Promoting the Quality of Medicines (PQM) Program
Quarterly Reports: FY14 Activities (October 1, 2013–September 30, 2014)

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Cross Bureau K. Chibwe					
Increase awareness about the importance of medicines quality					
Attend/present at national, regional, and int'l conferences		Dr. Mustapha Hajjou presented at the SciX 2013 Conference in October in Milwaukee, WI, and Dr. Kennedy Chibwe presented at the ASTMH Global Health Conference in November in Washington, DC.	Dr. Chibwe presented "Science Diplomacy and Global Health" at Georgetown University's Medical School in February. Dr. El Hadri, Dr. Hajjou, and Mr. Roth gave four presentations at the Global Health Mini-University at George Washington University in March.		
Use available media outlets to advocate need for medicines QA		USP issued three press releases related to PQM. These promoted PharmaCheck, the PQM program extension, and USP's membership in the "Fight the Fakes" campaign.	An editorial on the Medicines Quality Database (MQDB) was published in the Jan 2014 issue of the Bulletin of the World Health Organization.		
Produce up-to-date information about current issues in medicines quality					
Collect and publish reports of incidents of poor-quality medicine use	M McGinnis	38 reports were added to the *Media Reports on Medicine Quality;* there were 1,980 hits	34 reports were added to the *Media Reports on Medicine Quality*; there were 505 website hits		
Maintain and update PQM website	M Foster	On PQM's website, 4 new stories, 5 photos, 2 videos, and 3 new or updated resources were added	Added 7 articles and 8 photos; updated 2 webpages; added 12 new resources and updated 3		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support regional approaches and networks					
Participate in NEPAD's Technical Working Groups (TWG)		Dr. Karim Smine participated in a meeting of the African Medicines Regulatory Harmonization TWG, held in November in South Africa.	Mr. Boateng participated in TWG meetings held in South Africa in March.		
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: – Develop prototype – Field test & pilot – Develop platform for broad class of meds/ monographs	K Chibwe	Boston University is working with the design firm, Fikst, to develop an Alpha-prototype (field-ready), expected by Jan 2014. Artesunate and tetracycline will be used for the initial field tests in Ghana. BU is working with PQM to finalize the protocol for the field studies and carrying out validation work as well.	Dr. Chibwe and representatives from BU and the Center for Integration of Medicine and Innovative Technology conducted PharmaCheck device field studies at USP's CePAT facility in Accra, Ghana in March. Results of the studies will be available in Q3.		
Core Tuberculosis	A. Hong				
Increase the supply of quality-assured second-line TB medicines					
Continue to provide TA to identified API & FPP mfrs of SL-ATBs seeking WHO PQ		Shalina: dossier submitted to WHO; accepted and inspection scheduled for Q2 Varichem: dossier submitted to WHO but not accepted; will complete per WHO's request and resubmit Steril-Gene: dossier	**China:** Qilu: dossier received for review; comments provided to company for incorporation Fuzhou: WHO inspection in February Xinhua: process validation to be repeated per WHO **India:**		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		received for review but not in CTD format; committed to revising into new format Peili: IVD study protocol reviewed and provided comments	Concept: reformulated FPP and in process of technology transfer Shalina: currently dossier on hold for review due to API site not allowing WHO Inspection Steril-Gene: updated dossier received for review **Indonesia:** Zenith: implementing CAPA; plans to conduct IVD study **Korea:** Dong-A: cycloserine API PQ submission tentatively scheduled for Sep 2014; Terizidone FPP BE study protocol final and contract is in process Yuyu Pharm: GMP assessment conducted Enzychem: reviewed APIMF and provided comments for incorporation BCWP: visited existing facility – reviewed cleaning validation, some quality SOPs, process validation protocol CKD: GMP assessment		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			conducted KUP: met to discuss timeline and potential GMP assessment in June 2014 Hankook/Korus Pharm: new project – general discussion on potential path toward WHO PQ Ildong; new project – general discussion on potential path toward WHO PQ Theragenetex: general meeting to discuss timeline for formulation development and facility construction **Nepal:** DJPL: draft dossier reviewed but incomplete; committed to manufacturing pilot scale in late February **Philippines:** Hizon: dossier received for review Lloyd's: currently in FPP formulation development Unilab: dossier received for review **Taiwan:** Peili: IVD completed; dossier compilation in progress		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Zimbabwe: Varichem: API manufacturer committed to submitting APIMF in spring		
With GDF/WHO, conduct workshops in high burden countries; identify add'l mfrs not yet in PQM pipeline			Manila, Philippines: 10 manufacturers from Thailand, Vietnam, Cambodia, and Philippines attended; 2 manufacturers from Vietnam and 1 manufacturer from Cambodia expressed interest; 3 from Philippines and 1 from Thailand have already initiated work with PQM Casablanca, Morocco: 20+ manufacturers attended from Morocco – 3 were visited by PQM staff during the trip; 3 more manufacturers have expressed interest		
Participate in GDF and WHO meetings with mfrs to discuss PQ					
Conduct operational research to identify substandard/counterfeit second-line medicines on the market					
Carry out PMS (or if issues arise) of quality of second-line medicines in the country markets					
Develop OEM for at least two critical second-line anti-TB medicines					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Identify additional suppliers to implement the OEM model for select second- and third-line ATB medicines		Work with Baush Pharm and Interpharmaccess in progress	Interpharmaccess completed product development on Kanamycin; Baush Pharma completed product development on Capreomycin		
Support research to improve quality and yield of Kanamycin through genetic engineering					
Identify research group with expertise in fermentation to carry out proof-of-concept for higher quality/yield					
Support scale-up of technology to API manufacturer					
Provide support through capital investment to promising companies to obtain WHO PQ					
Obtain comparator products and assist select mfrs with funding for BE studies			CKD: Zyvox sent for formulation development Zenith: Levaquin sent for IVD DJPL: Levaquin sent for IVD Sanbe: Tavanic		
Support calibration and validation of mfg and analytical equipment					
Provide assistance for other capital costs, as necessary					
Develop public standards (pharmacopeial and Minilab® methods) for screening quality of second-line anti-TB medicines					
Develop Minilab® test methods for SL-ATBs or third-line ATBs					
Develop USP monographs for					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
prothionamide, terizidone					
Core Malaria	L Evans				
Conduct studies to monitor antimalarial medicines quality and the extent of diversion from the public to private sector					
Adapt study protocols for AM MQM study in new countries		Adaption of study protocols completed			
Conduct four new studies			Study completed in Ghana		
Develop reports and disseminate results					
Conduct follow-on studies					
Improve knowledge about the quality of antimalarials in PMI countries					
Obtain samples of meds requested by PMI team and test			In progress		
Increase the availability of standards and testing methods for selected antimalarials					
Develop monographs for pyronaridine API and pyronaridine-artesunate FDC			In progress		
Develop monographs for pediatric formu-lations of DHA-PIP FDC and/or pyronaridine-artesunate			In progress		
Core Maternal Health and Child Survival	L. Evans				
Increase the supply of quality assured maternal, newborn and child health medicines					
Provide support to Chi Pharmaceutical for WHO PQ of zinc sulfate			Developed responses to WHO dossier queries related to excipients in terms of choice and compatibility. A PQ audit		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			is tentatively scheduled for May 2014.		
Monitor maternal, newborn, and child health medicines quality (*in FY13 workplan; work being completed with carryover funds*)					
Conduct medicines quality testing of maternal health commodities		Performed assay analysis on 8 batches of vitamin A capsules from the Sudan for UNICEF. Full compendial analysis was performed on 4 batches of vitamin A capsules from 3 different manufacturers.			
Develop CHX gel monograph for USP MC			Monograph development began with sourcing of all potential impurities as identified in the USP, BP and EP monographs for the API.		
Support USAID medicines quality initiatives related to UN Commission Activities					
Participate in UN Commission activities/meetings		Led medicine quality and manufacturer GMP discussions and participated in bi-weekly teleconferences and the quarterly face-to-face meetings: Diarrhea and Pneumonia Working Group, Chlorhexidine Working Group, Maternal Health TRT, and the Injectable Antibiotics TRT	Provided input into the work plans, led medicine quality and manufacturer GMP discussions, and participated in bi-weekly teleconferences and quarterly face-to-face meetings: Diarrhea and Pneumonia Working Group, Chlorhexidine Working Group, Maternal Health TRT, and the Injectable Antibiotics TRT		
Conduct quality testing of zinc medicines sent by UNICEF, USAID,		Conducted full compendial analysis for UNICEF of zinc sulfate			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
and other partners (***in FY13 workplan; work being completed with carryover funds***)		tablet batches from 4 manufacturers to be used in the global zinc roll out.			
SUB-SAHARAN AFRICA					
Angola	R Okafor				
			Conducted the initial assessment of QA/QC capacities of Angola in collaboration with USAID (Maria Miralles) Drafted a study protocol and proposed an approach to establish the baseline of the quality of antimalarial medicines under PMI in four regions and submitted the proposal to Mission for validation by the local partners. There is no functional medicines authority and no national QC lab in Angola. Awaiting mission approval of the study proposal to finalize the work plan, timeline, and budget for this year's activities		
Burundi	M Hajjou				
Strengthen the capacity of the INSP QC laboratory					
Establish a three-year implementation plan to		Burundi activities will begin in Q3			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
strengthen lab capacity					
Equip the QC lab and train staff according to the first phase of the implementation plan					
Support the improved governance of the national medicines regulatory authority (DPML)					
Assist the DPML to build its medicines regulatory capacity		Burundi activities will begin in Q3			
– Establish the law and medicines regulation					
– Strengthen medicines registration system					
– Assist DPML to strengthen capacity for inspections					
Establish a national medicines quality monitoring system					
Implement use of basic tests as first step of QC for antimalarials – Procure Minilabs – Train analysts – Confirmatory testing – One round of MQM – Promote enforcement		Burundi activities will begin in Q3			
Ethiopia	Eshetu W.				
