PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Common Agenda					
Support global health initiatives by providing up-to-date information about current issues in drug quality and appropriate use					
Fine tune screening and testing protocol for medicine quality monitoring	A. Barojas	Harmonization team worked on finalizing "Guidelines to Establishing a Medicine Quality Monitoring Program" document and sent to select PQM staff for comments	Incorporated comments, finalized document, and sent it to USAID. PQM will implement this document and update it in 6-12 month cycles		
Evaluate alternative screening technologies for the detection of substandard and counterfeit medicines	K. Chibwe & D. Bempong			Procuring antimalarial samples to be used to evaluate Truscan (Raman handheld tool); evaluation should be complete in Q4	
Update and overhaul the DQI/PQM websites	M. Foster	Added PQM info to DQI landing page Designed PQM site and organization with USP-IT Added 13 new articles and 10 photos; updated 3 existing web pages and 2 AI reports; added or updated 3 resource materials	Continue to work with USP communications and IT groups to procure domain, organize website, create content and fix several broken links Added 6 new articles and 2 photos; updated 2 web pages and 1 AI report; added 2 resource materials	Continue to work with USP communications and IT groups to finalize content Created content for 7 landing pages, 3 new activities, and 23 descriptors; updated 9 activities and cross-referenced links to DQI site Created content and provided demographics for 23 countries and 2 initiatives Submitted 8 new articles and 5 photos; updated 2 AI reports and 1 page; added H1N1-2009 report and 1 resource	
Update and promote the Matrix of Medicine Quality Reports Affecting USAID-assisted Countries	M. McGinnis	Added 23 new reports Received 4,662 web hits Sent drug quality alerts to MRAs in relevant USAID-priority countries	Added 30 new reports Received 6,505 web hits Distributed at a Briefing for the House of Rep Foreign Affairs Subcmte on Africa	Added 28 new reports Received 2,378 web hits Distributed at Global Health Council annual conference	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Finalize e-learning modules on medicines quality assurance	A. Barojas	In progress	Updated outline; module content was sent to USAID for review	Awaiting USAID comments on latest submission	
Stimulate the interest of stakeholders in medicine quality					
Attend and present at conferences advocating public health issues	P. Lukulay		Made a presentation titled "The hunt for counterfeit/ substandard medicines" February 24 in Florida at the 5th Global Forum on Pharmaceutical Anticounterfeiting		
Tuberculosis (TB)	P Lukulay				
Reduce the spread of MDR- and XDR-TB through better access to second-line treatment					
Continue to provide technical assistance to manufacturers of second-line TB medicines identified in FY 09 seeking to obtain WHO pre-qualification		Evaluated UNILAB (Philippines) manufacturing facilities for Levofloxacin and Amikacin; briefed them on dossier requirements Continued to review dossier from Sintez (Russia) for Levofloxacin manufacturing	Reviewed Dossiers from: Sintez (Russia) Levofloxacin 500mg tablets and Kanamycin powder for injection; Unilab (Philippines) Levofloxacin 700mg tablets; Svicera (India) Capreomycin powder for injection, Ethionamide 250mg tablets, Levofloxacin 250mg tablets and Cycloserine 250mg tablets Sent comments to manufacturers to implement correctives actions	Continue TA to Sintez, Unilab, and Svicera toward prequal. PQM will visit Svicera in Q4. Svicera submitted Capreomycin powder for injection, Ethionamide 250mg tablets, Levofloxacin 250mg tablets, and Cycloserine 250mg tablets dossiers to WHO Prequal in June 2010.	
Liaise with GDF and WHO on behalf of USAID, especially with WHO Assessors and Scientific Working Group		Four PQM staff traveled to Geneva and met with the WHO Prequalification team to foster cooperation and collaboration between PreQ and PQM. Both WHO and PQM pledged to cooperate more closely.	Two PQM staff participated in a WHO dossier assessment workshop in Copenhagen, at the invitation of the WHO Prequalification team. PQM conducted a workshop for second-line TB manufacturers in Sao Paulo,		

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Brazil. Staff from WHO and GDF briefed the participants on requirements for prequalification. One company has committed to requesting PQM TA.		
