

**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
<b>Cross Bureau</b> K. Chibwe					
<b>Increase awareness about the importance of medicines quality</b>					
Attend/present at national, regional, and int'l conferences		Dr. Hajjou presented at the SciX 2013 Conference in October in Milwaukee, WI, and Dr. Chibwe presented at the ASTMH Global Health Conference in November in Washington, D.C.	Dr. Chibwe presented "Science Diplomacy and Global Health" at Georgetown University's Medical School in February.  Dr. El Hadri and Dr. Hajjou gave four presentations at the Global Health Mini-University at George Washington University in March.	Dr. Lukulay presented on securing the supply of quality-assured medicines in developing countries at Johns Hopkins University in April.  Ms. Krech presented on the Medicines Quality Database at the Unite for Sight 11 <sup>th</sup> Annual Global Health and Innovation Conference at Yale University in April.  Dr. Lukulay presented at the "Novartis Malaria Initiative: Best Practices Workshop" in Dar es Salaam, Tanzania in June.	
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.	USP issued two press releases promoting PQM activities related to improving access to TB medicines and the field testing of FDA's CD-3 device at CePAT in Ghana  PQM contributed to a USP blog post on medicines quality in the supply chain	

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		Q1	Q2	Q3	Q4
<b>Produce up-to-date information about current issues in medicines quality</b>					
Collect and publish reports of incidents of poor-quality medicine use	M McGinnis	38 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 1,980 hits	34 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 505 website hits	10 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 121 website hits	
Maintain and update PQM website	M Foster	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	Added 8 articles and 7 photos; update 2 webpages; added 3 new resources	
<b>Support regional approaches and networks</b>					
Participate in NEPAD's Technical Working Groups (TWG)		Dr. 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.	NEPAD designated 10 institutions as Regional Centers of Regulatory Excellence (RCOREs) in May and has prepared a draft RCOREs Guide; the RCOREs have submitted their curricula to NEPAD.	
<b>Explore improved tools to ensure quality control or to increase the knowledge base about quality assurance</b>					
Develop a field-based QC tool with increased accuracy, sensitivity, and reliability: <ul style="list-style-type: none"> <li>– Develop prototype</li> <li>– Field test &amp; pilot</li> <li>– Develop platform for broad class of meds/ monographs</li> </ul>	K Chibwe	Boston University (BU) 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 field studies at USP's CePAT facility in March. Results of the studies will be available in Q3.	Dr. Chibwe and Mr. Roth visited BU to carry out further post-field testing at the University. Results from the BU trip and the Ghana field studies were reported in two trip reports. While the artesunate injectables matched the HPLC data well, further refinement work will be needed for tablets testing optimization.	

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<b>Core Tuberculosis</b>	A. Hong				
<b>Increase the supply of quality-assured second-line TB medicines</b>					
Continue to provide TA to identified API & FPP mfrs of SL-ATBs seeking WHO PQ		<p>Shalina: dossier submitted to WHO; accepted and inspection scheduled for Q2</p> <p>Varichem: dossier submitted to WHO but not accepted; will complete per WHO's request and resubmit</p> <p>Steril-Gene: dossier received for review but not in CTD format; committed to revising into new format</p> <p>Peili: IVD study protocol reviewed and provided comments</p>	<p><b>China:</b>            Qilu: dossier received for review; comments provided to company for incorporation            Fuzhou: WHO inspection in February            Xinhua: process validation to be repeated per WHO</p> <p><b>India:</b>            Concept: reformulated FPP and in process of technology transfer            Shalina: currently dossier on hold for review due to API site refusal of inspection by WHO            Steril-Gene: updated dossier received for review</p> <p><b>Indonesia:</b>            Zenith: implementing CAPA; plans to conduct IVD study</p> <p><b>Korea:</b>            Dong-A: cycloserine API PQ submission tentatively scheduled for Sep 2014; Terizidone FPP BE study protocol</p>	<p><b>China:</b>            Hisun Pharma: received WHO PQ for Capreomycin API in May 2014; FPP listing expected in July/Aug 2014            Zhejiang Langhua: received WHO PQ inspection closing letter in June 2014; APIMF closing letter issued            Fuzhou: working on implementing CAPA from WHO inspection; also submitted second APIMF for non-sterile kanamycin API            Allsino Chemical Co.: product development completed            NCPC Formulation Co: dossier compilation in progress – scheduled to submit in Q4</p> <p><b>Georgia:</b>            GM Pharma: new project – potential visit Q4</p> <p><b>India:</b>            Concept: working on compiling dossier            Shalina: reformulating with new API source</p>	

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			<p>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 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</p> <p><b>Nepal:</b>            DJPL: draft dossier reviewed but incomplete; committed</p>	<p>Steril-Gene: working on compiling dossier for PQM review</p> <p><b>Indonesia:</b>            Zenith: implementing CAPA; plans to conduct IVD study            Sanbe: implementing CAPA            Kalbe: new project – potential assessment in Q4</p> <p><b>Korea:</b>            Dong-A: cycloserine API PQ submission tentatively scheduled for Sep 2014;            Terizidone FPP BE study protocol final and contract is in process            Enzychem: submitted to WHO for API PQ            BCWP: visited site to follow up on construction and provide input on HVAC, Water plans            CKD: conducted site visit to discuss proposal for HEPA installation construction            CKD Bio: new project – potential site visit in Q4            KUP: received qualification documents for review            Ildong; new project – potential site visit in Q4</p>	

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			<p>to manufacturing pilot scale in late February</p> <p><b>Philippines:</b>            Hizon: dossier received for review            Lloyd's: currently in FPP formulation development            Unilab: dossier received for review</p> <p><b>Taiwan:</b>            Peili: IVD completed; dossier compilation in progress</p> <p><b>Zimbabwe:</b>            Varichem: API manufacturer committed to submitting APIMF in spring</p>	<p>Hanmi Fine Chemicals: new project – potential site assessment in Q4</p> <p><b>Morocco:</b>            Pharmis: new project – potential visit in Q4            Pharma 5: new project – potential visit in Q4            Galenica: new project – potential visit in Q4</p> <p><b>Nepal:</b>            DJPL: completed pilot scale batches; conducted IVD study; 3-mo stability data received for review</p> <p><b>Philippines:</b>            Hizon: site assessment conducted in April            Lloyd's: IVD study in progress            Unilab: site assessment conducted in April</p> <p><b>Taiwan:</b>            Peili: IVD completed; dossier compilation in progress</p> <p><b>Vietnam:</b>            Imexpharm: site assessment conducted in May</p> <p><b>Zimbabwe:</b>            Varichem: API</p>	

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				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			<p>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</p> <p>Casablanca, Morocco: 20+ manufacturers attended from Morocco – 3 were visited by PQM staff during the trip; 3 more manufacturers have expressed interest</p>	Jakarta, Indonesia: 21 attendees from Indonesian manufacturers attended the information session at CPHI Jakarta. After the information session, one-on-one meetings with manufacturers were held	
Participate in GDF and WHO meetings with mfrs to discuss PQ					
<b>Conduct operational research to identify substandard/counterfeit second-line medicines on the market</b>					
Carry out PMS (if issues arise) of quality of second-line medicines in the country markets				No issues have been brought to PQM's attention	
<b>Develop OEM for at least two critical second-line anti-TB medicines</b>					
Identify additional suppliers to implement the OEM model for		Work with Baush Pharm and Interpharma Access in progress	Interpharma completed product development on Kanamycin; Baush	Interpharma and Baush Pharma have both completed the registration	

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select second- and third-line ATB medicines			Pharma completed product development on Capreomycin	batches and are working on compiling the dossiers for submission in Q4	
<b>Support research to improve quality and yield of Kanamycin through genetic engineering</b>					
Identify research group with expertise in fermentation to carry out proof-of-concept for higher quality/yield				RFA is in final stages of review before being advertised.	
Support scale-up of technology to API manufacturer					
<b>Provide support through capital investment to promising companies to obtain WHO PQ</b>					
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	Zenith: Levaquin sent for IVD (2 bottles resent due to short expiration date) Phapros: Levofloxacin comparator products Varichem: Levofloxacin comparator products Imexpharm: Levofloxacin RS and comparator products  Contract is being drafted to provide financial assistance for Dong-A to conduct a BE study on their second product	
Support calibration and validation of mfg and analytical equipment					
Provide assistance for other capital costs, as necessary					
<b>Develop public standards (pharmacopeial and Minilab<sup>®</sup> methods) for screening quality of second-line anti-TB medicines</b>					
Develop Minilab <sup>®</sup> test					

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		Q1	Q2	Q3	Q4
methods for SL-ATBs or third-line ATBs					
Develop USP monographs for prothionamide, terizidone					
<b>Core Malaria</b>		L Evans			
<b>Conduct studies to monitor antimalarial medicines quality and the extent of diversion from the public to private sector</b>					
Adapt study protocols for AM MQM study in new countries		Adaption of study protocols completed			
Conduct four new studies			Study completed in Ghana	Studies delayed in several countries due to Ebola outbreaks	
Develop reports and disseminate results					
Conduct follow-on studies				Study completed in Nigeria	
<b>Improve knowledge about the quality of antimalarials in PMI countries</b>					
Obtain samples of meds requested by PMI team and test				In progress	
<b>Increase the availability of standards and testing methods for selected antimalarials</b>					
Develop monographs for pyronaridine API and pyronaridine-artesunate FDC				In progress	
Develop monographs for pediatric formulations of DHA-PIP FDC and/or pyronaridine-artesunate				In progress	
<b>Core Maternal Health and Child Survival</b>		L. Evans			
<b>Increase the supply of quality assured maternal, newborn and child health medicines</b>					

