

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

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Common Agenda	K. Chibwe				
Increase awareness about the importance of medicines quality					
Attend/present at national, regional, and int'l conferences		<p>Four presentations were given by PQM staff:</p> <p>Dr. Lukulay presented at the AAPS lunch in Chicago, IL in Oct, the "Global Forum on Pharmaceutical Anti-Counterfeiting" in DC in Nov, and the ASTMG Meeting in Atlanta, GA in Nov</p> <p>Dr. Chibwe presented to the Library of Congress in DC in Nov</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; Dr. Lukulay gave an interview on counterfeits for the Care2 News Network</p>			
Pursue opportunities to advocate through the Voice of America		<p>In October, Dr. Patrick Lukulay was a panelist on the VOA TV2Africa daily magazine, In</p>			

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		Focus, addressing public health and economic aspects of poor quality medicines.			
Produce up-to-date information about current issues in medicines quality					
Collect and publish reports of incidents of poor-quality medicine use	M McGinnis	26 reports were added to the <i>Media Reports on Medicine Quality</i> ; there were 3,993 website hits			
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			
Support regional approaches and networks					
Contribute to NEPAD's "Institutionalization of Regulatory Training Programs in Africa using Existing Regional Structures" Technical Working Group (TWG)		Dr. Karim Smine presented at the first meeting of the African Medicines Regulatory Harmonization TWG on Regulatory Capacity Development in Africa held Nov 2012 in South Africa.			
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	Prototype developed – to undergo optimization			
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			

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		<p>capsules.</p> <p>TA continues to manufacturers in different stages of compliance with WHO PQ including Phapros, Indofarma, Dong-A, Arterium, Zhejiang Hisun Pharma, Shalina, Deurali Janta Pharma, Akrikhin, Simpex, Abbott, Sintez, and Farmasintez; Additional TA visits scheduled for next quarter: Korea United Pharma, Arterium, Phapros, Sandoz, and Indofarma</p>			
– To manufacturers currently in PQM pipeline		<p>Currently in PQM pipeline: Concept Pharma, Macleod's, Arterium, Zhejiang Hisun, Dong-A Pharma, Varichem, Simpex Pharma, Deurali Janta Pharma, Korea United Pharma, Abbott, Lloyd Labs, Hizon, Shalina, Humanwell, Sintez, Sandoz, Akrikhin, and Farmasintez</p>			
– To manufacturers on preparing dossiers		<p>Dossier assistance is being provided to Arterium, Zhejiang Hisun, Shalina, Dong-A, Korea United Pharm, and Simpex</p>			

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		Q1	Q2	Q3	Q4
– With GMP audits and support until products are PQ'ed		GMP assessment was performed for Abbott's CMO (Akorn); mock inspection was also performed at Hisun Pharma			
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			
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			
– To API mfrs in PQM pipeline		Total is now 11: Zhejiang Hisun, Shanghai Fosun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Shengxue Dacheng Pharma, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem			
– To new mfrs on dossiers		Zhejiang Xinhua Pharma			
– With GMP audits and support until products are PQ'ed		EnzyChem, Zhejiang Hisun Pharma, NCPC Huasheng, Hebei Shengxue Dacheng'			
Participate in GDF and WHO meetings with mfrs to discuss PQ		Attended meeting with WHO PQ team in Geneva			

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		Q1	Q2	Q3	Q4
Complete development of Minilab [®] test methods for SL-ATBs		Developed and published methods for Clarithromycin, Kanamycin, and Ofloxacin			
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)			
Reduce the prevalence of substandard and counterfeit SL-ATB medicines					
Develop USP monographs for Prothionamide and Terizidone		In progress			
Conduct quality monitoring for SL-ATBs		In progress			
Develop the API bank concept and engage FPP manufacturers					
Develop the API Bank concept; identify/engage FPP producers to manufacture FPPs for GDF		Two FPP contract manufacturers have been identified and meetings were held to discuss potential development for Capreomycin and Kanamycin. FPP prices have been negotiated to support GDF.			
Malaria		P Lukulay			
Conduct studies to assess the diversion of antimalarial medicines from public to private sector					
Adapt study protocols for antimalarial MQM		Protocol developed			

