

**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>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 Feb 2013.</p> <p>Dr. Lukulay presented an overview of the PQM program to visitors from Equatorial Guinea at USP HQ.</p> <p>Dr. Chibwe presented an overview of the PQM program to visitors from China FDA at USP HQ.</p> | <p>In April, Dr. Lukulay and Dr. Smine presented an overview of PQM and details of the GFATM QA policy to the Nigerian NMCP.</p> <p>In June, Ms. Derry gave a presentation on PQM activities at the USP Science & Standards Symposium in Korea.</p> | <p>Dr. Lukulay presented an overview of the PQM program to the USP executive team in September.</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</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</p> | <p>In May, USP issued a press release “Center for Pharmaceutical Advancement and Training Opens in Ghana” that recognized PQM’s groundwork identifying the need to build local capacity for medicines professionals.</p> <p>This quarter, PQM was</p> | <p>In July, USP issued a press release on “Thailand’s Ministry of Public Health Laboratory Achieves WHO Prequalification Status.”</p> <p>The Maternal Health Channel of Ghana interviewed Dr. Lukulay in September about the Ghana FDA/PQM study</p> |

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| | | interview on counterfeits for the Care2 News Network | Tested by PQM” and 12 media outlets published articles. In Mar, USP issued “Medication Quality in Russia and Region Strengthened with Official Laboratory’s Accreditation” and 2 media outlets published articles. | mentioned in 28 news articles as well as in Congressional testimony on the Neglected Diseases Treatment Gap | on oxytocin and ergometrine medicines. This quarter, PQM was mentioned in 11 news 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. | | The VOA interviewed Dr. Lukulay in April on TV2Africa about the Ghana FDA/PQM study on oxytocin and ergometrine medicines used during and after childbirth. | |
| 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 | 24 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 4,078 website hits. | 39 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 2,844 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 | 8 articles, 9 photos, and 2 new or updated resources were added, including the report on the Ghana FDA/PQM study on MCH medicines. A video of the VOA TV2Africa interview was also added. | 5 articles, 6 photos, 2 press releases, and 1 new resource were added to the PQM website; 2 webpages were updated. |
| Support regional approaches and networks | | | | | |
| Contribute to NEPAD’s “Institutionalization of | | Dr. Karim Smine presented at the first | The revised criteria for the establishment of | Dr. Smine represented PQM at the second | Dr. Smine reviewed drafts establishing criteria for |

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| Regulatory Training Programs in Africa using Existing Regional Structures” Technical Working Group (TWG) | | meeting of the African Medicines Regulatory Harmonization TWG on Regulatory Capacity Development in Africa held Nov 2012 in South Africa. | Regional Centers of Regulatory Excellence (RCOREs) in Africa were issued. | meeting of the AMRH/NEPAD TWG. | RCOREs and a pool of regulatory experts. These two drafts were created through the AMRH TWG and finalized by the AMRH/NEPAD coordinator. |
| 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 prototype; an oxytocin probe is also being developed. | A PharmaCheck Global Workplan has been developed and progress monitored using Clarizen project management tool. Initial development of probes for artemisinin, artesunate, and artemisinin family completed. Tetracycline and oxytocin probes are under development. | Boston University identified the design firm, Fikst, to develop an Alpha-prototype (field-ready). This prototype is expected to be ready by mid-November 2013. |
| 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 | | Dong-A Pharmaceutical Company was WHO prequalified in Nov 2012 for Cycloserine 250 mg capsules. TA continues to manufacturers in different stages of compliance with WHO PQ including Phapros, Indofarma, Dong-A, Arterium, Zhejiang Hisun Pharma, Shalina, | 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, | TA continues to manufacturers in different stages of compliance with WHO PQ, including Hisun Pharma, Arterium, HEC, Korea United Pharm, Abbott, Sintez, Shandong Reyoung Pharma, and Dong-A Additional TA visits scheduled for next quarter: Xinhua, Reyoung, Zibo Pharma, | TA continues to manufacturers in different stages of compliance with WHO PQ, including Beijing Yabao, Hisun Pharma, Varichem, Arterium, DJPL HEC, Shalina, Sintez, Hizon, Lloyds, Phapros, and Peili Additional TA visits scheduled for next quarter: DJPL, Concept Pharma, Arterium, Dong- |

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| | | Deurali Janta Pharma, Akrikhin, Simpex, Abbott, Sintez, and Farmasintez Additional TA visits scheduled for next quarter: Korea United Pharma, Arterium, Phapros, Sandoz, and Indofarma | Phapros, Sandoz, Xinhua, and Shanghai Fosun | HEC, Fuzhou, Chengda Biotech, Dong-A, Korea United, BC World Pharma, and Shalina | A, Korea United, BC World Pharma, and Shalina |
| – To manufacturers currently in PQM pipeline | | 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 Labs, Hizon, Shalina, Humanwell, Sintez, Sandoz, Akrikhin, and Farmasintez | 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, Akrikhin, Sandoz, and Unilab | Currently in PQM pipeline: Hisun Pharma, HEC pharma, Arterium, Korea United Pharm, DJPL, Abbott, Dong-A, Shalina, Beijing Yabao Pharma, Hizon Labs, BC World Pharm, Humanwell, Sintez, Macleod's, and Metiska | Currently in PQM pipeline: Hisun, HEC, Arterium, Shalina, Sintez, Baush Pharma, Interpharma, Varichem, Yabao Pharma, Hizon, Dong-A, Metiska, DJPL, Korea United Pharma, Abbott, Peili, BC World Pharm, Concept Pharma, Humanwell, 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 | Dossier assistance is being provided to Arterium, HEC Pharma, and EnzyChem Lifescience | Dossier assistance is being provided to Arterium, HEC, Hisun, Peili, Shalina, Sintez, Varichem, and BC World Pharm |
| – With GMP audits and support until products are PQ | | GMP assessment was performed for Abbott's CMO (Akorn); mock inspection was also | GMP mock inspection conducted for Arterium | Hisun GMP inspection closed by WHO; WHO public inspection report published May 2013 | GMP assistance is being provided to Arterium, Beijing Yabao, Baush Pharma, Interpharma, |

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| | | performed at Hisun Pharma | | GMP Inspection CAPA assistance to Arterium; GMP assessment to Shandong Reyoung Pharma | Hizon, and Lloyds |
| 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 | Manufacturers' workshop conducted in Ghana in May | Manufacturers' workshop conducted with CPhI in Sao Paulo, Brazil in August |
| 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 | Dong-A Pharma, Enzychem Lifescience, Hisun Pharma, Fuzhou Fuxing Pharma, HEC Pharma, Dandong Beiqi Pharma, NCPC Huasheng | Xinhua Pharma, Hisun Pharma, Dong-A, and Fuzhou Fuxin Zhejiang Second Pharma was prequalified in Sep 2013 for Isoniazid API; NCPC WHO public inspection report published in July 2013 |
| – To API mfrs in PQM pipeline | | Total is 11: Zhejiang Hisun, Shanghai Fosun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Shenxue Dachen Pharma, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem | Total is 14: Zhejiang Hisun, Shanghai Fosun, 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 | Total is 15: Zhejiang Hisun, 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, Shenxue Dachen Pharma, Zhejiang Second Pharma | Total is 15: NCPC, Xinhua, Hisun, Dong-A, HEC, Jinxin Pharma, Enzychem, Fuzhou Fuxin, Yongning Pharma, Apelo Kangyu, Zhejiang Neo Dankong, Suzhou Kaiyuan Minsheng, Dandong Beiqi, Zhejiang Excel Pharma, and Shenxue Dachen Pharma |
| – To new mfrs on | | Zhejiang Xinhua Pharma | Xinhua Pharma, Fuzhou Fuxin, Dong-A | Enzychem Lifesciences, HEC, Fuzhou Fuxing | Dong-A, NCPC, Fuzhou Fuxin |

