

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

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Common Agenda	K. Chibwe				
Increase awareness about the importance of medicines quality					
Attend/present at national, regional, and int'l conferences		<p>Dr. Lukulay presented at the AAPS lunch in Chicago, IL in Oct, the “Global Forum on Pharmaceutical Anti-Counterfeiting” in DC in Nov, and the ASTMH Meeting in Atlanta, GA in Nov.</p> <p>Dr. Chibwe presented to the Library of Congress in DC in Nov.</p>	<p>Dr. Lukulay was a member of the committee that drafted the consensus study, “Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products” published by the Institute of Medicine in Feb 2013.</p> <p>Dr. Lukulay presented an overview of the PQM program to visitors from Equatorial Guinea at USP HQ.</p> <p>Dr. Chibwe presented an overview of the PQM program to visitors from China FDA at USP HQ.</p>	<p>In April, Dr. Lukulay and Dr. Smine presented an overview of PQM and details of the GFATM QA policy to the Nigerian NMCP.</p> <p>In June, Ms. Derry gave a presentation on PQM activities at the USP Science & Standards Symposium in Korea.</p>	
Use available media outlets to advocate need for medicines QA		<p>Article on field-based QC tool published by Azerbaijan State Telegraph Agency; several articles documenting USP’s participation in the Global Forum for Pharmaceutical Anti-counterfeiting published by media outlets; Dr. Lukulay gave an</p>	<p>In Feb, USP issued a press release, “First Anti-TB Medicine under USAID-Supported PQM Achieves WHO Prequalification Status” and 2 media outlets published articles. USP also issued, “Handheld Device for Detecting Counterfeit and Substandard Medicines</p>	<p>In May, USP issued a press release “Center for Pharmaceutical Advancement and Training Opens in Ghana” that recognized PQM’s groundwork identifying the need to build local capacity for medicines professionals.</p> <p>This quarter, PQM was</p>	

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		interview on counterfeits for the Care2 News Network	Tested by PQM” and 12 media outlets published articles. In Mar, USP issued “Medication Quality in Russia and Region Strengthened with Official Laboratory’s Accreditation” and 2 media outlets published articles.	mentioned in 28 news articles as well as in Congressional testimony on the Neglected Diseases Treatment Gap	
Pursue opportunities to advocate through the Voice of America		In October, Dr. Lukulay was a panelist on the VOA TV2Africa daily magazine, In Focus, addressing public health and economic aspects of poor quality medicines.		The VOA interviewed Dr. Lukulay in April on TV2Africa about the Ghana FDA/PQM study on oxytocin and ergometrine medicines used during and after childbirth.	
Produce up-to-date information about current issues in medicines quality					
Collect and publish reports of incidents of poor-quality medicine use	M McGinnis	26 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 3,993 website hits	17 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 2,664 website hits	24 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 4,078 website hits.	
Maintain and update PQM website	M Foster	5 articles and 12 photos were added to the PQM website; 1 webpage was updated; 6 resources were added or updated	10 articles and 12 photos were added to the PQM website; 1 webpage was updated; 3 resources were added	8 articles, 9 photos, and 2 new or updated resources were added, including the report on the Ghana FDA/PQM study on MCH medicines. A video of the VOA TV2Africa interview was also added.	
Support regional approaches and networks					
Contribute to NEPAD’s “Institutionalization of		Dr. Karim Smine presented at the first	The revised criteria for the establishment of	Dr. Smine represented PQM at the second	

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Regulatory Training Programs in Africa using Existing Regional Structures” Technical Working Group (TWG)		meeting of the African Medicines Regulatory Harmonization TWG on Regulatory Capacity Development in Africa held Nov 2012 in South Africa.	Regional Centers of Regulatory Excellence (RCOREs) in Africa were issued.	meeting of the AMRH/NEPAD Technical Working Group.	
Explore improved tools to ensure quality control or to increase the knowledge base about quality assurance					
Develop a field-based QC tool with increased accuracy, sensitivity, and reliability	K Chibwe	PharmaCheck prototype developed – to undergo optimization	Dr. Chibwe visited Boston University in February to observe progress on the prototype; an oxytocin probe is also being developed.	A PharmaCheck Global Workplan has been developed and progress monitored using Clarizen project management tool. Initial development of probes for artemisinin, artesunate, and artemisinin family completed. Tetracycline and oxytocin probes are under development.	
Tuberculosis (TB)	A. Hong				
Increase the supply of quality-assured second-line TB medicines					
Provide TA to mfrs of SL-ATBs identified in FY12 seeking WHO PQ		Dong-A Pharmaceutical Company was WHO prequalified in Nov 2012 for Cycloserine 250 mg capsules. TA continues to manufacturers in different stages of compliance with WHO PQ including Phapros, Indofarma, Dong-A, Arterium, Zhejiang Hisun Pharma, Shalina,	TA continues to manufacturers in different stages of compliance with WHO PQ, including Hisun Pharma, Arterium, HEC, Korea United Pharm, Abbott, Sintez, Phapros, and Dong-A Additional TA visits scheduled for next quarter: Korea United Pharma, Arterium,	TA continues to manufacturers in different stages of compliance with WHO PQ, including Hisun Pharma, Arterium, HEC, Korea United Pharm, Abbott, Sintez, Shandong Reyoung Pharma, and Dong-A Additional TA visits scheduled for next quarter: Xinhua, Reyoung, Zibo Pharma,	

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

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		performed at Hisun Pharma		GMP Inspection CAPA assistance to Arterium; GMP assessment to Shandong Reyoung Pharma	
With GDF/WHO, conduct workshops in high burden countries; identify add'l mfrs not yet in PQM pipeline		Decision was made to collaborate with CPhI Conferences to perform half-day seminars. CPhI Jakarta will be the first, scheduled for Mar 2013	Manufacturers' workshop conducted with CPhI in Jakarta in March	Manufacturers' workshop conducted in Ghana in May	
Identify/provide TA to key SL-ATB API suppliers to WHO PQ		Zhejiang Hisun Pharma, Fuzhou Fuxing Pharma, North China Pharma, Dankang Pharma, Zhejiang Xinhua Pharma	Dong-A Pharma, Enzychem Lifescience, Zhejiang Hisun Pharma, Fuzhou Fuxing Pharma, North China Pharma, Dankang Pharma, Zhejiang Xinhua Pharma, Jinxin Pharma, HEC	Dong-A Pharma, Enzychem Lifescience, Hisun Pharma, Fuzhou Fuxing Pharma, HEC Pharma, Dandong Beiqi Pharma, NCPC Huasheng,	
– To API mfrs in PQM pipeline		Total is now 11: Zhejiang Hisun, Shanghai Fosun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Shenxue Dachen Pharma, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem	Total is now 14: Zhejiang Hisun, Shanghai Fosun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem, HEC, Suzhou Kaiyuan Minsheng, Dandong Beiqi, Zhejiang Excel Pharma	Total is now 15: Zhejiang Hisun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem, HEC, Suzhou Kaiyuan Minsheng, Dandong Beiqi, Zhejiang Excel Pharma, Shenxue Dachen Pharma, Zhejiang Second Pharma	
– To new mfrs on dossiers		Zhejiang Xinhua Pharma	Xinhua Pharma, Fuzhou Fuxin, Dong-A	Enzychem Lifesciences, HEC, Fuzhou Fuxing	

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– With GMP audits and support until products are PQ'ed		EnzyChem, Zhejiang Hisun Pharma, NCPC Huasheng, Hebei Shengxue Dacheng'	Enzychem, Zhejiang Hisun Pharma, NCPC Huasheng	Enzychem, Zhejiang Hisun Pharma, NCPC Huasheng, Fuzhou Fuxing, Dandong Beiqi	
Participate in GDF and WHO meetings with mfrs to discuss PQ		Attended meeting with WHO PQ team in Geneva	No meetings attended	Attended meeting in Geneva for GMP inspection harmonization Attended GDF stakeholders' meeting in Sri Lanka	
Complete development of Minilab® test methods for SL-ATBs		Developed and published methods for Clarithromycin, Kanamycin, and Ofloxacin	No new methods developed	No new methods developed	
Obtain comparator products and assist select mfrs with funding for BE studies/capital investments		Reference standards were provided to Shanghai Hefeng Pharma and Simpex; Comparator products were provided to KUP (Avelox), Farminguinhos (Trecator), and Simpex (Levaquin)	Comparator products provided to Hisun (Tarivid); Hefeng (Kanamycin); Shalina (Levaquin)	Comparator products provided to Hisun (Ofloxacin 200, 400 mg, Streptomycin, Levaquin); Hizon (Levaquin); Reference Standards provided to NCPC (Streptomycin); Liaoning (Kanamycin Sulfate); Hizon (Levofloxacin and Related Compounds); DJPL (Levofloxacin and Related Compounds); Reyoung Pharma (Capreomycin and Streptomycin)	
Reduce the prevalence of substandard and counterfeit SL-ATB medicines					
Develop USP monographs for Prothionamide and Terizidone		In progress	In progress	In progress	

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Conduct quality monitoring for SL-ATBs		In progress	In progress	In progress	
Develop the API bank concept and engage FPP manufacturers					
Develop the API Bank concept; identify/engage FPP producers to manufacture FPPs for GDF		Two FPP contract manufacturers have been identified; meetings were held to discuss potential development for Capreomycin and Kanamycin. FPP prices have been negotiated to support GDF.	This is currently on hold; legal matters are under review	This is currently on hold; legal matters are under review	
Malaria P Lukulay					
Conduct studies to assess the diversion of antimalarial medicines from public to private sector					
Adapt study protocols for antimalarial MQM study in new countries		Protocol developed	Completed		
Conduct four new studies		One antimalarial monitoring study is underway in Congo Brazzaville.	Two studies completed in Congo Brazzaville.	One study completed in Uganda; data is under review	
Develop reports and disseminate results			Two reports completed.	One report is being prepared.	
Conduct follow-on studies			One follow-up study completed in Congo Brazzaville.		
Conduct follow-on study of Liberian market for prevalence of artemisinin-based monotherapies					
Select two countries to conduct survey for monotherapies		Liberia was selected; the second country is still in discussion	Study in Liberia underway.	On hold per USAID/PMI Washington	
Develop sampling strategy and protocol; identify locations		Study protocol has been finalized and partners as well as USAID/Liberia have approved it; study	Study protocol is under review by NMCP and USAID.	On hold per USAID/PMI Washington	