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study in new countries					
Conduct four new studies		One antimalarial monitoring study is underway in Congo Brazzaville.			
Develop reports and disseminate results					
Conduct follow-on studies					
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			
Develop sampling strategy and protocol; identify locations		Study protocol has been finalized and partners as well as USAID/Liberia have approved it; study will begin on January 28.			
Travel to sites and conduct survey					
Procure samples and generate reports					
Develop monograph for Dihydroartemesinin-Piperaquine FDC					
Verify analytical methods					
Conduct method validation					
Characterize API and include in USP MC		PQM has identified the Italian company that is the innovator for DHA/PP and obtained their approval to provide background analytical method information as well as API to be			

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		characterized by USP for the purpose of developing reference standards.			
Develop Minilab[®] methods for Dihydroartemesinin-Piperaquine FDC					
Develop screening method		In progress. API has been obtained for analytical methods development.			
Validate analytical methods					
Publish method in manual					
Conduct quality control tests on antimalarials from developing countries					
Obtain samples of medicines at request of PMI team and test		No samples have been requested for testing.			
Maternal Health and Child Survival E Toledo					
Support selected United Nations Commission medicine manufacturers					
Conduct GMP baseline assessment of selected mfrs; present findings to USAID, stakeholders		GMP TA visit to Nepal Chlorhexidine manufacturer scheduled for Jan 2013			
Provide TA to mfrs of promise to improve GMP compliance		TA will begin for Nepal manufacturer in Q2, following assessment			
Conduct quality testing of select UN commission medicines		Chlorhexidine samples were procured from manufacturers in Nepal and India; will be tested in Q2			
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			

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		Q1	Q2	Q3	Q4
		manufacturers in Ghana and 1 in Kenya toward GMP compliance			
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			
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			
Assist National Malaria Control Program in developing a quality assurance policy for antimalarial medicines and diagnostics					
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			

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		USAID; concept paper supporting the establishment of technical committees for registration and licensing of foods and medical products is being developed.			
Strengthen FMHACA's registration and licensing system					
Identify critical areas where PQM can provide TA to Product Registration & Licensing Directorate		Developed GMP inspection service fee direct payment procedure for FMHACA; completed training material preparations and developed basic GMP principles for FMHACA staff.			
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.			
FMHACA to determine directorate to manage the system					
Support physico-chemical lab to maintain the accreditation 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			

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		dissolution testing at EDQM lab; assisted in purchasing lab supplies for the microbiology lab.			
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 Enresol Australia; PQAD condom analysts were trained at FHI360 lab in Thailand.			
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			
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					
Select sentinel areas, identify activities, set timelines					
Conduct PMS					
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		Feedback on the GMP compliance report			

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OI medicines mfrs		<p>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 road map.</p> <p>A confidentiality agreement for the direct support of Cadila Pharmaceutical (Ethiopia) for WHO PQ was signed</p>			
Identify activities to be supported, set timelines and expected outcomes					
Improve capacity and skills of local OI medicines manufacturers to ensure that their products and manufacturing sites comply with GMP					
Use results of GMP audit to identify gaps of local mfrs in compliance					
Select gaps most easily addressed w/PQM TA					
Provide TA to address select gaps & promote GMP compliance					
Monitor and evaluate program implementation					
Develop monitoring & evaluation tool					
Conduct monitoring & evaluation of program implementation					
Ghana	R. Okafor				

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		Q1	Q2	Q3	Q4
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			
Conduct two rounds of MQM at selected sites for testing					
Conduct confirmatory testing at FDB lab and CePAT					
Conduct onsite evaluations of selected sentinel sites					
Promote enforcement actions based on data					
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 Q2			
Procure equipment and supplies necessary for ISO accreditation		Provided standards for equipment qualification/maintenance; provided list of key equipment procured and at site			
Train staff on new equipment as needed in lab and at CePAT		Training planned for Q2			
Facilitate assessment audit and provide TA with CAPAs					
Collaborate with FDB and other stakeholders in the local pharmaceutical industry to build capacity for GMP improvement					
Conduct baseline GMP assessment of local manufacturers					