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| dossiers | | | | | |
| – 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 | Enzychem, Zhejiang Hisun Pharma, NCPC Huasheng, Fuzhou Fuxing, Dandong Beiqui | Xinhua Pharma |
| Participate in GDF and WHO meetings with mfrs to discuss PQ | | Attended meeting with WHO PQ team in Geneva | No meetings attended | Attended meeting in Geneva for GMP inspection harmonization Attended GDF stakeholders' meeting in Sri Lanka | Members of the GMP staff attended the Manufacturer's Meeting in Copenhagen, Denmark |
| Complete development of Minilab® test methods for SL-ATBs | | Developed and published methods for Clarithromycin, Kanamycin, and Ofloxacin | No new methods developed | No new methods developed | PAS, Amikacin, Capreomycin, Streptomycin |
| 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) | Comparator products provided to Hisun (Ofloxacin 200, 400 mg, Streptomycin, Levaquin); Hizon (Levaquin); Reference Standards provided to NCPC (Streptomycin); Liaoning (Kanamycin Sulfate); Hizon (Levofloxacin and Related Compounds); DJPL (Levofloxacin and Related Compounds); Reyoung Pharma (Capreomycin and Streptomycin) | Comparator products provided to Varichem (Levaquin 750 and 500 mg), Hizon (Levaquin 500 mg), Metiska (Levaquin 500 mg), Theragen Etex (Peteha 250 mg), Hisun (Seromycin 250 mg), Peili (Levaquin 250 and 500 mg) Reference Stds were provided to DJPL (Levofloxacin and related compounds), Metiska (Levofloxacin), Hizon Laboratories (Levofloxacin and related compounds) and Pharmgear Sciences |
| 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 | In progress | In progress |
| Conduct quality monitoring for SL-ATBs | | In progress | In progress | 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; 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 | This is currently on hold; legal matters are under review | Baush and Interpharma have been assessed for Capreomycin and Kanamycin FPP. Both companies are currently compiling dossiers to be submitted to WHO PQ. |
| 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. | A total of two studies have been completed in Congo Brazzaville. | One study was completed in Uganda; data is under review. | One study completed in Liberia. |
| Develop reports and disseminate results | | | Two reports for Congo Brazzaville completed. | One report for Uganda is being prepared. | One report for Uganda study completed; one report for Liberia also 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 | | Liberia was selected; the second country is still in | Study in Liberia underway. | On hold per USAID/PMI Washington | Study discontinued. Status report issued to |

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| monotherapies | | discussion | | | USAID |
| 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. | | Study discontinued. Status report issued to USAID |
| Travel to sites and conduct survey | | | Plans to travel to sites with partners to conduct studies are underway. | | Study discontinued. Status report issued to USAID |
| Procure samples and generate reports | | | | | Study discontinued. Status report issued to USAID |
| 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 innovator company for DHA/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. | Monograph posted in USP Medicines Compendium. | |
| 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. | Completed | |
| Validate analytical methods | | | | Completed | |

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| Publish method in manual | | | | In process | Completed |
| 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. | Completed and report shared with USAID PMI/Washington | |
| Maternal Health and Child Survival L. Evans | | | | | |
| 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) | Visited Madagascar manufacturers in Apr 2013; conducted GMP assessment and issued report | |
| 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. | Continued supporting Nepal manufacturer; visit to Nepal to evaluate the GMP implementation plan is scheduled for Q4. | Visited Lomus in Sep 2013 as follow-up to Jan 2013 visit to determine status of CAPAs. |
| 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 | No samples requested for testing | No samples requested for testing. |
| 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. | Visits to Ghana and Tanzania manufacturers planned in Q4. Continue to support Kenya manufacturer; their new facility is under | Visits to Ghana and Tanzania manufacturers will be rescheduled once some equipment has been installed and renovations completed. |

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| | | | | construction | Continue to support Kenya manufacturer. |
| 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 | PQM lab completed testing of 2 zinc samples from Ghana received at end of Q2. One zinc sample received in Q3 from Ghana will be tested in Q4. | PQM lab completed testing of 2 zinc samples received in Q3 from Ghana. |
| 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 (QAP) for antimalarial medicines and diagnostics | | | Information gathered to develop a quality assurance policy for the national malaria control program. | The QAP is being drafted. | PQM is coordinating with NMCP to finalize the QAP. |
| 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 | The implementation plan was developed and shared with the National Institute of Public Health. The Institute's lab provided feedback that was incorporated into the document. The plan will | Complete. The final implementation plan will be shared with stakeholders. |

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| | | | standards. | be shared with USAID-Burundi for approval. | |
| 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. | The draft law was reviewed and comments and recommendations were communicated to the medicines regulatory authority (DPML). | Complete. DPML will update PQM on the progress made in finalizing the Pharmaceutical Act. |
| Ethiopia | | Eshetu W. | | | |
| 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. | Supported FMHACA management in organizing a workshop at Yabelo, Borena Zone, Oromia Region to create public awareness of the illegal medicines trade (from bordering countries and leakage of medicines from public distribution systems) and to promote cooperation and collaboration in the fight against such illegal trade. | Supported the organization of a public awareness workshop in Togo-chale, The Somalia Region is to combat the illegal trade of medicines and promote cooperation among stakeholders. |
| 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 | Training on basic GMP held in Bishoftu in Jan-Feb; 40 participants from FMHACA and local pharmaceutical industry attended. | | Supported two FMHACA staff to go to Ghana for dossier assessment training provided by CePAT; provided in-house training on dossier assessment for 15 new |

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| | | GMP principles for FMHACA staff. | Training for FMHACA staff on basic dossier assessments held in Bishoftu in March; 32 participants from Ministry of Agriculture and FMHACA attended. | | staff. |
| Recommend solutions to gaps w/timelines & 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. | | SOW for IT expert to create an information and data management system prepared, together with SIAPS Concept paper prepared and submitted to FMHACA | Invitation advertised in the local newspaper for IT companies to submit bids. Final concept paper prepared and issued to IT companies. Evaluation of bids is in progress. |
| 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. | USP signed a tripartite agreement in March to move the PQAD lab to the new site. One PQAD staff sent to India for training on lab equipment maintenance Mar-May 2013. Lab equipment, | Practical training was given in May/June to 15 PQAD staff on compendial medicine analysis techniques. The PQAD laboratory (physic chemical) moved to the new site. Equipment was installed and IQ/OQ carried out to | Provided training on Good Documentation Practices (GDP) and Karl Fischer titration for new staff. Supported PQAD staff to train in Thailand for two weeks on microbiological methods of food testing. |

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| | | | chemicals, and reference standards purchased and supplied to FMHACA laboratory. Assisted PQAD to participate in proficiency testing for 3 tests; supplied reference standards and other laboratory supplies. | make them fully operational. Supported the PQAD lab's participation in Proficiency Testing (PT). Laboratory supplies purchased Supported five PQAD staff to attend hands-on training on equipment maintenance at Shimadzu laboratory in Japan. | |
| Support FMHACA condom lab to become ISO 17025 accredited and WHO prequalified | | | | | |
| Develop a detailed implementation plan with timelines and expected outcomes | | Condom testing lab will participate in PT by Enersol Australia; PQAD condom analysts were trained at FHI360 lab in Thailand. | Revised five SOPs; 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. | Provided Minilab training for branch staff. | |
| 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 | | Collected samples from one sentinel site | | Collected samples from six sentinel sites; testing | Testing of antimalarial samples completed. |