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		will begin on January 28.			
Travel to sites and conduct survey			Plans to travel to sites with partners to conduct studies are underway.	On hold per USAID/PMI Washington	
Procure samples and generate reports					
Develop monograph for Dihydroartemesinin-Piperaquine FDC					
Verify analytical methods			Analytical methods developed and verified.		
Conduct method validation			Method validation completed.		
Characterize API and include in USP MC		PQM has identified the Italian innovator company for DHA/PP and obtained their approval to provide background analytical method information as well as API to be characterized by USP for the purpose of developing reference standards.	API has been characterized, and MC monographs are in development.	Monograph posted in USP Medicines Compendium.	
Develop Minilab[®] methods for Dihydroartemesinin-Piperaquine FDC					
Develop screening method		In progress. API has been obtained for analytical methods development.	Methods are being developed and are nearing completion.	Completed	
Validate analytical methods				Completed	
Publish method in manual				In process	
Conduct quality control tests on antimalarials from developing countries					
Obtain samples of medicines at request of PMI team and test		No samples have been requested for testing.	Testing is underway on Ghana artesunate samples being sent by	Completed and report shared with USAID PMI/Washington	

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			USAID/Ghana to USP.		
Maternal Health and Child Survival L. Evans					
Support selected United Nations Commission medicine manufacturers					
Conduct GMP baseline assessment of selected mfrs; present findings to USAID, stakeholders		GMP TA visit to Lomus Pharmaceutical (chlorhexidine manufacturer) in Nepal scheduled for Jan 2013	Visited Lomus in Jan 2013; conducted GMP assessment and issued report Visits to manufacturers in Madagascar scheduled for Q3 (PATH-funded activity)	Visited Madagascar manufacturers in Apr 2013; conducted GMP assessment and issued report	
Provide TA to mfrs of promise to improve GMP compliance		TA will begin for Nepal manufacturer in Q2, following assessment	Started providing TA to Nepal manufacturer. EOI for CHX manufacturers will be issued in Nigeria during Q3	Continued supporting Nepal manufacturer; visit to Nepal to evaluate the GMP implementation plan is scheduled for Q4. There were 10 potential CHX manufacturers in Nigeria that submitted EOIs; plans are underway to visit 3 or 4 in Q4	
Conduct quality testing of select UN commission medicines		Chlorhexidine samples were procured from manufacturers in Nepal and India; will be tested in Q2	Chlorhexidine samples for Nepal and India manufacturers were collected and tested; report was disseminated	No samples requested for testing	
Support selected zinc manufacturers for local procurement					
Conduct QC/GMP assessments of zinc salt mfrs		Conducted GMP assessment at Medicamen, India; continued support to 2 manufacturers in Ghana and 1 in Kenya toward GMP compliance	Continued support to 2 manufacturers in Ghana and 1 in Kenya toward GMP compliance. Prepared EOI for zinc manufacturers in Nigeria to be disseminated early Q3; GMP assessments	Visits to Ghana and Tanzania manufacturers planned in Q4. Continue to support Kenya manufacturer; their new facility is under construction	

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		Q1	Q2	Q3	Q4
			will occur late Q3		
Conduct quality testing of zinc medicines sent by UNICEF, USAID, and other partners		Tested 4 samples from Ghana, India, and Kenya manufacturers and submitted report	2 samples from Ghana received at the end of Q2; will be tested in Q3	<p>PQM lab completed testing of 2 zinc samples from Ghana received at end of Q2.</p> <p>Two zinc samples were received in Q3 (one from Ghana, one from Nigeria); will be tested in Q4.</p> <p>Guyana samples received from PAHO were evaluated by PQM and a subsequent report generated.</p>	
SUB-SAHARAN AFRICA					
Burundi	M Hajjou				
Develop interventions to ensure the quality of antimalarial medicines					
Conduct a gap analysis of the country's medicine quality assurance system		Discussions were held with USAID-PMI in Burundi to prepare for the gap analysis, scheduled for Jan 2013; background information was gathered to facilitate the visit to the country.	Gap analysis conducted and report shared with stakeholders. A workplan was developed based on the results of the analysis and the funding available.		
Assist National Malaria Control Program in developing a quality assurance policy for antimalarial medicines and diagnostics			Information gathered to develop a quality assurance policy for the national malaria control program.	The QAP is being drafted.	
Develop an implementation plan to strengthen QC lab			In collaboration with the head of the QC lab, information was	The implementation plan was developed and shared with the National	

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capacity			gathered to develop an implementation plan to bring the National Institute of Public Health lab to international standards.	Institute of Public Health. The Institute's lab provided feedback that was incorporated into the document. The plan will be shared with USAID-Burundi for approval.	
Support developing a strong pharmaceutical law suited to the country's needs			Review of the draft law is underway. Comments and recommendations will be communicated in May.	The draft law was reviewed and comments and recommendations were communicated to the medicines regulatory authority (DPML).	
Ethiopia		Eshetu W.			
Strengthen FMHACA's management capacity based on findings from the gap analysis					
Support FMHACA in addressing gaps found, especially critical gaps		Guidance for undercover study of leakage of "Food By Prescription" products drafted and submitted to USAID; SOW for consultant(s) who will assess the current and future operational costs of FMHACA submitted to USAID; concept paper supporting the establishment of technical committees for registration and licensing of foods and medical products is being developed.	Prepared paper recommending the establishment of external expert committees to carry out assessments of safety, efficacy, and quality data for marketing authorization of medicines; submitted to FMHACA. Submitted technical and audit reports on USP/PQM Ethiopia office activities to the Charities and Societies Agency of the Government of Ethiopia.	Supported FMHACA management in organizing a workshop at Yabelo, Borena Zone, Oromia Region to create public awareness of the illegal medicines trade (from bordering countries and leakage of medicines from public distribution systems) and to promote cooperation and collaboration in the fight against such illegal trade.	
Strengthen FMHACA's registration and licensing system					
Identify critical areas where PQM can		Developed GMP inspection service fee	Training on basic GMP held in Bishoftu in Jan-		

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		Q1	Q2	Q3	Q4
provide TA to Product Registration & Licensing Directorate		direct payment procedure for FMHACA; completed training material preparations and developed basic GMP principles for FMHACA staff.	Feb; 40 participants from FMHACA and local pharmaceutical industry attended. Training for FMHACA staff on basic dossier assessments held in Bishoftu in March; 32 participants from Ministry of Agriculture and FMHACA attended.		
Recommend solutions to gaps w/timelines & expected outcomes					
Support the establishment of a centralized FMHACA information/ knowledge management system					
Provide TA to establish a central data system for registration, licensing, import/export control, inspection, enforcement		Concept paper for the data management system partially complete.		SOW for IT expert to create an information and data management system prepared, together with SIAPS	
FMHACA to determine directorate to manage the system					
Support physico-chemical lab to maintain and expand the accreditation to other test methods					
Develop a detailed implementation plan with timelines and expected outcomes		Surveillance quality audit of the PQAD lab was performed; helped PQAD participate in PT dissolution testing at EDQM lab; assisted in purchasing lab supplies for the microbiology lab.	USP signed a tripartite agreement in March to move the PQAD lab to the new site. One PQAD staff sent to India for training on lab equipment maintenance Mar-May 2013.	Practical training was given in May/Jun to 15 PQAD staff on compendial medicine analysis techniques. The PQAD laboratory (physic chemical) moved to the new site. Equipment was installed and IQ/OQ	

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			Lab equipment, chemicals, and reference standards purchased and supplied to FMHACA laboratory. Assisted PQAD to participate in proficiency testing for 3 tests; supplied reference standards and other laboratory supplies.	carried out to make them fully operational. Supported the PQAD lab's participation in Proficiency Testing (PT). Laboratory supplies purchased	
Support FMHACA condom lab to become ISO 17025 accredited and WHO prequalified					
Develop a detailed implementation plan with timelines and expected outcomes		Condom testing lab will participate in PT by Enersol Australia; PQAD condom analysts were trained at FHI360 lab in Thailand.	Revised five SOPs; training on ISO 17025 and ISO 4074 is planned for Q3.		
Strengthen two FMHACA branch offices, enabling them to carry out post-marketing surveillance inspection activities					
Identify two branch offices to be supported		Provided financial support	Installed lab equipment and trained the analysts of FMHACA's eastern branch.		
Identify critical areas of needed support					
Develop a detailed implementation plan, timelines, expected outcomes					
Support post-marketing surveillance of antimalarial medicines					
PQM, ISD and FMOH Malaria Program to revise protocol		Collected samples from one sentinel site		Collected samples from six sentinel sites; testing started	
Select sentinel areas, identify activities, set		Purchase of lab supplies initiated			

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timelines					
Conduct PMS			Collected antimalarial samples from three sentinel sites and provided lab supplies for testing; initiated testing		
Write report based on information gathered and data generated					
Support local OI medicines manufacturers to become GMP compliant and their OI products WHO prequalified					
PQM & PRLD will identify potential local OI medicines mfrs		<p>Feedback on the GMP compliance report received for three manufacturers; CAPA report for remaining manufacturer under discussion.</p> <p>A team made up of partner representatives was established to develop the GMP roadmap.</p> <p>A confidentiality agreement for the direct support of Cadila Pharmaceutical (Ethiopia) for WHO PQ was signed</p>	With the working group, prepared a first draft of the roadmap of local pharmaceutical manufacturing	Roadmap discussed at a workshop in which FMHACA, academia, and government agencies participated.	
Identify activities to be supported, set timelines and expected outcomes					
Improve capacity and skills of local OI medicines manufacturers to ensure that their products and manufacturing sites comply with GMP					
Use results of GMP audit to identify gaps of local mfrs in compliance					

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Select gaps most easily addressed w/PQM TA					
Provide TA to address select gaps & promote GMP compliance					
Monitor and evaluate program implementation					
Develop monitoring & evaluation tool					
Conduct monitoring & evaluation of program implementation					
Ghana	R. Okafor				
Support post-marketing surveillance of antimalarials at existing sentinel sites, establish two additional sites, and encourage FDB to take enforcement actions based on the results					
Select and supply two new sentinel sites		Requested quote for 2 Minilabs for 2 new sites; Discussed sites with FDB	Two Minilabs were ordered, shipped, and received by the FDA.	Minilabs shipped to 2 new sites.	
Conduct two rounds of MQM at selected sites for testing			Contract for MQM money transfer submitted.	Funds transferred to FDA in Jun. Training for new inspectors to be conducted by FDA.	
Conduct confirmatory testing at FDB lab and CePAT			Planned for Q3	Planned for Q4	
Conduct onsite evaluations of selected sentinel sites			Planned for Q3	Planned for Q4	
Promote enforcement actions based on data			Planned for Q3	Planned for Q4, pending results of MQM testing that will be confirmed at the CePAT.	
Strengthen the capacity of the FDB national QC lab and assist toward ISO 17025 accreditation					
Facilitate qualification, validation of equipment in new facilities		FDB move to the new facility is pending minor repainting of floor; move to occur in Q2	Painting of FDA lab to be completed in April; the move was delayed again.	Floor work completed; furniture currently being set up in lab.	