Develop literature on PQM technical assistance for manufacturers and update PQM website with current information					
Finalize the development of two pharmacopeial monographs for Prothionamide and Levofloxacin and develop Minilab methods for two additional second line anti TB medicines		Global Pharma Health Fund contacted to develop the Minilab methods and invoice is being prepared.	Minilab methods for levofloxacin, moxifloxacin, and prothionamide were completed		
Hire full-time GMP specialist to focus on technical assistance for SLD manufacturers		Lead candidates identified; interviewed 3 candidates	Search opened for new candidate		
Collaborate with GDF to identify and provide technical assistance to additional SLD manufacturers					
Conduct operational research to assess the quality and availability of second-line anti-TB medicines in the public and private sector in select countries		One country identified in collaboration with GDF-(Ethiopia) as it is a high burden TB country.	Preliminary survey completed in Ethiopia shows that 4% of private pharmacies sell SLD without prescription		

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Malaria	**K. Chibwe**				
Promote cooperation on drug quality issues through a network of African medicine quality control laboratories (NAMCOL)					
Disseminate QAMSA report and review lessons learned			Press release issued in February WebEx held in March to promote QAMSA report; attended by 43 participants		
Promote cooperation on drug quality issues through NAMCOL		Letters seeking formal sign-off on NAMCOL network sent to directors of national QC labs of Ethiopia, Mali, Ghana, Senegal, and Uganda First proficiency testing using quinine sulfate awaiting final approval for NAMCOL members	Virtual forum concept developed and awaiting launch Sourcing for quinine sulfate identified in India. Two sign-offs on NAMCOL still outstanding	Quinine sulfate sourced, distributed to NAMCOL members for testing Kenya became the newest member of NAMCOL First proficiency training scheduled for Q4	
Create reference standards system for Africa			Ongoing	Audited the Kenya lab (WHO prequalified lab) Presented at the Kenya Pharmaceutical Society Meeting in Mombasa May 2010 on the Reference Standards System for Africa	
Maternal Health and Child Survival	E Toledo				
Prevent and treat childhood diarrheal illness					
Assist Shelys Pharmaceutical, Tanzania, in WHO prequalification process		Provided TA to Shelys Pharmaceutical (Tanzania) on WHO prequal queries related to dossier submission	Shelys (Tanzania) was inspected by WHO Prequal in February with non-critical observations. PQM is providing TA to address WHO GMP-related queries.	PQM visited Shelys in August to review WHO queries. Shelys is investing $200,000 to bring facilities to compliance as part of GMP corrective actions. PQM performed Dissolution profile for zinc tablets as par of dossier requirements on Biowaiver. PQM continues with TA support toward	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				prequalification.	
Assist DJPL, Nepal, in obtaining WHO prequalification of zinc product		Provided TA to DJPL Pharmaceutical (Nepal) on dossier prep prior to submission to WHO Prequalification Program	DJPL submitted dossier to WHO January 2010.	DJPL is working with WHO queries related to dossier. PQM continues with TA toward prequalification.	
Continue technical assistance to Zenufa, Tanzania, to achieve certification of compliance with Tanzanian cGMP standards				Zenufa agreed with Nutriset to manufacture Zinc tablets in Tanzania. Zenufa will prepare a dossier for Zinc Sulfate Syrup. PQM continues with TA support toward prequalification.	
Provide QC/GMP technical assistance to additional zinc manufacturers in Indonesia, India, or other priority countries				Traveled to Indonesia to provide TA in dossier compilation to Kalbe Pharmaceutical toward WHO prequal. During the visit, Kalbe and AED Indonesia requested TA in dossier compilation and GMP for Zinc Sulfate.	
Develop one pharmacopeial monograph on zinc acetate formulations				Zinc acetate syrup monograph donated by Cipla India was submitted and is in the pipeline	
Conduct medicine quality testing of zinc samples sent by UNICEF and other partners		Tested one zinc sulfate sample from UNICEF		Zinc samples will arrive in Q4	
Improve newborn health outcomes					
Conduct GMP assessment of chlorhexidine manufacturers for global and local supply		Conducted GMP assessment on Lomus Pharmaceutical (Nepal) for chlorhexidine manufacturing; briefed them on zinc dossier preparation	Provided TA to Lomus on dossier prep prior to submission to WHO	Visit to Lomus planned for Q4 or FY11Q1	
Develop a pharmacopeial				Activity is pending the results	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
monograph for chlorhexidine gel formulation				of suitability studies from Bangladesh	
SUB-SAHARAN AFRICA					
Benin	M. Hajjou				
Provide basic supplies necessary to conduct training			Supplies procured	Supplies delivered	
Conduct training in GPL and dissolution to strengthen NQCL capabilities			Planned for Q3	Training in GLP and Fourier Transform Infrared (FTIR) spectroscopy provided to 7 staff of NQCL	
Evaluate and monitor NQCL staff conducting dissolution testing of selected antimalarials; review testing report drafted by NQCL, provide recommendations				Each participant in the training will run an ID test on a sample using FTIR and provide a report to PQM for review.	