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| revise protocol | | | | started | |
| 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 | | | | | Writing of the PMS report is in progress. |
| Support local OI medicines manufacturers to become GMP compliant and their OI products WHO prequalified | | | | | |
| PQM & PRLD will identify potential local OI medicines mfrs | | <p>Feedback on the GMP compliance report received for three manufacturers; CAPA report for remaining manufacturer under discussion.</p> <p>A team made up of partner representatives was established to develop the GMP roadmap.</p> <p>A confidentiality agreement for the direct support of Cadila Pharmaceutical (Ethiopia) for WHO PQ was signed</p> | With the working group, prepared a first draft of the roadmap of local pharmaceutical manufacturing | Roadmap discussed at a workshop in which FMHACA, academia, and government agencies participated. | Roadmap finalized and submitted to FMHACA. |
| 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 | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|--|--|---|
| | | Q1 | Q2 | Q3 | Q4 |
| 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 | | | | Supported training of pharmaceutical industry staff to be trained in medicine registration in Ghana (organized by CePAT) | |
| Monitor and evaluate program implementation | | | | | |
| Develop monitoring & evaluation tool | | | | | |
| Conduct monitoring & evaluation of program implementation | | | | | No monitoring and evaluation carried out. Funds allocated were used to organize a public awareness program to combat the illegal trade in medicines |
| 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 | | | | | |
| 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. | Minilabs shipped to 2 new sites. | Minilabs testing was completed and results sent to PQM |
| Conduct two rounds of MQM at selected sites for testing | | | Contract for MQM money transfer submitted. | Funds transferred to FDA in Jun. Training for new inspectors to be conducted by FDA. | First round completed |
| Conduct confirmatory testing at FDB lab and CePAT | | | Planned for Q3 | Planned for Q4 | Confirmatory testing ongoing; FDA lab just moved to new site in September |
| Conduct onsite | | | Planned for Q3 | Planned for Q4 | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| evaluations of selected sentinel sites | | | | | |
| Promote enforcement actions based on data | | | Planned for Q3 | Planned for Q4, pending results of MQM testing that will be confirmed at the CePAT. | Waiting for confirmatory testing |
| 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. | Floor work completed; furniture currently being set up in lab. | Lab move completed in September; Trip planned for qualification of equipments for ISO 17025 |
| 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. | Shipped calibrated thermometer to FDA. Provided consumables for Dissolution and eye wash for the lab. | Equipment and supplies list compiled that affect accreditation; Quotes pending for procurement |
| 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. | Training planned for Aug 2013 after the move to new site. | Trip planned for November 2013 for training and qualification. |
| Facilitate assessment audit and provide TA with CAPAs | | | Provided TA via e-mail and teleconferences. | Provided TA in weekly teleconferences regarding status of move and preparation for ISO. | Proposed for Q1 of new fiscal year |
| Collaborate with FDB and other stakeholders in the local pharmaceutical industry to build capacity for GMP improvement | | | | | |
| Conduct baseline GMP assessment of local manufacturers | | | | GMP workshop was held in May for manufacturers interested in receiving PQM technical assistance. | |
| 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 | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|--|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| Support data entry and develop statistics using MQM data | | To be entered in Q3 upon completion of MQM | | Results are pending ongoing MQM sampling and testing, to be completed in Q4 | Minilab testing completed and forwarded to PQM; waiting on confirmatory testing. |
| Sensitize the public to the dangers of substandard and counterfeit medicines through IEC activities | | | | | |
| Facilitate dissemination workshop for media, public re CSM findings | | | | Planned for Q4 upon receipt of MQM results | Delayed due to late start of MQM. |
| 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. | Minilab training completed for 24 participants. | |
| Conduct supervisory and M&E visits to sentinel sites | | | | Will be conducted Aug/Sep 2013 | Site visits to Kakamega and to Eldoret site completed. |
| Confirm validated samples at NQCL | | | | | Samples validated. |
| Provide TA to NQCL on using pharmacopeial methods to test failed samples, samples with reported ADEs, and any sample collected from refugee camps | | | | | The head of the PV program left PPB; therefore, only samples collected from refugee camps and from sentinel sites will undergo QC testing at NQCL (Oct-Nov 2013) |
| Continue to promote regulatory actions by sharing MQM data | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| Promote efforts to support enforcement actions by PPB based on data | | | | | PPB recalled and confiscated failed quinine tablets and injections found during round 3 at Kakamega and Kisumu sentinel sites. For round 4, PPB is awaiting the QC results from the lab. |
| Share data w/PPB, DOMC, and other stakeholders to raise awareness | | NQCL completed confirmatory testing on nine quinine sulfate products; two failed and the results were submitted to DOMC and PPB for action. A report on the second and third rounds of MQM activities will be shared at a stakeholders' meeting in Q2. | Report on third round drafted and will be shared with stakeholders in Q3. | Report on third round shared with stakeholders | Report on results of rounds 2 and 3 were shared at a meeting with stakeholders at the MSH office. |
| 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. | ILP report sent to PQM for review. | Revised ILP report was submitted to NQCL; a meeting will be held in Accra in Dec 2013 to discuss the ILP results from all NOMCOL members. |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|---|---|---|
| | | Q1 | Q2 | Q3 | Q4 |
| NQCL senior staff will participate in NOMCOL meeting | | PQM facilitated the participation of the NQCL deputy director in a NOMCOL directors meeting. | | | NQCL's new director and the lab analyst who conducted the ILP testing will attend the NOMCOL meeting in Dec 2013. |
| 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 | | Application submitted to SANAS. | |
| Review NQCL QMS documentation and quality manual | | NQCL quality manual revised and corrections / suggestions for improvements submitted to NQCL | | NQCL has updated their quality manual and the majority of the Quality Management documents. | |
| Assist NQCL in starting the process of SANAS pre-audit | | | Provided guidance and reviewed application forms to start ISO 17025 accreditation with SANAS. | NQCL is reviewing Corrective and Preventive Actions (CAPAs) and preparing for internal audit and management review | |
| Assist NQCL in addressing the major and minor findings | | | | Provided follow-up on the major findings from PQM audit and site visit; report submitted to NQCL following April visit. | |
| 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. | Additional lab supplies were sent to the lab | |
| Provide step-by-step training in compendial methods and Good | | Training is scheduled for Feb 2013 | Lab training provided for 5 staff; additional training on USP General | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|--|--|---|
| | | Q1 | Q2 | Q3 | Q4 |
| Laboratory Practices, according to international standards | | | Chapters and General Notices was also provided. | | |
| Assist the lab staff in conducting confirmatory testing on samples that failed Minilab testing | | PQM assisted the lab to test antimalarials (monotherapy and FDC) and selected ARVs; results will be submitted Jan 2013 | Using compendial methods, 3 ARVs and 7 antimalarials were tested; the ARVs all passed, but two antimalarials failed. | | |
| Procure a power stabilizer, fuel, and lubricants for the generator procured by LMRHA | | | | Provided guidance on combining solar energy with their new generator. Provided a list of vendors to LMHRA. | |
| 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. | | Additional new water system was installed and the existing one repaired. |
| Secure a contract for maintenance service to repair non-working lab equipment | | PQM provided TA to troubleshoot some lab equipment | | Will be completed in July | A lab maintenance contract was established. |
| Continue assisting LMHRA in strengthening its regulatory capacity | | | | | |
| Strengthen LMHRA inspection functions | | | | | New registration software was installed and 7 staff from the inspectorate department were trained |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---------|---|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | | | on the inspection module. |
| Strengthen LMHRA medicines registration system | | | | Registration system training and set up will be provided in July 2013. | New registration software was installed and 8 staff from the registration department were trained on its use. |
| 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 roles, responsibilities | | | Plans made to establish the MQM program | Planning complete | MQM protocol established |
| Select sampling sites in 1-2 counties | | | | | 2 counties, Margibi and Bomi ,were selected as sentinel sites for samples collection for round 4 |
| Conduct one round of sampling and testing of essential medicines | | | | Part of this activity will be conducted Jul/Aug | One round of sampling and testing with Minilab was completed at Margibi. Sampling and testing at Bomi will be completed in Nov 2013. |
| Provide Minilab [®] supplies & reagents; NQCL supplies & RS | | | Lab supplies provided | Ongoing | Additional lab supplies were provided to the lab. |
| Draft and share reports with stakeholders | | | | | Report on round 3 was submitted to stakeholders. Report on round 4 is pending completion of sampling from Bomi site. |
| Promote LMHRA taking enforcement actions based on MQM data | | | | Provided supporting documents to LMHRA to take action on collected samples. | More than 20 regulatory actions were taken by LMHRA on failed samples and on vendors selling unregistered pharmaceutical products |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | | | (full report of regulatory actions was given to the PMI advisor in August) |
| 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 | Provided training on advanced HPLC and follow up on KF; additional TA provided via e-mail. | Activity on hold due to availability of funds. |
| Procure and install equipment and supplies | | Procured and shipped reagents, lab supplies, and reference standards; ordered International Pharmacopeia; obtained quotes for major equipment | Procured and shipped lab consumables and equipment; ordered major equipment which is en route to Maputo | Shipped and installed major equipment (Dissolution, Disintegration, water distiller, and UV/Vis); Perkin Elmer qualified the UV and provided basic training. | Activity on hold due to availability of funds. |
| 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 | Strategic plan provided; will be translated into Portuguese. | Activity on hold due to availability of funds. |
| Sensitize the public to the a dangers of counterfeit and substandard medicines by publicizing LNCQM and PD 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 | MQM round 1 is ongoing. | MQM round 1 completed and results sent; PD advised PQM that political sensitivity precludes PQM from publicizing a message at this time. |
| Establish an IEC campaign to inform | | To be performed Q2-Q4 | | | PD advised PQM that political sensitivity |

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| Activity | Staff Lead | Quarter | | | |
|---|-------------------------------------|--|--|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| public about CSMs | | | | | precludes PQM from publicizing a message at this time. |
| Coordinate activities between LNCQM and ARV manufacturer | | Discussion meeting planned with head of PD, USAID, and SMM | | | ARV manufacturer still not producing any medicines |
| 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 | 2 Minilabs shipped to 2 new sites | MQM round 1 completed and results sent; issues with funding prevented the initiation of round 2 |
| 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. | Trained provincial staff in April 2013, and completed round 1 sample collection; compendial testing ongoing at LNCQM. | Results of round 1 sent to PQM; Round 2 pending availability of funds |
| 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. | Provided pertinent information to DF on taking actions in April. | PD advised PQM that political sensitivity precludes PQM from publicizing a message at this time. |
| Nigeria | M. Hajjou (Malaria); L. Evans (MCH) | | | | |
| Assess the quality assurance/quality control of antimalarial medicines | | | | | |
| Conduct field visit; meet with stakeholders involved in QA/QC | | | | Field visit conducted and meetings with stakeholders involved in medicines QA/QC were held to identify the needs of the National Malaria Control Program (NMCP) and the National Agency for Food and Drug Administration and Control (NAFDAC). Based on the | |