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Procure equipment and supplies necessary for ISO accreditation		Provided standards for equipment qualification/maintenance; provided list of key equipment procured and at site	Provided supplies for the lab – reference standards for qualification of dissolution tablet, certificate of analysis, lab consumables with proper certificate.	Shipped calibrated thermometer to FDA. Provided consumables for Dissolution and eye wash for the lab.	
Train staff on new equipment as needed in lab and at CePAT		Training planned for Q2	Lab move has delayed training; training scheduled for May 2013.	Training planned for Aug 2013 after the move to new site.	
Facilitate assessment audit and provide TA with CAPAs			Provided TA via e-mail and teleconferences.	Provided TA in weekly teleconferences regarding status of move and preparation for ISO.	
Collaborate with FDB and other stakeholders in the local pharmaceutical industry to build capacity for GMP improvement					
Conduct baseline GMP assessment of local manufacturers				GMP workshop was held in May for manufacturers interested in receiving PQM technical assistance.	
Conduct basic GMP training for local manufacturers					
Support inclusion of FDB data in the PQM MQDB, analyze trends to provide a basis for informed decision-making					
Support data entry and develop statistics using MQM data		To be entered in Q3 upon completion of MQM		Results are pending ongoing MQM sampling and testing, to be completed in Q4	
Sensitize the public to the dangers of substandard and counterfeit medicines through IEC activities					
Facilitate dissemination workshop for media, public re CSM findings				Planned for Q4 upon receipt of MQM results	
Provide FDB with resources to produce awareness-raising materials					

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Kenya	L El Hadri				
Continue strengthening medicines quality monitoring beyond sentinel sites					
Conduct fourth round of MQM; provide training on Minilab, sampling strategies, and reporting to the new staff and refresher training to team leaders		MQM planning activities are ongoing; Minilab supplies will be delivered by Feb 2013.	Minilab training scheduled for April 2013.	Minilab training completed for 24 participants.	
Conduct supervisory and M&E visits to sentinel sites				Will be conducted Aug/Sep 2013	
Confirm validated samples at NQCL					
Provide TA to NQCL on using pharmacopeial methods to test failed samples, samples with reported ADEs, and any sample collected from refugee camps					
Continue to promote regulatory actions by sharing MQM data					
Promote efforts to support enforcement actions by PPB based on data					
Share data w/PPB, DOMC, and other stakeholders to raise awareness		NQCL completed confirmatory testing on nine quinine sulfate products; two failed and the results were submitted to DOMC and PPB for action. A report on the second and third rounds of	Report on third round drafted and will be shared with stakeholders in Q3.	Report on third round shared with stakeholders	

