lab and 2 from FDA Central Lab for a 3-week training course at USP HQ; training topics TBD. | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Purchase needed laboratory equipment and reference materials for the FDA that is not included in the DOH budget or other budgets | | PQM met with reps from academia, healthcare, pharmaceutical industry, and FDA in Nov to explore opportunity to form a BA/BE center. | PQM sent the FDA two copies of the FCC 2 nd Supplement. | | |
| Provide technical and professional assistance in Quality Management System (QMS) to FDA Davao Satellite Laboratory for ISO17025 accreditation/certification. | | | The initial plan of providing TA to satellite lab has been discussed with PQM's QMS manager. A teleconference with Davao lab chief and QA staff will be conducted in Q3 or Q4. | | |
| Extend assistance to National Center for Disease Prevention and Control (NCDPC) of the Department of Health (DOH) to enhance National Tuberculosis Program (NTP) | | | | | |
| Provide TA to NTP program related to TB medicines quality | | PQM country consultant attended TB LINC event and NCDOC year-end consultative workshop in Nov in Iloilo City. PQM is seeking the opportunity to collaborate with NTP, and detailed activities will be identified after further discussions | Joined Inter-CA on TB Technical Working Group; Attended Inter-CA meetings and provided input for discussions. | | |
| Obtain evidence based quality data on selected generic anti-infective medicines | | | | | |
| Conduct quality checks and assessments on the generic medicines made by local pharmaceutical manufacturers | | PQM HQ staff met with FDA's chief of lab services to discuss plans to create a list of chosen generic medicines to be compared to brand-name imported products | Planned for Q3. | | |
| Vietnam S. Phanouvong | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Provide technical assistance to local production of methadone and procurement of methadone finished products for Hai Phong and HCMC | | | | | |
| Pursue obtaining an authorization letter to conduct GMP | | No progress due to political sensitivities and bureaucratic hurdles | No progress; awaiting MOH decision | | |
| Conduct GMP inspection on 1-2 mfrs and recommend how to address deficiencies | | Country consultant communicated with VIDIPHA, a potential manufacturer for local methadone production | PQM visited VIDIPHA in Jan to perform a quick assessment of its capacity for narcotic medicines production. | | |
| Provide TA to HCMC and Hai Phong PACs to select high-quality methadone from reliable suppliers | | Country consultant: - met with HCM PACs to present information on methadone procurement procedures - met with NIDQC expert to discuss and develop technical specifications for imported methadone and presented these to VAAC - contacted 3 methadone suppliers: Molteni (Italian), Rusan Pharma (Indian), and Dolder (Swiss) as well as a legal national importer (CPC1) - met Hai Phong DoH to discuss technical aspects to procure imported methadone | - Technical specifications for finished product and dispensing pump were finalized and shared with VAAC and HCMC PAC. - Template format of international tender documents was shared with VAAC. - Followed-up with 2 methadone suppliers and legal national importers (CPC1, HAPHARCO). The 2 suppliers sent their product specifications and quotations to CPC1 and VAAC. - Followed-up with HCMC and Hai Phong PACs on the progress of procurement of imported methadone. No progress on allocation of provincial funding. | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| Provide TA on pharmacovigilance system within the framework of the Global Fund Round 10 project of the National Drug Information and Adverse Drug Reactions Center at Hanoi University of Pharmacy | | | | | |
| Review all related documents, previous assessments, & reports | | Country consultant communicated with the national ADR&DI center and collected relevant documents; review of documents is being carried out by experts | PQM helped the national PV center to map all foreign TA to the GFR10. Based on that, PQM identified gaps and proposed areas where PQM could assist within the framework of the GFR10 project. | | |
| Train staff and develop operational manual for national and south DI / ADR centers | | Planned for Q2-Q3 | Could be changed due to duplication with a Nigerian expert who currently is working at the center. | | |