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| Activity | Staff Lead | Quarter | | | |
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| | | Q1 | Q2 | Q3 | Q4 |
| | | | | discussions, a work plan was developed. | |
| Monitor the quality of antimalarial medicines | | | | | |
| Establish an MQM program | | | | 24 participants from NAFDAC, the Federal Central Store, and the National Product Supply Chain Management Program were trained in medicines sampling and testing using Minilab. An MQM protocol was developed. | |
| Conduct one round of sampling and testing | | | | One round of sampling and testing is expected to take place in August. | Resources provided to NMCP for conducting one round of sampling and testing antimalarials. The first round is expected to complete by the end of this calendar year |
| Promote enforcement actions | | | | | |
| Monitor MQM activities | | | | | NMCP and NAFDAC will conduct visits to sentinel sites to monitor the implementation of MQM protocol |
| Strengthen the regulatory capacity of NAFDAC | | | | | |
| Train staff in select competencies | | | | Training for 4 NAFDAC staff in dossier evaluation at the Center for Pharmaceutical Advancement and Training in Ghana is underway; 2 additional NAFDAC staff will be trained in quality control | Two staff received training on Dossier Evaluation in September; NAFDAC sponsored two additional staff. |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---------|----|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | | in September. | |
| Assist NAFDAC's central QC lab in attaining ISO 17025 accreditation | | | | | |
| Review the lab QMS and analytical capacity | | | | Yaba lab was evaluated; Nonconformities and recommendations for corrective actions were identified and provided to NAFDAC management; a timeline to prepare for an audit by an accreditation body was also provided to NAFDAC management. | |
| Develop implementation plan toward ISO 17025 accreditation | | | | The implementation plan will be provided to NAFDAC by Sep 2013. | PQM provided a detailed audit report which serves as an implementation plan; this report contains all of the actions that NAFDAC needs to take to address identified gaps. |
| Support the NMCP in developing a quality assurance policy for antimalarial medicines and diagnostics | | | | | |
| Collect key information from NMCP on current practices & procedures for medicines and diagnostics QA | | | | The scope of the QA policy has been expanded to include TB and HIV/AIDS. | |
| Assist NMCP draft a QA policy document based on practices and available resources | | | | The QA policy is being drafted. The policy will cover TB and HIV-AIDS in addition to malaria. | |
| Build capacity in GMP of selected local manufacturers of zinc sulfate, chlorhexidine, and other MCH commodities for global and local supply | | | | | |
| Identify (map) and conduct baseline GMP assessments of selected manufactures | | | | Requests for expressions of interest to identify manufacturers of zinc sulfate tablets, ORS, and CHX gel were issued and responses received from local manufacturers. | Rapid assessments were conducted of 6 manufacturers who submitted EOIs for the production of CHX gel. |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | | | GMP assessment of Chi Pharmaceutical's zinc sulfate tablets manufacturing line was conducted and rapid assessments of other companies who intend to manufacture zinc were conducted as well. | |
| Provide TA to promising companies to improve GMP compliance. | | | | | PQM provided TA to 2 manufacturers regarding API source and input on facilities. |
| Conduct medicines quality testing of selected medicines | | | | PQM received zinc samples (4 different lots) from a Nigerian manufacturer and public market. | PQM completed testing of 4 zinc samples from Nigerian manufacturer and public market. |
| 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 medicines at nine sites | | <p>Round 2012: Sample collection and testing using basic tests completed in the remaining 4 sentinel sites; prelim report submitted to major stakeholders; confirmatory testing of 2012 round will be completed by Jan 2013.</p> <p>Round 2013: Initiated planning for one round of MQM activities</p> | <p>The majority of confirmatory testing has been completed.</p> <p>Budget and plans made to start 2013 round.</p> | 2013 round started at selected sites; sample collection and Minilab testing will be completed by August. | Sample collection and testing using Minilab completed. |
| Monitor and evaluate MQM activities at | | | | | Site visits conducted by the focal point for selected |

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|---|------------|---|---|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| selected sentinel sites and share pharmacovigilance tools with the MCR of each region | | | | | sites. Due to change in DPM management, the PV reports were not prepared by the site visits. |
| 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. | Meeting was conducted and presented to the technical committee | |
| 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. | | Workshop postponed until FY13 because of change in DPM management. |
| 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. | | ILP testing of ciproflaxin completed, and the revised report by PQM was sent to LNCM. |
| 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. | | Follow-up with the lab showed that LNCM has resolved the major inspection issues and is improving on the minor issues. | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| 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. | | Site visits conducted to review the progress toward ISO 17025 accreditation. | |
| 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. | PQM has revised and/or drafted 20+ SOPs. | |
| 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. | LNCM plans to complete the technical and managerial documents by the end of August. | Managerial document (section 5) was submitted to PQM for review. |
| Assist the lab in selecting accrediting bodies for testing, calibration, and proficiency testing (PT) and submitting the accreditation applications | | With PQM assistance, LNCM selected TUNAC as their accrediting body for testing; PQM and LNCM initiated the process of submitting the application to TUNAC and for selecting the accrediting bodies for calibration and PT | | TUNAC submission delayed due to the delays in the revision of the QA manual and completion of the section 5 technical documents and PT. | TUNAC submission is pending the new organization of LNCM. |
| 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 | Preventive maintenance and training provided by ZefSci Corporation, an external vendor | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|---|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| 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. | Met with local partners and conducted sentinel sites visits (Binh Phuoc) in Vietnam for situation analysis and insights for use in the improved sampling protocol. | An improved sampling strategy (targeted to locations based on intelligence gathered from the MRA) and technique (improved mystery shopper) were put in place to collect antimalarial samples from hotspot areas in Cambodia (Ratanakiri and Mondulakiri). Samples are being tested at NHQC and Chula PTSC Lab. Similar strategies and techniques were used in Rakhine State. |
| Help GMS partners conduct 2 MQM rounds in hot-spot border areas using new protocols | | Planned for Q3 | Planned for Q4 | Planned for Q4 | 35 samples were collected from Cambodia and Burma using the improved sampling protocol. Samples are being analyzed. Samples were not collected in Laos, Vietnam or Thailand this quarter. |
| 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 | Followed-up on CAPA implementation and reviewed SOPs submitted from Laos and Cambodia labs. | Review of the Quality Manuals and SOP documents from Laos FDQCC and NHQC is ongoing. |

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|--|------------|---|---|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | were requested. | <p>Drafted a joint press release on Thailand BDN lab achieving WHO PQ status.</p> <p>PQM has been notified that the Vietnam NIDQC has achieved WHO re-qualification status; official re-certification to be received in Q4.</p> | <p>A joint press release was issued.</p> <p>Notification of NIDQC's official re-qualification for another 3 years has been received.</p> |
| Train Mahidol GMP-compliance faculty on WHO PQ process | | Planned for Q4 | Initial discussions were held with Mahidol team re: training schedule and logistics | Planned for Q4 | This training was modified to fit the situation in the region. The training was conducted in collaboration with the ASEAN Secretariat for country MRAs with financial contribution from USAID missions in the Philippines, Indonesia, and PMI-RDMA. This regional training was conducted in Sep in Manila with 38 participants from ASEAN countries. |
| 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 | Chula team and PQM Lab Services team developed a training preparation plan and training materials, identified modules, and acquired samples and RS. | Due to delays in acquiring new lab equipment (HPLC and Dissolution tester) at the Burma FDA and their recent restructuring, the training is postponed to FY14 Q1. |
| Support regional and in-country coordination for effective enforcement through BREMERE and, possibly, WHO SSFFC mechanism | | | | | |
| Support BREMERE quarterly meetings to share information, and | | Implementation meeting scheduled for Feb 2013 in Cambodia | Implementation meeting held in Feb. An action plan was developed and | Requested official confirmation of nomination of BREMERE | Burma, Cambodia, Laos, and Vietnam have officially confirmed their |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|---|--|---|
| | | Q1 | Q2 | Q3 | Q4 |
| coordinate enforcement | | | disseminated among the BREMERE countries. | membership from countries: Laos, Cambodia, Thailand, Vietnam, Myanmar, Indonesia, and Philippines | membership, with focal persons, to BREMERE. Indonesia, the Philippines, and Thailand are waiting for high-level approval. Some priority products were identified from investigations (artesunate tablets and other artemisinin monotherapy products, chloramphenicol tablets, clarithromycin tablets, and methronidazole tablets) |
| Support investigations on timely reporting and enforcement with WHO-INTERPOL | | Planned for Q4, after obtaining the results of the comparative study of AML quality | | Planned for Q4 | A meeting among PQM, WHO/WPRO, SEARO, and INTERPOL took place in Bangkok Aug 2013 to discuss action plans for collaboration under BREMERE. |
| Disseminate findings of investigations and report data to MQDB | | Planned for Q4 | | Planned for Q4 | Due to the delay in implementing the comparative study, results were not obtained this year for response action. Laos and Vietnam are in the process of collecting data, while Thailand and Cambodia are still obtaining official clearance from the MOH. |
| 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 were presented at the BREMERE meeting in Siem Reap, Cambodia | Data and PQM program activities were presented at the Pathways to Safe Medicines: Protecting Patients through Unified Global | PQM presented its program strategies, accomplishments, challenges, and lessons learned at the WHO Bi-regional Meeting on |