Ethiopia	A. Smine				
PEPFAR					
Strengthen DACA quality control lab capacities with training, equipment, planning, and move to new facility		– Trained 27 DACA analysts on HPLC and dissolution in Oct 2009 – Finalized key SOPs – One PQM staff member is assisting the lab for first two-week rotation in Jan 2010 – Prepared to purchase a power generator for new QC lab – Provided specialized lab design through PQM-hired consultant	– Made a list of all lab equipment – Finalized 13 SOPs and trained all lab staff on quality systems and basics of GC – Purchased a power generator for DACA's new facility – Signed MOU with DACA and Regional Health Bureau of Oromia – Made a database of all lab chemicals – Hired an architect to make ISO17025 design for the new lab – Two PQM staff did lab rotations in January and March	– Trained the DACA lab staff on quality systems and analytical methods – The implementation plan was revised by USP consultant and PQM staff – Specialized consultant completed the design draft of new DACA QC lab facility – Training for DACA lab on IR and QS planned for early Q4	
Strengthen DACA drug		Planned for Q2-Q3	– Drug registration	Conducted a training for	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
registration through assessment, training, and TA			assessment done – Training on drug registration with WHO will be done in April	DACA on GMP and drug registration, in collaboration with WHO	
Establish medicine quality monitoring program for ARVs and antimalarials		Planned for Q2-Q3	Planned for Q3	Part of the sampling has been done; MQM plan will be finalized early Q4	
Promote enforcement actions by DACA		Pending data	Pending data	Pending data	
PMI					
Establish Medicine Quality Monitoring program in Oromia region		– New teams established for sentinel sites – Equipment and supplies for sentinel sites purchased and received – Refresher training conducted in Jan 2010 – First round of 2010 will begin in Q2	– Equipment and supplies delivered for sentinel sites – Trained 15 staff on basic tests – Finalized the FY09 data report – First round will start in April	Completed the sampling and basic tests at five sentinel sites in Oromia region. Confirmatory tests are ongoing in DACA lab.	
Expand MQM to two sites outside Oromia region (depending upon success of first round).		Planned only if first round is well done	Pending the results of the first round, planned for Q4	Pending the results of the first round, planned for Q4	
Disseminate MQM data, raise awareness and promote enforcement actions		FY09 data shared with USAID and PMI partners	Pending FY10 data	Pending FY10 data	
Ghana	P. Lukulay				
Monitor medicine quality at 5 selected sentinel sites		– Purchased and sent necessary Minilab equipment – First round planned for Q2	Testing round to begin soon		
Increase awareness about drug quality issues and promote enforcement actions by FDB		P. Lukulay met with new CEO of FDB and obtained commitment for enforcement action			
Provide TA toward ISO accreditation					
Kenya	L. El Hadri				

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct a comprehensive assessment of the capability of PPB to test the quality of antimalarials		Conducted in-country assessment			
Establish post-marketing surveillance program with Minilab training in testing the quality of antimalarials		– Developed MQM protocol for monitoring antimalarials – Identified 5 sentinel sites – Procured 3 Minilabs – Provided supplies to conduct one round of MQM activities – Replenished supplies for 2 existing Minilabs	– Trained 14 staff on Minilab basic tests – Finalized and submitted MQM protocol to partners – Provided budget to carry out first round of testing in 5 sites – First round will begin in May 2010	– First round completed at sentinel site level – 536 samples collected from 5 sentinel sites – 26 samples failed Minilab basic tests; 94 were sent to NQCL for confirmatory testing	
Liberia	A. Smine				
Support development of LMRC legislation		– Organized two-day workshop with local stakeholders Nov 2009 – Finalized LMRA draft zero legislation	Legislation passed the Ministry of Justice and is being finalized	Legislation is now at the President's office and will soon be sent to Parliament to be enacted	
Strengthen quality control of antimalarial medicines		– Sent Minilab reference standards, supplies and sampling plan – LMRC staff will conduct sampling in Q2 – Testing planned for Q2	– Collected 300 antimalarials from Monrovia, Kataka, and Ganta – PQM trained staff from LMRC, MOH, Board of Pharmacy, and MCP on basic tests – PQM and trained staff tested 254 samples and drafted a report. – Provided all RS for testing – Purchased 2 air conditioners for LMRC – Testing of samples will begin soon	– Testing completed; data was disseminated to all stakeholders – Recommendations were made for LMRC to take quick actions based on the data	
Mali	M. Hajjou				
Strengthen the capacity		Procured laboratory		To strengthen LNS'	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
of the medicine quality control division of the LNS by helping plan QC testing, equip the lab, and provide TA on insecticides		supplies		capacity, training in FTIR was provided to nine staff from the lab. Small lab supplies were provided for the training.	