Strengthen marketing authorization (MA) of medicines and local medicine manufacturers					
Strengthen FMHACA Product Registration & Licensing Directorate					
Build capacity in dossier assessment, GMP/GCP inspections			Training on dossier evaluation was conducted Developed training materials on basic GMP		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			and conducted training in March for 31 staff from FMHACA, Veterinary Drugs and Feed Control and Administration and Authority, and the Food, Beverage and Pharmaceutical Development Institute		
Provide TA to develop tools, SOPs, etc., to operate MA		Guidance provided on Training and Qualification Requirements for GMP Inspectors; Inspection of Foreign Pharmaceutical Manufacturers; Foreign Manufacturers Inspection Application Form; and GMP Inspection Report Writing. Strategy paper for the assessment of dossiers in backlog drafted and submitted to FMHACA	Reviewed and submitted the Medicine Manufacturing Establishment directive to FMHACA. The Directive is now under discussion. Good Manufacturing Guidelines for Pharmaceutical Products-Basic Principles: was reviewed, edited, and submitted for printing USP/PQM staff supervised and guided the assessment of over 300 dossiers in backlog. Initiated review of the medicine registration guidelines, Common Technical Documents (CTD) which conform with ICH countries guidelines		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Initiated review of the medical devices registration guidelines One staff from USP/PQM participated in a workshop on the development of traditional medicines guidelines organized by FMHACA at Bishoftu in February Meetings conducted with School of Pharmacy, Addis Ababa University; Ethiopian Veterinary Drug and Feed Administration and Control Authority; Beverage, Food, and Pharmaceutical Development Institute to discuss future collaborative work Technical assistance provided to Cadela Pharmaceutical regarding bioequivalence study waiver and comparator products selection		
Support to develop or adopt data and info management system			Two USP/PQM staff participated in an IT meeting organized by USAID/Ethiopia in Feb		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Train staff to operate and manage system					
Strengthen FMHACA's quality control laboratories to become compliant with cGMP, ISO 17025 accredited, and WHO Prequalified					
Strengthen FMHACA Product Quality Assessment Directorate (PQAD)					
Maintain 7 ISO accredited methods		PQAD lab was re-assessed and found to be compliant with ISO requirements for the seven test methods; accreditation was extended for two years.			
Obtain WHO PQ for same 7 methods		Preparations for WHO PQ were initiated and the laboratory information file (LIF) and expression of interest were submitted to WHO.	Proficiency testing results for six physicochemical test methods were obtained from RTC PT provider; results were found to be acceptable.		
Move condom lab to new site; get ISO accredited					
Move microbiologic lab to new site, calibrate/ qualify equipment					
ISO accredit additional test methods					
Have labs participate in QMS, proficiency tests		The lab participated in PT organized by RTC-sigma-Aldrich Corporation for six physico-chemical test methods	The lab participated in PT organized by RTC-sigma-Aldrich Corporation for six physico-chemical test methods		
Support FMHACA to maintain, calibrate, and qualify lab equipment			Paperwork was finalized to get waiver for maintenance of condom machines		
Train staff in test					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
methods and QMS					
Train staff in condom QMS (ISO 4074)					
Train staff in microbiological test methods					
Strengthen post-marketing surveillance of AM, ARV, and OI medicines circulating in Ethiopia					
Train participating staff in sampling & testing			Training was organized for PMS sample collectors; a report was submitted to USAID		
Develop generic guideline and protocols for PMS of AM, ARV, OIs meds		Generic PMS guidelines were developed The PMS protocol was prepared for conducting PMS of ARV and OI medicines	Protocol was prepared for conducting PMS of ARV and OI medicines		
Support & coordinate sampling of AM, ARV, OI meds per protocols		USP reference standards for testing ARV and OI medicines were procured and supplied to FMHACA.	Sample collection of selected ARV and OI medicines was carried out at four sites: Borena, Jijiga, Metema, and Addis Ababa		
Support testing of AM meds per protocol					
Support testing of ARV & OI meds per protocol			Lab supplies for PMS of selected ARV and OI medicines were procured and supplied to FMHACA Reference standards for testing ARV and OI medicines were		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			purchased and provided to the lab		
Support FMHACA in fight against illegal trade of medicines through workshops & seminars; encourage regulatory actions		A proposal to establish a national taskforce to combat the illegal trade of food and medicines was prepared and submitted to FMHACA, USAID/Ethiopia, and USP/PQM			
Assist local medicines manufacturers toward GMP compliance and WHO Prequalification					
Improve knowledge and skills of local med manufacturers in GMP					
Get local OI mfrs to get products QA'ed					
Support local mfrs in implementation of GMP Roadmap					
Strengthen FMHACA's branch quality control laboratories to become capable of monitoring the quality of medicines					
Conduct needs assessments of branch laboratories		Tool for rapid assessment of FMHACA branch labs was developed	Assessments of four FMHACA branch laboratories were conducted Workplan to develop the branch labs was drafted and is being discussed with FMHACA		
Support branch labs based on needs assessment					
Strengthen FMHACA's branch quality control laboratories to become capable of monitoring the quality of medicines					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct needs assessments of branch laboratories		Tool for rapid assessment of FMHACA branch labs was developed	Assessments of four FMHACA branch laboratories were conducted Workplan to develop the branch labs was drafted and is being discussed with FMHACA		
Support branch labs based on needs assessment					
Strengthen regional/city administration medicine food and healthcare control and administration bodies					
Development of assessment tool		Tool developed for rapid assessment of regional/city administration medicine, food, and healthcare regulatory bureaus. Preliminary discussions with Addis Ababa City Administration and Oromia Regional Bureau carried out			
Assessment of five regional/city administration agencies			Assessments of Amhara and Tigrai Regional Food, Medicine and Healthcare regulatory core processes were undertaken in Jan and Feb and reports submitted to HQ to be reviewed and edited		
Assist Pharmaceutical Funds and Supply Agency (PFSA)in establishing internal quality control laboratory					
Develop assessment tool		Tool developed			
Conduct assessment		Assessment of the QC	Workplan prepared		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		needs of PFSA was completed	based on the assessment results		
Ghana	R. Okafor				
Support post-marketing surveillance of antimalarial medicines at seven sentinel sites					
Conduct two rounds of MQM at selected sites for testing			To be completed in Q3; MQM contractual delay		
– Conduct confirmatory testing of R1 at FDA lab		Round 1 confirmatory testing completed for FY13	To be completed in Q3; MQM contractual delay		
– Conduct confirmatory testing of R2 at CePAT			To be completed in Q3		
Conduct onsite evaluations of selected sites (PQM-FDA team)			To be completed in Q3 MQM contractual delay		
Promote enforcement actions based on data			To be completed in Q3 MQM contractual delay		
Strengthen the capacity of the national Food and Drugs Authority QC laboratory and assist toward ISO 17025 accreditation					
Assess FDA lab QMS, equipment qualification/ calibration		Provided key consumables needed for accreditation: HPLC columns, parts for dissolution, thermohygrometer, digital thermometer, stop watches, safety consumables	Facilitated with in-country representatives to service key equipment for ISO 17025 accreditation		
Train staff as needed based on assessment		Installed key equipment for the scope of accreditation; offered training in GDP, Safety in the Lab, Karl Fischer, FTIR, and ISO 17025	Trained staff on Karl Fischer, root cause analysis, loss on drying, effectively reading and understanding the pharmacopeia, and uniformity of dosage unit		
Provide QMS training to FDA QA team		Trained QA staff on how to conduct good	Internal auditing training provided to key QA		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		corrective and preventive actions; reviewed CAPAs with QA team; facilitated proper arrangement of sample receipt room under QA	personnel and lab appointed auditors		
Facilitate pre-accreditation audit		Selected key staff to perform demonstration of test during audit	Pre-audit was conducted by PQM; official audit is scheduled for April 2014		
Provide TA post-audit with CAPAs		Trained QA staff on how to conduct good corrective and preventive actions; reviewed CAPAs with QA team; facilitated proper arrangement of sample receipt room under QA	Assisted and reviewed corrective actions with QA and provided feedback for corrections		
Facilitate ISO 17025 accreditation pre-audit and ACLASS audit		Reviewed key SOPs and quality manuals and offered recommendations and corrections	Submitted all documents to ACLASS and scheduled accreditation assessment for April 7-11, 2014		
Provide training for FDA GMP Inspections staff in risk-based compliance module; strengthen capacity of GMP Inspectorate Qaulity System					
Provide FDA Inspectors with GMP assessment training			Planned for Q3-Q4		
Improve internal system of GMP Inspectorate			Planned for Q3-Q4		
Support inclusion of FDA data in the PQM MQDB					
Support data entry and develop statistics using MQM data			Data available from MQM first round provided for MQDB		
Collaborate with the Maternal Health Channel of Creative Storm Network to develop advocacy and public sensitization programs					
Produce short documentary on PMS			Planned for Q3-Q4		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
process					
Facilitate public policy dialogue through radio and TV discussions			Planned for Q3-Q4		
Facilitate dissemination workshop for identified stakeholders about findings on CSMs			Planned for Q3-Q4		
Guinea	L El Hadri				
Build the capacity of the National Quality Control Laboratory (LNQCM)					
Assist LNCQM with plans and guidance to remodel and renovate the chemistry lab area and install one AC unit and one generator.			PQM conducted an initial assessment of the country's QA/QC capabilities in January. Currently awaiting approval from the Mission on proposed activities.		