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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 is tentatively scheduled for May 2014.		
<b>Monitor maternal, newborn, and child health medicines quality</b>					
Conduct medicines quality testing of maternal health commodities ( <i>in FY13 workplan; work being completed with carryover funds</i> )		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.		Completed QC analysis on one batch of Chlorhexidine gel samples.	
Develop CHX gel monograph for USP MC ( <i>in FY13 workplan; work being completed with carryover funds</i> )			Monograph development began with sourcing of all potential impurities as identified in the USP, BP and EP monographs for the API.	Monograph development continued with the start of method validation.	
<b>Support USAID medicines quality initiatives related to UN Commission Activities</b>					
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	PQM provided input into the development of the UN Commission workplans.  PQM participated in the Pneumonia and Diarrhea Meeting and the Chlorhexidine working group quarterly face-to-face-meetings. PQM continued to participate in bi-weekly teleconferences	

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			Antibiotics TRT	with the 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, and other partners <i>(in FY13 workplan; work being completed with carryover funds)</i>		Conducted full compendial analysis for UNICEF of zinc sulfate tablet batches from 4 manufacturers to be used in the global zinc roll out.		Full compendial analysis was performed on several batches of zinc sulfate tablets from different manufacturers.	
<b>SUB-SAHARAN AFRICA</b>					
<b>Angola</b>	R Okafor		<p>Conducted the initial assessment of QA/QC capacities of Angola in collaboration with USAID (Maria Miralles)</p> <p>Drafted a study protocol and proposed an approach to establish a baseline of the quality of antimalarials in four regions and submitted it to the Mission for validation by the local partners. There is no functional medicines authority and no national QC lab in Angola.</p> <p>Awaiting mission approval to finalize the work plan, timeline, and budget</p>	Still awaiting Mission approval	

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<b>Burundi</b>	M Hajjou				
<b>Strengthen the capacity of the INSP QC laboratory</b>					
Establish a three-year implementation plan to strengthen lab capacity		Burundi activities will begin in Q3		USAID-PEPFAR contacts are reviewing the PQM workplan; activities will begin following approval	
Equip the QC lab and train staff according to the first phase of the implementation plan					
<b>Support the improved governance of the national medicines regulatory authority (DPML)</b>					
Assist the DPML to build its medicines regulatory capacity					
– Establish the law and medicines regulation					
– Strengthen medicines registration system					
– Assist DPML to strengthen capacity for inspections					
<b>Establish a national medicines quality monitoring system</b>					
Implement use of basic tests as first step of QC for antimalarials – Procure Minilabs – Train analysts – Confirmatory testing – One round of MQM – Promote enforcement					
<b>Ethiopia</b>	Eshetu W.				
<b>Strengthen marketing authorization (MA) of medicines and local medicine manufacturers</b>					
<i>Strengthen FMHACA Product Registration &amp; Licensing Directorate</i>					
Build capacity in			Training on dossier	Assisted in the	

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dossier assessment, GMP/GCP inspections			<p>evaluation was conducted</p> <p>Developed training materials on basic GMP 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</p>	<p>assessment of 391 dossiers which have been in backlog for two years</p>	
Provide TA to develop tools, SOPs, etc., to operate MA		<p>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.</p> <p>Strategy paper for the assessment of dossiers in backlog drafted and submitted to FMHACA</p>	<p>Reviewed and submitted the Medicine Manufacturing Establishment directive to FMHACA. The Directive is now under discussion</p> <p>Good Manufacturing Guidelines for Pharmaceutical Products-Basic Principles: was reviewed, edited, and submitted for printing</p> <p>USP/PQM staff supervised and guided the assessment of over 300 dossiers in backlog.</p> <p>Initiated review of the medicine registration</p>	<p>Finalized and published Good Manufacturing Practices Guidelines for Pharmaceutical Products</p> <p>Finalized the Guidance on Training and Qualification Requirement of GMP Inspectors and submitted it to FMHACA</p> <p>Finalized Foreign GMP Inspection Application Form and reviewed it with FMHACA</p> <p>Finalized Guidance on Writing GMP Inspection Reports and submitted it to FMHACA</p> <p>Draft Medicine Manufacturing</p>	

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			<p>guidelines, Common Technical Documents (CTD) which conform with ICH countries guidelines</p> <p>Initiated review of the medical devices registration guidelines</p> <p>One staff from USP/PQM participated in a workshop on the development of traditional medicines guidelines organized by FMHACA at Bishoftu in February</p> <p>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</p> <p>Technical assistance provided to Cadela Pharmaceutical regarding bioequivalence study waiver and comparator</p>	<p>Establishment Directive reviewed and submitted to FMHACA</p> <p>Finalized Directive for foreign medicine manufacturers GMP inspection</p> <p>Guidelines for registration of medicines common technical document (CTD) reviewed and posted on FMHACA's website</p> <p>Guidelines for registration of medical devices drafted</p> <p>Developed draft Guidelines for Submission of Medicine Variations Application</p> <p>Guidance for biowaiver draft prepared and is being reviewed</p> <p>Inventory of tools essential for effective regulatory management was developed and submitted to FMHACA to be used for self-assessment</p> <p>Preparatory work in progress to send five regional medicine</p>	

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			products selection	inspectors for training on inspection principles and techniques at CePAT, Ghana  Preparations in progress for a ten-day training on advanced GMP to be held in Addis Ababa	
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		
Train staff to operate and manage system					
<b>Strengthen FMHACA's quality control laboratories to become compliant with cGMP, ISO 17025 accredited, and WHO Prequalified</b>					
<i>Strengthen FMHACA Product Quality Assessment Directorate (PQAD)</i>					
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		Training on analytical method validation given to 18 FMHACA staff in Apr  Report on qualification of VALENDOR branded instruments prepared by VALENDOR and submitted to USP  A two-week hands-on training was provided for 4 branch FMHACA staff on basic analytical techniques and quality management systems in Jun-Jul at FMHACA'S Product Quality Assessment Directorate Laboratory	

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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	A three-day visit by the WHO assessor was carried out; the assessor's report identified the gaps observed and expected corrective actions	
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	Maintenance and qualification of VALENDOR condom testing machine carried out in May; the machine is operational	
Train staff in test methods and QMS					
Train staff in condom QMS (ISO 4074)					
Train staff in microbiological test methods					
<b>Strengthen post-marketing surveillance of AM, ARV, and OI medicines circulating in Ethiopia</b>					
Train participating staff in sampling & testing			Training was organized for PMS sample		

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			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	Collection of samples of antimalarial, ARV, and OI medicines completed from all eight sites	
Support testing of AM meds per protocol				Necessary input supplied to the laboratory; testing of the collected samples has begun	
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 purchased and provided to the lab	Necessary input supplied to the laboratory; testing of the collected samples has begun	
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		In May and June, three workshops (in Amhara and Tigray regions) were organized to promote public awareness of the illegal food and medicines trade	

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		USP/PQM			
<b>Assist local medicines manufacturers toward GMP compliance and WHO Prequalification</b>					
<i>Improve knowledge and skills of local med manufacturers in GMP</i>					
Get local OI mfrs to get products QA'ed					
Support local mfrs in implementation of GMP Roadmap					
<b>Strengthen FMHACA's branch quality control laboratories to become capable of monitoring the quality of medicines</b>					
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				Lab instruments were installed at the FMHACA Southern Branch lab and training was provided to the staff on how to use the instruments	
<b>Strengthen FMHACA's branch quality control laboratories to become capable of monitoring the quality of medicines</b>					
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					

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based on needs assessment					
<b>Strengthen regional/city administration medicine food and healthcare control and administration bodies</b>					
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 Tigray Regional Food, Medicine and Healthcare regulatory core processes were undertaken in Jan and Feb and reports submitted to HQ to be reviewed and edited	Assessment of the Oromia Regional Food, Medicine and Healthcare Regulatory Core Processes shared with USP/HQ and Oromia region  Assessments of Southern Nations Nationalities and Peoples Regional Health and Health-related Services and Products Quality Control Authority conducted and report shared with the region	
<b>Assist Pharmaceutical Funds and Supply Agency (PFSA) in establishing internal quality control laboratory</b>					
Develop assessment tool		Tool developed			
Conduct assessment		Assessment of the QC needs of PFSA was completed	Workplan prepared based on the assessment results		

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<b>Ghana</b>	R. Okafor				
<b>Support post-marketing surveillance of antimalarial medicines at seven sentinel sites</b>					
Conduct two rounds of MQM at selected sites for testing			To be completed in Q3; MQM contractual delay	Funds were transferred to the FDA Ghana account in April, after months of contract delays, to complete FY13 activities and initiate FY14 sampling and collection	
– Conduct confirmatory testing of R1 at FDA lab		Round 1 confirmatory testing completed for FY13	To be completed in Q3; MQM contractual delay	FDA Ghana completed confirmatory testing and sent a report to PQM	
– Conduct confirmatory testing of R2 at CePAT			To be completed in Q3	Funds for the FY14 first milestone were sent to FDA Ghana in June; sampling has begun for both PMI and MCH projects	
Conduct onsite evaluations of selected sites (PQM-FDA team)			To be completed in Q3; MQM contractual delay	Training planned at FDA site by select FDA team and PQM consultant	
Promote enforcement actions based on data			To be completed in Q3; MQM contractual delay	In progress, based on finalized results	
<b>Strengthen the capacity of the national Food and Drugs Authority QC laboratory and assist toward ISO 17025 accreditation</b>					
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	Procured key supplies and consumables necessary for accreditation; assisted the lab to revise key documents and submitted them to the accreditation body	
Train staff as needed based on assessment		Installed key equipment for the scope of accreditation; offered	Trained staff on Karl Fischer, root cause analysis, loss on drying,	Conducted several technical and ISO/QMS trainings to prepare staff	