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		Q1	Q2	Q3	Q4
Conduct basic GMP training for local manufacturers					
Support inclusion of FDB data in the PQM MQDB, analyze trends to provide a basis for informed decision-making					
Support data entry and develop statistics using MQM data		To be entered in Q3 upon completion of MQM			
Sensitize the public to the dangers of substandard and counterfeit medicines through IEC activities					
Facilitate dissemination workshop for media, public re CSM findings					
Provide FDB with resources to produce awareness-raising materials					
Kenya	L El Hadri				
Continue strengthening medicines quality monitoring beyond sentinel sites					
Conduct fourth round of MQM; provide training on Minilab, sampling strategies, and reporting to the new staff and refresher training to team leaders		MQM planning activities are ongoing; Minilab supplies will be delivered by Feb 2013			
Conduct supervisory and M&E visits to sentinel sites					
Confirm validated samples at NQCL					
Provide TA to NQCL on using pharmacopeial methods to test failed samples, samples with reported ADEs, and any sample collected from refugee camps					

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Continue to promote regulatory actions by sharing MQM data					
Promote efforts to support enforcement actions by PPB based on data					
Share data w/PPB, DOMC, and other stakeholders to raise awareness		<p>NQCL completed confirmatory testing on nine quinine sulfate products; two failed and the results were submitted to DOMC and PPB for action.</p> <p>A report on the second and third rounds of MQM activities will be shared at a stakeholders' meeting in Q2.</p>			
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 (IPT)		NOMCOL charter was established; Ciproflaxin was the molecule agreed upon to be tested in ILP.			
Review data of the IPT and provide guidance to improve testing techniques					
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					

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Assist NQCL in submitting their ISO 17025 application to SANAS		First part of the ISO 17025 application submitted to SANAS			
Review NQCL QMS documentation and quality manual		NQCL quality manual revised and corrections / suggestions for improvements submitted to NQCL			
Assist NQCL in starting the process of SANAS pre-audit					
Assist NQCL in addressing the major and minor findings					
Liberia	L El Hadri				
Continue building the capacity of the Quality Control Laboratory					
Provide lab supplies and reagents needed to conduct Minilab and compendial testing on antimalarial, ARV, and OI medicines		Needed supplies will be delivered in Q2			
Provide advanced training in compendial methods focused on Good Laboratory Practices, according to international standards		The training is scheduled for Feb 2013			
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			
Procure a power stabilizer, fuel, and					

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lubricants for the generator procured by LMRHA					
Assist the lab in repairing the water purification system		Lab supplies procured to repair the system will be delivered in January 2013; installation will be completed in Feb 2013 Other lab supplies procured for the lab include: Minilab RS to test Ciprofloxacin 250 mg Sulfamethoxazole/Trimethoprim 100/20 mg 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			
Continue assisting LMHRA in strengthening its regulatory capacity					
Strengthen LMHRA inspection functions					
Strengthen LMHRA medicines registration system					
Support NDS, LMHRA, and major health programs in monitoring the quality of essential medicines and promote regulatory actions					
Develop MQM protocol for sampling strategies, list of meds; define roles, responsibilities					
Select sampling sites in 1-2 counties					
Conduct one round of sampling and testing of essential medicines					

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		Q1	Q2	Q3	Q4
Provide Minilab [®] supplies & reagents; NQCL supplies & RS					
Conduct M&E visit to sentinel site, NQCL					
Draft and share reports with stakeholders					
Promote LMHRA taking enforcement actions based on MQM data					
Mozambique	R. Okafor				
Strengthen the capacity of the National Laboratory for Medicines Quality Control					
Strengthen quality management capacity by training the staff		Staff trained on Karl Fischer and received refresher training on basic HPLC			
Procure and install equipment and supplies		Procured and shipped reagents, lab supplies, and reference standards; ordered International Pharmacopeia; obtained quotes for major equipment			
Assist LNCQM to refine strategic plan for ISO accreditation/WHO PQ		Strategic plan for ISO written; will be discussed with the head of the PD and new director of LNCQM			
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			
Establish an IEC campaign to inform public about CSMs		To be performed Q2-Q4			

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Coordinate activities between LNCQM and ARV manufacturer		Discussion meeting planned with head of PD, USAID, and SMM			
Support the MQM program					
Extend MQM to 2 new sites; conduct 2 rounds MQM sampling, testing		Sites identified; first round to start in March			
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			
Support DF efforts on enforcement actions based on MQM data		Proposal to the head of the PD to be discussed during visit in February			
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>			
Monitor and evaluate					

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MQM activities at selected sentinel sites and share pharmacovigilance tools with the MCR of each region					
Present MQM results and promote DPM regulatory actions		MQM results (2011 and 2012) will be presented at a meeting with relevant stakeholders and MCRs in Q2			
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			
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			
Continue strengthening the capacity of LNCM and guide the lab toward ISO 17025 accreditation					
Assist LNCM in participating in NOMCOL inter-laboratory testing (ILP)		NOMCOL charter established; Ciproflaxin was the molecule agreed upon to be tested in ILP.			
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.			