| Help the national DI / ADR center identify int'l experts for GF R10 | | Planned for Q2 | A former WHO consultant was identified as a potential expert in PV communication and will be introduced to the national PV center. | | |
| Strengthen the post-marketing surveillance system of Opportunistic Infections (OI) in the public sector distribution chain | | | | | |
| Allocate funds for testing costs to NIDQC, HCM IDQC & pDQCCs | | PQM allocated funds to drug quality control labs. NIDQC will dispatch to HCM IDQC & pDQCCs where OI samples are being tested | Testing of OI medicines finished; data entry done. Data analysis and report writing is ongoing. | | |
| Disseminate final report to stakeholders | | Planned for Q4 | Planned for Q4 | | |
| Maintain country consultant to improve project coordination, implementation, and effectiveness | | | | | |
| Support consultant's salary and misc. expenses for FY13 | | Local consultant actively involved in implementing PQM activities, meeting with partners, and attending local meetings | Local consultant actively involved in implementing PQM activities, meeting with partners, and attending local meetings | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|-------------------------------------|---------------------------|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | and events. | and events. | | |
| Provide office furniture and equipment | | Ongoing | Ongoing | | |
| Europe and Eurasia | | | | | |
| Kazakhstan E. Toledo | | | | | |
| Conduct baseline GMP assessments of select anti-TB medicines manufacturers | | | | | |
| Conduct baseline GMP assessment of four manufacturers | | Assessments will be conducted in Q2 | Awaiting mission approval | | |
| Present findings to USAID and stakeholders | | Findings will be presented in Q2 | Awaiting mission approval | | |
| Provide technical assistance to promising companies to improve their GMP compliance | | | | | |
| Provide TA to select mfrs to improve their GMP compliance | | Planned for Q2 | Awaiting mission approval | | |
| Assist manufacturers in preparation and submission of dossiers to WHO | | | | | |
| Assist manufacturers with dossier prep and submission to WHO | | Planned for Q4 | | | |
| Russia K. Burimski | | | | | |
| <p>In September 2012, USAID was requested by the Russian Government to cease its activities in Russia and close out all activities by December 31, 2012. A final report on the PQM Program in Russia (September 18, 2009-September 30, 2012) was developed and submitted to USAID.</p> <p>PQM worked with three Russian second line anti-TB medicines manufacturers—Sintez (Kanamycin and Levofloxacin), Pharmasintez (PAS and Prothionamide), and Akrikhin (Prothionamide). In December 2012, PQM conducted a second audit of Sintez to provide recommendations on improving GMP compliance and assist in dossier compilation. Sintez provided 9-months stability study data. Also, PQM conducted teleconferences with Pharmasintez and meetings with Akrikhin to discuss current issues, progress, and next steps.</p> <p>PQM informed the TB dispensaries/institutes that carried out the Minilab MQM project that support for the project through PQM is no longer available.</p> <p>Two Raman spectrometers were purchased by PQM and delivered to the Roszdravnadzor lab. Roszdravnadzor requested that PQM provide technical assistance on establishing the Raman spectral database for anti-TB medicines and conduct training on Raman spectroscopy for MQCL staff.</p> <p>PQM provided TA to Roszdravnadzor regional MQCLs in ISO 17025 accreditation and WHO PQ. In October 2012, PQM supported an accreditation</p> | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| <p>assessment by ACLASS, an internationally recognized accrediting body, for the lab at Rostov-on-Don. As a result of the assessment, the Rostov-on-Don MQCL was awarded accreditation by ACLASS for seven laboratory tests. It is the first MQCL in Russia to receive ISO 17025 accreditation.</p> <p>At the request of Roszdravnadzor, PQM conducted training courses on microbiological aspects of medicines quality for MQCL staff in October. The training courses were held at the newly established MQCL in Saint Petersburg. Three training courses were developed and translated into Russian. Fifteen individuals representing eight regional/federal district labs participated in the training courses.</p> | | | | | |