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		training in GDP, Safety in the Lab, Karl Fischer, FTIR, and ISO 17025	effectively reading and understanding the pharmacopeia, and uniformity of dosage unit	for the audit; conducted a mock audit session to prepare staff	
Provide QMS training to FDA QA team		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	Internal auditing training provided to key QA personnel and lab appointed auditors	FDA QA team was trained on how to answer audit questions; final documents were reviewed with the QA team before submission	
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	PQM provided the technical assistance necessary for the pre-audit	
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	Assisted the FDA to resolve all corrective actions in the system and from previous PQM audits	
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	ACLASS audit took place in April. PQM assisted with solving all CAPAs and submitting them to ACLASS. FDA became officially accredited in June 2014	
<b>Provide training for FDA GMP Inspections staff in risk-based compliance module; strengthen capacity of GMP Inspectorate Quality System</b>					
Provide FDA Inspectors with GMP assessment training			Planned for Q3-Q4	GMP training for inspectors has been planned for July. A meeting with key FDA	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				participants was conducted in June outlining what is expected for this training	
Improve internal system of GMP Inspectorate			Planned for Q3-Q4	Planned for Q4 – in progress	
<b>Support inclusion of FDA data in the PQM MQDB</b>					
Support data entry and develop statistics using MQM data			Data available from MQM first round provided for MQDB	MQM data from round 1 was provided to PQM consultant for MQDB and for journal paper and analysis	
<b>Collaborate with the Maternal Health Channel of Creative Storm Network to develop advocacy and public sensitization programs</b>					
Produce short documentary on PMS process			Planned for Q3-Q4	Based on meeting and discussion with USAID, PQM emphasis is to remain on MQM testing and provision of results	
Facilitate public policy dialogue through radio and TV discussions			Planned for Q3-Q4	Based on meeting and discussion with USAID, PQM emphasis is to remain on MQM testing and provision of results	
Facilitate dissemination workshop for identified stakeholders about findings on CSMs			Planned for Q3-Q4	Planned for Q4 upon receipt of final data that is ongoing	
<b>Guinea</b>	L El Hadri				
<b>Build the capacity of the National Quality Control Laboratory (LNQCM)</b>					
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.		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Procure and deliver one Minilab <sup>®</sup> to the lab					
Provide lab supplies and reagents needed to conduct hands-on Minilab <sup>®</sup> and basic tests training of selected medicines				One Minilab procured and delivered to the lab	
Assist the lab staff during the testing of samples collected for the survey				Completed	
Assist the lab with reporting of Minilab <sup>®</sup> and compendial data obtained from the field				Planned for Q4	
<b>Strengthen the capacity of the Drug Regulatory Authority (DNPL)</b>					
Support DNLP by reviewing the current version of the National Pharmaceutical Policy (NPP) and new registration directives				Planned for Q4	
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					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
and functions of the registration department					
<b>Strengthen the quality control of medicines by initiating the establishment of a Medicines Quality Monitoring program (MQM) and promote taking regulatory actions</b>					
Organize a meeting w/ key stakeholders to discuss the sampling and testing of selected medicines circulating in Guinea				Planned for Q4	
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 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					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
survey data					
<b>Kenya</b>	L El Hadri				
<b>Continue strengthening medicines quality monitoring of antimalarials at existing sentinel sites and expand to new sites</b>					
Conduct one round of sampling and testing of AMs at 11 sites		Planned for Q3		MQM sub-award completed and sent to PPB; sampling will start in Q4	
– 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		Training on Minilab tests, sampling strategies, and reporting provided to 22 staff from the 11 sites	
Conduct M&E visits to three sentinel sites and one port of entry				Planned for Q4	
<b>Continue promoting regulatory actions by sharing MQM data with stakeholders and by raising awareness</b>					
Promote efforts to support enforcement actions by PPB based on MQM data				Planned for Q4	
Raise awareness about quality and share data w/PPB, DOMC, and other stakeholders					
<b>Continue strengthening capacity of the NQCL and assist the lab toward improving its QMS and toward reaching ISO 17025 accreditation</b>					
Improve technical capacity of NQCL staff on QMS				Lab visit conducted and review of QMS activities completed	
– 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	SANAS audit completed	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
– Review required documentation			Progress report reviewed		
– Facilitate audit by SANAS and follow up report findings			Planned for Q3 and Q4	Follow up on audit conducted; report on findings will be submitted in Q4	
– Review CAPA actions and facilitate accreditation visit			Planned for Q3 and Q4	CAPAs reviewed	
<b>Liberia</b>	L El Hadri				
<b>Continue building the capacity of the LMHRA Quality Control Laboratory</b>					
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 planned for Q3	QMS assessment will be conducted in Q4	
Establish an action plan to prepare the lab for ISO 1705 accreditation			Activities planned for Q3	Planned for Q4	
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			
<b>Continue strengthening LMHRA's regulatory capacity</b>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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		
<b>Strengthen monitoring the quality of antimalarial medicines at four sentinel sites and promote regulatory actions</b>					
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	Will be conducted in Q4	
Conduct M&E visits, review data, review final report					
Draft and share reports with stakeholders			Planned for Q3 or Q4	Report of round 4 completed and will be disseminated at round table meeting in Q4	
Promote LMHRA taking enforcement actions based on MQM data			Planned for Q3 or Q4	LMHRA took more than 10 regulatory actions on non-conforming medicines	
Raise public awareness by filming regulatory actions (confiscation of failed samples in the market) for media			Planned for Q3 or Q4	Will be conducted in Q4	
<b>Mali</b>	M Hajjou				
<b>Strengthen the capacity of the National Laboratory of Health (LNS) to attain ISO 17025 accreditation</b>					
Strengthen technical					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
capacity					
– Procure needed lab supplies & equipment				<p>A new detector for the HPLC system was procured and delivered to the lab</p> <p>A qualification kit for the UV-Vis spectrophotometer was procured and used to qualify two spectrophotometers</p> <p>Adequate reagents for Karl Fischer titration were procured</p>	
– 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	2 staff received training in Karl Fischer titration, and 2 trainers received refresher training in UV-Vis spectrophotometer qualification, allowing them to qualify two instruments	
Strengthen QMS by developing SOPs, a training program, internal audit system, and raising managers' QA awareness		22 SOPs finalized	<p>Refresher training in Good Documentation Practices provided to 8 LNS staff</p> <p>Work flow of QC lab at LNS reviewed and recommendations provided to develop necessary SOPs</p>	The implementation plan to help the QC lab attain ISO 17025/WHO prequalification was developed and revised, and is under review.	
Monitor and evaluate				Follow-up practices of	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
training				analytical methods included in previous training were supervised by the head of the QC lab	
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.			
<b>Support pre- and post-marketing quality monitoring of antimalarial medicines</b>					
Conduct MQM of antimalarial meds				In process	
– 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.  3 Minilabs procured for the sentinel sites in Gao, Timbuktu, and the new sentinel site in Kidal.  19 staff from Regional	Resources to start sampling and testing of antimalarial medicines were provided to LNS  80 samples were collected in the district of Bamako, and 48 samples were collected at the	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Directorates of Health, LNS, PNLP, and PNLT received training in sampling and screening of medicines using Minilabs	Koulikoro sentinel site. Minilab screening was completed on all samples collected  Refresher training and sampling plans for the remaining sentinel sites have been developed	
Monitor and evaluate MQM activities w/supervisory visits and review/validate data				Raw data from Minilab testing as well as sampling documentation were reviewed; doubtful and failed samples were verified	
Raise awareness of counterfeit and substandard medicines and promote corrective actions				The issue of taking corrective actions was discussed with the head of the Directorate of Pharmacy and Medicine (DPM). The DPM is developing internal procedures that include responding with corrective actions when substandard or counterfeit medicines are found	
<b>Support coordination of PQM activities in the country</b>					
Hire a locally-based consultant		Consultant position description drafted	Consultant position was advertised in the local newspaper, and a candidate has been selected; the hiring process is underway	The consultant was hired and has started working closely with local partners	
<b>Mozambique</b>	R. Okafor				
<b>Strengthen the capacity of the National Laboratory for Medicines Quality Control (LNCQM)</b>					
Strengthen quality		New QA staff appointed;	Training planned in May	Training was initiated with	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
management capacity by training the staff		assessed personnel to properly plan for training	for new QMS	new quality manager; however, PD director asked PQM to hold off on the training until 2 new staff begin working	
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	Training on Uniformity of Dosage Units and how to use USP and other pharmacopeia was conducted	
Assist LNCQM to refine strategic plan for ISO accreditation/WHO PQ		Discussed changes and delays to ISO accreditation due to recent staff changes with director of DF	Presented the discussed plan to director of DF; pending translation service approval to forward translated document	A refined roadmap to accreditation was provided to DF and LNCQM management as well as USAID; it was translated into Portuguese	
<b>Strengthen the capacity of Departamento Farmacêutico (DF)</b>					
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		This issue was revisited with the new CMAM director during a meeting among USAID, PQM, CMAM, and other partners to discuss PQM activities in the country; future meetings will be held to discuss assistance with regulatory actions	
Encourage and train DF staff at port directorate			Planned for Q3	3 Minilabs were ordered for the 3 ports chosen by USAID, PQM, and DF; training at the new sites will take place in August.	
Encourage DF to		Discussions held with	Planned for Q3	MOH and Permanent	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
dedicate funds for LNCQM sustainability		DF and key staff during visit in December; provided technical assistance to MOH staff on procurement list of items/regents and consumables		Secretary have promised to set aside funds to support the lab	
<b>Support the MQM program by expansion into the ports of entry</b>					
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	Contractual delays resulted in improperly collected MQM samples (not enough funds to purchase medicines); results nonetheless have been submitted for the FY13 rounds. FY 14 funds were transferred in June	
Supply new sites; train provincial staff and DF inspectors			MQM delayed due to contractual delays; planned for Q3-Q4	Training planned for August at LNCQM	
Support DF efforts on enforcement actions based on MQM data			MQM delayed due to contractual delays; planned for Q3-Q4	In progress, pending MQM results	
<b>Nigeria</b>	M. Hajjou (Malaria); L. Evans (MCH)				
<b>Monitor the quality of antimalarial and maternal child health medicines</b>					
Conduct two rounds of sampling and testing of antimalarial meds		Budget provided to the National Malaria Control Program for conducting one round of MQM activities	Sampling protocol drafted, revised, and finalized  Sampling conducted at all sentinel sites; testing of samples is underway	Completed testing of all antimalarial samples.	
Conduct QC testing of each batch of zinc sulfate tablets procured by USAID from Chi			PQM received 8 batches of zinc sulfate tablets from CHI Pharmaceutical	PQM completed QC analysis of 8 batches of zinc sulfate tablets from CHI Pharmaceutical and	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Pharmaceutical			procured by USAID Deliver. The batches are to undergo QC analysis prior to release by DELIVER.	provided the results to DELIVER	