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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.			
Review the SOPs drafted by LNCM staff		Using SOP template provided by PQM, LNCM submitted 20 SOPs, which are under review by PQM.			
Assist LNCM in finalizing managerial and technical documents		Planned for Q2			
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			
Assist LNCM to prepare additional SOPs and train staff in analytical tests					
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		In discussions with MRAs in GMS to adapt			

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protocols to improve strategies & techniques		protocol			
Help GMS partners conduct 2 MQM rounds in hot-spot border areas using new protocols		Planned for Q3			
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			
Train Mahidol GMP-compliance faculty on WHO PQ process		Planned for Q4			
Support Chula PTSC to conduct a regional workshop on analysis of DHA/PIP, AVQ/PGN		Planned for Q4			
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			
Support investigations on timely reporting and enforcement with WHO-INTERPOL		Planned for Q4, after obtaining the results of the comparative study of AML quality			
Disseminate findings of investigations and report data to MQDB		Planned for Q4			
Participate and present data at relevant mtgs		Presented at Annual Consciousness on CSMs in the Philippines in Nov and at the 2012 Malaria Conference in Australia in Oct/Nov			

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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			
Submit final curriculum for ratification by responsible agency		Panned for Q3			
Field-test the new curriculum at two Pharmacy schools		Planned for 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			
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.			
Burma	S. Phanouvong				
Establish a formal presence in Burma through an MOC with Ministry of Health or Food and Drug Administration and hire a country consultant to help operationalize PQM activities					
Consult with relevant partners for pragmatic		No tangible progress made due to political			

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advice on establishing an MOC with MOH		sensitivities and restrictions. An office space in Yangon will be established under an agreement with CAP-Malaria.			
Recruit a country consultant		Recruitment of a country consultant reached final stages, but the candidate was hired by another NGO; recruitment has to start from scratch again.			
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.			
Train lab staff to test A/L , DHAP/PIP FDCs		Planned for Q2-3			
Conduct program implementation review and develop a strategic document for improving the quality of essential medicines for Burma					
Hold national mtg to present MQM data; document strategy for proposed improvement		Planned for Q4			
Cambodia E. Yuan					
Improve detection of poor-quality medicines, sustaining activities in 12 established sentinel sites while transitioning program ownership to the Cambodian government					
With DDF begin pilot in four sites to form, train teams to oversee transition process		Held initial discussions with DDF-MoH on MQM phase-out project to seek their cooperation in jointly developing ways to keep existing operations sustainable. PQM will visit Cambodia in Feb to meet with			

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		DDF-MoH to discuss strategies.			
Coordinate with GFATM, JPMA, WHO to streamline PMS; identify other funding		After approaching JPMA and WHO in Cambodia, there is no progress.			
Maintain essential PMS activities at 12 sites during transition		MQM activities were temporarily held off because funding from GFR6 is on hold. Confirmatory testing is ongoing; preliminary results were released showing there were no failed samples out of 72 tested.			
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.			
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.			
Establish/strengthen tie between MQM and enforcement actions		Continuous collaboration with IMC/DDF/MoH to support inspections of			