| Latin America and the Caribbean | | | | | |
| Amazon Malaria Initiative V. Pribluda | | | | | |
| Strengthening quality assurance (QA) and quality control (QC) systems | | | | | |
| <i>Build capacity to perform basic testing</i> | | | | | |
| Conduct regional seminar in Nicaragua (w/Honduras) on 3-LA & basic tests of AMLs | | | Coordination with Nicaragua's personnel postponed because of a change in sanitary authorities. If a response is not received, funds will be transferred to support implementation of 3-LA in another AMI country. | | |
| Procure Minilab [®] for Nicaragua | | | See above. | | |
| Conduct regional training in Bolivia for Bolivian and Nicaraguan staff on basic tests for AMLs | | | See above. Training may be performed for Bolivia personnel in coordination with personnel of another AMI country. | | |
| <i>Build capacity to perform testing according to registration methodologies</i> | | | | | |
| Host an intern at USP for Suriname OMCL staff focusing on pharmaceutical analysis | | Discussions were held with the Suriname OMCL Director regarding the scope of the activity and 2 potential candidates were identified | The scope and objective of the internship along with the detailed curriculum were developed. | | |
| Conduct regional | | | Training is scheduled for | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| training for compendial analysis of Artemether Lumefantrine FDC for Brazil, Colombia, Ecuador, Guyana, and Suriname | | | June in Colombia. The training agenda was developed by PQM and approved by the host lab. | | |
| <i>Implement Three-level Approach for sustainable medicines quality monitoring (MQM) activities throughout the supply chain</i> | | | | | |
| Help Ecuador develop and implement guidelines and SOPs for 3-LA for new regulations | | | | | |
| Finalize MOU between Guyana stakeholders; develop normatives and documents for 3-LA; get MOH concurrence | | | Participated in a supply chain workshop in Guyana and presented the 3-LA; met with stakeholders to advance the completion of the MOU. | | |
| Present 3-LA for AMLs at NMCP meeting w/ANVISA and LACEN's representatives | | | In discussions with the head of the NMCP, it was agreed that the best way to pursue this will be to send ANVISA a short document in Portuguese describing the 3-LA and success stories of implementation in LAC | | |
| Increasing the Supply of Quality Assured Medicines | | | | | |
| <i>Support Farmanguinhos to attain WHO prequalification for Artesunate/Mefloquine (ASMQ) FDC Tablets</i> | | | | | |
| Conduct mock pre-audit of ASMQ FDC tablets; provide TA as needed | | PQM performed mock pre-audit in Nov 2012. Next steps towards WHO prequalification were established. | ASMQ has been included in the list of medicines that LAC countries may purchase through the Strategic Fund. This inclusion was based on ANVISA GMP certification, for which | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | PQM provided TA. The inclusion is conditional for one year and continuation requires WHO prequalification for ASMQ. | | |
| <i>Increase accessibility to USP and Minilab reference standards through PAHO's Strategic Fund</i> | | | | | |
| Establish a means for countries to purchase USP/Minilab [®] RS using PAHO Strategic Fund | | Initial contacts were made with PAHO. A meeting to discuss implementation is planned for Q2. | PAHO stated that it might be possible for countries to purchase USP and Minilab [®] RS through the Strategic Fund, with the pricing agreed between USP-TAP and the countries. The feasibility and logistics for this need to be discussed at USP. | | |
| Combating substandard and counterfeit medicines | | | | | |
| <i>Evaluate the quality of malaria medicines in decentralized areas</i> | | | | | |
| Coordinate with local authorities to study MQ in Peru decentralized areas w/new 3-LA regs | | | DIGEMID, Peru's MRA, included the 3-LA in regulations that will be sent for approval; began coordinating with DIGEMID for a study in several regions from the Macroregion Oriente. | | |
| Guatemala V. Pribluda Remaining Activities from FY 11 funding for FY 12 activities | | | | | |
| Strengthening Quality Assurance (QA) & Quality Control (QC) Systems | | | | | |