Procure and deliver one Minilab® to the lab					
Provide lab supplies and reagents needed to conduct hands-on Minilab® and basic tests training of selected medicines					
Assist the lab staff during the testing of samples collected for the survey					
Assist the lab with reporting of Minilab® and compendial data obtained from the field					
Strengthen the capacity of the Drug Regulatory Authority (DNPL)					
Support DNLP by reviewing the current					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
version of the National Pharmaceutical Policy (NPP) and new registration directives					
Organize three-day meeting with PQM consultant to present the revised NPP to key stakeholders; finalize it					
Present final copy to MSHP for its homologation					
Assess the existing registration system at DNPL; identify gaps					
Provide TA to address identified gaps in order to improve the structure and functions of the registration department					
Strengthen the quality control of medicines by initiating the establishment of a Medicines Quality Monitoring program (MQM) and promote taking regulatory actions					
Organize a meeting w/ key stakeholders to discuss the sampling and testing of selected medicines circulating in Guinea					
Identify survey team and select source of sample collection from public, private, and informal sectors					
Train survey team in sampling strategies and lab team in testing selected medicines					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
using Minilab® tests					
Collect samples from selected outlets					
Supervise testing at LNCQM					
Provide the LNCQM with ref standards and reagents to conduct Minilab® tests on collected samples					
Conduct confirmatory testing at CePAT					
Share results of final report with relevant partners, country MOH					
Promote enforcement actions to be taken by DNPL based on the survey data					
Kenya	L El Hadri				
Continue strengthening medicines quality monitoring of antimalarials at existing sentinel sites and expand to new sites					
Conduct one round of sampling and testing of AMs at 11 sites		Planned for Q3			
– Procure Minilabs and establish 6 new sites		Minilabs procured and delivered to the sites			
Conduct training on Minilab basic tests, sampling strategies and reporting MQM data		Planned for Q3			
Conduct M&E visits to three sentinel sites and one port of entry					
Continue promoting regulatory actions by sharing MQM data with stakeholders and by raising awareness					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Promote efforts to support enforcement actions by PPB based on MQM data					
Raise awareness about quality and share data w/PPB, DOMC, and other stakeholders					
Continue strengthening capacity of the NQCL and assist the lab toward improving its QMS and toward reaching ISO 17025 accreditation					
Improve technical capacity of NQCL staff on QMS					
– Facilitate participation of NQCL in NOMCOL activities/meetings			One lab staff participated in the NOMCOL meeting		
Prepare lab to be audited by SANAS		Assisted the lab with resubmission of SANAS forms	SANAS audit scheduled for July 2014		
– Review required documentation			Progress report reviewed		
– Facilitate audit by SANAS and follow up report findings			Planned for Q3 and Q4		
– Review CAPA actions and facilitate accreditation visit			Planned for Q3 and Q4		
Liberia	L El Hadri				
Continue building the capacity of the LMHRA Quality Control Laboratory					
Provide lab supplies and reagents needed to complete R4 of MQM and to conduct R5		Provided lab supplies and reagents needed to complete round 4.			
Assess the lab's QMS and technical capacity			LMHRA is preparing the lab for the upcoming QMS assessment		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			planned for Q3		
Establish an action plan to prepare the lab for ISO 1705 accreditation			Activities planned for Q3		
Provide one-year maintenance contract for lab equipment in collaboration w/LMHRA			Maintenance contract provided to the lab		
Train lab staff in preventive maintenance and troubleshooting of major lab equipment			All 3 designated lab staff trained in preventive maintenance		
Support Lab participation in the NOMCOL-Africa		The LMHRA MD and the QC manager participated in the NOMCOL meeting and training in Ghana			
Continue strengthening LMHRA's regulatory capacity					
Establish database for inspectors to control meds entering the country and circulating in the Liberian market		Database established	New virtual inspection tool established and all 15 inspectors and registration staff trained in its use		
Assist strengthening PV system – modifying reporting forms for new software and training on data entry/analysis			New pharmacovigilance electronic form established and LMHRA staff trained on data entry and analysis		
Strengthen monitoring the quality of antimalarial medicines at four sentinel sites and promote regulatory actions					
Complete R4 sampling & testing at Bomi site		Sampling and testing at the site completed			
Select two new sampling sites for R5 w/LMHRA & NMCP			2 new sites selected and added to MQM round 5		
Facilitate R5 sampling & testing following new protocol at four sites			Planned for Q3		

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		Q1	Q2	Q3	Q4
Conduct M&E visits, review data, review final report					
Draft and share reports with stakeholders			Planned for Q3 or Q4		
Promote LMHRA taking enforcement actions based on MQM data			Planned for Q3 or Q4		
Raise public awareness by filming regulatory actions (confiscation of failed samples in the market) for media			Planned for Q3 or Q4		
Mali	M Hajjou				
Strengthen the capacity of the National Laboratory of Health (LNS) to attain ISO 17025 accreditation					
Strengthen technical capacity					
– Procure needed lab supplies & equipment					
– Provide TA for servicing, maintaining equipment					
– Train laboratory staff			8 lab staff were trained in UV-Vis including calibration/qualification of spectrophotometer and identification and assay tests using UV-Vis according to USP and BP		
Strengthen QMS by developing SOPs, training program, internal audit system, and raising mgrs' QA awareness		22 SOPs finalized	Refresher training in Good Documentation Practices provided to 8 LNS staff Work flow of QC lab at LNS reviewed and		

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		Q1	Q2	Q3	Q4
			recommendations provided to develop necessary SOPs		
Monitor and evaluate training					
Support participation in NOMCoL-Africa		Facilitated the participation of the LNS Director General in the third annual meeting of NOMCoL. The DG is currently the Chairperson of the Network.			
Support pre- and post-marketing quality monitoring of antimalarial medicines					
Conduct MQM of antimalarial meds					
– Revise the MQM protocol		MQM draft protocol developed and shared with local partners for feedback	Workshop organized to revise MQM protocol in collaboration with local partners including LNS the medicine regulatory authority (DPM), the malaria control program (PNLP), the tuberculosis control program (PNLT), the pharmacovigilance center, and the national directorate of health (DNS)		
– Prepare and facilitate one round of sampling & testing			Existing Minilabs replenished. Three Minilabs procured for the sentinel sites in Gao, Timbuktu, and the new sentinel site in Kidal.		

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		Q1	Q2	Q3	Q4
			19 staff from Regional Directorates of Health, LNS, PNLP, and PNLT received training in sampling and screening of medicines using Minilabs		
Monitor and evaluate MQM activities w/supervisory visits and review/validate data					
Raise awareness of CSMs and promote corrective actions					
Support coordination of PQM activities in the country					
Hire a locally-based consultant		Consultant position description drafted	Consultant position advertised in local newspaper. One candidate selected. Hiring process underway.		
Mozambique	R. Okafor				
Strengthen the capacity of the National Laboratory for Medicines Quality Control (LNCQM)					
Strengthen quality management capacity by training the staff		New QA staff appointed; assessed personnel to properly plan for training	Training planned in May for new QMS		
Strengthen analytical capacity of LNCQM		Trained staff in December on key QC tests: HPLC – calculation and running, UV/Vis, and KF Also trained 2 new staff on effectively using pharmacopeias	Training planned in May for new QMS		
Assist LNCQM to refine		Discussed changes and	Presented the discussed		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
strategic plan for ISO accreditation/WHO PQ		delays to ISO accreditation due to recent staff changes with director of DF	plan to director of DF; pending translation service approval to forward translated document		
Strengthen the capacity of Departamento Farmacêutico (DF)					
Assist DF and encourage to take regulatory actions		Discussed the decree for DF and CMAM that will allow autonomy to take regulatory actions; more discussion needed pending response from MOH	To be discussed during May trip with DF director		
Encourage and train DF staff at port directorate			Planned for Q3		
Encourage DF to dedicate funds for LNCQM for sustainability		Discussions held with DF and key staff during visit in December; provided technical assistance to MOH staff on procurement list of items/regents and consumables	Planned for Q3		
Support the MQM program by expansion into the ports of entry					
Extend MQM to 2 new sites; conduct 2 rounds MQM sampling, testing at 3 additional sites			MQM delayed due to contractual delays; planned for Q3-Q4		
Supply new sites; train provincial staff and DF inspectors			MQM delayed due to contractual delays; planned for Q3-Q4		
Support DF efforts on enforcement actions based on MQM data			MQM delayed due to contractual delays; planned for Q3-Q4		
Nigeria	M. Hajjou (Malaria); L. Evans (MCH)				
Monitor the quality of antimalarial and maternal child health medicines					
Conduct two rounds of		Budget provided to the	Sampling protocol		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
sampling and testing of antimalarial meds		National Malaria Control Program for conducting one round of MQM activities	drafted, revised, and finalized Sampling conducted at all sentinel sites; testing of samples is underway		
Conduct QC testing of each batch of zinc sulfate tablets procured by USAID from Chi Pharmaceutical			PQM received 8 batches of zinc sulfate tablets from CHI Pharmaceutical procured by USAID Deliver. The batches are to undergo QC analysis prior to release by DELIVER.		