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		the sentinel sites and promote appropriate enforcement actions.			
Continue strengthening PQM/IMC efforts on enforcement actions		Supported annual IMC meeting held in Dec.			
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.			
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			
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.			
Strategically introduce "systematic steps" to strengthen DFF QA/QC		Provided TA to DDF/MoH to develop National Guideline for Pharmacy Practitioners			
Develop local expertise in QA/QC, medicines regs by expanding		Local consultant met with the Dean of Faculty of Pharmacy of Int'l Univ			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
pharmacy curriculum		<p>to ask for permission to conduct an evaluation of the medicines QA/QC and regulation syllabus; a meeting with the Univ of Health Sciences is planned for Q2.</p> <p>Questionnaires are being developed to survey final-year pharmacy students on their QA/QC knowledge.</p> <p>After BREMERE's inauguration, PQM has collaborated with DDF/MOH to prepare for the Feb meeting to be held in Cambodia; Cambodia is co-chair.</p>			
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					
Collaborate with PAC to publish bulletins, newsletter and conduct educational workshops					
Introduce BREMERE; move countries toward timely reporting and enforcement actions		In collaboration with PQM, DDF-MoH will host the meeting to kick off the BREMERE action plan in Feb 2013.			
Indonesia	S Phanouvong				
Maintain existing technical assistance to TB medicines manufacturers to obtain WHO prequalification for selected TB medicines					
Support first-line ATB		Provided TA to Phapros			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
mfrs (Indofarma, Phapros, Kimiafarma) toward WHO PQ		<p>and Indofarma while Kimiafarma dropped out due to lack of commitment to address critical observations found during a facility inspection. A private company, Sandoz Indonesia, has recently begun working with PQM.</p> <p>Phapros has completed about 90% of CAPA items recommended, invested in upgrading some manufacturing equipment, and renovated the solid dosage form production plant which is ready for PQM inspection. The equipment and process validation and dissolution profiling of its reformulated products (2 FDC (RH) and 4 FDC (RHZE) have been completed. A pilot BE 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>			