| <i>Improve processes of evaluation of medicines' quality certificates for purchases made by the Ministry of Public Health and Social Services</i> | | | | | |
| Hold workshop to discuss practices in place, identify changes to be made in the required documents, and define the SOPs to | | <u>Q1: Completed</u> In Dec 2012, workshop held for 22 staff from the Medicine Regulatory Authority, the Logistics Department of the Ministry of Health, the Official Medicines Control Laboratory, the Vice-Ministry of Hospitals, and decentralized Departmental Health Offices. | | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| be developed | | | | | |
| <i>Building QC capacity</i> | | | | | |
| Conduct training on Minilab use and implementation of the three-level approach for the quality control of medicines. | | <p><u>Q1: Completed</u> In Dec 2012, training delivered to 24 staff from the Medicine Regulatory Authority, Logistics Department of the Ministry of Health, the Official Medicines Control Laboratory, the Vice-Ministry of Hospitals, and decentralized Departmental Health Offices.</p> | | | |
| <i>Implement QC activities in decentralized areas</i> | | | | | |
| Conduct a pilot study to evaluate the quality of medicines in the private and informal sector using the 3-level approach | | <p><u>Q1: Protocol development and sampling completed. Medicines collected are being analyzed at the OMCL.</u> The San Pedro Sacatepéquez municipality, in the San Marcos Department, was selected for the study. In Nov 2012, 74 samples (26 from the informal market) were collected, including antibiotics, analgesics, and anti-inflammatory products. Medicines were delivered to the OMCL, which will perform analysis according to the three-level approach.</p> <p><u>Q2: Level 1 and 2 analyses have been completed.</u> 5 samples failed disintegration (4 metronidazol and 1 trimetoprim/sulfametoxazol) and 1 failed visual and physical inspection (paracetamol-acetaminophen). 4 samples (1 Erythromycin Estolate and 3 Prednisone) were not analyzed because there is no methodology in the Minilab[®]. 17 samples will be analyzed by compendial methods (Level 3).</p> <p>USP standards were sent and received at the lab.</p> | | | |
| Guatemala V. Pribluda | | | | | |
| Strengthening Quality Assurance (QA) & Quality Control (QC) Systems | | | | | |
| <i>Strengthen the legal and regulatory framework</i> | | | | | |
| Review laws and regs about medicines quality and responsible agents | | Reviewed regulations and guidelines and offered suggestions for changes to quality requirements and QC of medicines during procurement by MoH at the Dec 2012 workshop | Sent suggestions for the Certificates of Analysis, which will be requested for all medicines purchased by the MoH. | | |
| <i>Building regulatory capacity</i> | | | | | |
| Assess the capabilities of the DRCPFA | | | | | |
| Upgrade DRCPFA's | | | Contract with consultant signed. Installation of | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---------|--|----|----|
| | | Q1 | Q2 | Q3 | Q4 |
| registration software | | | new software and transfer of information initiated. | | |
| <i>Build capacity to perform quality control testing in compliance with internationally recognized standards</i> | | | | | |
| Follow-up on CAPAs from previous UM-LNS assessments | | | CAPAs to observations received and reviewed. Follow up will be done by CNCC staff during training (see below) | | |
| Perform a mock-audit of UM-LNS to assess readiness for WHO PQ/ ISO accreditation | | | | | |
| Conduct training on Uncertainty Measurement | | | Training scheduled for April 2013; agenda developed in coordination with CNCC. | | |
| <i>Evaluate the quality of medicines in the private and informal sector</i> | | | | | |
| Conduct pilot study of select medicines quality from private & informal sector using 3-LA | | | Coordination for protocol development and logistics initiated by virtual conference with all relevant stakeholders (DRCPFA-MRA; DAS and Regional Hospital from Huehuetenango, PQM consultant). Agreed that Minilab® will be transferred from the UM-LNS to the DAS | | |
| <i>Strengthen DRCPFA capabilities to ensure manufacturers comply with cGMP</i> | | | | | |
| Conduct Current Good Manufacturing Practices (cGMP) training for Inspectors | | | Training scheduled for June 2013; list of topics for training identified. | | |