Promote enforcement actions					
Monitor MQM activities w/NAFDAC & NMCP			NAFDAC is supervising sample testing at NAFDAC labs; NMCP and Supply Chain Management are monitoring the implementation of MQM activities		
Strengthen the regulatory capacity of NAFDAC					
Support training of NAFDAC staff in GMP and dossier evaluation					
Prepare the QC Lab for WHO Prequalification					
– Strengthen analytical capacity			Trained NAFDAC lab staff in proper use of pharmacopeia and HPLC		
– Strengthen QMS		Drafted implementation plan for NAFDAC lab to	Trained NAFDAC lab staff in understanding		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		attain WHO PQ/ISO 17025 accreditation	ISO 17025, internal audit process and methods, reporting and reviewing test results, and corrective and preventive actions		
Support NMCP in finalizing the quality assurance policy for its medicines and diagnostics					
Assist NMCP in finalizing draft QAP					
Assist NMCP in drafting & reviewing procedures to implement QAP					
Build capacity in GMP of selected local manufacturers of zinc sulfate, ORS, chlorhexidine, and amoxicillin commodities for global and local supply					
Provide TA to selected local mfrs of CHX by conducting gap analysis, technology transfer, and formulation activities		Conducted a gap analysis of Drugfield's CHX manufacturing line for compliance with cGMP.	Provided a detailed report of observations from the gap analysis to the manufacturer who developed a CAPA plan on which PQM provided feedback. By the end of the quarter, 60% of the CAPAs were closed by the manufacturer. PQM analyzed samples of the first batch of CHX gel developed by Drugfield. In March, Drugfield received NAFDAC approval to market CHX gel.		
Provide support to CHI ORS mfg to enable procurement by local					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
orgs and USAID					
Support add'l local mfrs of zinc sulfate tablets			PQM provided TA to Swipha (sourcing of API and QC services for API and excipients) and Emzor (product development)		
Support add'l local mfrs of ORS					
Issue EOI w/NAFDAC to identify mfrs of amoxicillin dispersible tablets		EOI issued in collaboration with NAFDAC and 3 Nigerian manufacturers (Daily Needs, Europharm, and Emzor) responded. PQM visited Daily Needs to determine if they had the infrastructure and capacity to produce the product under GMP.			
Conduct GMP baseline assessments of select mfrs of amoxicillin dispersible tablets					
Support one+ mfrs of amoxicillin dispersible tablets to develop for local procurement			PQM began providing TA to Daily Needs by providing API sources with certificates of suitability and product information required by UNICEF.		
Senegal L El Hadri					
Continue strengthening the capacity of LNCM and prepare the lab for TUNAC ISO 17025 audit					
Continue improving technical capacity of		QMS training conducted at CePAT			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
LNCM staff to conduct testing and improve managerial skills					
– Facilitate participation in NOMCoL IPT					
– Provide TA, supplies for IPT and advise on improvements		Supplies provided for ITP testing			
– Support two senior LNCM staff to take part in NOMCoL trainings at CePAT		2 senior lab staff attended the NOMCOL training at CePAT			
– Provide quotes, specs for new HPLC; provide 1-year maintenance contract; facilitate delivery of unit and reagents			Provided quote and specifications for HPLC to be procured by LNCM		
Prepare the lab for TUNAC ISO audit			Planned for Q3		
– Provide TA prior to LNCM application					
– Review all required documents and forms			In progress		
– Conduct mock audit and report finding, recommend how to address CAPAs			Planned for Q3		
Strengthen the capacity of DPM and support enforcement of its regulatory actions					
Organize workshop for DPM and customs on enforcing regulations					
Assist LNCM to prepare additional SOPs		Provided SOP templates to the lab			
ASIA					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
RDMA Mekong Malaria S. Phanouvong					
Continue to strengthen the post-marketing surveillance capacity of Laos FDD and BFDI, Vietnam DAV, and select authorities of Burma and Thailand at main trade cities and border areas between countries and checkpoints by maintaining MQM and collecting data to support enforcement against use of oral artemisinin-derivative monotherapies.					
Collect samples of AMLs and suspect ABTs in targeted areas; Collect info on availability of oral artemisinin AML monotherapies; report to all relevant agencies		PQM continued to support the collection of samples and completion of analyses for the Comparative Study. Sample collection has finished in Laos, Vietnam, and Cambodia, and is ongoing in Thailand. Performed data analysis using the MQDB and recent Cambodia and Thai data (not yet in MQDB) to create a flyer for RDMA/PMI entitled Highlights of the Quality of Medicines Collected and Tested in the Greater Mekong Sub-region 2005-2012	Samples were not collected during this reporting period.		
Purchase and replenish essential Minilab® / QC lab supplies to maintain MQM and confirmatory analyses at the Laos FDQCC and Vietnam NIDQC and HIDQC.		PQM provided some 100 reference standards and products to FDQCC; will be distributed to the sentinel sites for MQM	Taking inventory and gathering information from the countries.		
Conduct 3-4 supervisory / M&E visits to select sites with MRA, National QC Lab		Site visits were carried out in Cambodia, Vietnam, Laos, and Burma	Site visits are in the planning stages for Thailand and later in Burma.		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
staff and/or NMCP			Site visit carried out in Vietnam to Binh Phuoc province (jointly with USAID HQ and RDMA)		
Analyze data; Laos, Vietnam and PQM produce end-of-FY reports. Burma, Cambodia, Thailand will use their own funding.			Planned for Q4		
Continue to strengthen the capacity of the Laos FDQCC toward ISO 17025 accreditation, and of Chulalongkorn University Pharmaceutical Technology Service Center (PTSC) toward WHO Prequalification for reliable test results					
Continue to work with FDQCC management on road map and goal of submitting appl. by mid-2014. PQM will assist in reviewing QM and SOPs, advise which accrediting body FDQCC should apply, and help the FDQCC respond to any queries.		PQM has been working with BDN to identify an accreditation body and review the Quality Manuals and other documents from FDQCC. PQM attended the ISO 17025 accreditation ceremony in November 2013 where the Laos FDQCC received accreditation for two products (amoxicillin and paracetamol).	FDQCC submitted a revised QM and SOPs to PQM for review		
PQM will continue to support the Chula PTSC lab toward WHO PQ by the end of 2014 so that it can increase its services in training of advanced methods.		Initial assessment visit was completed and recommendations provided to PTSC	PQM is providing assistance to the PTSC toward WHO PQ; full assessment will occur in Q3.		
Support in-country and inter-country efforts and coordination among GMS countries for cooperation and enforcement through BREMERE, WHO SSFFC medical products working group, INTERPOL's Storm Enforcement Network, and ASEAN Post-marketing Alert System (PMAS).					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all SCM cases among enforcement agencies in Laos and Vietnam.		The new regional PQM consultant participated in Minilab training in Myanmar in December 2013 to increase coordination across the region. In December, meetings were held in Thailand with BDN and FDA focal points to review progress for the year and provide an introduction to the regional PQM consultant. Joint site visits with USAID RDMA and local government partners are planned for Q2. In October, BREMERE representatives from national testing labs were trained on Bioequivalence/Bioavailability testing methods. In November 2013, Thailand provided the final nominees needed to complete the BREMERE team.	In addition to all GMS countries nominating two representatives, the Philippines FDA also nominated 2 representatives One antimalarial product (Quinine Sulphate tablet, batch no. 1-QL724, labeled to be manufactured by Macleods Pharmaceuticals, India, had no active ingredient, and found in Ghana, Ethiopia, and Kenya) was investigated through BREMERE. The outcome of the investigation was that this product has not been found in the GMS countries.		
Support inter-country / regional BREMERE, ASEAN PMAS, and INTERPOL cases through timely sharing		Ongoing information sharing on product samples collected and tested among in-country partners	PQM held a meeting with the USFDA, the WHO SSFFC responsible team, and USAID Washington at		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
of information and data, and joint investigation and enforcement.			USP HQ to discuss complementing each other's' efforts in combating CSMs at regional & international levels. The meeting resulted in concrete follow up action items.		
Increase the availability of quality-assured AMLs by improving inspections in supply and distribution chains, supporting selected manufacturing facilities to produce quality ACTs, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of CSMs in the GMS.					
Improve inspector practices in supply and distribution chains with training of trainers and hands-on inspection exercises to support oral monotherapy ban.			Planned for Q3 and Q4		
Strengthen Laos pharmacy practices through national/local training of operators in targeted containment priority areas and help implement the oral monotherapy ban.			Planned for Q3-Q4		
Conduct initial assessment of dossier and GMP compliance of two potential mfrs in Vietnam to receive TA toward producing ACTs for the region.		Identifying manufacturers in Vietnam in close consultation with local partners	In March, PQM staff and the local consultant held meetings with selected manufacturers of ACTs in Vietnam to explain the WHO PQ process. PQM sent questionnaires to the manufacturers to collect additional information to help in the selection process.		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Engage final-year students and faculty members of Laos Univ. of Health Sciences Faculty of Pharmacy in PQM efforts to improve pharmaceutical practices by improving curriculum/participation in relevant pharmacy school forums, scientific meetings, and conferences about medicines quality.			PQM staff and consultant met with the Deputy Dean and two members of the Faculty of Pharmacy to discuss potential involvement of pharmacy students in supporting the MOH/FDD and provincial authorities' efforts in the reduction of poor-quality essential medicines in Laos. The Deputy Dean shared the Pharmacy curricula for PQM to review and provide comments; PQM regional consultant has begun initial review.		