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		Q1	Q2	Q3	Q4
		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.			
Encourage mfrs of levofloxacin tabs and kanamycin powder toward WHO PQP		No progress			
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		5 Minilabs were provided and training conducted; additional RS and supplies were purchased and shipped. In Oct 2012, an action plan to implement the 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 USP.			
Open a PQM office in Jakarta; recruit GMP technical staff		Potential local partners (Indonesia Univ. and BaliExpat Services) identified to assist in this			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		regard			
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.			
Follow up inspections and support two to conduct BE studies		A WHO consultant conducted an inspection as part of educational audit training of NA-DFC staff in BA/BE in Nov 2012 and found a few minor observations which Equilab has already addressed. Equilab 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			
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.			
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			
Train investigators on sampling protocols		Planned for Q2-Q3			
Collect and test samples at NQCL-DF/ regional reference lab		Planned for Q2-Q3			
Analyze data and report		Planned for Q4			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
recommendations					
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			
Set up sampling team		Planned for Q3			
Conduct testing		Planned for Q4			
Write a report, disseminate to stakeholders		Planned for Q4			
Encourage NTP and NA-DFC to take action on failed ATBs		Will be on a case-by-case basis			
Expand MQM systems to cover antimalarial (AML) and antiretroviral (ARV) medicines					
Train staff of NQCL-DF & provincial QCLs on Minilab [®] , compendial test methods for select AMLs and ARVs					
Purchase reference products, solvents and reagents for Minilabs [®]		Planned for Q2			
Add 150 AMLs, 100 ARVs to ATB sampling & testing in field		Planned for Q3-Q4			
Conduct confirmatory tests at NQCL-DF		Planned for Q4			
Produce a combined report for ATB, AML, and ARV data		Planned for Q4 and FY14 Q1			
Encourage NA-DFC and NTP to take enforcement actions		ongoing			
Provide technical support to NQCL-DF toward renewing ISO 17025 accreditation with better, product-based scope					
Conduct ISO 1705 assessment; propose		Discussions initiated with the NQCL-DF			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
changes to scope and quality system		management who have agreed to change the scope			
Produce assessment report and CAPA recommendations		Planned for Q2			
Philippines E. Yuan					
Sustain the MQM activities in established sentinel sites					
Continue to support MQM at 6 existing sites plus 2 newly established sites on first line TB medicines quality checking		Communicated with the sites re: supplies, RS; processed Minilab orders for two new labs; supplied FDA satellite lab Davao with USP-NF, FCC; visited Davao and Malolos sites in Oct; attended meetings for Minilab updates.			
Expand MQM to include four SL-ATBs		Planned for Q2			
Expand MQM to include select antibiotics		Planned for Q2			
Improve pharmaceutical management and quality assurance systems at both the national and local levels					
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.			
Enhance capacity of the FDA through training and visiting scientist program					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
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.			
Provide training on areas identified through gap analysis and request from FDA.		PQM met with reps from academia, healthcare, pharmaceutical industry, and FDA in Nov to explore opportunity to form a BA/BE center.			
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 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.			
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			
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			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		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			
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			
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			
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			
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			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		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			
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			
Train staff and develop operational manual for national and south DI / ADR centers		Planned for Q2-Q3			
Help the national DI / ADR center identify int'l experts for GF R10		Planned for Q2			
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			
Disseminate final report to stakeholders		Planned for Q4			
Maintain country consultant to improve project coordination, implementation, and effectiveness					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support consultant's salary and misc. expenses for FY13		Local consultant actively involved in implementing PQM activities, meeting with partners, and attending local meetings and events.			
Provide office furniture and equipment		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			
Present findings to USAID and stakeholders		Findings will be presented in Q2			
Provide technical assistance to promising companies to improve their GMP compliance					
Provide TA to select mfrs to improve their GMP compliance					
Assist manufacturers in preparation and submission of dossiers to WHO					
Assist manufacturers with dossier prep and submission to WHO					
Russia K. Burimski					
<p>In September 2012, USAID was requested by the Russian Government to cease its activities in Russia and close out all activities by December 31, 2012. A final report on the PQM Program in Russia (September 18, 2009-September 30, 2012) was developed and submitted to USAID.</p> <p>PQM worked with three Russian second line anti-TB medicines manufacturers—Sintez (Kanamycin and Levofloxacin), Pharmasintez (PAS and Prothionamide), and Akrikhin (Prothionamide). In December 2012, PQM conducted a second audit of Sintez to provide recommendations on improving GMP compliance and assist in dossier compilation. Sintez provided 9-months stability study data. Also, PQM conducted teleconferences with Pharmasintez and meetings with Akrikhin to discuss current issues, progress, and next steps.</p> <p>PQM informed the TB dispensaries/institutes that carried out the Minilab MQM project that support for the project through PQM is no longer available.</p> <p>Two Raman spectrometers were purchased by PQM and delivered to the Roszdravnadzor lab. Roszdravnadzor requested that PQM provide technical</p>					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<p>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					
Procure Minilab [®] for Nicaragua					
Conduct regional training in Bolivia for Bolivian and Nicaraguan staff on basic tests for AMs					
<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			
Conduct regional training for compendial analysis of Artemether Lumefantrine FDC for Brazil, Colombia,					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Ecuador, Guyana, and Suriname					
<i>Implement Three-level Approach for sustainable medicines quality monitoring (MQM) activities throughout the supply chain</i>					
Help Ecuador develop and implement guidelines and SOPs for 3-LA for new regulations					
Finalize MOU between Guyana stakeholders; develop normatives and documents for 3-LA; get MOH concurrence					
Present 3-LA for AMs at NMCP meeting w/ANVISA and LACEN's representatives					
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.			
<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.			
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					
Guatemala	V. Pribluda	Remaining Activities from FY 11 funding for FY 12 activities			
Strengthening Quality Assurance (QA) & Quality Control (QC) Systems					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<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>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>Completed</u> In Dec 2012, training delivered to 24 staff from the Medicine Regulatory Authority, Logistics Department of the Ministry of Health, the Official Medicines Control Laboratory, the Vice-Ministry of Hospitals, and decentralized Departmental Health Offices.			
<i>Implement QC activities in decentralized areas</i>					
Conduct a pilot study to evaluate the quality of medicines in the private and informal sector using the 3-level approach		<u>Protocol development and sampling completed. Medicines collected are being analyzed at the OMCL.</u> The San Pedro Sacatepéquez municipality, in the San Marcos Department, was selected for the study. In Nov 2012, 74 samples (26 from the informal market) were collected, including antibiotics, analgesics, and anti-inflammatory products. Medicines were delivered to the OMCL, which will perform analysis according to the three-level approach.			
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			
<i>Building regulatory capacity</i>					
Assess the capabilities of the DRCPFA					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Upgrade DRCPFA's registration software					
<i>Build capacity to perform quality control testing in compliance with internationally recognized standards</i>					
Follow-up on CAPAs from previous UM-LNS assessments					
Perform a mock-audit of UM-LNS to assess readiness for WHO PQ/ISO accreditation					
Conduct training on Uncertainty Measurement					
<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					