Promote enforcement actions				Report on MQM activities was drafted by NAFDAC central laboratory management; it is under review by NAFDAC headquarters	
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		
<b>Strengthen the regulatory capacity of NAFDAC</b>					
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	<p>Procured lab supplies including consumables and devices to monitor the lab environment.</p> <p>Trained 25 NAFDAC lab staff in the following:</p> <ul style="list-style-type: none"> <li>• Dissolution: Theory and Best Practices</li> <li>• UV-Vis Absorption Spectrophotometry</li> <li>• Loss on Drying</li> <li>• Disintegration</li> </ul>	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				<ul style="list-style-type: none"> <li>Uniformity of Dosage Units</li> </ul>	
– Strengthen QMS		Drafted implementation plan for NAFDAC lab to attain WHO PQ/ISO 17025 accreditation	Trained NAFDAC lab staff in understanding ISO 17025, internal audit process and methods, reporting and reviewing test results, and corrective and preventive actions	Developed 9 SOPs and reviewed quality manual; NAFDAC lab participated in proficiency testing for Karl Fischer titration, Loss on Drying, UV spectrophotometry, pH, and HPLC. The lab also participated in NOMCoL inter-laboratory testing and submitted a report  NAFDAC lab implemented corrective action plan in the following areas: <ul style="list-style-type: none"> <li>Safety and good housekeeping</li> <li>Handling of test items</li> <li>Document control</li> <li>Personnel training and training records</li> <li>Monitoring of environment</li> <li>Corrective actions and preventive actions</li> <li>Reporting and evaluation of tests results</li> </ul>	
<b>Support NMCP in finalizing the quality assurance policy for its medicines and diagnostics</b>					
Assist NMCP in finalizing draft QAP					
Assist NMCP in drafting & reviewing procedures to implement QAP					
<b>Build capacity in GMP of selected local manufacturers of zinc sulfate, ORS, chlorhexidine, and amoxicillin commodities for global and local</b>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<b>supply</b>					
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.	<p>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.</p> <p>PQM analyzed samples of the first batch of CHX gel developed by Drugfield.</p> <p>In March, Drugfield received NAFDAC approval to market CHX gel.</p>	<p>PQM participated in the Meeting of the Informal Network of Chlorhexidine Gel Manufacturers in Abuja. The objectives of the meeting were to:</p> <ul style="list-style-type: none"> <li>• Exchange updates on Chlorhexidine 4%</li> <li>• Address challenges from local manufacturers on progress made regarding gel production</li> <li>• Provide a forum for private sector, policy makers, ministries and departments, donor agencies, and others concerned with policy and barriers to local production and use of Chlorhexidine 4% gel</li> </ul>	
Provide support to CHI ORS mfg to enable procurement by local 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)	<p>PQM visited 2 zinc sulfate tablet manufacturing facilities that are under construction and provided layout recommendations to ensure GMP compliance.</p> <p>Pilot batches were</p>	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				evaluated by physical and visual inspection and technical assistance was given to improve the physical properties of the tablets	
Support add'l local mfrs of ORS				PQM visited one ORS manufacturing facility that is under construction and provided layout recommendations to ensure GMP compliance	
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.	Amoxicillin manufacturers were invited to the CHX informal network meeting to discuss establishing a group for amoxicillin manufacturers. PQM presented its role and the type of TA it can provide.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				PQM met with JSI-TSHIP to discuss the strategic priorities and next steps for the informal network of amoxicillin manufacturers	
<b>Senegal</b> L El Hadri					
<b>Continue strengthening the capacity of LNCM and prepare the lab for TUNAC ISO 17025 audit</b>					
Continue improving technical capacity of LNCM staff to conduct testing and improve managerial skills		QMS training conducted at CePAT			
– Facilitate participation in NOMCoL IPT				Completed	
– Provide TA, supplies for IPT and advise on improvements		Supplies provided for ITP testing		Completed	
– 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	Documents prepared and reviewed	
– Provide TA prior to LNCM application					
– Review all required documents and forms			In progress	Ongoing	
– Conduct mock audit and report finding,			Planned for Q3	Completed	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
recommend how to address CAPAs					
<b>Strengthen the capacity of DPM and support enforcement of its regulatory actions</b>					
Organize workshop for DPM and customs on enforcing regulations					
Assist LNCOM to prepare additional SOPs		Provided SOP templates to the lab		SOPs reviewed	
<b>ASIA</b>					
<b>RDMA Mekong Malaria S. Phanouvong</b>					
<b>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.</b>					
Collect samples of AMLs and suspect ABTs in targeted areas; Collect info on availability of oral artemisinin AML monotherapies; report to all relevant agencies		<p>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.</p> <p>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</p>	Samples were not collected during this reporting period.	<p>Analysis of samples collected in Thailand under GFATM, with technical support from PQM, indicated the presence of artesunate monotherapies. Data collected in Laos is awaiting analysis, but monotherapies were not identified.</p> <p>Data analysis in support of the regional assessment of poor quality medicines has been prepared for a journal submission.</p>	
Purchase and replenish essential Minilab <sup>®</sup> / QC		PQM provided some 100 reference standards	Taking inventory and gathering information	Laos FDQCC, NIDQC, and HIDQC have	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
lab supplies to maintain MQM and confirmatory analyses at the Laos FDQCC and Vietnam NIDQC and HIDQC.		and products to FDQCC; will be distributed to the sentinel sites for MQM	from the countries.	received necessary RS, and FDQCC has ordered and received additional Minilab supplies	
Conduct 3-4 supervisory / M&E visits to select sites with MRA, National QC Lab staff and/or NMCP		Site visits were carried out in Cambodia, Vietnam, Laos, and Burma	Site visits are in the planning stages for Thailand and later in Burma.  Site visit carried out in Vietnam to Binh Phuoc province (jointly with USAID HQ and RDMA)	Site visits in Thailand were postponed due to political unrest. Visits in other countries were held as planned and additional visits by PQM HQ staff and USAID/RDMA were organized in Vietnam	
Analyze data; Laos, Vietnam and PQM produce end-of-FY reports. Burma, Cambodia, Thailand will use their own funding.			Planned for Q4	Working with Laos FDD to complete financial and technical reports	
<b>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</b>					
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	Results from March internal review not yet received due to staff shortages at FDQCC  Inter-laboratory testing samples sent to FDQCC for testing in Q4  PQM QMS team continued to review the FDQCC's Quality Manual and SOP documents	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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.	Assessments in Thailand postponed due to political unrest. Meetings held with Chula in May indicate a high degree of interest in training and testing service provision for the region	
<b>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).</b>					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all SCM cases among enforcement agencies in Laos and Vietnam.		<p>The new regional PQM consultant participated in Minilab training in Myanmar in December 2013 to increase coordination across the region.</p> <p>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.</p> <p>In October, BREMERE representatives from national testing labs were trained on Bioequivalence/Bioavail</p>	<p>In addition to all GMS countries nominating two representatives, the Philippines FDA also nominated 2 representatives</p> <p>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.</p>	<p>Testing results presented to Thai authorities in May indicate ongoing quality issues. Release of information to BREMERE has not yet been authorized.</p> <p>Discussion on potential collaboration between PQM and ASEAN working groups on pharmaceuticals continued.</p> <p>A concept note on 'Potential Areas of PQM Technical Assistance to Strengthen the Technical and Regulatory Capacity of ASEAN Countries' was developed and submitted to AOR team</p>	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		ability testing methods. In November 2013, Thailand provided the final nominees needed to complete the BREMERE team.			
Support inter-country / regional BREMERE, ASEAN PMAS, and INTERPOL cases through timely sharing of information and data, and joint investigation and enforcement.		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 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.	Presented Thai data to RDMA under limited release due to lack of approval for dissemination	
<b>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.</b>					
Improve inspector practices in supply and distribution chains with training of trainers and hands-on inspection exercises to support oral monotherapy ban.				Planned for Q4	
Strengthen Laos pharmacy practices through national/local training of operators in targeted containment priority areas and help implement the oral monotherapy ban.				IEC study in Laos indicates high awareness of the general danger of counterfeit medicines but limited understanding of the concept of resistance.	
Conduct initial		Identifying	In March, PQM staff and	PQM received responses	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
assessment of dossier and GMP compliance of two potential mfrs in Vietnam to receive TA toward producing ACTs for the region.		manufacturers in Vietnam in close consultation with local partners	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.	to the manufacturer questionnaire from two manufacturers (SaoKim Pharmaceutical JSC and OPC Pharmaceutical joint-stock company) and PQM GMP Manager paid an initial visit to each of them. Observations with associated remedial actions were provided to the companies.	
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.	Outlines of curricula from Cambodian and Laos universities were received and are under PQM review; additional information will be collected.	
<b>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.</b>					
Disseminate publicly data and findings from PQM activities through appropriate means; also present PQM work		PQM submitted an editorial to the Bulletin of WHO about MQDB, to be published in the Jan 2014 issue	A journal article entitled 'Cambodian Ministry of Health Takes Decisive Actions in the Fight against Substandard	Data on SE Asia, including the Mekong Sub-region, was presented at the WPRO Regional Meeting on	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
progress/achievements at conferences and meetings on medicines quality issues.		<p>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.</p> <p>A draft report was prepared describing the effects of IEC initiatives in Laos. The report will be finalized in Q2.</p>	<p>and Counterfeit Medicines' was published in the Journal of Tropical Medicine and Surgery.</p> <p>The report on a 'Pilot Project on Information, Education, and Communication (IEC) Strategy for combating counterfeit and substandard medicines in Lao PDR' is being finalized.</p>	<p>Regulatory Capacity Strengthening and shared with relevant parties, including PMI and USAID teams in the region.</p> <p>A journal article on global trends in poor quality medicines is being prepared; anticipated publication in AmJTropMedHyg in Q4</p>	
<b>Burma</b> S. Phanouvong					
<b>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.</b>					
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.	Sample collection and field testing finished in two border areas (Tamu and Muse). Sample collection from 2 sentinel sites (Rakhine and Tanintharyi) conducted in collaboration with CAP-Malaria. Sample collection from another 2 sites (Bago East and Mon) to be conducted by DFDA in Q4.	
Purchase and replenish essential Minilab <sup>®</sup> / QC			In Feb 2014, PQM provided 21 essential	Completed	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
lab supplies to maintain MQM activities and confirmatory analyses			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	Plan for supervisory visit at Burma-Thailand border and 3-4 sentinel sites in Q4	
Compile and analyze data (country mgmt. team) from sites and results from DFDA QC lab; PQM consolidates data and reports.			Planned for Q3	Planned for Q4	
<b>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.</b>					
Provide essential laboratory equipment and hands on training to DFDA QC Lab staff in Nay Pyi Taw		PQM donated one 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	PQM donated one 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	3 site visits to proposed relocation sites of the DFDA Nay Pyi Taw QC laboratory were conducted. Technical suggestions were provided to DFDA. The renovation of the building to house the Pharmaceutical Chemistry lab has started in line with input from PQM.	