Establish a medicine quality monitoring/ postmarketing surveillance program with training, collecting and reporting of antimalarials		Procured Minilabs and laboratory supplies	Organized a training workshop to establish medicine quality monitoring at 8 sites; 21 participants were trained in basic tests and sampling procedures	Refresher training in basic tests was provided to the teams at the sentinel sites. Minilabs were installed and resources provided to conduct one round of sampling and testing	
Strengthen the pharmacovigilance program by facilitating training for a CNRP staff member and by providing reference books and technical assistance		Finalized and disseminated reporting form		Training for one CNRP staff is planned for Q4 at the Morocco Center for PV; Reference materials will also be sent in Q4	
Rwanda	A. Smine				
Assess Rwanda's existing medicine quality control systems and capacity and recommend possible improvements		– Conducted assessment of Rwanda's QA/QC capacity – Proposed work plans for PMI and PEPFAR			
Equip and ensure repairs of NUR Faculty of Pharmacy QC lab and provide reagents needed to test antimalarial medicines		Planned for Q2		Hired a local supplier to deliver all needed reagents for testing antimalarials As possible, repairs of the lab equipment will take place during training	
Train NUR QC Lab staff, MOH-PTF pharmacists, and a local manufacturer in key QC methods		Planned for Q2-Q3	Procured all materials for training on HPLC, TLC, and dissolution	– Shipped all training materials – Hired a local supplier to deliver all needed reagents for the training – The training is planned	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				for Q4. Delays were caused by difficulty in finding a local supplier for chemicals and the time needed to get them into Rwanda	
Build capacity through QC testing of antimalarials from private and public sectors by NUR QC Lab and PQM evaluation		Planned for Q2–Q4			
Senegal	L. El Hadri				
Strengthen and expand national capacity for medicine quality monitoring of antimalarial, anti-TB, and antiretroviral medicine and oral contraceptives by providing equipment, supplies, and training		– Identified one sentinel site – Procured and delivered one Minilab – Provided supplies for MQM activities – Trained 24 staff in Minilab basic tests	– Revised sentinel site report for June-December 2009 round and provided comments – Summary of this report was submitted to USAID/Senegal – FY10 round will start May 2010 – Revised the new protocol to include role of family planning and to give mandate of MQM program to DPL – QC testing for oral contraceptive is ongoing at USP lab	– Sentinel site report for June-December 2009 round will be disseminated July 2010 – Budget submitted for 2010 Minilab program – USP RS delivered to LNCM – Funds to procure chemicals to LNCM provided – 4 columns will be delivered to LNCM by July 2010 – 2010 Minilab activities will be completed July 2010 – New protocol signed by relevant partners – MQM program under the supervision of DPL – QC testing for one oral contraceptive completed. The remaining QC testing will be completed in Q4.	