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| | | | | Action in London in June | Healthy Borders in the Greater Mekong Subregion in Aug 2013 in Bangkok. |
| 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 | Planned for Q4 | A follow-up meeting was conducted with the Dean and team of University of Health Sciences Faculty of Pharmacy in Cambodia; the activity will take place in FY14 Q2. |
| Submit final curriculum for ratification by responsible agency | | Planned for Q3 | | Planned for Q4 | Postponed to FY14 Q2 |
| Field-test the new curriculum at two Pharmacy schools | | Planned for Q4 | | Planned for Q4 | Postponed to FY14 Q2 |
| 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 Kamponcham by the French Fonds de Solidarité Prioritaire and the Cambodia Economic Police team. | The final version of Pharmacide: Mekong was translated and subtitled into Thai language. In Q4, the film will be publicly screened in Indonesia, as well as at a USAID/Indonesia roundtable lecture series in Jakarta. Plans are in place to translate and subtitle the film into Bahasa Indonesia by the US Dept of State during Q4 or FY14 Q1. | The film was screened at the Pharmacide Arts and Documentary Film on Counterfeit Medicines Exhibition in Bangkok by the French Ministry of Foreign Affairs Priority Solidarity Funds Mekong Project and partners (PQM, Soho Films International, WIPO, Cecil and Hilda Trust, and Meta House Cambodia); the event was attended by some 20,000 viewers according to the organizer. |
| Adapt and disseminate | | Leaflets, brochures, and | Leaflets on basic | Leaflets and posters on | Several hundred leaflets |

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| BCC/IEC materials to raise awareness in high-risk areas | | <p>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.</p> | <p>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.</p> <p>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.</p> <p>A preliminary report of the survey on awareness of retail pharmacists was presented by the MOH/FDD and the Embassy. Interventions have been introduced and evaluation is planned for Q4.</p> | <p>awareness of poor-quality medicines, jointly produced with CAP-Malaria, were converted into booklets and are ready for printing and dissemination among elementary school students and their families.</p> | <p>and posters on awareness of malaria and poor-quality medicines are being printed for dissemination with the help of CAP-Malaria and other partners in Cambodia for all elementary schools in malaria hot-spot areas.</p> <p>The MOH/FDD of Laos has submitted the findings of the pre-intervention survey of retail pharmacies in Vientiane to the US Embassy in Vientiane and to PQM for comment and advice for the intervention phase. Post-intervention phase interviews are ongoing and a report will be available in FY14 Q1.</p> |
| 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 | | No tangible progress | Awaiting clearance and | After receiving clearance | After extensive efforts, the |

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| partners for pragmatic advice on establishing an MOC with MOH | | made due to political sensitivities and restrictions. An office space in Yangon will be established under an agreement with CAP-Malaria. | 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. | from RDMA, the draft Letter of Agreement was submitted to Myanmar FDA MOH for input; after review/minor edits, the FDA recommended the LOA should be signed by USP or USAID/Burma and counter-signed by the International Health Department of MOH. CAP-Malaria has agreed to provide an office with some administrative support to PQM. An agreement is under review by both parties. | Letter of Agreement between the MOH of Burma and USP has been signed by USP and submitted to the MOH for signature. To enhance the collaboration between CAP-Malaria and PQM, an MOU has been signed by both parties. A PQM office was opened in Burma in Aug with the assistance of CAP-Malaria. |
| 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 hired and will begin in May. | A second full-time consultant was hired in May. | Completed |
| 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 | Still awaiting authorization from both RDMA, USAID/Burma, and USAID/HQ | Authorization to purchase and provide 1 HPLC and 1 Dissolution tester to FDA Burma was obtained from USAID (PMI, RDMA, and Burma). The equipment should arrive in Burma in FY14 Q1. |
| Train lab staff to test A/L , DHAP/PIP FDCs | | Planned for Q2-3 | Postponed to Q4 | Planned for Q4 | Delays in receiving the new lab equipment led to postponement of training to FY14 Q1. |

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| 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 | | Planned for Q4 | Due to delays in formalizing a program presence in Burma and receiving the test results from the NIDQC and IDQC labs in Vietnam, the meeting is postponed to FY14 Q1. |
| 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. | No substantial progress been made because: - DDF attempted, but failed, to convince the MoH to allocate a budget for FY14 PMS activities in National Annual Operational Plan - GF has not issued new funding to resume MQM activities. | This activity has been on hold because there is no financial commitment in Cambodia's annual operational plan (AOP), although DDF submitted the proposal to national budget committee. |
| 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 | PQM was informed unofficially that there will be new GF funds for 5 countries in GMS, including Cambodia, for malaria activities. PQM has been in close discussions with WHO,GF, UNOPS, and MoH to understand GF's new funding mechanism and application for potential collaboration and involvement | PQM made several attempts to engage these institutes to financially support or offer similar programs like MQM to continue to help DDF in monitoring the quality of medicines with little progress. |

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| 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 | No further sample collection and testing at 12 sentinel sites. The previous collected samples and failed samples are undergoing confirmatory testing at NHQC. | 9 antimalarials (AMLs) were collected during PQM's field visit to Rattanakiri and Mondulkiri in July 2013. 5 AMLs were sent to NHQC for quality testing. PQM is planning to support the following sites in FY14: Battambang, Pailin, Pursat, Kratie, Rattanakiri, Mondulkiri, Steung Treng, Preah Vihear, Oddar Meanchey. |
| Focus efforts on non-MQM regions of growing AMR & borders with Thailand, Vietnam | | In Oct, PQM, in collaboration with local 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. | Sampling and testing within 9 non-MQM sites is ongoing. A study team is ready to start the comparative study after funding is allocated and a protocol is in place. | 160 samples were collected and tested from the 9 non-MQM sites; 13 samples failed quality tests. The IMC secretariat team held a meeting to evaluate the 13 failed samples in June and decided to: - Remove the registration numbers of 2 products (Levofloxacin 500mg manufactured by Flamingo-India and Cetirizine manufactured by Troikaa Pharmaceuticals Ltd.-India). - Buy 4 more samples (2 samples in duplicate) and re-test the quality for further investigation. - Officially give warning to | Following the receipt of MQM testing results, the Cambodian MoH decided to ban all product registrations from Flamingo Pharmaceutical Limited-India due to its products' poor quality and repeated failures in quality tests. PQM re-submitted its request to the MOH's Secretary of State, His Excellency Chou Yin Sim, to authorize sample collection from the public sector in addition to the private sector (previously approved). The MOH requested that the request should be submitted after the general election. |

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| | | | | <p>the 6 pharmaceutical companies (Mega, Ratanak Ratana, Vimpex, Zifam, Medical Supply, and Vignesh)</p> <p>The comparative study on the quality of antimalarials was delayed because approval from the MOH to sample at public health facilities was not been received; PQM will submit a letter for MOH approval in Q4 and activities will begin thereafter.</p> | |
| 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. | Summaries on the data analysis from MQDB have been drafted. | PQM made progress in improving and upgrading the MQDB and summarized Cambodia's information. |
| 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. | An action plan was developed. | Guideline on Recall of Pharmaceuticals Products is being reviewed by the DDF technical working group. |
| Continue strengthening PQM/IMC efforts on enforcement actions | | Supported annual IMC meeting held in Dec. | PQM and IMC have closer collaboration through BREMERE. | DDF-MoH/IMC Secretariat is developing guidelines for enforcement action after finding poor quality | DDF adaptation of the PQM guidelines is ongoing. |

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| | | | | medicines. PQM sent the Enforcement Action Guidelines to DDF-MOH for adaptation. | |
| Strengthen medicines quality assurance and quality control systems by building up the capacity of DDF and NHQC | | | | | |
| 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. | NHQC management, the Arc2lab consultant, and PQM held a teleconference in May to: - Receive updates about NHQC’s situation relating to lab construction. - Discuss providing TA re: lab equipment and furniture specifications. - Discuss how to work together more effectively - Receive updates on NHQC’s quality management System status and follow-up steps | PQM met with the NHQC, DDF, and MOH Secretary of State for Health to get updates on the new national laboratory construction and the lab’s Quality Management System (QMS) progress; revisions to the FY14 action plan were discussed. |
| 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. | NHQC sent a master list of documents available and currently being implemented in their lab to PQM for review. | The next steps have been discussed to help the lab in producing its Quality Manual and Document Control and to develop SOPs. |
| Enhance the capacity | | PQM has proposed | PQM in-country | PQM discussed with the | The training plan for |

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| of NHQC to conduct confirmatory testing | | inviting one senior scientist from NHQC, via USP's visiting scientist program, to come to USP for 2-4 weeks of hands-on training. | consultant collaborating with NHQC management on logistics of training. | NHQC director nominating one senior scientist to be trained at USP HQ in September | NHQC has been finalized. |
| 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 | Training modules are being developed. DDF-MoH will submit these modules to PQM for review in Q4. | No progress made due to political tension following the election. |
| Develop local expertise in QA/QC, medicines regs by expanding pharmacy curriculum | | 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. Questionnaires are being developed to survey final-year pharmacy students on their QA/QC knowledge. 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. | No progress | Survey questionnaires have been drafted and are being reviewed A letter requesting permission to give the survey to pharmacy students has been sent to the dean of IU; a similar request to the school's ethics committee will also be sent A meeting with the University of Phnom Penh requesting their participation in the study is planned for Q4. | PQM met with the Dean and team of the University of Health Sciences Faculty of Pharmacy to discuss action items which will be implemented in Q1-Q2 FY14. |