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		MQM activities will be shared at a stakeholders' meeting in Q2.			
Strengthen NQCL's capacity and assist the lab toward ISO 17025 accreditation					
Improve NQCL staff's technical capacity and facilitate participation of NQCL in NOMCOL inter-laboratory proficiency testing (ILP)		NOMCOL charter was established; Ciproflaxin was the molecule agreed upon to be tested in ILP.	Resources provided to start ILP testing of Ciproflaxin.		
Review data of the ILP and provide guidance to improve testing techniques			ILP is ongoing.	ILP report sent to PQM for review.	
NQCL senior staff will participate in NOMCOL meeting		PQM facilitated the participation of the NQCL deputy director in a NOMCOL directors meeting.			
Accompany the lab toward ISO 17025 accreditation					
Assist NQCL in submitting their ISO 17025 application to SANAS		First part of the ISO 17025 application submitted to SANAS		Application submitted to SANAS.	
Review NQCL QMS documentation and quality manual		NQCL quality manual revised and corrections / suggestions for improvements submitted to NQCL		NQCL has updated their quality manual and the majority of the Quality Management documents.	
Assist NQCL in starting the process of SANAS pre-audit			Provided guidance and reviewed application forms to start ISO 17025 accreditation with SANAS.	NQCL is reviewing Corrective and Preventive Actions (CAPAs) and preparing for internal audit and management review	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Assist NQCL in addressing the major and minor findings				Provided follow-up on the major findings from PQM audit and site visit; report submitted to NQCL following April visit.	
Liberia	L El Hadri				
Continue building the capacity of the Quality Control Laboratory					
Provide lab supplies and reagents needed to conduct Minilab and compendial testing on antimalarial, ARV, and OI medicines		Needed supplies will be delivered in Q2	Lab supplies procured and delivered to the lab.	Additional lab supplies were sent to the lab	
Provide step-by-step training in compendial methods and Good Laboratory Practices, according to international standards		Training is scheduled for Feb 2013	Lab training provided for 5 staff; additional training on USP General Chapters and General Notices was also provided.		
Assist the lab staff in conducting confirmatory testing on samples that failed Minilab testing		PQM assisted the lab to test antimalarials (monotherapy and FDC) and selected ARVs; results will be submitted Jan 2013	Using compendial methods, 3 ARVs and 7 antimalarials were tested; the ARVs all passed, but two antimalarials failed.		
Procure a power stabilizer, fuel, and lubricants for the generator procured by LMRHA				Provided guidance on combining solar energy with their new generator. Provided a list of vendors to LMHRA.	
Assist the lab in repairing the water purification system		Lab supplies procured to repair the system will be delivered in January 2013; installation will be completed in Feb 2013	Assisted in cleaning, sanitizing, and installing new filters.		
		Other lab supplies			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		procured for the lab include: Minilab RS to test Ciprofloxacin 250mg Sulfamethoxazole/Trimet hoprime 100/20mg and parts to repair the UV Vis and HPLC			
Secure a contract for maintenance service to repair non-working lab equipment		PQM provided TA to troubleshoot some lab equipment		Will be completed in July	
Continue assisting LMHRA in strengthening its regulatory capacity					
Strengthen LMHRA inspection functions					
Strengthen LMHRA medicines registration system				Registration system training and set up will be provided in July 2013	
Support NDS, LMHRA, and major health programs in monitoring the quality of essential medicines and promote regulatory actions					
Develop MQM protocol for sampling strategies, list of meds; define roles, responsibilities			Plans made to establish the MQM program	Planning complete	
Select sampling sites in 1-2 counties					
Conduct one round of sampling and testing of essential medicines				Part of this activity will be conducted Jul/Aug	
Provide Minilab [®] supplies & reagents; NQCL supplies & RS			Lab supplies provided	Ongoing	
Conduct M&E visit to sentinel site, NQCL					
Draft and share reports with stakeholders					
Promote LMHRA taking enforcement actions				Provided supporting documents to LMHRA to	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
based on MQM data				take action on collected samples.	
Mozambique	R. Okafor				
Strengthen the capacity of the National Laboratory for Medicines Quality Control					
Strengthen quality management capacity by training the staff		Staff trained on Karl Fischer and received refresher training on basic HPLC	Staff provided with exercises to assess proficiency following training; reports were submitted by the lab for PQM review Provided TA via e-mail and telephone on HPLC issues	Provided training on advanced HPLC and follow up on KF; additional TA provided via e-mail.	
Procure and install equipment and supplies		Procured and shipped reagents, lab supplies, and reference standards; ordered International Pharmacopeia; obtained quotes for major equipment	Procured and shipped lab consumables and equipment; ordered major equipment which is en route to Maputo	Shipped and installed major equipment (Dissolution, Disintegration, water distiller, and UV/Vis); Perking Elmer qualified the UV and provided basic training.	
Assist LNCQM to refine strategic plan for ISO accreditation/WHO PQ		Strategic plan for ISO written; will be discussed with the head of the PD and new director of LNCQM	Meeting scheduled for April 2013	Strategic plan provided; will be translated into Portuguese.	
Sensitize the public to the a dangers of counterfeit and substandard medicines by publicizing LNCQM and DF activities					
Assist LNCQM to develop quarterly Q&A sessions w/local media to highlight activities		To be performed Q2-Q3	Meeting to happen in Q3 after MQM round 1 has been initiated in April	MQM round 1 is ongoing.	
Establish an IEC campaign to inform public about CSMs		To be performed Q2-Q4			
Coordinate activities between LNCQM and		Discussion meeting planned with head of			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
ARV manufacturer		PD, USAID, and SMM			
Support the MQM program					
Extend MQM to 2 new sites; conduct 2 rounds MQM sampling, testing		Sites identified; first round to start in March	2 sites selected; Minilabs have been purchased and shipped	2 Minilabs shipped to 2 new sites	
Supply new sites; train provincial staff and DF inspectors		Minilabs ordered for new sites; provincial staff identified; approval letter sent to minister for training; training arranged for February 2013 at LNCQM	Training re-scheduled for April 2013; wire transfer issues delayed initiation of training.	Trained provincial staff in April 2013, and completed round 1 sample collection; compendial testing ongoing at LNCQM.	
Support DF efforts on enforcement actions based on MQM data		Proposal to the head of the PD to be discussed during visit in February	Meeting scheduled for April.	Provided pertinent information to DF on taking actions in April.	
Nigeria	M. Hajjou				
Assess the quality assurance/quality control of antimalarial medicines					
Conduct field visit; meet with stakeholders involved in QA/QC				Field visit conducted and meetings with stakeholders involved in medicines QA/QC were held to identify the needs of the National Malaria Control Program (NMCP) and the National Agency for Food and Drug Administration and Control (NAFDAC). Based on the discussions, a work plan was developed.	
Monitor the quality of antimalarial medicines					
Establish an MQM program				24 participants from NAFDAC, the Federal Central Store, and the National Product Supply Chain Management	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Program were trained in medicines sampling and testing using Minilab. An MQM protocol was developed.	
Conduct one round of sampling and testing				One round of sampling and testing is expected to take place in August.	
Promote enforcement actions					
Monitor MQM activities					
Strengthen the regulatory capacity of NAFDAC					
Train staff in select competencies				Training for 4 NAFDAC staff in dossier evaluation at the Center for Pharmaceutical Advancement and Training in Ghana is underway; 2 additional NAFDAC staff will be trained in quality control in September.	
Assist NAFDAC's central QC lab in attaining ISO 17025 accreditation					
Review the lab QMS and analytical capacity				Yaba lab was evaluated; Nonconformities and recommendations for corrective actions were identified and provided to NAFDAC management; a timeline to prepare for an audit by an accreditation body was also provided to NAFDAC management.	
Develop implementation plan toward ISO 17025 accreditation				The implementation plan will be provided to NAFDAC by Sep 2013.	
Support the NMCP in developing a quality assurance policy for antimalarial medicines and diagnostics					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Collect key information from NMCP on current practices & procedures for medicines and diagnostics QA				The scope of the QA policy has been expanded to include TB and HIV/AIDS.	
Assist NMCP draft a QA policy document based on practices and available resources				The QA policy is being drafted. The policy will cover TB and HIV-AIDS in addition to malaria.	
Senegal	L El Hadri				
Continue to support monitoring the quality of medicines at the nine established sentinel sites, encourage DPM to take enforcement actions based on the results of MQM data, and monitor the Minilab® activities at the sites					
Conduct supervised round of monitoring the quality of essential medicines at nine sites		<p>Round 2012: Sample collection and testing using basic tests completed in the remaining 4 sentinel sites; prelim report submitted to major stakeholders; confirmatory testing of 2012 round will be completed by Jan 2013.</p> <p>Round 2013: Initiated planning for one round of MQM activities</p>	<p>The majority of confirmatory testing has been completed.</p> <p>Budget and plans made to start 2013 round.</p>	2013 round started at selected sites; sample collection and Minilab testing will be completed by August.	
Monitor and evaluate MQM activities at selected sentinel sites and share pharmacovigilance tools with the MCR of each region					
Present MQM results and promote DPM regulatory actions		MQM results (2011 and 2012) will be presented at a meeting with relevant stakeholders	Meeting postponed until Q3.	Meeting was attended by the technical committee; another meeting is planned in Q4	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		and MCRs in Q2			
Strengthen the capacity of DPM and support enforcement of its regulatory actions					
Procure and install a new server for DPM to improve data mgmt		Specifications of the server finalized; process of procuring and shipping the server to Senegal/DPM ongoing	Server for storing data from the newly established registration software was procured and delivered to DPM.		
Organize workshop for DPM and customs on enforcing regulations		Change of the Minister of Interior resulted in change of the general directors of the customs and judiciary police. PQM will plan the workshop once the new directors are appointed	Plans made and tentative agenda shared with the director of customs operations for his review.		
Continue strengthening the capacity of LNCM and guide the lab toward ISO 17025 accreditation					
Assist LNCM in participating in NOMCOL inter-laboratory proficiency (ILP) testing		NOMCOL charter established; Ciproflaxin was the molecule agreed upon to be tested in ILP.	Resources provided to start the ILP testing.		
Present the results of PQM QMS and lab audit to LNCM staff		Results of QMS and lab audit presented to LNCM staff and action plan established to correct minor and major deficiencies.		Follow-up with the lab showed that LNCM has resolved the major inspection issues and is improving on the minor issues.	
Develop implementation plan; conduct site visit to review progress toward ISO 17025 accreditation		Implementation plan developed and presented to lab staff; site visit to review implementation progress is scheduled for March 2013.	Follow up visit to the lab postponed until Q3.	LNCM completed all section 4 requirements and documentation pertaining to ISO 17025.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Review the SOPs drafted by LNCM staff		Using SOP template provided by PQM, LNCM submitted 20 SOPs, which are under review by PQM.	10 SOPs reviewed.	LNCM has revised or drafted 20+ procedures.	
Assist LNCM in finalizing managerial and technical documents		Planned for Q2	Technical (section 4) and managerial documents (section 5) of ISO 17025 requirements are under review.	LNCM plans to complete the technical documents by the end of August.	
Assist the lab in selecting accrediting bodies for testing, calibration, and proficiency testing (PT) and submitting the accreditation applications		With PQM assistance, LNCM selected TUNAC as their accrediting body for testing; PQM and LNCM initiated the process of submitting the application to TUNAC and for selecting the accrediting bodies for calibration and PT		TUNAC submission delayed due to the delays in the revision of the QA manual and completion of the section 5 technical documents and PT.	
Assist LNCM to prepare additional SOPs and train staff in analytical tests			Guidance provided to draft new SOPs and training provided to 11 staff on Karl Fisher titration, LOD, pH meter, and GDP according to ISO 17025 accreditation requirements	Preventive maintenance and training provided by ZefSci Corporation, an external vendor	
ASIA					
RDM-A Mekong Malaria S. Phanouvong					
Support medicines quality surveillance by maintaining the sub-regional MQM to obtain evidence-based data to support policy decision-making and enforcement action					
Adapt existing MQM & special investigation protocols to improve strategies & techniques		In discussions with MRAs in GMS to adapt protocol	Further discussions with country partners and USAID-PMI team planned for April 3-5,	Met with local partners and conducted sentinel sites visits (Binh Phuoc) in Vietnam for situation	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			2013 at the PMI partners meeting and CAP-Malaria Cross-border Working Group meetings in Yangon.	analysis and insights for use in the improved sampling protocol.	
Help GMS partners conduct 2 MQM rounds in hot-spot border areas using new protocols		Planned for Q3	Planned for Q4	Planned for Q4	
Build the capacity of NQCLs in pharmaceutical analysis toward compliance with ISO 17025 and/or WHO prequalification for both pre- and post-marketing surveillance of medicines quality, with support provided by ANEQAM and BREMERE					
Assess documentation, procedures of Laos and Thailand NQCLs; provide TA on CAPAs		Assessment agenda completed; to be implemented in Q2	Assessment completed in February and CAPA recommendations provided to each of the labs; regular reports were requested.	Followed-up on CAPA implementation and reviewed SOPs submitted from Laos and Cambodia labs. Drafted a joint press release on Thailand BDN lab achieving WHO PQ status. PQM has been notified that the Vietnam NIDQC has achieved WHO re-qualification status; official re-certification to be received in Q4.	
Train Mahidol GMP-compliance faculty on WHO PQ process		Planned for Q4	Initial discussions were held with Mahidol team re: training schedule and logistics	Planned for Q4	
Support Chula PTSC to conduct a regional workshop on analysis of DHA/PIP, AVQ/PGN		Planned for Q4	Initial discussions were held with Mahidol team re: training schedule and logistics	Chula team and PQM Lab Services team developed a training preparation plan and training materials, identified modules, and acquired	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				samples and RS.	
Support regional and in-country coordination for effective enforcement through BREMERE and, possibly, WHO SSFFC mechanism					
Support BREMERE quarterly meetings to share information, and coordinate enforcement		Implementation meeting scheduled for Feb 2013 in Cambodia	Implementation meeting held in Feb. An action plan was developed and disseminated among the BREMERE countries.	Requested official confirmation of nomination of BREMERE membership from countries: Laos, Cambodia, Thailand, Vietnam, Myanmar, Indonesia, and Philippines	
Support investigations on timely reporting and enforcement with WHO-INTERPOL		Planned for Q4, after obtaining the results of the comparative study of AML quality		Planned for Q4	
Disseminate findings of investigations and report data to MQDB		Planned for Q4		Planned for Q4	
Participate and present data at relevant mtgs		Presented at Annual Consciousness on CSMs in the Philippines in Nov and at the 2012 Malaria Conference in Australia in Oct/Nov	Data from MQDB were presented at the BREMERE meeting in Siem Reap, Cambodia	Data and PQM program activities were presented at the Pathways to Safe Medicines: Protecting Patients through Unified Global Action in London in June	
Support the pharmacy schools to improve last-year pharmacy student curriculum on medicines policy, quality assurance and regulations to prepare them for real-world experiences with different types of pharmaceutical practices					
Develop review methodology and tools; meet with key parties to recommend changes		Ongoing at two Cambodian Faculties of Pharmacy	Ongoing	Planned for Q4	
Submit final curriculum for ratification by responsible agency		Planned for Q3		Planned for Q4	
Field-test the new curriculum at two Pharmacy schools		Planned for Q4		Planned for Q4	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Maintain the momentum of awareness-raising about the danger of using CSMs in the GMS through existing and proven means and tools					
Disseminate copies of "Pharmacide: The Mekong" documentary; produce trailer for use on YouTube and media		Finalization has been delayed by 3-4 months due to clearance issues in some countries	The film was finalized in Feb and disseminated; was also played at the BREMERE mtg and the Awareness Campaign in Kamponcham by the French Fonds de Solidarité Prioritaire and the Cambodia Economic Police team.	The final version of Pharmacide: Mekong was translated and subtitled into Thai language. In Q4, the film will be publicly screened in Indonesia, as well as at a USAID/Indonesia roundtable lecture series in Jakarta. Plans are in place to translate and subtitle the film into Bahasa Indonesia by the US Dept of State during Q4 or FY14 Q1.	
Adapt and disseminate BCC/IEC materials to raise awareness in high-risk areas		Leaflets, brochures, and play scripts were developed in collaboration with CAP-Malaria in Cambodia for schoolchildren and communities in remote areas; awareness-raising activities for pharmacy retailers were conducted in Laos in collaboration with MOH/FDD and the U.S. Embassy's PR Unit.	Leaflets on basic knowledge of counterfeit medicines were printed and distributed to pharmacy outlets in all 24 provinces in Cambodia through DDF/MoH-PHDs channel and to community villagers through URC-CAP Malaria and other partners. In collaboration with URC-CAP Malaria project, PQM produced and presented a poster in elementary schools to educate children about counterfeit antimalarials.	Leaflets and posters on awareness of poor-quality medicines, jointly produced with CAP-Malaria, were converted into booklets and are ready for printing and dissemination among elementary school students and their families.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			<p>Printing production is planned for Q3.</p> <p>A preliminary report of the survey on awareness of retail pharmacists was presented by the MOH/FDD and the Embassy. Interventions have been introduced and evaluation is planned for Q4.</p>		
<p>Burma S. Phanouvong</p>					
<p>Establish a formal presence in Burma through an MOC with Ministry of Health or Food and Drug Administration and hire a country consultant to help operationalize PQM activities</p>					
Consult with relevant partners for pragmatic advice on establishing an MOC with MOH		No tangible progress made due to political sensitivities and restrictions. An office space in Yangon will be established under an agreement with CAP-Malaria.	Awaiting clearance and authorization from PMI-USAID Washington. A draft Project Agreement Letter between USP and Burma MOH was submitted to PMI-USAID/RDMA and Burma Missions for suggestions before its submission to the AOTR for review and authorization to extend the letter to the MOH.	<p>After receiving clearance from RDMA, the draft Letter of Agreement was submitted to Myanmar FDA MOH for input; after review/minor edits, the FDA recommended the LOA should be signed by USP or USAID/Burma and counter-signed by the International Health Department of MOH.</p> <p>CAP-Malaria has agreed to provide an office with some administrative support to PQM. An agreement is under review by both parties.</p>	
Recruit a country consultant		Recruitment of a country consultant reached final	A part-time consultant has been hired and will	A second full-time consultant was hired in	