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		Q1	Q2	Q3	Q4
<p>PQM and Chula PTSC will train the lab staff on GLP, QMS, and concept of ISO 17025 accreditation process</p> <p>Provide technical guidance on how to build capacity of the lab in HR, developing technical expertise, equipment specs, etc.</p>		<p>Training on advanced analysis on dissolution property of antimalarials was conducted in Dec 2013. 10 participants from DFDA and 2 from DMR-LM attended.</p>	<p>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.</p>	Completed	
<p><b>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).</b></p>					
<p>Support in-country BREMERE to enhance communication, coordination, and joint investigation of all SCM cases among enforcement agencies</p>		<p>The new regional PQM consultant participated in Minilab training in Myanmar in Dec to increase coordination across the region.</p> <p>Two regional trainings were conducted in the Philippines in Sep and 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.</p>	<p>Results of the baseline survey in Burma were submitted to the DFDA for action</p>	<p>PQM continued to follow up on engaging DFDA to take action on non-conforming samples found in the baseline survey and hope to share the results with BREMERE focal points in each country</p>	
<p><b>Increase the availability of quality-assured AMLs by improving inspections in supply and distribution chains, enhancing pharmacy</b></p>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<b>practices, and engaging pharmacy school students and faculty in the reduction of CSMs in the country.</b>					
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	Training workshop for 28 DFDA central and state/division level FDA staff on PMS and MQM conducted in Nay Pyi Taw in March 2014		
Engage faculty and final-year students (50) of a pharmacy school in Yangon to improve pharmaceutical practices in various settings through curriculum/syllabi improvement.				Delay in final review of the curricula of Schools of Pharmacy in Cambodia and Laos that could be used for Burma has resulted in a delay in activity in Burma as well.	
<b>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.</b>					
PQM or rep from DFDA, VBDC, or Dept. of Medical Research-Lower Myanmar will present PQM's work progress/achievements at conferences and meetings on medicines quality issues.				Results of the baseline survey were shared with relevant partners, including DFDA, PMI, and USAID missions (Burma and RDMA)	
<b>Cambodia</b> E. Yuan					
<b>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.</b>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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.	Confirmatory testing of 52 samples (selected from total collected samples) is in progress with results expected in Jul. If there are any failures, the IMC Secretariat team will evaluate and take appropriate action.	
Purchase and replenish essential Minilab <sup>®</sup> / 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	This activity is complete for FY14	
Conduct 4-5 PQM supervisory / M&E to sites representatives from DDF, NHQC and NCM.		The PQM local consultant joined with representatives of DDF, NHQC, CNM and provincial drug inspectors to conduct inspections in drug outlets within 6 provinces	N/A	Accompanied by DDF-MoH's inspectors, PQM conducted two sentinel site visits to check MQM sampling & testing procedures and replenish materials if needed. Also, certain pharmacies and drug outlets were checked to monitor and enforce good pharmacy practices.	
Analyze data and produce end-of-FY				Planned for Q4	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
technical reports for country and PQM.					
<b>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.</b>					
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.				PQM met with NHQC, who stated that NHQC currently lacks the skills to achieve this currently; in addition, moving to the new building created staff shortages and made it difficult to focus on this activity	
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.		During the move to the new building, there is no need for equipment or instrument installation and calibration	
<b>Support in-country and inter-country and regional coordination, cooperation and enforcement through BREMERE to enhance collective action at national and regional levels.</b>					
Support in-country BREMERE to enhance communication, coordination, and joint investigation of all CSM cases, emphasizing AMLS, among the IMC members as well the Provincial Sectoral Committee members at the provincial level..		2 drugs inspectors are representatives of Cambodia for communicating with other countries in the regions			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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	Continuous communication	
<b>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.</b>					
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.				Since there has been no evidence showing the presence of artemisinin monotherapies in Cambodia, the workshop is on hold	
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.		A meeting was held with the new Dean of the University of Pharmacy. The importance of improving the curriculum by adding QA/QC was discussed, and a proposal to develop a plan of action will be further discussed.	
<b>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.</b>					
PQM or rep from DDF, NHQC, or CNM will present PQM's work progress/achievements at conferences and meetings on medicines		PQM supported the Mekong Bio-Pharma conference in Cambodia in Oct for 400 participants.	PQM's local consultant: --attended USAID's workshop on "Introduction to USAID's Legal Regulation, Financial Management	PQM's local consultant attended GPP training for drug inspectors in May	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
quality issues.		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.	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.		
<b>FY13 Activities to be implemented in FY14 with carry-over funds</b>					
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 chains to all DDF and selected provincial inspectors and key pharmacists from artemisinin-resistant containment areas.		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.	DDF-MoH received the budget for GPP training. 14 GPP trainings for pharmacists and drug outlet owners will be conducted between Jul-Oct 2014.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Continue to provide TA to the NHQC to successfully prepare its national QC lab's QMS toward achieving the ISO17025 accreditation					
<b>Indonesia</b> C. Raymond					
<b>Work plans for TB and HIV are still under review by USAID and PQM</b>					
<b>Support the quality assurance of antiretroviral medicines used by the HIV program in Indonesia</b>					
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			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	An initial GMP assessment was conducted at Kimia Farma's (KF) anti-retroviral manufacturing facility, revealing some observations regarding KF's compliance with GMP for FPP. A follow up and plan for CAPA implementation was agreed upon during the next 6 months. ARVs manufactured by KF were sampled for testing by the PPOMN National QC lab (sampled by National AIDS Program, BPOM, and PQM). Testing to be completed in Q4 with reports for the NAP and the Global Fund.	
Assess QA/QC capacity of [Papua and West Papua (TBD)] including provincial and district warehouses, health facilities and				This activity is scheduled for Q4, including assessment and training on MQM, compendial testing of ARVs & TB medicines, and district-	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
provincial BPOM QC labs				level sampling from warehouses in the public sector	
Provide training for central BPOM lab on HIV, STI, & OI medicines sampling & testing				PQM led a team from BPOM, BINFAR, HIV and TB health programs and conducted sampling of first and second line TB medicines and HIV medicines from GFATM (imported) and those paid for by the Indonesian government (locally manufactured). Samples were collected from three central-level warehouses. All participants were trained on sampling and participated in the sampling exercises. Training and testing of these medicines is scheduled for Q4.	
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.	An implementation plan was drafted and agreed upon between BPOM (PPOMN) and PQM, including scheduling for training and assessments at the provincial and district levels. These trainings are tentatively scheduled for Q4 or early FY15 Q1 based on QC staff availability  -conducted a site visit together with USAID	