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| 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 | | | <p>Leaflets on basic knowledge of counterfeit medicines were printed and distributed to drug 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> | URC and PQM converted the poster into booklets to more effectively raise awareness among elementary school students and their families. These booklets will be printed in Q4. | Printing is delayed to FY14 Q1. |
| Collaborate with PAC to publish bulletins and newsletters and conduct educational workshops | | | No progress | 1 bulletin is being prepared for Q4. | 1 bulletin was issued |
| 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 | The DDF Director nominated 2 representatives (Drug Inspectors) to join the BREMERE regional | PQM is in the process of helping DDF (in their first term of Chairmanship) compile the official nomination list from each |

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| | | | <p>participants from Cambodia, Laos, Vietnam, Thailand, and South Korea, and other partners such as FSP. Dr. Heng Bunkiet, DDF Director, was selected to be BREMERE's Chair for the next two years.</p> | <p>working group. An action plan for 2013-2014 was developed.</p> | <p>country in the region to join BREMERE operations. Some priority products were identified from investigations (artesunate tablets and other artemisinin monotherapy products, chloramphenicol tablets, clarithromycin tablets, and methronidazole tablets)</p> |
| Indonesia C. Raymond | | | | | |
| Maintain existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines | | | | | |
| <p>Support first-line ATB mfrs (Indofarma, Phapros, Kimiafarma) toward WHO PQ</p> | | <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</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>Senior GMP experts from PQM conducted on-site follow up assessments for Phapros, Kimia Farma, Indofarma, and Sandoz Indonesia to establish revised implementation timelines and reporting agreements. The PQM team also explored providing TA to new manufacturers in Indonesia under the WHO PQ program, including: Novell Pharmaceutical Laboratories, Dexa Medica, and Metiska Farma.</p> <p>Phapros: PQM conducted follow up document audit and revision of implementation timeline during Q3. PQM reviewed</p> | <p>Phapros: PQM reviewed results and provided feedback for testing the related substance 3-formyl Rifamycin; PQM helped to locate a new source for pyrazinamide API due to issues with previous supplier closing down; Lupin, an Ethambutol API supplier, was contacted regarding supplying DMF and LOA to Phapros; PQM met with Phapros and Lupin to negotiate release of LOA for Ethambutol, results pending.</p> <p>PQM reviewed the dossier and evaluated the pilot BE study, which was submitted to BPOM for clearance (PQM facilitated</p> |

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| | | <p>validation and dissolution profiling of its reformulated products (2 FDC (RH) and 4 FDC (RHZE) have been completed. A pilot BE 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>Sandoz: submitted questionnaire to PQM; PQM evaluated stability data (incomplete) on 2FDC, 3FDC, and 4FDC adult and pediatric 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</p> | <p>cleaning validation and impurity determination protocols; 4FDC dossier was reviewed; Pilot BE study protocol was approved and will begin in Q4; stability data is in progress.</p> <p>Indofarma: PQM Senior GMP experts conducted an on-site review of the blueprints for the new facility design. Indofarma revised the blueprint design to incorporate recommendations and the new design was submitted to NA-FDC for review. NA-FDC is committed to fast-tracking approval on the design. New project implementation timelines and reporting agreements were drafted and approved.</p> <p>Kimia Farma: PQM Senior GMP experts conducted an on-site inspection of Kimia in order to re-initiate the PQM technical assistance program. PQM reviewed CAPA implementation progress (from 2011) and drafted a new CAPA with</p> | <p>a meeting with BPOM, Equilab, and Phapros on BE study approval). BPOM is fast-tracking clearance on the BE study contingent on ethical approval from University of Indonesia. Phapros is in the final 3 months of stability studies data collection (to be completed by December, 2013). Plan to submit PD following BE study by Feb 2014.</p> <p>Indofarma: PQM received full CAPA report and provided review and feedback on amended blueprint designs for the Microbiology Lab and Analytical Lab of RnD, and production Site 2. Plans will be submitted to BPOM for fast-track approval. PQM sent comparator products and reference standards for Indofarma.</p> <p>Sandoz Indonesia: Product selected for prequalification: RIMACTAZID PAED TBC 75/50 MG 5x10's Rifampicin 75 mg + Isoniazid 50 mg and RIMCURE PAED TBC 75/50/150 MG 6x10's and</p> |

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| | | | March. | <p>6-month implementation timelines. Kimia plans to complete dissolution profiling and BE study in Q4.</p> <p>Sandoz Indonesia: PQM conducted two on-site assessments of Sandoz and met with senior management to agree upon implementation timelines for their dossier submission. PQM performed an initial assessment and document review to determine capacity for the 2FDC and 3FDC pediatric FPP for TB.</p> <p>Comparator products were supplied to Phapros this quarter; in Q4, comparator products will be provided to Indofarma (Rimactan, Isoniazid, Pyrazinamide, Ethambutol) and to Kimia Farma (RIF and INH).</p> | <p>Rifampicin 75 mg + Isoniazid 50 mg + Pyrazinamide 150 mg; Letter of commitment received and project timeline and milestones and reporting in agreement with PQM Confidential GMP assessment report was submitted to Sandoz; PQM provided feedback on queries from Sandoz Global regarding the PQP process and TA under PQM; PQM sent comparator products to Sandoz by the end of Q4.</p> <p>Kimia Farma: Kimia received feedback and review from PQM on Pressure Cascades and Air Flow Designs for facility renovations; Stability Study Protocol and Data reviewed and feedback provided; Kimia submitted dossier compilation status report to PQM; PQM provided USP reference standards to Kimia, and is sourcing comparator products; PQM provided feedback and review on Verification of Analytical Methods for 2FDC product; PQM</p> |

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| | | | | | provided feedback and review on Cleaning Validation Protocol. |
| Encourage mfrs of levofloxacin tabs and kanamycin powder toward WHO PQP | | No progress | <p>Sanbe Farma, based in Bandung, Java, expressed interest in receiving TA from PQM for two products: 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> | <p>PQM met with Metiska Farma regarding their dossier submission for Levofloxacin 500mg tablets with a target of Q4 or FY14 Q1.</p> <p>Sanbe Farma conducted in-house preparations and documentary compilation for submitting their Levofloxacin 500mg (Levocin FCT) dossier by the end of FY14 Q1.</p> <p>PQM met with Novell Pharmaceutical Laboratories in Jakarta to discuss their Levofloxacin and Moxifloxacin products. They are undergoing TGA and EMEA inspections, so they will revisit the potential for WHO PQ in 2014.</p> | <p>Sanbe Farma: Preparing for FY14 Q1 audit by PQM on levofloxacin 500mg; Advised on API sourcing for levofloxacin</p> <p>Zenith Pharmaceuticals: Preparing for FY14 Q1 audit by PQM at manufacturing facilities in Semarang</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</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</p> | <p>A total of 869 anti-TB and antibiotic medicines were sampled and testing using basic methods and a sub-set of samples was sent for confirmatory testing. Results will be available in Q4. Total</p> | <p>Conducted MQM special site visit to Medan BBPOM on behalf of USAID for the former US Special Envoy for Science and former President of US National Academy of Science, together with President of</p> |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | <p>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 USP.</p> | <p>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 hospital, city warehouse, and the provincial QC lab where testing is taking place.</p> | <p>numbers of samples tested by provincial BBPOM sites:</p> <p>Medan: 160 Serang: 167 Surabaya: 148 Mataram: 262 Makassar: 132</p> <p>PQM also conducted a site visit to the Medan BBPOM Minilab site together with USAID/Indonesia and NQCL-DF representatives to follow up on activities. PQM also provided USP-NF to Medan during Q3.</p> | <p>Indonesian Academy of Science to highlight USP PQM activities on medicines quality monitoring in Indonesia</p> <p>Confirmatory test results from testing in 5 provincial BBPOM labs being finalized by end of September</p> <p>Results are still pending, however, partial data are: one sample from Serang (confirmed at Bandung) failed assay, two samples from Makassar (confirmed at Yogyakarta) failed dissolution, and one sample from Surabaya (confirmed at Semarang) failed dissolution. Results from Mataram (confirmation in Denpasar) are still pending, and no samples failed from Medan (confirmed at Padang). For the failed samples, the results have already been communicated to Deputy 1 at BPOM to take regulatory action, and USP PQM will follow up with them directly.</p> |
| Open a PQM office in Jakarta; recruit GMP | | Potential local partners (Indonesia Univ. and | Signed a contract with Bali Expat Services as a | Activity completed. | |