Participate in/present at meetings and conferences to share the findings and achievements of and challenges to PQM program activities, in national, regional, and international arenas.					
Disseminate publicly data and findings from PQM activities through appropriate means; also present PQM work progress/achievements at conferences and meetings on medicines quality issues.		PQM submitted an editorial to the Bulletin of WHO about MQDB, to be published in the Jan 2014 issue A journal article detailing the success of Cambodia's efforts in reducing counterfeit medicines was written and sent to Cambodian authorities for approval. Publication is expected in Q2. A draft report was	A journal article entitled 'Cambodian Ministry of Health Takes Decisive Actions in the Fight against Substandard and Counterfeit Medicines' was published in the Journal of Tropical Medicine and Surgery. The report on a 'Pilot Project on Information, Education, and Communication (IEC) Strategy for combating counterfeit and		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		prepared describing the effects of IEC initiatives in Laos. The report will be finalized in Q2.	substandard medicines in Lao PDR' is being finalized.		
Burma S. Phanouvong					
Strengthen PMS capacity of Burma DFDA and selected authorities, primarily at Malaria Containment Zones/Tiers 1 and 2, border checkpoints with Laos, Thailand, and China, through MQM activities to obtain evidence-based data and reduce oral artemisinin-derivative monotherapies.					
Collect samples of AMLs and suspect ABTs in targeted geographical areas. Collect info on availability of oral artemisinin AML monotherapies; report to all relevant agencies		Training on MQM was given to 34 participants from DFDA, DMR-LM, VBDC and WHO in Dec 2014	Training on MQM given to 28 participants from DFDA in March 2014. Sample collection in 5 sentinel sites and Burma-India border began at the end of March. Field testing will occur at the end of April.		
Purchase and replenish essential Minilab® / QC lab supplies to maintain MQM activities and confirmatory analyses			In Feb 2014, PQM provided 21 essential Minilab supplies to replenish the sentinel sites, as well as some for use in the training discussed above.		
Conduct 3-4 supervisory / M&E visits to select sites by PQM consultant(s) with DFDA and VBDC.		Formal clearance requested	Supervisory visit will be conducted on Burma-China border and 3 sentinel sites in Q3		
Compile and analyze data (country mgmt. team) from sites and results from DFDA QC lab; PQM consolidates data and reports.			Planned for Q3		
Continue to strengthen the capacity of the national quality control laboratory of DFDA in Nay Pyi Taw to comply with basic principles of Good Laboratory Practices and help it conceptualize the ISO 17025 accreditation process.					
Provide essential		PQM donated one	PQM donated one		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
laboratory equipment and hands on training to DFDA QC Lab staff in Nay Pyi Taw		dissolution tester to the DFDA lab in Nov 2013 In addition, PQM donated essential laboratory and personnel safety supplies, reference standards, and reagents to DFDA lab in Nay Pyi Taw to support the trainings conducted in March 2014	Agilent HPLC auto-sampler system to DFDA. The machine was installed in Feb by Agilent. PQM donated two copies of USP-37 NF-32 to DFDA and one copy of USP-37 NF-32 to DMR-LM in Jan 2014		
PQM and Chula PTSC will train the lab staff on GLP, QMS, and concept of ISO 17025 accreditation process Provide technical guidance on how to build capacity of the lab in HR, developing technical expertise, equipment specs, etc.		Training on advanced analysis on dissolution property of antimalarials was conducted in Dec 2013. 10 participants from DFDA and 2 from DMR-LM attended.	A workshop on advanced analytical methods using HPLC was conducted in Mar in collaboration with WHO Country Office for Myanmar and Faculty of PTSC. 12 participants from DFDA, 2 from DMR-LM, and 10 observers from DFDA attended.		
Support in-country and inter-country efforts and coordination among GMS countries for cooperation and enforcement through BREMERE, WHO SSFFC medical products working group, INTERPOL's Storm Enforcement Network, and ASEAN Post-marketing Alert System (PMAS).					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all SCM cases among enforcement agencies		The new regional PQM consultant participated in Minilab training in Myanmar in Dec to increase coordination across the region. Two regional trainings were conducted in the Philippines in Sep and			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		Oct. Training in Sep focused on GMP; n Oct, the BREMERE reps from national testing labs were trained on Bioequivalence/Bioavail ability testing methods. In Nov, Thailand provided the final nominees needed to complete the BREMERE team.			
Increase the availability of quality-assured AMLs by improving inspections in supply and distribution chains, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of CSMs in the country.					
Conduct a training workshop for 8-10 DFDA central inspectors and 15-18 township inspectors (in containment Zones/ Tiers 1 and 2) to improve inspection practices in the supply and distribution chains to support the ban on oral monotherapies.		Activity is pending			
Engage faculty and final-year students (50) of a pharmacy school in Yangon to improve pharmaceutical practices in various settings through curriculum/syllabi improvement.					
Participate in / present at meetings and conferences to share the findings and achievements of and challenges to PQM program activities, in national, regional, and international arenas.					
PQM or rep from					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
DFDA, VBDC, or Dept. of Medical Research-Lower Myanmar will present PQM's work progress/achievements at conferences and meetings on medicines quality issues.					
Cambodia E. Yuan					
Continue to support strengthening the Cambodia DDF post-marketing surveillance system at national and local levels by implementing the enhanced medicines quality monitoring to obtain evidence-based data, especially on AMLs, to support enforcement action.					
Collect samples of AMLs and suspect ABTs in targeted geographical areas; collect information on the availability of oral artemisinin AML monotherapies and report to the relevant agencies.		Country study teams organized an orientation and refresher training on testing by TLC/Minilab in Nov for 12 participants from 3 MQM-sites and 3 non-MQM sites Sampling and testing started and is ongoing; confirmatory testing at NHQC is planned for Q2 DDF-MoH prepared Guidelines on Recall of Pharmaceutical Products; will be submitted to H.E Chou Yin Sim for his approval	137 samples including AMLs and 2 ABTs were collected from 6 provinces (3 MQM sites and 3 non-MQM sites). Basic testing by Minilab was conducted; confirmatory testing will be done in Q3 No oral antimalarial monotherapies were found.		
Purchase and replenish essential Minilab® / QC lab supplies to maintain MQM activities and confirmatory analyses.		Supplies were replenished.	Reference tablets and reagents were replenished for 3 sites (Pailin, Battambang, and Mondulkiri) and NHQC		
Conduct 4-5 PQM supervisory / M&E to sites representatives		The PQM local consultant joined with representatives of DDF,			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
from DDF, NHQC and NCM.		NHQC, CNM and provincial drug inspectors to conduct inspections in drug outlets within 6 provinces			
Analyze data and produce end-of-FY technical reports for country and PQM.					
Continue to strengthen the capacity of National Health Product Quality Control (NHQC) toward compliance with ISO 17025 international standards of performance and practices for reliable test results.					
PQM QMS specialists will continue to provide TA to support NHQC lab toward achieving ISO 17025 as agreed upon in 2012 road map. This will entail a visit to meet w/NHQC mgmt. to verify progress.					
Provide technical guidance to the final stage of new lab construction which may include, but not be limited to, positioning, qualifying & calibrating major lab equipment; and determining the training needs of staff.		PQM provided TA in reviewing the list of lab furniture and equipment. Now PQM is waiting for final construction of the NHQC building.			
Support in-country and inter-country and regional coordination, cooperation and enforcement through BREMERE to enhance collective action at national and regional levels.					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all CSM		2 drugs inspectors are representatives of Cambodia for communicating with other countries in the			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
cases, emphasizing AMLS, among the IMC members as well the Provincial Sectoral Committee members at the provincial level..		regions			
Support inter-country / regional BREMERE, ASEAN PMAS, and INTERPOL cases through timely sharing of information and data, and joint investigation and enforcement.		Continuous communication	Continuous communication		
Increase the availability of quality-assured AMLs by improving inspections in distribution chains, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of CSMs in Cambodia.					
Conduct a local 3-day training workshop for each of the four provinces, for operators in targeted areas of artemisinin-resistant malaria containment provinces and help implement the ban on monotherapies.					
Engage faculty and final-year students of two university Faculty of Pharmacy schools in Phnom Penh to improve pharmaceutical practices in various settings through curriculum/syllabi improvement.		Initial discussions with the university and the faculty of pharmacy were held.			
Participate in / present at meetings and conferences to share the findings and achievements of and challenges to PQM program activities, in national, regional, and international arenas.					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
PQM or rep from DDF, NHQC, or CNM will present PQM's work progress/achievements at conferences and meetings on medicines quality issues.		PQM supported the Mekong Bio-Pharma conference in Cambodia in Oct for 400 participants. PQM submitted an article "Cambodia Takes Aggressive Action in Fight Against Substandard and Counterfeit Medicines" for publication in the Journal of Tropical Medicine and Surgery.	PQM's local consultant: --attended USAID's workshop on "Introduction to USAID's Legal Regulation, Financial Management and Procurement Policies" in March in Phnom Penh. --met with MSH consultant (Mr. Kov Buntor) for the project "Analysis of the Regulatory Capacity to Assure the Quality of Antimalarial Medicine in Selected Countries of the Great Mekong Sub-region of Asia" to provide information on PQM activities and any help if possible. --met USAID's evaluation team in March to provide information on the CAP-Malaria project.		