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		Q1	Q2	Q3	Q4
				Washington to San Clin EQ, Caprifarmindo, and the Bandung provincial BBPOM QC laboratory to see project progress	
Scale-up integration of ARVs into the national post-marketing surveillance program			-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	Together with BPOM (Deputy 1) and PPOMN National QC lab, PQM identified areas for scale-up in 50 priority districts for the national post-marketing surveillance program. Unanticipated National Govt budget cuts may require additional PQM funds to make up the temporary budget shortfall. A PMS workshop and planning meeting are scheduled for Q4.	
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	One BPOM officer was supported to attend the regional ASEAN-USP Scientific Symposium held in Vietnam; also supported additional training following the symposium.	
<b>Continue existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines</b>					
Assessment, CAPA, and dossier compilation for levofloxacin 500mg of Caprifarmindo		GMP team conducted initial site assessment and provided report for CAPA to Sanbe/Caprifarmindo	-Caprifarmindo implemented CAPA and provided closure report on CAPA items; also updated on status of product development and procurement of new API source from	Caprifarmindo (Sanbe) attended CPhI workshop on WHO PQ and consulted with PQM's GMP team. Additionally, a tentative training plan is being developed at the request of Sanbe as part	

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		Q1	Q2	Q3	Q4
			Zhejiang Apeloa, China which already has CEP; production to scale up during Q3 -comparator products provided to Sanbe	of the WHO PQ program. Caprifarmindo has changed its API source to Zhejiang Apeloa and started their first commercial batch in Q3. The product dossier should be available by Oct. A CAPA plan is being implemented based on the PQM audit. --conducted a site visit together with USAID Washington to San Clin EQ, Caprifarmindo, and the provincial BBPOM QC laboratory to see project progress	
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	A revised CAPA implementation plan and timeline was submitted to PQM; scheduled to submit to WHO PQ by late 2014. PQM met with Zenith, who attended the CPhI WHO PQ workshop, to discuss Levo 500mg.	
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		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		PQM conducted a WHO PQ workshop at the CPhI conference, which was attended by manufacturers currently receiving PQM TA, as well as companies from Cambodia, Philippines, and China	

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		Q1	Q2	Q3	Q4
impurity of finished product and impurity of raw material, Validation in Dissolution Test Pharmaceutical development		GFATM HSS grant to BPOM as sub-recipient			
Provide TA to Phapros on stability studies, dissolution, BE studies, dossier compilation, etc. for 4FDC product		Assisted Phapros to get clearance and approval 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	-Provided feedback on results from BE pilot 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	-Phapros attended the CPHI workshop on WHO PQ and met with PQM's GMP team to discuss progress on 4FDC product - PQM still in process for fixed price award for BE cost-share support -levofloxacin comparators supplied to Phapros -new potential source for rifampicin API identified and contacted: CKD Bio Corp from South Korea -4 subjects to be reevaluated from pilot BE study -Lupin of India was re-engaged on behalf of Phapros by GDF in an attempt to get an LOA for the APIMF for rifampicin	
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 BE study protocol and amended according to PQM and WHO comments -appointed Equilab as CRO to conduct BE studies -submitted due diligence	-New potential source for rifampicin API identified and contacted: CKD Bio Corp from South Korea -impurities reference standards for rifampicin provided to KF -revised BE study	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		<ul style="list-style-type: none"> <li>-reviewed and provided comments on facility renovation that will be submitted to BPOM for govt approval</li> <li>-reviewed and revised analytical methods verification for 2FDC</li> <li>-in progress on comparative dissolution</li> <li>-submitted BE study protocol for PQM review</li> </ul>	<ul style="list-style-type: none"> <li>documentation to PQM for sub-award consideration for 50% cost share for BE studies</li> <li>-discussions on alternative API sourcing for rifampicin from Hebei to another potential source, in discussion with PQM on this</li> <li>-excipients incompatibility study protocol for 2FDC under review by PQM</li> </ul>	<ul style="list-style-type: none"> <li>protocol review and feedback submitted by PQM</li> <li>- A fixed obligation grant is being established between PQM and Equilab for the financial contribution to the costs of the BE studies for Phapros 4 FDCs (both pilot and full BE studies)</li> </ul>	
Provide TA to Indofarma on stability studies, dissolution, BE studies, dossier compilation, etc. for 2FDC product		<ul style="list-style-type: none"> <li>-Design for new production facility finalized and submitted to BPOM for review, pending approval in Q2</li> <li>-delivered comparator products and reference standards</li> <li>-issues with rif stability data on 4FDC and 2 FDC products submitted for review to PQM, with the need to potentially reformulate</li> <li>-Indofarma also considering changing rif API source from Shenyang to possibly Sandoz Indonesia (CEP)</li> <li>-BE study protocol under development</li> <li>-discussed other potential products for</li> </ul>	<ul style="list-style-type: none"> <li>-Indofarma developing BE study protocol and will appoint Equilab as CRO</li> <li>-new facility blueprints approved by BPOM, contracting and construction to begin this year with 2 year completion anticipated</li> </ul>	<ul style="list-style-type: none"> <li>-Management and director structure changes at Indofarma resulted in slow progress during Q3</li> <li>-moving forward on construction of new production facility, and pilot plant. R&amp;D still working on 2FDC reformulation and API substitution/formulation for BE study</li> <li>- Indofarma requested to take time for building the new facility and working on documentation and system and will inform PQM at a later stage to resume its participation in the WHO PQ process.</li> </ul>	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		TA: levofloxacin, zinc sulfate, OI medicines			
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 from replacement and senior management	PQM met with Sandoz during the CPhI workshop; some international policies at Sandoz require them to reevaluate the WHO PQ program. It was decided that they would determine a new timeline, since they anticipate having their TB product procured under the JKN universal health coverage	
<b>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</b>					
Continue to provide TA and support to Equilab International to conduct BE studies under PQM program		<ul style="list-style-type: none"> <li>-Completed CAPA from van Zyl final audit</li> <li>-completed pilot BE study on Phapros 4FDC product</li> <li>-facility renovation and movement of patient beds to ground floor for better evacuation and emergency access</li> <li>-parent company Dexa Medica purchased building and will be upgrading facilities at Equilab</li> <li>-PQM-sponsored Equilab staff participated in BE workshop conducted by PQM in Manila as part of an ASEAN regional training</li> </ul>	<ul style="list-style-type: none"> <li>-Drafting sub-award to Equilab for cost share of Phapros 4FDC BE study</li> <li>-PQM sr mgmt. met with Equilab to discuss preliminary results on pilot BE study for Phapros</li> <li>-Equilab appointed as CRO for Phapros, Indofarma, and Kimia Farma for conducting their BE studies under the PQ program</li> </ul>	<ul style="list-style-type: none"> <li>-Met with Equilab to follow up on Phapros pilot study, to re-evaluate 4 investigative subjects, and additional requirements for 50% cost-share for Phapros</li> </ul>	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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	Conducted a site visit together with USAID Washington to San Clin EQ, Caprifarmindo, and the provincial BBPOM QC laboratory to see project progress	
<b>Provide TA to the BPOM National QC lab towards application for WHO PQ by 2015</b>					
<b>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 2019</b>					
Build QC capacity of selected BPOM provincial QC labs			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	A PQM consultant reviewed the CAPA report with the PPOMN QC lab and responses made by the lab. Major areas where urgent TA is needed were identified, and an implementation plan to address needs has been established. A plan to qualify all Shimadzu equipment (11HPLC, 3GC, 1UV, 1 IFTR), balances, and dissolution testers was made. The plan includes timelines and deliverables for 1 year of activities.	
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	Sr PQM mgmt. team and technical advisor met with national managers for National AIDS program and National TB program on	PQM has established a testing plan for all TB and HIV medicines collected from the central level. BPOM will start testing medicines for which it has	