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		Q1	Q2	Q3	Q4
		stages, but the candidate was hired by another NGO; recruitment has to start from scratch again.	begin in May.	May.	
Support the FDA Nay Pyi Taw QC lab to perform compendial monograph testing of key antimalarials and fixed-dose combination products					
Procure dissolution tester, install, calibrate		Specifications established and supplier identified, waiting for clearance.	Awaiting authorization from USAID Washington	Still awaiting authorization from both RDMA, USAID/Burma, and USAID/HQ	
Train lab staff to test A/L , DHAP/PIP FDCs		Planned for Q2-3	Postponed to Q4	Planned for Q4	
Conduct program implementation review and develop a strategic document for improving the quality of essential medicines for Burma					
Hold national mtg to present MQM data; document strategy for proposed improvement		Planned for Q4		Planned for Q4	
Cambodia E. Yuan					
Improve detection of poor-quality medicines, sustaining activities in 12 established sentinel sites while transitioning program ownership to the Cambodian government					
With DDF begin pilot in four sites to form, train teams to oversee transition process		Held initial discussions with DDF-MoH on MQM phase-out project to seek their cooperation in jointly developing ways to keep existing operations sustainable. PQM will visit Cambodia in Feb to meet with DDF-MoH to discuss strategies.	Dr. Phanouvong met with H.E. Chou Yin Sim, Dr. Heng Bunkiet, and their deputies to clarify PQM's role and discuss MQM sustainability issues.	No substantial progress been made because: - DDF attempted, but failed, to convince the MoH to allocate a budget for FY14 PMS activities in National Annual Operational Plan - GF has not issued new funding to resume MQM activities.	
Coordinate with GFATM, JPMA, WHO to streamline PMS; identify other funding		After approaching JPMA and WHO in Cambodia, there is no progress.	Attempts were made with no progress	PQM was informed unofficially that there will be new GF funds for 5 countries in GMS, including Cambodia, for malaria activities. PQM	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				has been in close discussions with WHO,GF, UNOPS, and MoH to understand GF's new funding mechanism and application for potential collaboration and involvement	
Maintain essential PMS activities at 12 sites during transition		MQM activities were temporarily held off because funding from GFR6 is on hold. Confirmatory testing is ongoing; preliminary results were released showing there were no failed samples out of 72 tested.	No activity this quarter	No further sample collection and testing at 12 sentinel sites. The previous collected samples and failed samples are undergoing confirmatory testing at NHQC.	
Focus efforts on non-MQM regions of growing AMR & borders with Thailand, Vietnam		In Oct, PQM, in collaboration with local partners, conducted training in Vietnam on sampling methods for comparative studies; participants came from MRAs, QC labs, and national malaria control programs of Cambodia, Laos, Thailand, and Vietnam.	Sampling and testing within 9 non-MQM sites is ongoing. A study team is ready to start the comparative study after funding is allocated and a protocol is in place.	160 samples were collected and tested from the 9 non-MQM sites; 13 samples failed quality tests. The IMC secretariat team held a meeting to evaluate the 13 failed samples in June and decided to: <ul style="list-style-type: none"> - Remove the registration numbers of 2 products (Levofloxacin 500mg manufactured by Flamingo-India and Cetirizine manufactured by Troikaa Pharmaceuticals Ltd.- India). - Buy 4 more samples (2 samples in duplicate) and 	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				<p>re-test the quality for further investigation. - Officially give warning to the 6 pharmaceutical companies (Mega, Ratanak Ratana, Vimpex, Zifam, Medical Supply, and Vignesh)</p> <p>The comparative study on the quality of antimalarials was delayed because approval from the MOH to sample at public health facilities was not been received; PQM will submit a letter for MOH approval in Q4 and activities will begin thereafter.</p>	
Strengthen authorities for timely reporting; share data with key stakeholders		Several meetings and conference calls were conducted to expand current MQDB to make it more useful for country health authorities and national QC labs.	Improvements continue to be made to MQDB.	Summaries on the data analysis from MQDB have been drafted.	
Establish/strengthen tie between MQM and enforcement actions		Continuous collaboration with IMC/DDF/MoH to support inspections of the sentinel sites and promote appropriate enforcement actions.	IMC/MOH/DDF were actively involved in the BREMERE initiative and hosted the implementation meeting in Siem Reap in February. The DDF Director was selected to lead BREMERE for the next two years.	An action plan was developed.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Continue strengthening PQM/IMC efforts on enforcement actions		Supported annual IMC meeting held in Dec.	PQM and IMC have closer collaboration through BREMERE.	DDF-MoH/IMC Secretariat is developing guidelines for enforcement action after finding poor quality medicines. PQM sent the Enforcement Action Guidelines to DDF-MOH for adaptation.	
Strengthen medicines quality assurance and quality control systems by building up the capacity of DDF and NHQC					
Continue TA to NHQC; ensure new lab is built to WHO/ISO standards		A teleconference was conducted in Oct with PQM and its consultants including arc2lab architect and the World Bank (WB) lab experts; a face- to-face meeting among arc2lab, the WB, HSSP2-MoH, NHQC, and the local design company will take place in January 2013.	Face- to-face meeting among USP's consultant (arc2lab), the World Bank and its lab technical officials, HSSP2-MoH, NHQC management and technical staff, and local engineer designers took place in Jan to clarify roles for supporting the NHQC construction and necessary TA. PQM and NHQC held a teleconference in Feb with arc2lab to discuss the status of lab construction and some technical issues.	NHQC management, the Arc2lab consultant, and PQM held a teleconference in May to: <ul style="list-style-type: none"> - Receive updates about NHQC's situation relating to lab construction. - Discuss providing TA re: lab equipment and furniture specifications. - Discuss how to work together more effectively - Receive updates on NHQC's quality management System status and follow-up steps 	
Work w/NHQC mgmt & staff to implement ISO accreditation roadmap		The agenda for reviewing NHQC lab's QMS has been drafted; PQM plans to visit NHQC in Q2	PQM QMS manager visited NHQC in Feb to perform an assessment of the NHQC lab, evaluate ISO 17025 preparations, review training & documentation records, and schedule	NHQC sent a master list of documents available and currently being implemented in their lab to PQM for review.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			further discussions with the QA manager and deputies on ISO accreditation.		
Enhance the capacity of NHQC to conduct confirmatory testing		PQM has proposed inviting one senior scientist from NHQC, via USP's visiting scientist program, to come to USP for 2-4 weeks of hands-on training.	PQM in-country consultant collaborating with NHQC management on logistics of training.	PQM discussed with the NHQC director nominating one senior scientist to be trained at USP HQ in September	
Strategically introduce "systematic steps" to strengthen DFF QA/QC		Provided TA to DDF/MoH to develop National Guideline for Pharmacy Practitioners	Guideline for Good Pharmacy Practices was developed and approved by the MoH; English version was reviewed by PQM, edited, and sent back to DDF/MOH	Training modules are being developed. DDF-MoH will submit these modules to PQM for review in Q4.	
Develop local expertise in QA/QC, medicines regs by expanding pharmacy curriculum		Local consultant met with the Dean of Faculty of Pharmacy of Int'l Univ to ask for permission to conduct an evaluation of the medicines QA/QC and regulation syllabus; a meeting with the Univ of Health Sciences is planned for Q2. Questionnaires are being developed to survey final-year pharmacy students on their QA/QC knowledge. After BREMERE's inauguration, PQM has collaborated with	No progress	Survey questionnaires have been drafted and are being reviewed A letter requesting permission to give the survey to pharmacy students has been sent to the dean of IU; a similar request to the school's ethics committee will also be sent A meeting with the University of Phnom Penh requesting their participation in the study is planned for Q4.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		DDF/MOH to prepare for the Feb meeting to be held in Cambodia; Cambodia is co-chair.			
Raise awareness about medicines quality issues and disseminate information among regulators, health care professionals, and the public					
With partners, develop & disseminate BCC/IEC materials at grass roots levels			<p>Leaflets on basic knowledge of counterfeit medicines were printed and distributed to drug outlets in all 24 provinces through DDF/MoH-PHDs channel and to community villagers through implementation partners).</p> <p>In collaboration with URC-CAP Malaria project, PQM produced and presented a poster in elementary schools to educate children about counterfeit antimalarials. Pre-testing with students was conducted in March at Pa'hee Elementary School in Pailin province. Printing production is planned for Q3.</p>	URC and PQM converted the poster into booklets to more effectively raise awareness among elementary school students and their families. These booklets will be printed in Q4.	
Collaborate with PAC to publish bulletins, news-letter and conduct educational workshops			No progress	1 bulletin is being prepared for Q4.	
Introduce BREMERE; move countries toward		In collaboration with PQM, DDF-MoH will	The BREMERE implementation meeting	The DDF Director nominated 2	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
timely reporting and enforcement actions		host the meeting to kick off the BREMERE action plan in Feb 2013.	was held in February in Siem Reap, Cambodia. There were 32 participants from Cambodia, Laos, Vietnam, Thailand, and South Korea, and other partners such as FSP. Dr. Heng Bunkiet, DDF Director, was selected to be BREMERE's Chair for the next two years.	representatives (Drug Inspectors) to join the BREMERE regional working group. An action plan for 2013-2014 was developed.	
Indonesia S Phanouvong					
Maintain existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines					
Support first-line ATB mfrs (Indofarma, Phapros, Kimiafarma) toward WHO PQ		<p>Provided TA to Phapros and Indofarma while Kimiafarma dropped out due to lack of commitment to address critical observations found during a facility inspection. A private company, Sandoz Indonesia, has recently begun working with PQM.</p> <p>Phapros has completed about 90% of CAPA items recommended, invested in upgrading some manufacturing equipment, and renovated the solid dosage form production plant which is ready for PQM inspection. The</p>	<p>Phapros: in March, PQM staff conducted a site inspection at the Semarang plant following renovation and facility upgrades. During Q2 they prepared the pilot biobatch for 4FDC; the dossier will be recompiled & submitted to PQM in April.</p> <p>Indofarma: approval for new construction was sent for NA-DFC review in Q1, BPOM will give final decision in Q3. Indofarma submitted new facility blueprints to PQM for review. Following construction, PQ process will be reinitiated at new site.</p>	<p>Senior GMP experts from PQM conducted on-site follow up assessments for Phapros, Kimia Farma, Indofarma, and Sandoz Indonesia to establish revised implementation timelines and reporting agreements. The PQM team also explored providing TA to new manufacturers in Indonesia under the WHO PQ program, including: Novell Pharmaceutical Laboratories, Dexa Medica, and Metiska Farma.</p> <p>Phapros: PQM conducted follow up document audit and revision of implementation timeline</p>	