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|---|------------|---|--|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| technical staff | | Bali Expat Services) identified to assist in this regard. | 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. | PQM coordinated and prepared for GCP/GLP audits to be conducted during Q4 at both San Clin EQ and Equilab. PQM received CAPA implementation updates from both Equilab and San Clin EQ during Q3. | Followed up on previous CAPA and provided new CAPA recommendations following audits at San Clin EQ and Equilab International. |
| 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 staff in BA/BE in Nov 2012 and found a few minor observations which Equilab has already addressed. | Equilab BE study protocol for Phapros 2FDC was reviewed by PQM and the WHO PQP team. PQM submitted a report to Equilab, who will be ready to conduct the 4FDC BE study for Phapros, starting in Q3. | Both CROs are prepared for final audits in July. Based on findings, they can begin conducting BE studies for the manufacturers receiving PQM TA for anti-TB medicines during this calendar year. PQM has reviewed protocols and | Equilab is addressing CAPA following inspection by the Malaysian Medicines Control Board in Feb/Mar 2013 on GLP and GCP PQM conducted final audits on GLP and GCP at Equilab in South Jakarta |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | 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 | PQM visited the San Clin EQ facility in Bandung to follow up on recent renovations and adjustments made towards compliance with GLP/GCP. | will advise manufacturers accordingly based on progress made in Q4. | and San Clin EQ in Bandung to determine CAPA implementation and readiness to conduct BE studies as part of the WHO PQP in Indonesia. The companies each received a confidential audit report and will follow up on CAPA implementation over the next few months. |
| 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. | A TOR will be drafted for an Indonesian consultant to conduct basic interviews following study design and development by PQM during Q4. This will potentially be a joint research project with TBCare through the PMDT program in addition to stakeholders at NA-DFC. | A TOR was submitted to PQM, and the project discussed with program partners. Awaiting approval of TOR to hire a short-term consultant. |
| 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 | Planned for Q4 | Discussions with partners were held to implement this project before the end of the calendar year. Some delays are expected due to GFATM grant renewal and preparations for universal health care starting in 2014. |
| Train investigators on | | Planned for Q2-Q3 | Planned for Q3-Q4 | Planned for Q4 | Delayed until FY14 Q1-2 |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|---|--|---|
| | | Q1 | Q2 | Q3 | Q4 |
| sampling protocols | | | | | |
| Collect and test samples at NQCL-DF/ regional reference lab | | Planned for Q2-Q3 | Planned for Q3-Q4 | Planned for Q4 | Delayed until FY14 Q1-2 |
| Analyze data and report recommendations | | Planned for Q4 | Planned for Q3-Q4 | Planned for Q4 | Delayed until FY14 Q1-2 |
| 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. | PQM Indonesia staff met regularly with BINFAR (DG-PPD) and SCM partners to discuss potential for this project. Some difficulties need to be overcome including assigning authority via MoU for NA-DFC to conduct testing at DG-PPD managed sites. Adapted sampling protocol will be available and introduced in Q4 | Delayed to FY14 Need to set up a sampling team, establish project parameters, and identify key target sampling sites at points of distribution—most first-line ATBs are distributed directly to the provincial and district levels and will need to adapt sampling protocols accordingly. Some difficulty in identifying lead agency due to decentralization and finance issues. |
| Set up sampling team | | Planned for Q3 | Planned for Q3 | Planned for Q4 | Delayed to FY14 |
| Conduct testing | | Planned for Q4 | Planned for Q4 | Planned for Q4 | Delayed to FY14 |
| Write a report, disseminate to stakeholders | | Planned for Q4 | Planned for Q4 | Planned for Q4 | Delayed to FY14 |
| 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. | Planned for Q4 | Delayed to FY14 |
| Expand MQM systems to cover antimalarial (AML) and antiretroviral (ARV) medicines | | | | | |
| Train staff of NQCL-DF & provincial QCLs on | | | Planned for Q3 | Planned for Q4 | Delayed to FY14 |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|---|---|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| Minilab [®] , compendial test methods for select AMLs and ARVs | | | | | |
| Purchase reference products, solvents and reagents for Minilabs [®] | | Planned for Q2 | Planned for Q3 | Planned for Q4 | Delayed to FY14 |
| Add 150 AMLs, 100 ARVs to ATB sampling & testing in field | | Planned for Q3-Q4 | Planned for Q3-Q4 | Planned for Q4 | Delayed to FY14 |
| Conduct confirmatory tests at NQCL-DF | | Planned for Q4 | Planned for Q4 | Planned for Q4 | Delayed to FY14 |
| Produce a combined report for ATB, AML, and ARV data | | Planned for Q4 and FY14 Q1 | Planned for Q4 and FY14 Q1 | Planned for Q4 | Delayed to FY14 |
| Encourage NA-DFC and NTP to take enforcement actions | | ongoing | ongoing | Planned for Q4 | Delayed to FY14 |
| 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 | PQM assisted the NQCL-DF and the NTP to respond to queries from GFATM regarding the SSF grant renewal for TB. PQM also worked with the NQCL-DF lab to plan for an on-site lab assessment to be conducted by PQM during Q4. PQM will coordinate an advanced compendial training at the NQCL-DF in Aug/Sep in cooperation with GFATM. | Conducted week-long assessment at PPOMN and training on GLP, document review, and expansion of ISO 17025, and developed a two-year action plan for applying for WHO PQ. PQM also facilitated week one of a two-week, advanced training on compendial science for 26 provincial BBPOM labs together with the NQCL-DF laboratory. |
| Produce assessment report and CAPA recommendations | | Planned for Q2 | Planned for Q3 | Planned for Q4 | CAPA recommendations and implementation plan submitted to NQCL-DF, to |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|---|--|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | | | be signed off on prior to the Director's retirement. |
| 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. | Replenished Minilab supplies and reagents; Collected expired medicine samples for proper disposal at FDA Visited sentinel sites in Bicol, Calabarzon, Davao, Malolos, and Zamboanga. | Visited sentinel sites in Iloilo and Cebu City. Completed training for TLC testing on 1 st line TB meds with participants from Davao City. |
| 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. | Minilab staff at the sentinel sites were trained to do TLC testing for Ciprofloxacin. | Completed training for TLC testing on Ciprofloxacin with participants from Davao City. |
| 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. | Minilab staff at the sentinel sites were trained to do TLC testing for Amoxicillin and Cefalexin. | Completed training for TLC testing on Amoxicillin and Cefalexin with participants from Davao City. |
| 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; provide TA in the | | Received the tentative list; will finalize in Q2. PQM team met with local pharmaceutical mfrs in Nov to follow up with those interested in WHO PQ, with the focus | Planned for Q3. Hizon and Lloyd Laboratories submitted their accomplished questionnaire for WHO PQ. | Planned for Q4 | Visited Hizon and Lloyd Laboratories in preparation for WHO PQ. Hizon expressed interest; already receiving TA from USP GMP expert. |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|---|--|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| pharmaceutical mgmt system (PMS) and QA/QC system. | | 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. | GMP training in line with the PIC/S guidelines will be conducted with 25 FDROs and ASEAN MRAs in September | Completed regional training on GMP and pharmaceutical supply chain inspection in Sep with 35 participants from Phil. FDA and ASEAN Member Countries. |
| 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> | BA/BE training scheduled for September. | Regional BA/BE Training will follow in Oct; a joint training workshop among PQM, ASEAN, and Phil. FDA, the participants will visit FDA lab for dissolution testing demonstration and visit a BA/BE center. |
| 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. | Postponed because the USP lab is under renovation. The training at USP HQ will be conducted in September. | Activity moved to FY14. |

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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. | The FDA received the following from PQM: 1) USP FCC 8 th Edition (Book) - Qty. #1 2) 2013 USP Dictionary Print (Book) - Qty. #1 3) 2012 USP Dietary Supplements Compendium (Two Volume Set/ Books) - Qty. #2 4) USP 36 – NF 31 2013 Supplement 1 (Flash Drive Single User) - Qty. #2 | The FDA received the following from PQM: 1) HPLC Columns - Qty. #6 (however returned 3 HPLC Columns to USP HQ for replacement) 2) GPHF Minilab Supplies 3) USP Ref Standards 4) USP 36 – NF 31 2013 Supplement 1 (Book) 3 Volume Set - Qty. #3 5) USP 36 – NF 31 2013 Supplement 2 (Book) 3 Volume Set - Qty. #3 6) USP FCC 8 th Edition 3 rd Supplement Only (Book) - Qty. #2 |
| 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. | Planned for Q4 | PQM has been in close contact with FDA chief regarding providing TA on Davao's QMS, and Davao is making good progress toward achieving ISO accreditation. |
| 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, | Joined Inter-CA on TB Technical Working Group; Attended Inter-CA meetings and provided input for discussions. | Attended several meetings and participated in exhibits to showcase PQM | Joined stakeholders and TB partners in meetings and project activities. PQM team met with IMPACT (Innovations and Multisectoral Partnerships) |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | and detailed activities will be identified after further discussions | | | to Achieve Control of Tuberculosis) in Sep to discuss TA and collaboration with TB programs in Philippines. |
| 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. | Planned for Q4. | PQM and the FDA chief officer agree that this task is important and should be kept in the workplan for FY14. |
| Vietnam S. Phanouvong | | | | | |
| 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 | MOH selected 5 qualified local manufacturers and may open a tender for local production among the 5 manufacturers. | Undergoing final selection at the Government and Ministry of Health level. |
| 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. | Will depend on which manufacturer is chosen (see above). | By informal communication with DAV, three (VIDIPHA, DANAPHA, and BIDIPHA) among these five are most potential manufacturers. |
| 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 | - 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 | - VAAC is still preparing the national tender. The challenge for the tender is that there is no reference price of methadone in Vietnam, except as supplied by PEPFAR. There is no clear mechanism for opening | VAAC is waiting for formal approval from the Vice Minister of MoH on the bidding plan (quantity of methadone, technical specification, and referenced price per unit...) |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | 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 | 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. | the tender (selected or opened tender or international tender). It will depend on the decision of MOH. - There is no progress at the HCM PAC due to the same challenge as above. | PAC in HCMC is requesting DAV to guide or instruct on national rules/regulations of in-country procurement for methadone. Hai Phong PAC allocated provincial budget to procure methadone but is still waiting for results from national bidding of VAAC. |
| 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. | Completed | |
| 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. | Stopped due to duplicated with GFR10 supported activities | |
| 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 | PQM introduced the WHO PV expert to the center; if the center receives GF funding for | |