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		Q1	Q2	Q3	Q4
		and BINFAR) and BPOM to scale up sampling and testing of GFATM and non-GFATM products	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	the capacity. PQM will assist the lab with the training, supplies, and equipment needed to test the remainder of the medicines. The plan includes a timeline to complete the testing of all samples	
Support the BPOM QC lab to be an active member in international and regional initiatives under USP, ASEAN and other development partners (WHO PQ, PIC/S, etc.)		4 officials from BPOM's national QC lab received two week training under the visiting scientists program at USP HQ laboratories as a cooperative support between GFATM and PQM		One BPOM officer was supported to attend the regional ASEAN-USP Scientific Symposium held in Vietnam, including additional training following the symposium.  Training on ARVs at Vietnam NIDQC is planned for Q4.  The Director of PPOMN QC lab and a staff officer from BPOM attended the Public-Private Partnerships Strategy Workshop at WHO SEARO in India, working with the National TB Program and Persehabatan Hospital	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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)	A consignment of RS was procured for PPOMN laboratory to support training and testing for antibiotics, first and second line TB medicines, ARVs, and impurities. Clearance through the diplomatic cargo of the US Embassy was in process at the end of Q3	
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	A workshop on post-marketing surveillance data and MQM results is planned for Q4	
<b>Develop collaborative mechanisms and support for disease programs (NTP, NAP), BINFAR, and BPOM to enhance QC capacity in Indonesia</b>					
Participate and provide inputs to activities under People that Deliver, GFATM grants (HIV, TB, and HSS) and other partner activities		-Conducted TDY site visits under the HSS grant activity for warehouse strengthening at the district level, with WHO, MOH, JSI -ongoing monthly meetings with People that Deliver Indonesia --participated in	-Participated in TDY for PtD's Executive Director for meetings with WHO-WR, USAID, MOH, and other partners -provided inputs into -participated as member of national technical working groups for HSS and TB GF grants -provided inputs into	-PQM participated in the GF technical working groups, including providing input for continued projects on HSS, HIV, and TB with QA/QC components -met with Global Fund country team from Geneva -participated in TB Care's	

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		Q1	Q2	Q3	Q4
		Strategic Management Team meetings under KNCV/TBCare (WHO, MSH, FHI, JSI, MOH, USP PQM, USAID)	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)	Strategic Mgmt Team meetings -participated in GF country team assessment for TB and HIV -participated in monthly meetings with BINFAR, WHO, BPOM, JSI, and others	
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 2 <sup>nd</sup> line TB medicines warehouse (GFATM) and BINFAR central warehouse during GDF mission	-Planning on HIV pilot project in 2 provinces/10 districts under Oblik building in sampling and testing components at district and provincial levels  Following coordination meetings convened by PQM, an official letter from the Director General of BINFAR was drafted and disseminated through BINFAR and BPOM which instructs sampling from 100 district warehouses in 33 provinces to be conducted by BPOM with coordination by BINFAR/MOH. This is a major achievement of PQM's advocacy in this area towards better interagency collaboration.	
<b>Establish USP PQM office as an officially-registered entity in Indonesia</b>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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 -drafted SOWs for staffing country office	-Met with USAID, law firms, and implementing partners to assist in appropriate mechanisms and options for legal registration in Indonesia -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	-Negotiated, drafted, and finalized contract with CEO Suite for outsourcing employee contracts until PQM is officially registered with MOFA, Tax Authority, etc. (anticipated by the end of the year) -secured Moores and Rowland as legal firm to perform all registrations on PQM's behalf -amended SOWs for office staff, placed job advertisements, began interviews to identify candidates for at least 4 positions in the PQM Indonesia office	
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	Offices will expand in Q4	
<b>Philippines</b> E. Yuan					
<b>Establish and sustain medicines quality monitoring activities</b>					
Continue to support MQM at 8 existing sites by replenishing		Visited CALABARZON in October	Additional sentinel site visits are scheduled to take place in Q3-Q4	Attended PIDS-DOH-PHIC Sharing Seminar in April	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Minilab <sup>®</sup> supplies, providing needed training, conducting site visits, and updating MQDB. Report progress regularly.				The MQM data and relevant information on TB medicines have been shared with other implementing partners	
Expand MQM of ATBs to 4 sites: Regions II, IV-B, X, and XII			Planned for Q4		
<b>Strengthen the capacity of the FDA and its QC Lab to enhance the medicine regulatory system in pre- and post-marketing surveillance</b>					
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		Phil. FDA joined NOMCoL Asia Pacific inter-lab testing in June	
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 Visiting Scientist Program (VSP) or International Training Program (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		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Purchase needed lab equipment & reference materials not included in DOH/FDA budgets through USP TAP		Received 2 USP flash drives (single user)	List of equipment for purchase has been submitted for review and approval	Received 1 USP RS for NOMCoL Asia-Pacific inter-lab testing: Cipro Ethylenediamine Analog, Cipro HCL, Artemeter & Lumefantrine	
<b>Collaborate with NTP and TB Partners on relevant disease control programs</b>					
Provide TA to the DOH-NTP, DOH-NCPAM and TB partners for activities relevant to ATB quality. Provide TA to NTP based on 2014-16 PhilPACT objectives: Tracking and monitoring the TB meds by sampling and testing their quality on retails stores (pharmacies and private clinics)& wholesale supplies chains, hospital and DOTS facilities		Held meetings with implementing partners (IMPACT and SIAPs) on identifying the TA that our partners need and how best to collaborate	Met with NCPAM managers to discuss the activities that PQM can perform.  Held workshop on WHO PQ for TB medicines  The participants were from ASEAN countries	Organized and conducted a stakeholders discussion in May to solicit feedback from partners to strengthen QA/QC of TB meds in the Philippines	
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		
Provide Technical input from pharmaceutical quality perspective to the current draft DOH administrative order on : securing the availability & affordability of quality-					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
assured essential medicines in the public sector” through the consultation to NCPAM when required					
<b>Support local manufacturers towards WHO PQ for first- and second-line TB medicines</b>					
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	Workshop held in March regarding TA toward WHO PQ	Assisted PQM GMP audit team in April at Amherst and Hizon laboratories	
Plan and process to recruit two (2) additional consultants (technical and administrative) to strengthen current PQM team in the Philippines to perform assigned activities			Recruiting has begun	Five candidates were interviewed and two candidates were selected. Background and reference checks are underway	
<b>Provide leadership in promoting global public health and technical excellence ensuring medicines quality and safety through innovations</b>					
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-Q4 to closely discuss and plan with FDA and local pharmaceutical MFRs how to upload the registration information into the device		
<b>Vietnam S. Phanouvong</b>					
<b>Provide technical assistance to local production of methadone</b>					
Work with MoH (DAV & VAAC) to determine a		Follow-up the selection process at MoH (DAV	Vidipha won the VAAC tender with an amount of	Vidipha is producing methadone syrup	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
selection process of 1-2 methadone manufacturers for technical assistance from PQM		&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	2300 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	10mg/ml 2,300 L to supply to VAAC through a tender process	
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	Pending	
Conduct GMP inspection on 1-2 mfrs and recommend how to address deficiencies			Pending official authorization from MOH/DAV and VAAC	Pending	
<b>Provide technical support to the procurement and importation of methadone finished products for VAAC &amp; Ho Chi Minh City PAC</b>					
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 2300 L of methadone syrup 10mg/ml with financial support from Ausaid. Vidipha was the winner and delivery of this amount is expected at	No feedback/update from HCMC PAC and VAAC  Vidipha recently obtained MoH approval and is authorized to distribute their product directly to treatment centers. In Q4, PQM will provide technical advice on maintaining product quality from distribution to the dispensing centers.  HCMC confirmed that it will allocate 7.7 million	

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		Q1	Q2	Q3	Q4
			the end of 2014.  US\$0.5 million will be funded from the local government to procure methadone finished product for HCMC PAC.	VND (US\$ 363,000) to procure methadone via the city procurement center. Open bidding will be implemented soon.	
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		No response from VAAC and HCMC PAC	
<b>Strengthen the capacity of the NIDQC and HCM IDQC quality control labs</b>					
Assess QMS and practices of NIDQC & HCM IDQC labs for WHO PQ readiness; identify aspects needing TA		Follow-up with NIDQC on the upgrade 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.	Due to security issues in Thailand and some demonstrations in Vietnam, the assessment trip to Vietnam in combination with regional assessment trips was postponed to Aug or Sep	
Provide TA towards ISO/WHO PQ; assess and report progress		PQM helped review the NIDQC micro lab design	Upgrading of the NIDQC microbiological lab is ongoing	Ongoing	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<b>Provide TA on pharmacovigilance system within the framework of the Global Fund Round 10 project of the National DI&amp;ADR Center at HUP</b>					
Review all related documents, previous assessments, & reports <i>(Continuing activities from FY13)</i>		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			
<b>Maintain country consultant to improve project coordination, implementation, and effectiveness</b>					
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	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	Completed	
Provide stationery, comms & admin costs		Done in compliance with the approved WP	Done in compliance with the approved WP	Done in compliance with the approved WP	
<b>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</b>					
<i>Technical assistance for ARV's quality assurance through post-marketing surveillance in both public and private sectors</i>					
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	A NIDQC qualified analyst attended technical training at USP HQ for 3 weeks in May	
Support NIDQC to hold the national technical				The training workshop has been designed as a	

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		Q1	Q2	Q3	Q4
training on ARV testing methods				“training of trainers” and is scheduled for Aug. It is anticipated that 3 analysts from national and provincial QC labs will attend in addition to 10 analysts from the NIDQC.	
Support VAAC, DAV to develop the post-marketing surveillance plan/QA & QC guideline for ARV quality		In discussions	In discussions	In discussions	
<i>Technical assistance to strengthen the capacity of Pharmaceutical Management Practices at the Peripheral Level for the ARV distribution system</i>					
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	Workplan was approved by USAID headquarters at the end of May	
Present at HCMC and two regional training workshops and advise				PQM attended a regional training workshop in May at HCMC for Southern provinces	
Provide TA to 12 provinces to install and use technical tools and documents				In progress	
<i>Provide administrative and program operation support</i>					
Recruit two technical staff, one admin staff, and one part-time accountant/consultant				In Q4, job ads will be posted on NGO Resource Center and Vietnamworks websites; deliverables for the new staff are being	