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		Q1	Q2	Q3	Q4
		<p>equipment and process validation and dissolution profiling of its reformulated products (2 FDC (RH) and 4 FDC (RHZE) have been completed. A pilot BE study for 4FDC has started at Equilab</p> <p>Indofarma decided to build a new facility. A preliminary design will be sent to PQM for review.</p> <p>PQM and USAID arranged a high level visit of the MOH's delegate, Professor Dr. Tjandra Yoga Aditima, to USP HQ in Dec 2012 to discuss next steps; action items were agreed upon.</p>	<p>Sandoz: submitted questionnaire to PQM; PQM evaluated stability data (incomplete) on 2FDC, 3FDC, and 4FDC adult and pediatric formulations and conducted a baseline survey of the manufacturing facility in South Jakarta. PQM met with the Country Director and the Regional QC Manager who committed to achieving WHO PQ; Sandoz will form a PQ team for this purpose.</p> <p>Kimia Farma: following a PQ Coordination meeting at the NTP with NA-DFC, NTP, and state-owned manufacturers, Kimia expressed that it would like to be reconsidered for receiving TA for PQ. They submitted their CAPA report to PQM team, and PQM will re-engage with them beginning in Q3.</p> <p>Phapros, Indofarma, and other manufacturers attended the CPhI WHO PQ Seminar, co-hosted</p>	<p>during Q3. PQM reviewed cleaning validation and impurity determination protocols; 4FDC dossier was reviewed; Pilot BE study protocol was approved and will begin in Q4; stability data is in progress.</p> <p>Indofarma: PQM Senior GMP experts conducted an on-site review of the blueprints for the new facility design. Indofarma revised the blueprint design to incorporate recommendations and the new design was submitted to NA-FDC for review. NA-FDC is committed to fast-tracking approval on the design. New project implementation timelines and reporting agreements were drafted and approved.</p> <p>Kimia Farma: PQM Senior GMP experts conducted an on-site inspection of Kimia in order to re-initiate the PQM technical assistance program. PQM reviewed CAPA implementation progress (from 2011) and</p>	

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		Q1	Q2	Q3	Q4
			by PQM in Jakarta in March.	<p>drafted a new CAPA with 6-month implementation timelines. Kimia plans to complete dissolution profiling and BE study in Q4.</p> <p>Sandoz Indonesia: PQM conducted two on-site assessments of Sandoz and met with senior management to agree upon implementation timelines for their dossier submission. PQM performed an initial assessment and document review to determine capacity for the 2FDC and 3FDC pediatric FPP for TB.</p> <p>Comparator products were supplied to Phapros this quarter; in Q4, comparator products will be provided to Indofarma (Rimactan, Isoniazid, Pyrazinamide, Ethambutol) and to Kimia Farma (RIF and INH).</p>	
Encourage mfrs of levofloxacin tabs and kanamycin powder toward WHO PQP		No progress	Sanbe Farma, based in Bandung, Java, expressed interest in receiving TA from PQM for two products: kanamycin 1g powder for injection and	PQM met with Metiska Farma regarding their dossier submission for Levofloxacin 500mg tablets with a target of Q4 or FY14 Q1.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			<p>levofloxacin 500mg tablets. PQM conducted a baseline survey of the manufacturing facilities in Bandung. PQM will conduct a full inspection in Q3. The team met with the Owner-Director and senior management who all expressed commitment to achieving WHO PQ.</p> <p>Sanbe attended the CPhI WHO PQ Seminar, co-hosted by PQM in Jakarta in March 2013.</p>	<p>Sanbe Farma conducted in-house preparations and documentary compilation for submitting their Levofloxacin 500mg (Levocin FCT) dossier by the end of FY14 Q1.</p> <p>PQM met with Novell Pharmaceutical Laboratories in Jakarta to discuss their Levofloxacin and Moxifloxacin products. They are undergoing TGA and EMEA inspections, so they will revisit the potential for WHO PQ in 2014.</p>	
Support implementation of MQM for anti-TB medicines at five pilot sentinel sites that completed training in June 2012					
Procure equipment, provide training, and establish MQM sentinel sites for TB and selected antibiotics		<p>5 Minilabs were provided and training conducted; additional RS and supplies were purchased and shipped.</p> <p>In Oct 2012, an action plan to implement MQM activities was agreed upon among PQM and implementing partners. Delays have occurred due to bureaucratic hurdles, especially regarding opening a bank account in Indonesia and transferring money from</p>	<p>Minilabs were deployed to the 5 provincial sentinel sites. One round of sampling was completed in Q2, and testing with Minilabs is ongoing. Confirmatory testing and a second round of sampling will take place in Q3.</p> <p>PQM conducted a monitoring site visit to Makassar (a Minilab site) together with the NQCL-DF Director and staff, including sampling, site visits to a provincial</p>	<p>A total of 869 anti-TB and antibiotic medicines were sampled and testing using basic methods and a sub-set of samples was sent for confirmatory testing. Results will be available in Q4. Total numbers of samples tested by provincial BBPOM sites:</p> <p>Medan: 160 Serang: 167 Surabaya: 148 Mataram: 262 Makassar: 132</p>	

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		Q1	Q2	Q3	Q4
		USP.	hospital, city warehouse, and the provincial QC lab where testing is taking place.	PQM also conducted a site visit to the Medan BBPOM Minilab site together with USAID/Indonesia and NQCL-DF representatives to follow up on activities. PQM also provided USP-NF to Medan during Q3.	
Open a PQM office in Jakarta; recruit GMP technical staff		Potential local partners (Indonesia Univ. and Bali Expat Services) identified to assist in this regard.	Signed a contract with Bali Expat Services as a local service provider for work permits and visas, as well as for securing a country office. PQM contracted with consultant Chris Raymond to serve as Chief of Party for the Indonesia program, based in Jakarta. A new country office will be opened in April, following assessment of at least 12 potential locations in Jakarta.	Activity completed.	
Continue to assist two local contract research organizations (CROs) toward compliance with Good Clinical Practices (GCP) for bioequivalence studies of ATB medicines					
Provide TA to Equilab Int'l and San Clin EQ Lab to complete CAPA		Equilab CAPA implementation report received.	Equilab CAPA implementation is nearly complete as of the end of Q2. San Clin EQ is in the process of implementing PQM recommendations to comply with GLP/GCP	PQM coordinated and prepared for GCP/GLP audits to be conducted during Q4 at both San Clin EQ and Equilab. PQM received CAPA implementation updates from both Equilab and San Clin EQ during Q3.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			guidelines.		
Follow up inspections and support two to conduct BE studies		<p>A WHO consultant conducted an inspection as part of educational audit training of NA-DFC staff in BA/BE in Nov 2012 and found a few minor observations which Equilab has already addressed.</p> <p>Equilab drafted BE study protocols for 2 and 4 FDCs and submitted to PQM for review. The review of the 4 FDC will be complete in Jan 2013</p>	<p>Equilab BE study protocol for Phapros 2FDC was reviewed by PQM and the WHO PQP team. PQM submitted a report to Equilab, who will be ready to conduct the 4FDC BE study for Phapros, starting in Q3.</p> <p>PQM visited the San Clin EQ facility in Bandung to follow up on recent renovations and adjustments made towards compliance with GLP/GCP.</p>	<p>Both CROs are prepared for final audits in July. Based on findings, they can begin conducting BE studies for the manufacturers receiving PQM TA for anti-TB medicines during this calendar year. PQM has reviewed protocols and will advise manufacturers accordingly based on progress made in Q4.</p>	
Strengthen regulatory systems and measures of Ministry of Health and National Agency for Drug and Food Control to better control and regulate ATB medicines, particularly 2nd-line ATBs, in the market to support the MDR-TB program					
Review requirements on ATB MAs and licensing systems for clinics, pharmacies		Preliminary discussions and consultations with relevant stakeholders were held.	This activity is planned for Q3-Q4.	A TOR will be drafted for an Indonesian consultant to conduct basic interviews following study design and development by PQM during Q4. This will potentially be a joint research project with TBCare through the PMDT program in addition to stakeholders at NA-DFC.	
Assess the availability, quality and main source of all first- and second-line ATB medicines in the main supply chains					
Develop assessment protocols		Under consultation with relevant partners	Protocol is being developed	Planned for Q4	
Train investigators on sampling protocols		Planned for Q2-Q3	Planned for Q3-Q4	Planned for Q4	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Collect and test samples at NQCL-DF/ regional reference lab		Planned for Q2-Q3	Planned for Q3-Q4	Planned for Q4	
Analyze data and report recommendations		Planned for Q4	Planned for Q3-Q4	Planned for Q4	
Assist NA-DFC and DG-PPD to sample and test (lot-based) for quality ATBs in the main warehouses of Jakarta and main cities prior to distribution					
Adapt existing sampling and testing protocols		Further discussion among key stakeholders is necessary.	Further discussion among key stakeholders is necessary.	PQM Indonesia staff met regularly with BINFAR (DG-PPD) and SCM partners to discuss potential for this project. Some difficulties need to be overcome including assigning authority via MoU for NA-DFC to conduct testing at DG-PPD managed sites. Adapted sampling protocol will be available and introduced in Q4	
Set up sampling team		Planned for Q3	Planned for Q3	Planned for Q4	
Conduct testing		Planned for Q4	Planned for Q4	Planned for Q4	
Write a report, disseminate to stakeholders		Planned for Q4	Planned for Q4	Planned for Q4	
Encourage NTP and NA-DFC to take action on failed ATBs		Will be on a case-by-case basis.	Will be on a case-by-case basis.	Planned for Q4	
Expand MQM systems to cover antimalarial (AML) and antiretroviral (ARV) medicines					
Train staff of NQCL-DF & provincial QCLs on Minilab [®] , compendial test methods for select AMLs and ARVs			Planned for Q3	Planned for Q4	
Purchase reference products, solvents and		Planned for Q2	Planned for Q3	Planned for Q4	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
reagents for Minilabs®					
Add 150 AMLs, 100 ARVs to ATB sampling & testing in field		Planned for Q3-Q4	Planned for Q3-Q4	Planned for Q4	
Conduct confirmatory tests at NQCL-DF		Planned for Q4	Planned for Q4	Planned for Q4	
Produce a combined report for ATB, AML, and ARV data		Planned for Q4 and FY14 Q1	Planned for Q4 and FY14 Q1	Planned for Q4	
Encourage NA-DFC and NTP to take enforcement actions		ongoing	ongoing	Planned for Q4	
Provide technical support to NQCL-DF toward renewing ISO 17025 accreditation with better, product-based scope					
Conduct ISO 1705 assessment; propose changes to scope and quality system		Discussions initiated with the NQCL-DF management who have agreed to change the scope	During a national workshop for the NQCL-DF provincial QC labs in Palembang, Sumatra, PQM met with the national Director and senior staff to discuss timelines; planned for Q3 with a week-long, on-site training and assessment	PQM assisted the NQCL-DF and the NTP to respond to queries from GFATM regarding the SSF grant renewal for TB. PQM also worked with the NQCL-DF lab to plan for an on-site lab assessment to be conducted by PQM during Q4. PQM will coordinate an advanced compendial training at the NQCL-DF in Aug/Sep in cooperation with GFATM.	
Produce assessment report and CAPA recommendations		Planned for Q2	Planned for Q3	Planned for Q4	
Philippines E. Yuan					
Sustain the MQM activities in established sentinel sites					
Continue to support MQM at 6 existing sites plus 2 newly established sites on		Communicated with the sites re: supplies, RS; processed Minilab orders for two new labs;	Replenished Minilab supplies and reagents; Collected expired medicine samples for	Replenished Minilab supplies and reagents; Collected expired medicine samples for	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
first line TB medicines quality checking through Minilab replenishment, site visits, training and refresher training, and database updates.		supplied FDA satellite lab Davao with USP-NF, FCC; visited Davao and Malolos sites in Oct; attended meetings for Minilab updates.	proper disposal at FDA.	proper disposal at FDA Visited sentinel sites in Bicol, Calabarzon, Davao, Malolos, and Zamboanga.	
Expand MQM to include SL-ATB Ciprofloxacin		Planned for Q2	Used Minilab test procedures to analyze the new products; Consultant performed confirmatory testing at FDA for Ciprofloxacin.	Minilab staff at the sentinel sites were trained to do TLC testing for Ciprofloxacin.	
Expand MQM to include antibiotics Amoxicillin and Cefalexin		Planned for Q2	Used GPHF-Minilab test procedures to analyze the new products; Consultant performed confirmatory testing at FDA for Amoxicillin and Cefalexin.	Minilab staff at the sentinel sites were trained to do TLC testing for Amoxicillin and Cefalexin.	
Strengthen FDA capacity and its QC Lab to enhance the medicine regulatory system in drug registration and post-marketing surveillance					
Finalize inventory of TB mfrs, importers, and distributors on sources, supply chains, products. Determine improved sampling points; provide TA in the pharmaceutical mgmt system (PMS) and QA/QC system.		Received the tentative list; will finalize in Q2. PQM team met with local pharmaceutical mfrs in Nov to follow up with those interested in WHO PQ, with the focus on 2 nd -line ATB manufacturers.	Planned for Q3. Hizon and Lloyd Laboratories submitted their accomplished questionnaire for WHO PQ.	Planned for Q4	
Provide training on areas identified through gap analysis and request from FDA.		Held hands-on training on Compendia Analysis of ATB Meds and Intro to GLP in Oct in Davao Sat Lab, Tagum City for	Follow-on training will be in-line with the previous PV training that was given to 25 FDA regulatory staff; training	GMP training in line with the PIC/S guidelines will be conducted with 25 FDROs and ASEAN MRAs in September	