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| Activity | Staff Lead | Quarter | | | |
|---|------------|--|--|--|--|
| | | Q1 | Q2 | Q3 | Q4 |
| | | | will be introduced to the national PV center. | phase II, the center can hire this expert. | |
| 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. | Data analysis and final technical report are being drafted. | Results show that among 101 collected samples, none failed for appearance, ID, content of API, dissolution under USP-34 and VNP-IV. |
| Disseminate final report to stakeholders | | Planned for Q4 | Planned for Q4 | Planned for Q4 | Planned for FY14 Q1. |
| 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 and events. | Local consultant actively involved in implementing PQM activities, meeting with partners, and attending local meetings and events. | Local consultant actively involved in implementing PQM activities, meeting with partners, and attending local meetings and events. | Local consultant actively involved in implementing PQM activities, meeting with partners, and attending local meetings and events. |
| Provide office furniture and equipment | | Ongoing | Ongoing | Ongoing | Continued in FY14 Q1 |
| Europe and Eurasia | | | | | |
| Kazakhstan E. Toledo | | | | | |
| Conduct baseline GMP assessments of select anti-TB medicines manufacturers | | | | | |
| Conduct baseline GMP assessment of four manufacturers | | Assessments planned for Q2 | Awaiting Mission approval | Kazakhstan MOH/Pharmaceutical Committee stated that only 1 out of 4 manufacturers have confirmed that they are ready to work with PQM; that manufacturer is scheduled to meet with PQM at USP HQ in Aug to discuss their new facility layout and other critical documentation. | Manufacturer visit to USP HQ cancelled. PQM team plans to visit the manufacturer in mid October to perform an assessment, discuss the WHO PQ process, and evaluate the new facility design and quality documents. PQM will also visit the Mission for debrief and next steps. |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | | | Due to the facility construction, an assessment will not occur until late Q4. | |
| Present findings to USAID and stakeholders | | | | | |
| Provide technical assistance to promising companies to improve their GMP compliance | | | | | |
| Provide TA to select mfrs to improve their GMP compliance | | | | | |
| Assist manufacturers in preparation and submission of dossiers to WHO | | | | | |
| Assist manufacturers with dossier prep and submission to WHO | | | | | |
| 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 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> | | | | | |

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| Activity | Staff Lead | Quarter | | | |
|--|------------|--|---|--|----|
| | | Q1 | Q2 | Q3 | Q4 |
| 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. | At the April AMI Steering Committee Meeting (SCM), PQM suggested suspending activities in Bolivia and Nicaragua due to lack of country response and transferring support to Ecuador; suggestion was subsequently approved. | |
| Procure Minilab [®] for Nicaragua | | | See above. | 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. | See above. In addition, all USAID activities in Bolivia were suspended as of May 2013. | |
| <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. | Due to timing conflicts, Suriname interns will travel to USP by the end of Q4 or beginning of FY14 Q1 | |
| Conduct regional training for compendial analysis of Artemether Lumefantrine FDC for Brazil, Colombia, Ecuador, Guyana, and Suriname | | | Training is scheduled for June in Colombia. The training agenda was developed by PQM and approved by the host lab. | Training was held in June for 10 participants. All training objectives were met, and PQM was also able to include training on Lumefantrine impurity analysis. | |

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|---|------------|---|---|--|---|
| | | Q1 | Q2 | Q3 | Q4 |
| <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 | | | | Coordinated a visit in July to finalize regulations that include the 3-LA and to plan MQM activities. Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) is the new National Regulatory Authority, splitting from the former National Institute for Hygiene and Tropical Medicine. | Dr. Pribluda met with the Executive Director of ARCSA to discuss re-establishing the 3-LA in Ecuador. Dr. Pribluda also met with the Coordinator of Processes, Registration and Sanitary Control from ARCSA, the Chief of the OMCL, and the TB program. A draft of the regulations for post-marketing surveillance that includes the 3-LA was finalized. |
| 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. | An advanced draft of the MOU has been finalized and is currently under review by Guyana stakeholders. | |
| 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 | | PQM held discussions with the head of the NMPC to address the need to implement rapid testing of antimalarials in endemic areas, in light of the recently reported onset of resistance to artemisinin in border mining areas in Guyana and Suriname. |
| 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; | | PQM performed mock pre-audit in Nov 2012. | ASMQ has been included in the list of | | |

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| | | Q1 | Q2 | Q3 | Q4 |
| provide TA as needed | | Next steps towards WHO prequalification were established. | medicines that LAC countries may purchase through the Strategic Fund. This inclusion was based on ANVISA GMP certification, for which 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. | USP confirmed that under TAP, countries can purchase RS through any procurement process available at PAHO. PAHO is currently evaluating the appropriate mechanism to implement the procurement of USP RS by the countries. | |
| 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. | PQM will attend a planning meeting with country stakeholders to be held in Peru in August. | Dr. Pribluda attended a planning meeting with country stakeholders in Peru to discuss implementation of the 3-LA. Agreements were made among participants to strengthen national capacity to monitor medicines' quality and establish the 3-LA as a monitoring mechanism. A |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | | | | follow-up meeting will be convened during FY14 Q1. |
| 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 be developed | | <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. | | | |
| <i>Building QC capacity</i> | | | | | |
| Conduct training on Minilab use and implementation of the three-level approach for the quality control of medicines. | | <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. | | | |
| <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 | | <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. <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). USP standards were sent and received at the lab. <u>Q3: Level 3 compendial analysis at the OMCL.</u> 18 samples sent for analysis. 2 samples failed, one that previously had passed level 2 testing and one that had failed. The only remaining sample (Erythromycin Estolate) is currently being analyzed. | | | |
| Guatemala V. Pribluda | | | | | |

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| 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. | | In Sep, Dr. Pribluda reviewed with OMCL representatives the final version of the Certificate of Analysis template that will be used for analysis performed during registration of medicines and purchases made by the MoH. Also, increasing medicine registration fees was discussed with the Minister of Health and the Technical Vice-Minister; additional documentation was sent to the DRCPFA in support of a new MoH project to reassess fees. |
| <i>Building regulatory capacity</i> | | | | | |
| Assess the capabilities of the DRCPFA | | | | | A document with recommendations made during an assessment performed by PAHO has been received and will be reviewed by PQM to address future support to the DRCPFA. |
| Upgrade DRCPFA's registration software | | | Contract with consultant signed. Installation of new software and transfer of information initiated. | IT equipment and software required for upgrade purchased. Phase 1 of 5 of the installation process finalized; phase 2 to be completed in August. | The MoH enhanced internet capabilities at the DRCPFA so the new software can be used. Phase 1 of the installation of WebSIAMED is complete; Phase 2 is underway. A pilot assessment of online |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | | | | renewals will be performed with selected manufacturers in Oct 2013. Dr. Pribluda requested Phase 3 (OMCL procedures) to be conducted in parallel with completion of Phase 2. |
| <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) | Follow-up on CAPAs and re-assessment of the lab performed in April. | |
| 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. | Training delivered in April. | |
| <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 | A list of medicines proposed by the DAS and the Regional Hospital from Huehuetenango sent to the DRCPFA-MRA for evaluation. Study protocol is being developed. This is the first time that medicines sampling for routine MQM will be performed at dispensing sites; to avoid shortages, the DRCPFA is assessing ways to replenish the | Medicines will be sampled in the public sector (Health Areas and Hospitals). The list of medicines has been agreed upon; a protocol will be complete by Nov 2013. The Technical Vice-Minister of Health and the General Director of Regulations agreed that this activity will be a pilot to assess a new modality for MQM by the DRCPFA and regional authorities; in |

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| | | Q1 | Q2 | Q3 | Q4 |
| | | | | sampled units. | FY14, this approach may be extended to additional areas. |
| <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. | GMP training workshop delivered to DRCPFA-MRA personnel in Guatemala City in June; the training included a visit to a local manufacturer. Good Storage and Distribution Practices (GSDP) training workshop delivered in Guatemala City in June; the training included a visit to a Ministry of Health storage facility. | |