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		Q1	Q2	Q3	Q4
				prepared	
Support salary for additional job allowance to COP-Consultant and fringe benefits				Scope of work for COP is being revised	
Support office rental and other office maintenance expenses				PQM is seeking office space for the in-country team; several options are being considered	
Procure office equipment and support other mgmt costs				Planned for Q4	
Review recruitment process of country office				Planned for Q4	
<b>Europe and Eurasia</b>					
<b>Kazakhstan</b> J. Derry & K. Burimski					
<b>Conduct baseline GMP assessments of Pavlodar Pharmaceutical Factory, provide technical assistance to the Factory towards reaching WHO Prequalification</b>					
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 Guidance on GMP Principles to Pavlodar Pharmaceutical Factory, reviewed quality documents of the factory (SOPs) and provided their recommendations on improvements.	PQM team followed-up the results of general GMP assessment and provided additional recommendations on CAPAs and SOPs	

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		Q1	Q2	Q3	Q4
<b>Conduct one onsite general GMP training for specialists of Pavlodar Pharmaceutical Factory</b>					
Conduct one general GMP training for the factory's GMP specialists			Tentative time for training determined – August 2014	Preparations for the training initiated, training agenda drafted and discussed with the Pavlodar Pharmaceutical Factory	
<b>Support two GMP consultants for onsite work at Pavlodar Pharmaceutical Factory</b>					
Support one consultant on QMS to provide 3-mo. onsite/3-mo. remote TA			Scope of work identified and agreed with Pavlodar Pharmaceutical Factory; potential consultants identified and their CVs collected	Teleconferences with a number of potential consultants held; preferable candidates identified	
– 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	Teleconferences with a number of potential consultants held; preferable candidates identified	
– Assist w/construction and start-up of new mfg facility to ensure compliance					
<b>Translate technical documents for Romat Pharmaceutical into English</b>					
Provide translation services to prepare GMP certification and WHO PQ documents into English				No progress	

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		Q1	Q2	Q3	Q4
<b>Identify, assess, and support additional manufacturers for WHO Prequalification</b>					
Conduct baseline assessments of select anti-TB medicines mfrs				Contacts with three additional manufacturers of anti-TB medicines established; the questionnaire intended to facilitate the process of evaluating pharmaceutical manufacturers interested in receiving technical assistance was sent to them	
Provide TA to promising companies to improve their GMP compliance					
<b>Translate WHO Prequalification documents into Russian for manufacturers of anti-TB medicines</b>					
Determine whether or not these documents already exist			The set of documents 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				Translator identified	
<b>Expand the pool of viable manufacturers of anti-TB medicines by raising awareness of WHO PQ/PQM technical assistance program</b>					
Conduct two-day workshop for mfrs in Central Asian Region on WHO PQ and PQM TA available				Dates of the workshop determined – October 2014 Preliminary agenda of the workshop developed; Potential speakers of the workshop identified and	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				contacted	
<b>Uzbekistan</b> J. Derry and K. Burimski					
<b>Identify gaps in the country's medicines quality assurance system and propose interventions to address them</b>					
Conduct a field gap analysis to identify status of QA/QC systems for anti-TB medicines to help define priority needs				PQM assessment visit scheduled for Aug  Visit agenda developed, anticipated contacts discussed and agreed upon with Uzbek partners	
Meet w/Uzbek national MRA, Ministry of Health, and relevant partners to discuss findings				Meetings with the MRA, MOH, and other relevant partners scheduled for the August visit	
<b>Latin America and the Caribbean</b>					
<b>Amazon Malaria Initiative</b> V. Pribluda					
<b>Strengthen quality assurance and quality control systems</b>					
<i>Build capacity to perform Level 2 testing (Brazil)</i>					
Reinstate rapid testing in endemic areas of Brazil			Discussions held with the NMCP and PAHO/Brazil to plan a meeting with ANVISA	In discussions with the NMCP, it was agreed that PQM would send a proposal to complement the QC support provided to the NMCP by PAHO and the School of Pharmacy of the Federal University of Minas Gerais. Subsequently PQM sent the proposal to NMCP, which was forwarded to ANVISA (Brazil MRA)	
- Develop policy for ANVISA					
- Provide logistical					

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		Q1	Q2	Q3	Q4
support for training on basic tests					
<i>Build capacity to perform Level 3 testing according to registration methodologies</i>					
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 <sup>®</sup> to evaluate regional OMCL capabilities				Process to implement inter-laboratory proficiency testing of Coartem initiated.  Samples of Coartem purchased and support documentation sent to the labs; samples will be sent at the beginning of Q4	
<i>Implement three-level approach for sustainable medicines quality monitoring activities throughout the supply chain</i>					
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				The MRA and lab in	

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		Q1	Q2	Q3	Q4
approach in Ecuador				Ecuador underwent changes recently. No feedback was provided by stakeholders to PQM requests to fulfill proposed plans	
Finalize MOU and documents to implement 3-level approach in Guyana				Request to finalize MOU was sent to the country but there was no follow-up by stakeholders	
<i>Identify and establish mechanisms to ensure sustainable south-south collaborations among OMCLs and MRAs in AMI countries</i>					
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	Terms of reference were finalized  Academic institutions to be invited were identified  Stakeholders agreed that the workshop will be conducted in FY15 Q1	
<b>Combating substandard and counterfeit medicines</b>					
<i>Develop virtual library of images of antimalarials in use in AMI countries</i>					
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			Six potential consultants	RFP finalized and sent to	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
develop library			identified and a request for proposals is being developed; will be sent by early Q3	potential consultants  Based on responses two potential consultants have been identified and are currently being evaluated  Final contractor selection and initiation of work will occur in Q4	
- Assess methodology					
- Access medicines info in countries					
- Create library in a format for distribution					
- Disseminate information					
<b>Provide technical leadership and global advocacy</b>					
<i>Disseminate results of quality study performed in three departments in Colombia</i>					
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					
<b>Disseminate information about PQM activities</b>					
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? <i>Malaria Journal 2014,</i>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			13:77 - The Three-level Approach: A framework for ensuring medicines quality in limited resource countries <i>Pharmaceut Reg Affairs 2014, 3:1</i>		
<b>Attend Meetings</b>					
Attend semi-annual Steering Committee and annual RAVREDA technical meetings			Attended and presented at meetings in Nicaragua in March		
<b>Guatemala</b> V. Pribluda					
<b>Strengthen quality assurance and quality control systems</b>					
<i>Build regulatory capacity</i>					
Upgrade DRCPFA's registration software to allow internet access for registration (WebSIAMED)  <b>*This activity is conducted with carryover funding from the FY13 Work Plan</b>		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	Online renewal of registrations is fully operational. By May, more than 200 applications have been processed  Starting June 2014, all applications are processed exclusively online  The launch for all registrations (new and renewal) planned for Q4	
Train MRA medicines registration staff on dossier evaluation			Training coordinated with MRA to be delivered in June	This training was rescheduled for July because the training on equipment and water/air system validation was	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				delivered in June (see below)	
<i>Build OMCL capacity to perform QC testing</i>					
Ensure OMCL operations are in compliance w/int'l standards					
– Review QMS documentation			Documentation requested from OMCL and review initiated	All documentation sent was reviewed	
– Assess UM-LNS to follow-up previous CAPAs			Assessment visit planned for May	Assessment visit completed in May; a full report was sent to the lab and a trip report sent to appropriate stakeholders	
– Establish road map to expand scope and attain ISO 17025 accreditation				Lab management committed to expansion of accreditation and a tentative road map was sent to lab management  Pending the availability of funds, and if all observations are addressed, an audit for expansion of the accreditation is planned for FY15 Q1	
<i>Strengthen proficiency in quality control testing</i>					
Conduct trainings on GLP, Karl Fischer, Dissolution, UV-Vis					
<i>Implement three-level approach for sustainable medicines quality monitoring</i>					
Support MQM at selected 'Area(s) de Salud' utilizing the three-level approach			Protocol for MQM in Huehuetenango completed	Trainings and sampling in health centers performed  Samples that cannot be	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
(Huehuetenango Health Area)  <b><i>*This activity is conducted with carryover funding from the FY13 Work Plan</i></b>			MQM activities coordinated with MRA, Health Area Office, and the OMCL will be performed in April	<p>screened with the Minilab were sent to the lab for analysis; USP Reference Standards required for analysis were donated to the lab</p> <p>Sampling at the hospital and storage facilities still needs to be conducted</p> <p>MQM report is being prepared</p> <p>As a follow up to this activity, and in discussion with the MRA, the regulations for MQM are in the process of being modified to include the Three-level Approach; the modified regulations are being finalized by the MRA to be sent for approval</p>	
Expand MQM activities to additional areas.					
– Equip sites with Minilab® and supplies					
– Provide support to MRA, DAS, OMCL for logistics/supplies					
<b>Increase the supply of quality assured medicines</b>					
<i>Strengthen DRCPFA capabilities to ensure manufacturers comply with current Good Manufacturing Practices</i>					
Train DRCPFA staff on equipment, and water & air system validation			Training coordinated with MRA to be delivered in July	Training delivered in June 2014 instead of July 2014 (see above)	
<b>Provide oversight, monitor and evaluate PQM programs</b>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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	PQM met with MOH, OMCL, and the MRA during the May visit	