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		Q1	Q2	Q3	Q4
		5 Davao staff, 2 Cebu staff, 3 Central lab staff, and several observers Held Pharmaceutical Process Validation training in Nov in Alabang Muntinlupa City with 26 participants and several observers.	is planned for Q4, and topics are TBD.		
Sponsor two visiting scientists from FDA central office coming to USP to receive training on BA/BE		Met with USP's VSP coordinator to discuss logistics.	Selected 1 regulatory officer and 1 lab tech for a 12-week training course at USP HQ; training topics TBD. Alternatively: The BA/BE training might be offered in the Philippines to benefit local stakeholders more.	BA/BE training scheduled for September.	
Provide training opportunity through USP's International Training Program (ITP) to the scientists and staff from FDA satellite labs		Met with ITP coordinator to discuss training topics	Selected 2 participants from FDA Davao Sat Lab and 2 from FDA Central Lab for a 3-week training course at USP HQ; training topics TBD.	Postponed because the USP lab is under renovation. The training at USP HQ will be conducted in September.	
Purchase needed laboratory equipment and reference materials for the FDA that is not included in the DOH budget or other budgets		PQM met with reps from academia, healthcare, pharmaceutical industry, and FDA in Nov to explore opportunity to form a BA/BE center.	PQM sent the FDA two copies of the FCC 2 nd Supplement.	The FDA received the following from PQM: 1) USP FCC 8 th Edition (Book) - Qty. #1 2) 2013 USP Dictionary Print (Book) - Qty. #1 3) 2012 USP Dietary Supplements Compendium (Two Volume Set/ Books) -	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Qty. #2 4) USP 36 – NF 31 2013 Supplement 1 (Flash Drive Single User) - Qty. #2	
Provide technical and professional assistance in Quality Management System (QMS) to FDA Davao Satellite Laboratory for ISO17025 accreditation/ certification.			The initial plan of providing TA to satellite lab has been discussed with PQM's QMS manager. A teleconference with Davao lab chief and QA staff will be conducted in Q3 or Q4.	Planned for Q4	
Extend assistance to National Center for Disease Prevention and Control (NCDPC) of the Department of Health (DOH) to enhance National Tuberculosis Program (NTP)					
Provide TA to NTP program related to TB medicines quality		PQM country consultant attended TB LINC event and NCDOC year-end consultative workshop in Nov in Iloilo City. PQM is seeking the opportunity to collaborate with NTP, and detailed activities will be identified after further discussions	Joined Inter-CA on TB Technical Working Group; Attended Inter-CA meetings and provided input for discussions.	Attended several meetings and participated in exhibits to showcase PQM	
Obtain evidence based quality data on selected generic anti-infective medicines					
Conduct quality checks and assessments on the generic medicines made by local pharmaceutical manufacturers		PQM HQ staff met with FDA's chief of lab services to discuss plans to create a list of chosen generic medicines to be compared to brand-name imported products	Planned for Q3.	Planned for Q4.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Vietnam S. Phanouvong					
Provide technical assistance to local production of methadone and procurement of methadone finished products for Hai Phong and HCMC					
Pursue obtaining an authorization letter to conduct GMP		No progress due to political sensitivities and bureaucratic hurdles	No progress; awaiting MOH decision	MOH selected 5 qualified local manufacturers and may open a tender for local production among the 5 manufacturers.	
Conduct GMP inspection on 1-2 mfrs and recommend how to address deficiencies		Country consultant communicated with VIDIPHA, a potential manufacturer for local methadone production	PQM visited VIDIPHA in Jan to perform a quick assessment of its capacity for narcotic medicines production.	Will depend on which manufacturer is chosen (see above).	
Provide TA to HCMC and Hai Phong PACs to select high-quality methadone from reliable suppliers		Country consultant: - met with HCM PACs to present information on methadone procurement procedures - met with NIDQC expert to discuss and develop technical specifications for imported methadone and presented these to VAAC - contacted 3 methadone suppliers: Molteni (Italian), Rusan Pharma (Indian), and Dolder (Swiss) as well as a legal national importer (CPC1) - met Hai Phong DoH to discuss technical aspects to procure imported methadone	- Technical specifications for finished product and dispensing pump were finalized and shared with VAAC and HCMC PAC. - Template format of international tender documents was shared with VAAC. - Followed-up with 2 methadone suppliers and legal national importers (CPC1, HAPHARCO). The 2 suppliers sent their product specifications and quotations to CPC1 and VAAC. - Followed-up with HCMC and Hai Phong PACs on the progress of procurement of imported methadone. No progress on allocation of	- VAAC is still preparing the national tender. The challenge for the tender is that there is no reference price of methadone in Vietnam, except as supplied by PEPFAR. There is no clear mechanism for opening the tender (selected or opened tender or international tender). It will depend on the decision of MOH. - There is no progress at the HCM PAC due to the same challenge as above.	