FY13 Uncompleted Activities to be implemented in FY14 with carry-over funds					
Provide technical guidance to the DDF to develop training materials and help deliver a national workshop on QA/QC of AMLs covering GPP, GSDP, and inspections of supply-distribution		DDF-MoH prepared training materials for GPP training and submitted them to PQM for review.	DDF is revising the training materials and budget plan. Training is scheduled for May or Jun 2014.		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
chains to all DDF and selected provincial inspectors and key pharmacists from artemisinin-resistant containment areas.					
Continue to provide TA to the NHQC to successfully prepare its national QC lab's QMS toward achieving the ISO17025 accreditation					
Indonesia C. Raymond					
Work plans for TB and HIV still under review by USAID and PQM					
Support the quality assurance of antiretroviral medicines used by the HIV program in Indonesia					
Provide support to Kimia Farma to manufacture quality HIV medicines – Conduct a GMP audit of mfg facilities – Identify areas that need improvement – Provide TA to strengthen mfg		Planned for Q3	Met with Kimia Farma production team to identify areas of cGMP support and potential project startup in Q3 in coordination with the National AIDS program of Indonesia		
Assess QA/QC capacity of [Papua and West Papua (TBD)] including provincial and district warehouses, health facilities and provincial BPOM QC labs			Planned for Q3		
Provide training for central BPOM lab on HIV, STI, & OI medicines sampling &			Planned for Q3		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
testing					
Provide training for two provincial BPOM labs on sampling & testing of HIV, STI, OI, and TB meds		Met with National AIDS program manager (MOH) and WHO HIV country team on testing of ARVs at TUV Lab Singapore, discussion on GFATM QA Policy, and planning for implementation of PQM program; received support and agreement from NAP and WHO	Conducted follow-up meeting with the National AIDS Program Management team (MOH) and PQM senior mgmt. and technical advisor on HIV project under PQM support including QC and cGMP activities, along with post-marketing surveillance, etc.		
Scale-up integration of ARVs into the national post-marketing surveillance program		Planned for Q3	-Conducted follow-up meeting with BPOM and PQM senior mgmt. and technical advisor on HIV project under PQM support including QC and cGMP activities, along with post-marketing surveillance, etc. -participated in meetings on decentralization SOPs for AIDS program coordinated by CHAI, NAP, JSI, WHO		
Support BPOM to take part in ASEAN QC activities by identifying where BPOM can play a visible regional role		BPOM representatives attended regional ASEAN workshops on GMP and BE (two separate workshops, duration of one week each) held in Manila, Philippines in October	Signed 5-year MOU with BPOM including areas of support for BPOM on GMP and BE inspectors to participate in regional ASEAN-led initiatives and training		
Continue existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines					
Assessment, CAPA,		GMP team conducted	-Caprifarmindo		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
and dossier compilation for levofloxacin 500mg of Caprifarmindo		initial site assessment and provided report for CAPA to Sanbe/Caprifarmindo	implemented CAPA and provided closure report on CAPA items; also updated on status of product development and procurement of new API source from Zhejiang Apeloa, China which already has CEP; production to scale up during Q3 -comparator products provided to Sanbe		
Action plan, CAPA, dossier compilation for levofloxacin 500mg for Zenith Pharmaceutical Laboratories		GMP team conducted initial site assessment and provided report for CAPA to Zenith Pharmaceutical laboratories	CAPA report submitted for review by Zenith to PQM GMP team, comparator products provided to Zenith		
Specialized training for manufacturers under PQM support on WHO PQ, Validation method of analysis for assay of finished product and assay for raw material (using instrumentation and microbiological method), Validation method of analysis for impurity of finished product and impurity of raw material, Validation in Dissolution Test Pharmaceutical development		PQM provided two-day GMP training for 10 national and provincial MRA offices, MOH representatives, and 17 local pharmaceutical manufacturers. This training was conducted on WHO PQ and GMP requirements, and was co-funded through the GFATM HSS grant to BPOM as sub-recipient	Planned for Q3		
Provide TA to Phapros on stability studies,		Assisted Phapros to get clearance and approval	-Provided feedback on results from BE pilot		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
dissolution, BE studies, dossier compilation, etc. for 4FDC product		from BPOM on BE protocol; reviewed initial protocol, started the due diligence process for sub-award to Equilab to conduct BE studies on Phapros 4FDC product -conducted site visit to Phapros Semarang, identified potential new areas of support on amikacin and levofloxacin -helped to identify potential new API source for Ethambutol at Linaria, Thailand -Phapros conducted BE pilot study with 14 subjects at Equilab International on 4FDC product	study that Phapros conducted during Q1 -PQM sr mgmt. and technical advisor met with Phapros to discuss project progress, upcoming BE study, stability study data, and cost-share sub-award for BE study -PQM in the process of drafting and approving FOG sub-award to Equilab to conduct pilot and full BE studies on Phapros 4FDC product -comparator products provided to Phapros -discussion on initiating levofloxacin project with Phapros		
Provide TA to Kimia Farma on stability studies, dissolution, BE studies, dossier compilation, etc. for 2FDC product		-provided reference standards and comparators -provided comments and feedback on stability study data -revised ongoing stability protocols -reviewed and provided comments on facility renovation that will be submitted to BPOM for govt approval -reviewed and revised analytical methods verification for 2FDC	-reviewed BE study protocol and amended according to PQM and WHO comments -appointed Equilab as CRO to conduct BE studies -submitted due diligence documentation to PQM for sub-award consideration for 50% cost share for BE studies -discussions on alternative API sourcing for rifampicin from Hebei		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		-in progress on comparative dissolution -submitted BE study protocol for PQM review	to another potential source, in discussion with PQM on this -excipients incompatibility study protocol for 2FDC under review by PQM		
Provide TA to Indofarma on stability studies, dissolution, BE studies, dossier compilation, etc. for 2FDC product		-design for new production facility finalized and submitted to BPOM for review, pending approval in Q2 -delivered comparator products and reference standards -issues with rif stability data on 4FDC and 2 FDC products submitted for review to PQM, with the need to potentially reformulate -Indofarma also considering changing rif API source from Shenyang to possibly Sandoz Indonesia (CEP) -BE study protocol under development -discussed other potential products for TA: levofloxacin, zinc sulfate, OI medicines	-Indofarma developing BE study protocol and will appoint Equilab as CRO -new facility blueprints approved by BPOM, contracting and construction to begin this year with 2 year completion anticipated		
Provide TA to Sandoz Indonesia on stability studies, dissolution, BE studies, dossier compilation, etc. for 2FDC pediatric product			Head of Technical Operations and PQM point of contact resigned from Sandoz, PQM is awaiting updates on PQ program engagement		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			from replacement and senior management		
Continue to assist two Indonesian Contract Research Organizations (CROs) to enhance their compliance with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) for BA/BE studies on ATB medicines					
Continue to provide TA and support to Equilab International to conduct BE studies under PQM program		-completed CAPA from van Zyl final audit -completed pilot BE study on Phapros 4FDC product -facility renovation and movement of patient beds to ground floor for better evacuation and emergency access -parent company Dexa Medica purchased building and will be upgrading facilities at Equilab -PQM-sponsored Equilab staff participated in BE workshop conducted by PQM in Manila as part of an ASEAN regional training	-drafting sub-award to Equilab for cost share of Phapros 4FDC BE study -PQM sr mgmt. met with Equilab to discuss preliminary results on pilot BE study for Phapros -Equilab appointed as CRO for Phapros, Indofarma, and Kimia Farma for conducting their BE studies under the PQ program		
Continue to provide TA and support to San Clin EQ to conduct BE studies under PQM program		-18 CAPAs completed from van Zyl final audit and submitted to PQM at end of Q1 --PQM-sponsored San Clin EQ staff participated in BE workshop conducted by PQM in Manila as part of an ASEAN regional training	-CAPA review conducted by PQM during Q2		
Provide TA to the BPOM National QC lab towards application for WHO PQ by 2015					
NOTE: a five-year MOU between USP and the Head of BPOM was signed in February, ushering in a new phase of the PQM project through					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
2019					
Build QC capacity of selected BPOM provincial QC labs		Planned for Q3	-Sr PQM mgmt. and technical advisors met with new Head of BPOM, Deputies, and new Director of the National Lab to sign 5-year MOU between BPOM and PQM and discuss implementation and scale up of provincial-level assessments, trainings, and equipping		
Assist the health programs (TB, HIV and Malaria) to comply with GFATM QA policy		CoP Met with NAP and NTP and KNCV/TBCare to discuss socialization of QA manual and appropriate protocols for engaging MOH (CDC and BINFAR) and BPOM to scale up sampling and testing of GFATM and non-GFATM products	Sr PQM mgmt. team and technical advisor met with national managers for National AIDS program and National TB program on implementing QA policy and coordination with BPOM -CoP in Indonesia participated in and provided technical inputs into the week-long Global Drug Facility mission to Indonesia, as follow up to JEMM 2013 and recent issues on forecasting for NTP. Discussions on progress for sampling and testing as well as WHO PQ for local manufacturers		
Support the BPOM QC lab to be an active		4 officials from BPOM's national QC lab received	Planned for Q3 or Q4		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
member in international and regional initiatives under USP, ASEAN and other development partners (WHO PQ, PIC/S, etc.)		two week training under the visiting scientists program at USP HQ laboratories as a cooperative support between GFATM and PQM			
Supply TB medicines reference standards, HPLC columns, USP-NF Pharmacopeial reference books		Reference standards, USP-NF, HPLC columns provided to national QC lab	Additional USP-NF (latest edition), Food Chemicals Codex, and Dietary Supplements documentary standards supplied to BPOM -Technical Assistance Program agreement signed by Deputy Director of BPOM facilitating and increase in supplies in cooperation with PQM funding streams (TB and HIV)		
Continue to support medicines Quality Monitoring (MQM) for ATBs, ARVs, and AMLs, and selected antibiotics at 5 pilot provincial BBPOM sentinel sites and 5 confirmatory sites		All provincial level data had been submitted to BPOM for review -round two currently on hold due to financial matters internal to the government of Indonesia	-PQM still awaiting final report on MQM initial results -planning for additional training, scale up of MQM under HIV, and additional MQM sampling under planning and to be better incorporated into the national PQM system		
Develop collaborative mechanisms and support for disease programs (NTP, NAP), BINFAR, and BPOM to enhance QC capacity in Indonesia					
Participate and provide inputs to activities under People that Deliver, GFATM grants		-conducted TDY site visits under the HSS grant activity for warehouse	-participated in TDY for PtD's Executive Director for meetings with WHO-WR, USAID, MOH, and		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
(HIV, TB, and HSS) and other partner activities		strengthening at the district level, with WHO, MOH, JSI -ongoing monthly meetings with People that Deliver Indonesia --participated in Strategic Management Team meetings under KNCV/TBCare (WHO, MSH, FHI, JSI, MOH, USP PQM, USAID)	other partners -provided inputs into -participated as member of national technical working groups for HSS and TB GF grants -provided inputs into GDF mission -fielded queries from Global Fund Geneva country team managing the Indonesian portfolio -participated in Strategic Management Team meetings under KNCV/TBCare (WHO, MSH, FHI, JSI, MOH, USP PQM, USAID)		
Coordinate with BINFAR on QC-related activities on supply chain (warehousing, etc.)		-monthly meetings with SCM team (CHAI, WHO, JSI, USP PQM, MSH, KNCV/TBCare, MOH) on current issues: decentralization, universal health coverage, etc. and impacts on QC activities -provided inputs into drafting of 3-year PSM strategy document for BINFAR	-monthly meetings with SCM team (CHAI, WHO, JSI, USP PQM, MSH, KNCV/TBCare, MOH) -provided QC-aspect inputs into 2nd line TB medicines warehouse (GFATM) and BINFAR central warehouse during GDF mission		
Establish USP PQM office as an officially-registered entity in Indonesia					
Legal Registration and scale-up of hiring staff		-Met with USAID, law firms, and implementing partners to assist in appropriate mechanisms and options for legal registration in Indonesia	-Met with USAID, law firms, and implementing partners to assist in appropriate mechanisms and options for legal registration in Indonesia		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		-drafted SOWs for staffing country office	-Sr PQM mgmt. held meetings to discuss registration, staffing, and other legal requirements for Indonesia during TDY -engaged with High Street Partners and a local representative of the Baker and MacKenzie law firm to begin process of official registration and approval with Ministry of Foreign Affairs as international NGO in Indonesia		
Office expansion		Discussions began on PQM country office staffing needs, developing SOWs, and identifying office space required to accommodate scaled-up staff and program expansion	Began negotiations on increasing office capacity for scaling up and accommodating more staff for the country program with CEO Suite		
Philippines E. Yuan					
Establish and sustain medicines quality monitoring activities					
Continue to support MQM at 8 existing sites by replenishing Minilab® supplies, providing needed training, conducting site visits, and updating MQDB. Report progress regularly.		Visited CALABARZON in October	Additional sentinel site visits are scheduled to take place in Q3-Q4		
Expand MQM of ATBs			Planned for Q4		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
to 4 sites: Regions II, IV-B, X, and XII					
Strengthen the capacity of the FDA and its QC Lab to enhance the medicine regulatory system in pre- and post-marketing surveillance					
Build capability of CDRR by training new & existing staff to evaluate anti-TB and anti-infective meds		Completed training on USP PQM – ASEAN – Philippines FDA Joint Training Workshop on BA/BE Studies in October			
Provide training opportunity to FDROs to participate in USP's International Training Program (ITP) on BA/BE studies			In preparation stages		
Provide training opportunity to FDA scientist to participate in USP's ITP on a broad range of topics			Discussing topics and logistics with USP experts/scientists		
Provide technical and professional assistance in QMS to FDA Davao Satellite Laboratory for ISO17025 accreditation			Planned for Q4		
Purchase needed lab equipment & reference materials not included in DOH/FDA budgets through USP TAP			List of equipment for purchase has been submitted; will be processed in Q3/4		
Collaborate with NTP and TB Partners on relevant disease control programs					
Provide TA to NTP based on 2014-16 PhilPACT objectives: Tracking and monitoring the TB meds by sampling and testing		Held meetings with implementing partners (IMPACT and SIAPs) on identifying the TA that our partners need and how best to collaborate			

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
their quality on retails stores (pharmacies and provate clinics)& wholesale supplies chains, hospital and DOTS facilities					
NCPAM Activity: Baseline survey on the quality of TB drugs in the public and private sectors			Met with NCPAM managers to discuss the activities that PQM can perform		
NCPAM Activity: Assessment on the status of the Quality Assurance and Good Manufacturing Practice in local TB mfrs.			Held workshop on WHO PQ for TB medicines		
Support local manufacturers towards WHO PQ for first- and second-line TB medicines					
Provide GMP TA to local manufacturers toward WHO PQ			Lloyd, Hizon, and Amherst completed the WHO PQ questionnaire and submitted the Expression of Interest for WHO PQ and product evaluation		
Conduct training workshop on WHO PQ for Philippine ATB mfrs			Workshop held in March regarding TA toward WHO PQ		
Provide leadership in promoting global public health and technical excellence ensuring medicines quality and safety through innovations					
Provide the CHDs with CD-3 device to check the quality of doubtful products and train staff on their proper use			Activity will be performed Q3-4		
Vietnam S. Phanouvong					
Provide technical assistance to local production of methadone					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Work with MoH (DAV & VAAC) to determine a selection process of 1-2 methadone manufacturers for technical assistance from PQM		Follow-up the selection process at MoH (DAV &VAAC). MoH's inspection team finished the assessment of the 5 potential manufacturers Vidipha obtained the registration/production license from DAV after piloting bio-batch production	Vidipha won the VAAC tender with an amount of 2000 L methadone 10mg/ml Other 4 manufacturers are procuring a small amount of methadone API (0.5-1 kg) from difference sources (Sanofi, Siegfried) to pilot the bio-batch production for registration with DAV		
Pursue obtaining an authorization letter to assess GMP of mfrs			DAV& VAAC have been reluctant to issue an authorization letter to PQM to conduct GMP assessment of mfrs		
Conduct GMP inspection on 1-2 mfrs and recommend how to address deficiencies			Pending official authorization from MOH/DAV and VAAC		
Provide technical support to the procurement and importation of methadone finished products for VAAC & Ho Chi Minh City PAC					
Support VAAC and HCMC PACs to select high quality methadone products from reliable suppliers		Follow-up with the national VAAC & HCMC tender for 2014 Arranged meetings with VAAC leaders and HCMC PAC to obtain updates and provide technical guidance	Sent an assessment tool for obtaining relevant information from overseas mfrs of methadone to HCMC PAC and VAAC Follow-up with the VAAC tender. VAAC opened the tender with 2000 L of methadone syrup 10mg/ml with financial support from Ausaid. Vidipha was the winner		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			and delivery of this amount is expected at the end of 2014. US$.5mil will be funded from the local government to procure methadone finished product for HCMC PAC.		
Establish a technical support group to support VAAC and HCMC during procurement/import process		Proposed to help review tender documents of VAAC and HCMC PAC regarding product quality aspects			
Strengthen the capacity of the NIDQC and HCM IDQC quality control labs					
Assess QMS and practices of NIDQC& HCM IDQC labs for WHO PQ readiness; identify aspects needing TA		Follow-up with NIDQC on the upgrades to the microbiological lab. NIDQC receives US$200K from government to upgrade the micro lab. PQM had a meeting with HCM IDQC management in Jan to obtain updates on their preparation of WHO PQ documents, provide advice on WHO PQ process and procedures, and schedule the QMS assessment (May 2014) and submission to WHO PQ (Sep 2014).	PQM experts helped review the HCMC IDQC quality manual. A quality management team of HCM IDQC is established and a study tour to gain some insight and experience into other labs that have WHO PQ was undertaken.		
Provide TA towards ISO/WHO PQ; assess		PQM helped review the NIDQC micro lab design	Upgrading of the NIDQC microbiological lab is		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
and report progress			ongoing.		