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

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		attending local meetings and events.	attending local meetings and events.	attending local meetings and events.	
Provide office furniture and equipment		Ongoing	Ongoing	Ongoing	
Europe and Eurasia					
Kazakhstan E. Toledo					
Conduct baseline GMP assessments of select anti-TB medicines manufacturers					
Conduct baseline GMP assessment of four manufacturers		Assessments will be conducted in Q2	Awaiting mission approval	Kazakhstan MOH/Pharmaceutical Committee stated that only 1 out of 4 manufacturers have confirmed that they are ready to work with PQM; that manufacturer is scheduled to meet with PQM at USP HQ in Aug to discuss their new facility layout and other critical documentation. Due to the facility construction, an assessment will not occur until late Q4.	
Present findings to USAID and stakeholders		Findings will be presented in Q2	Awaiting mission approval		
Provide technical assistance to promising companies to improve their GMP compliance					
Provide TA to select mfrs to improve their GMP compliance		Planned for Q2	Awaiting mission approval		
Assist manufacturers in preparation and submission of dossiers to WHO					
Assist manufacturers with dossier prep and submission to WHO		Planned for Q4			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Russia K. Burimski					
<p>In September 2012, USAID was requested by the Russian Government to cease its activities in Russia and close out all activities by December 31, 2012. A final report on the PQM Program in Russia (September 18, 2009-September 30, 2012) was developed and submitted to USAID.</p> <p>PQM worked with three Russian second line anti-TB medicines manufacturers—Sintez (Kanamycin and Levofloxacin), Pharmasintez (PAS and Prothionamide), and Akrikhin (Prothionamide). In December 2012, PQM conducted a second audit of Sintez to provide recommendations on improving GMP compliance and assist in dossier compilation. Sintez provided 9-months stability study data. Also, PQM conducted teleconferences with Pharmasintez and meetings with Akrikhin to discuss current issues, progress, and next steps.</p> <p>PQM informed the TB dispensaries/institutes that carried out the Minilab MQM project that support for the project through PQM is no longer available.</p> <p>Two Raman spectrometers were purchased by PQM and delivered to the Roszdravnadzor lab. Roszdravnadzor requested that PQM provide technical assistance on establishing the Raman spectral database for anti-TB medicines and conduct training on Raman spectroscopy for MQCL staff.</p> <p>PQM provided TA to Roszdravnadzor regional MQCLs in ISO 17025 accreditation and WHO PQ. In October 2012, PQM supported an accreditation assessment by ACLASS, an internationally recognized accrediting body, for the lab at Rostov-on-Don. As a result of the assessment, the Rostov-on-Don MQCL was awarded accreditation by ACLASS for seven laboratory tests. It is the first MQCL in Russia to receive ISO 17025 accreditation.</p> <p>At the request of Roszdravnadzor, PQM conducted training courses on microbiological aspects of medicines quality for MQCL staff in October. The training courses were held at the newly established MQCL in Saint Petersburg. Three training courses were developed and translated into Russian. Fifteen individuals representing eight regional/federal district labs participated in the training courses.</p>					
Latin America and the Caribbean					
Amazon Malaria Initiative V. Pribluda					
Strengthening quality assurance (QA) and quality control (QC) systems					
<i>Build capacity to perform basic testing</i>					
Conduct regional seminar in Nicaragua (w/Honduras) on 3-LA & basic tests of AMLs			Coordination with Nicaragua's personnel postponed because of a change in sanitary authorities. If a response is not received, funds will be transferred to support implementation of 3-LA in another AMI country.	At the April AMI Steering Committee Meeting (SCM), PQM suggested suspending activities in Bolivia and Nicaragua due to lack of country response and transferring support to Ecuador; suggestion was subsequently approved.	
Procure Minilab [®] for Nicaragua			See above.	See above.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct regional training in Bolivia for Bolivian and Nicaraguan staff on basic tests for AMLs			See above. Training may be performed for Bolivia personnel in coordination with personnel of another AMI country.	See above. In addition, all USAID activities in Bolivia were suspended as of May 2013.	
<i>Build capacity to perform testing according to registration methodologies</i>					
Host an intern at USP for Suriname OMCL staff focusing on pharmaceutical analysis		Discussions were held with the Suriname OMCL Director regarding the scope of the activity and 2 potential candidates were identified	The scope and objective of the internship along with the detailed curriculum were developed.	Due to timing conflicts, Suriname interns will travel to USP by the end of Q4 or beginning of FY14 Q1	
Conduct regional training for compendial analysis of Artemether Lumefantrine FDC for Brazil, Colombia, Ecuador, Guyana, and Suriname			Training is scheduled for June in Colombia. The training agenda was developed by PQM and approved by the host lab.	Training was held in June for 10 participants. All training objectives were met, and PQM was also able to include training on Lumefantrine impurity analysis.	
<i>Implement Three-level Approach for sustainable medicines quality monitoring (MQM) activities throughout the supply chain</i>					
Help Ecuador develop and implement guidelines and SOPs for 3-LA for new regulations				Coordinated a visit in July to finalize regulations that include the 3-LA and to plan MQM activities. Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) is the new National Regulatory Authority, splitting from the former National Institute for Hygiene and Tropical Medicine.	
Finalize MOU between Guyana stakeholders; develop normatives and			Participated in a supply chain workshop in Guyana and presented	An advanced draft of the MOU has been finalized and is currently under	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
documents for 3-LA; get MOH concurrence			the 3-LA; met with stakeholders to advance the completion of the MOU.	review by Guyana stakeholders.	
Present 3-LA for AMLs at NMCP meeting w/ANVISA and LACEN's representatives			In discussions with the head of the NMCP, it was agreed that the best way to pursue this will be to send ANVISA a short document in Portuguese describing the 3-LA and success stories of implementation in LAC		
Increasing the Supply of Quality Assured Medicines					
<i>Support Farmanguinhos to attain WHO prequalification for Artesunate/Mefloquine (ASMQ) FDC Tablets</i>					
Conduct mock pre-audit of ASMQ FDC tablets; provide TA as needed		PQM performed mock pre-audit in Nov 2012. Next steps towards WHO prequalification were established.	ASMQ has been included in the list of medicines that LAC countries may purchase through the Strategic Fund. This inclusion was based on ANVISA GMP certification, for which PQM provided TA. The inclusion is conditional for one year and continuation requires WHO prequalification for ASMQ.		
<i>Increase accessibility to USP and Minilab reference standards through PAHO's Strategic Fund</i>					
Establish a means for countries to purchase USP/Minilab [®] RS using PAHO Strategic Fund		Initial contacts were made with PAHO. A meeting to discuss implementation is planned for Q2.	PAHO stated that it might be possible for countries to purchase USP and Minilab [®] RS through the Strategic Fund, with the pricing agreed between USP-	USP confirmed that under TAP, countries can purchase RS through any procurement process available at PAHO. PAHO is currently evaluating the appropriate mechanism to	

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		Q1	Q2	Q3	Q4
			TAP and the countries. The feasibility and logistics for this need to be discussed at USP.	implement the procurement of USP RS by the countries.	
Combating substandard and counterfeit medicines					
<i>Evaluate the quality of malaria medicines in decentralized areas</i>					
Coordinate with local authorities to study MQ in Peru decentralized areas w/new 3-LA regs			DIGEMID, Peru's MRA, included the 3-LA in regulations that will be sent for approval; began coordinating with DIGEMID for a study in several regions from the Macroregion Oriente.	PQM will attend a planning meeting with country stakeholders to be held in Peru in August.	
Guatemala V. Pribluda Remaining Activities from FY 11 funding for FY 12 activities					
Strengthening Quality Assurance (QA) & Quality Control (QC) Systems					
<i>Improve processes of evaluation of medicines' quality certificates for purchases made by the Ministry of Public Health and Social Services</i>					
Hold workshop to discuss practices in place, identify changes to be made in the required documents, and define the SOPs to be developed		<u>Q1: Completed</u> In Dec 2012, workshop held for 22 staff from the Medicine Regulatory Authority, the Logistics Department of the Ministry of Health, the Official Medicines Control Laboratory, the Vice-Ministry of Hospitals, and decentralized Departmental Health Offices.			
<i>Building QC capacity</i>					
Conduct training on Minilab use and implementation of the three-level approach for the quality control of medicines.		<u>Q1: Completed</u> In Dec 2012, training delivered to 24 staff from the Medicine Regulatory Authority, Logistics Department of the Ministry of Health, the Official Medicines Control Laboratory, the Vice-Ministry of Hospitals, and decentralized Departmental Health Offices.			
<i>Implement QC activities in decentralized areas</i>					
Conduct a pilot study to evaluate the quality of medicines in the private and informal sector		<u>Q1: Protocol development and sampling completed. Medicines collected are being analyzed at the OMCL.</u> The San Pedro Sacatepéquez municipality, in the San Marcos Department, was selected for the study. In Nov 2012, 74 samples (26 from the informal market) were collected, including antibiotics, analgesics, and anti-inflammatory products. Medicines were delivered to the OMCL, which will perform analysis according to the			

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		Q1	Q2	Q3	Q4
using the 3-level approach		<p>three-level approach.</p> <p><u>Q2: Level 1 and 2 analyses have been completed.</u> 5 samples failed disintegration (4 metronidazol and 1 trimetoprim/sulfametoxazol) and 1 failed visual and physical Inspection (paracetamol-acetaminophen). 4 samples (1 Erythromycin Estolate and 3 Prednisone) were not analyzed because there is no methodology in the Minilab®. 17 samples will be analyzed by compendial methods (Level 3). USP standards were sent and received at the lab.</p> <p><u>Q3: Level 3 compendial analysis at the OMCL.</u> 18 samples sent for analysis. 2 samples failed, one that previously had passed level 2 testing and one that had failed. The only remaining sample (Erythromycin Estolate) is currently being analyzed.</p>			
Guatemala V. Pribluda					
Strengthening Quality Assurance (QA) & Quality Control (QC) Systems					
<i>Strengthen the legal and regulatory framework</i>					
Review laws and regs about medicines quality and responsible agents		Reviewed regulations and guidelines and offered suggestions for changes to quality requirements and QC of medicines during procurement by MoH at the Dec 2012 workshop	Sent suggestions for the Certificates of Analysis, which will be requested for all medicines purchased by the MoH.		
<i>Building regulatory capacity</i>					
Assess the capabilities of the DRCPFA					
Upgrade DRCPFA's registration software			Contract with consultant signed. Installation of new software and transfer of information initiated.	IT equipment and software required for upgrade purchased. Phase 1 of 5 of the installation process finalized; phase 2 to be completed in August.	
<i>Build capacity to perform quality control testing in compliance with internationally recognized standards</i>					
Follow-up on CAPAs from previous UM-LNS assessments			CAPAs to observations received and reviewed. Follow up will be done by CNCC staff during	Follow-up on CAPAs and re-assessment of the lab performed in April.	

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		Q1	Q2	Q3	Q4
			training (see below)		
Perform a mock-audit of UM-LNS to assess readiness for WHO PQ/ ISO accreditation					
Conduct training on Uncertainty Measurement			Training scheduled for April 2013; agenda developed in coordination with CNCC.	Training delivered in April.	
<i>Evaluate the quality of medicines in the private and informal sector</i>					
Conduct pilot study of select medicines quality from private & informal sector using 3-LA			Coordination for protocol development and logistics initiated by virtual conference with all relevant stakeholders (DRCPFA-MRA; DAS and Regional Hospital from Huehuetenango, PQM consultant). Agreed that Minilab® will be transferred from the UM-LNS to the DAS	A list of medicines proposed by the DAS and the Regional Hospital from Huehuetenango sent to the DRCPFA-MRA for evaluation. Study protocol is being developed. This is the first time that medicines sampling for routine MQM will be performed at dispensing sites; to avoid shortages, the DRCPFA is assessing ways to replenish the sampled units.	
<i>Strengthen DRCPFA capabilities to ensure manufacturers comply with cGMP</i>					
Conduct Current Good Manufacturing Practices (cGMP) training for Inspectors			Training scheduled for June 2013; list of topics for training identified.	GMP training workshop delivered to DRCPFA-MRA personnel in Guatemala City in June; the training included a visit to a local manufacturer. Good Storage and Distribution Practices (GSDP) training	

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		Q1	Q2	Q3	Q4
				workshop delivered in Guatemala City in June; the training included a visit to a Ministry of Health storage facility.	