Provide TA on pharmacovigilance system within the framework of the Global Fund Round 10 project of the National DI&ADR Center at HUP					
Review all related documents, previous assessments, & reports *(Continuing activities from FY13*)		Pending for FY15	PQM met with the national PV center to discuss potential collaboration for FY15		
Train staff and develop operational manual for national and south DI&ADR Centers – Provide training in project mgmt to staff – Assist staff to adapt Ops Manual for a PV center		Pending for FY15	Pending for FY15		
Maintain country consultant to improve project coordination, implementation, and effectiveness					
Support consultant's salary and misc. expenses for FY13		Country consultant participated in USAID/PEPFAR meetings and reported to PQM HQ and USAID/Vietnam in a timely manner	Country consultant participated in USAID/PEPFAR meetings and reported to PQM HQ and USAID/Vietnam in a timely manner		
Provide laptop, office furniture and equipment			A laptop was procured in compliance with USAID and USP financial policy		
Provide stationery, comms & admin costs		Done in compliance with the approved WP	Done in compliance with the approved WP		
Build and strengthen the capacity of the pharmaceutical management practices of the national ARV system at the peripheral/provincial levels, working towards a sustainable system					
Technical assistance for ARV's quality assurance through post-marketing surveillance in both public and private sectors					
A NIDQC analyst is trained in USP		PQM discussed with NIDQC and scheduled the training for May 2014 at Rockville	Logistics for NIDQC analyst's training are being finalized at USP HQ		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support NIDQC to hold the national technical training on ARV testing methods		The national training will be held in July 2014 by NIDQC	Training is scheduled for July 2014 at NIDQC - Hanoi		
Support VAAC, DAV to develop the post-marketing surveillance plan/QA & QC guideline for ARV quality		DAV, VAAC, and NIDQC are in discussions	DAV, VAAC, and NIDQC are in discussions		
Technical assistance to strengthen the capacity of Pharmaceutical Management Practices at the Peripheral Level for the ARV distribution system					
Contribute to the finalization of technical tools & documents		New workplan was prepared PQM attended a pre-testing workshop of technical tools and documents at HCMC PAC and provided comments for finalizing these tools	Workplan was approved by USAID mission PQM attended a technical meeting led by VAAC; joined with SCMC and CHAI to review and finalize the technical tools		
Present at HCMC and two regional training workshops and advise					
Provide TA to 12 provinces to install and use technical tools and documents					
Provide administrative and program operation support					
Recruit two technical staff, one admin staff, and one part-time accountant/consultant					
Support salary for additional job allowance to COP-Consultant and fringe benefits					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support office rental and other office maintenance expenses					
Procure office equipment and support other mgmt costs					
Review recruitment process of country office					
Europe and Eurasia					
Kazakhstan J. Derry & K. Burimski					
Conduct baseline GMP assessments of Pavlodar Pharmaceutical Factory, provide technical assistance to the Factory towards reaching WHO Prequalification					
Conduct baseline GMP assessments of Pavlodar Pharmaceutical Factory		General assessment was conducted, trip report and confidential assessment report provided; thorough GMP assessment to be conducted once new facility is complete			
Provide technical assistance to the Factory towards reaching WHO Prequalification			PQM team provided Guidances on GMP principles to Pavlodar Pharmaceutical Factory, reviewed quality documents of the factory (SOPs) and provided their recommendations on improvements.		
Conduct one onsite general GMP training for specialists of Pavlodar Pharmaceutical Factory					
Conduct one general GMP training for the factory's GMP specialists			Tentative time for training determined – August 2014		
Support two GMP consultants for onsite work at Pavlodar Pharmaceutical Factory					
Support one consultant			Scope of work identified		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
on QMS to provide 3-mo. onsite/3-mo. remote TA			and agreed with Pavlodar Pharmaceutical Factory; potential consultants identified and their CVs collected		
– Set up documentation system					
– Train staff on its use and on SOPs					
Support one consultant on Validation to provide 1.5-mo. onsite/1.5-mo. remote TA			Scope of work identified and agreed with Pavlodar Pharmaceutical Factory; potential consultants identified and their CVs collected		
– Assist w/construction and start-up of new mfg facility to ensure compliance					
Translate technical documents for Romat Pharmaceutical into English					
Provide translation services to prepare GMP certification and WHO PQ documents into English					
Identify, assess, and support additional manufacturers for WHO Prequalification					
Conduct baseline assessments of select anti-TB medicines mfrs					
Provide TA to promising companies to improve their GMP compliance					
Translate WHO Prequalification documents into Russian for manufacturers of anti-TB medicines					
Determine whether or			The set of documents		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
not these documents already exist			has been additionally reviewed; confirmation from WHO obtained that the versions of the documents are up-to-date and there is no translation into Russian; 2 documents will be taken for translation		
Perform translation, scientific editing, proofing, and formatting					
Expand the pool of viable manufacturers of anti-TB medicines by raising awareness of WHO PQ/PQM technical assistance program					
Conduct two-day workshop for mfrs in Central Asian Region on WHO PQ and PQM TA available					
Uzbekistan	J. Derry and K. Burimski				
Identify gaps in the country's medicines quality assurance system and propose interventions to address them					
Conduct a field gap analysis to identify status of QA/QC systems for anti-TB medicines to help define priority needs			No progress		
Meet w/Uzbek national MRA, Ministry of Health, and relevant partners to discuss findings					
Latin America and the Caribbean					
Amazon Malaria Initiative V. Pribluda					
Strengthen quality assurance and quality control systems					
Build capacity to perform Level 2 testing (Brazil)					
Reinstate rapid testing in endemic areas of			Discussions held with the NMCP and		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Brazil			PAHO/Brazil to plan a meeting with ANVISA		
– Develop policy for ANVISA					
– Provide logistical support for training on basic tests					
Build capacity to perform Level 3 testing according to registration methodologies					
Support USP internship for Suriname OMCL staff member on QMS		2 staff of the BGVS lab in Suriname completed a 3 week internship at USP on pharmaceutical analysis of antimalarial medicines			
Conduct training on testing of AMLs for the Suriname lab					
Conduct proficiency testing on Coartem® to evaluate regional OMCL capabilities					
Implement three-level approach for sustainable medicines quality monitoring activities throughout the supply chain					
Support MRAs and NMCPs of Colombia, Guatemala, Peru and Suriname to expand implementation of 3LA to decentralized areas			Initiated coordination between MRA and NMCP to include antimalarials in MQM activities Provided guidelines to MRA, OMCL, and Loreto's Regional Medicines Office for expansion of methodologies for implementation of the Three-Level Approach		
Implement 3-level					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
approach in Ecuador					
Finalize MOU and documents to implement 3-level approach in Guyana					
Identify and establish mechanisms to ensure sustainable south-south collaborations among OMCLs and MRAs in AMI countries					
Conduct a regional workshop to discuss sustainable mechanism to foster/support south-south collaborations			Initiated discussions with international partners to develop terms of reference for attendants		
Combating substandard and counterfeit medicines					
Develop virtual library of images of antimalarials in use in AMI countries					
Coordinate with local authorities to study MQ in Peru decentralized areas w/new 3-LA regs			The scope of the tool has been expanded beyond images to assess most relevant information included in the visual and physical inspection of medicines. Pilot assessment of the tool will be done in Colombia and/or Peru, because both countries are the most advanced in the institutionalization of the Three-level Approach		
– Identify entity to develop library			Six potential consultants identified and a request for proposals is being developed; will be sent by early Q3		
– Assess methodology					
– Access medicines info in countries					
– Create library in a					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
format for distribution					
– Disseminate information					
Provide technical leadership and global advocacy					
Disseminate results of quality study performed in three departments in Colombia					
Develop final report w/ country stakeholders; disseminate internally		The report was prepared by PQM and circulated internally			
Develop draft for wider dissemination by publishing results in peer-reviewed media					
Disseminate information about PQM activities					
Develop draft and submit to peer-reviewed journals			Papers accepted and published: - Were medicine quality and pharmaceutical management contributing factors in diminishing artemisinin efficacy in Guyana and Suriname? *Malaria Journal 2014, 13:77* - The Three-level Approach: A framework for ensuring medicines quality in limited resource countries *Pharmaceut Reg Affairs 2014, 3:1*		
Attend Meetings					
Attend semi-annual Steering Committee and annual RAVREDA technical meetings			Attended and presented at meetings in Nicaragua in March		

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Guatemala V. Pribluda					
Strengthen quality assurance and quality control systems					
Build regulatory capacity					
Carryover from FY13 Work Plan					
Upgrade DRCPFA's registration software to allow internet access for registration (WebSIAMED)		Upgrade of online registration renewals completed. Pilot assessment of online renewal with selected manufacturers was successful	16 training sessions offered to prospective users. There were 110 applications, of which 65 were approved in 48hrs; the rest failed adjustments. 70 professionals registered to use the system. Online regular registration will start in May 2014 and the system will be fully operational by the end of Q3		
Train MRA medicines registration staff on dossier evaluation			Training coordinated with MRA to be delivered in June		
Build OMCL capacity to perform QC testing					
Ensure OMCL operations are in compliance w/int'l standards					
– Review QMS documentation			Documentation requested from OMCL and review initiated		
– Assess UM-LNS to follow-up previous CAPAs			Assessment visit planned for May		
– Establish road map to expand scope and attain ISO 17025 accreditation					

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Strengthen proficiency in quality control testing					
Conduct trainings on GLP, Karl Fischer, Dissolution, UV-Vis					
Implement three-level approach for sustainable medicines quality monitoring					
Carryover from FY13 Work Plan					
Support MQM at selected 'Area(s) de Salud' utilizing the three-level approach (Huehuetenango Health Area)			Protocol finalized and MQM activities in Huehuetenango completed MQM coordinated with MRA, Health Area Office, and the OMCL will be performed in April		
Expand MQM activities to additional areas.					
– Equip sites with Minilab® and supplies					
– Provide support to MRA, DAS, OMCL for logistics/supplies					
Increase the supply of quality assured medicines					
Strengthen DRCPFA capabilities to ensure manufacturers comply with current Good Manufacturing Practices					
Train DRCPFA staff on equipment, and water & air system validation			Training coordinated with MRA to be delivered in July		
Provide oversight, monitor and evaluate PQM programs					
Meet w/country stakeholder to plan activities, follow up on implementation, report PQM achievements			PQM had several virtual meetings with country stakeholders (MRA, OMCL, and USAID) to coordinate and advance the implementation of activities; in-country visit is planned for May		