Provide information, education, and		Submitted report for 2007-2008 Minilab round	– Final report of 2008-2009 is under review	Report will be submitted by July 2010	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
communication on medicine quality through data reporting and communication campaigns			– Meetings held to discuss IEC activities for the upcoming communication campaign		
Strengthen pharmacovigilance system			– Pharmacovigilance action plan provided to USAID/Senegal – Preparation for PV workshop is ongoing	PV workshop agenda finalized and budget submitted. Workshop will be held July 2010	
Uganda	L. El Hadri				
Provide TA on antimalarial MQM by providing M&E guidelines to improve the implementation of the protocol; review data from the previous round of sampling and testing and assist in disseminating the report				Visit is planned in Q4 to ensure the implementation of the new protocol, monitor and evaluate Minilab activities on site, and review MQM data	
Strengthen the capacity of the NDQCL to test antimalarials		– Procured and delivered one dissolution tester – Procured one UV-vis spectrophotometer – Procured one printer and computer	– Provided training on installation and proper use of dissolution tester – Provided printer for dissolution tester – Installation of UV vis spectrophotometer is pending	Dissolution tester and UV-vis Spectrophotometer installed and training on proper use of equipment provided	
ASIA					
RDM-A Mekong Malaria S Phanouvong					
Obtain evidence-based data on antimalarial, selected antibiotics and HIV/AIDS medicines through a regional monitoring program					
Continue evidence-based data collection through existing medicine quality monitoring to support regulatory actions in the region	S. Phanouvong	– Laos collected and tested 232 samples (1 counterfeit) – Vietnam collected and tested 38 samples – Thailand collected 984 samples and tested 182	Laos FDD established a local team to organize the meeting Regional Efforts to Improve Medicines Quality in Southeast Asia: Accomplishments,	Laos contract agreement finalized. Thailand and Vietnam to finalize MOC for continuing MQM activities with collaboration between reg authority, national QC lab, and disease programs	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		with Minilab (11 failed so far) – Produced 2009 Annual Report with data summary of all countries; submitted to USAID/ RDM-A – Produced report on Vietnam data 2003-2009 and submitted to USAID/ Vietnam	Challenges and Future Strategies. 5,128 antimalarial samples and 3,021 antibiotics have been collected and tested by Cambodia, Laos, Thailand and Vietnam from 2005-2009.	with PQM support. (This activity is jointly funded by RDM-A TB, and AI)	
Strengthen national, provincial and district health authorities to provide timely reporting and share the medicines quality data that is routinely collected for in-country enforcement and regional action against violators					
Strengthen national, provincial and district authorities for effective regulatory action and enforcement in Laos, Thailand, and Vietnam	S. Phanouvong	Completed review of relevant regulatory enforcement current practices to develop SOPs	Drafted guidance document for taking regulatory and enforcement action against poor quality medicines and collected PQM input. Presented the document at the Regional Meeting and requested country input.	Incorporated comments into draft guidance document. Drafted 5-year strategy document on MQM (resulting from Laos regional meeting in Q20 Worked with Thai FDA Director of Drug Control division and BVBD Malaria Cluster, and BDN to finalize MOC for PQM-supported program, incl. MQM and taking effective action. Worked with Vietnam DAV, NIDQC, and NIMPE to finalize MOC for PQM-supported program, incl. MQM and taking effective action. (This activity is also funded by RDM-A TB)	
Intensify collaboration and data-sharing with relevant partners in the region for collective	S. Phanouvong	Data is being compiled by country	At the Regional Meeting in Laos, concrete ideas were discussed regarding information sharing. A	Concept for regional mechanism for enforcement action among national authorities discussed at	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
action			timely report on failed samples should be shared among relevant MRAs. Confirmed cases should be shared with WHO Rapid Alert System, and Interpol. PQM is creating a publicly accessible medicine quality database on the USP website which will be ready for internal review and testing by Q3.	Lower Mekong Initiative conference in Vietnam. Received USAID clearance to collaborate with INTERPOL and other enforcement agencies on counterfeit and substandard medicines. (This activity is also funded by RDM-A TB)	
Raise public awareness about the dangers of counterfeit and substandard medicines					
Re-edit public service announcements (PSAs) to meet country broadcast requirements (Laos, Vietnam, and Thailand) and get PSA cleared by relevant authorities in Cambodia, Laos, Vietnam, and Thailand; finalize regional documentary, and if possible produce a new documentary.	S. Phanouvong	– Documentary film proposal developed; budget awaiting approval from PQM. – Re-edits of PSAs completed. Cambodia PSA on hold indefinitely due to political issues. – Completed filming and editing *Combating counterfeit medicines on the frontlines in SE Asia*	- Revised proposal with budget sent to PQM for final approval. -Approval for PSAs to be broadcast in Laos and Thailand given by FDD and FDA. -Awaiting further funding sources to begin documentary -Awaiting further review of PSAs by Vietnam DAV	Written clearance from Laos authority obtained to broadcast PSAs in Laos. Verbal approval given by Director of DAV contingent on contract agreement with O2 TV, which can then expand to other stations as part of a national campaign. Verbal approval given by the FDA Drug Control Division to broadcast PSA in Thailand. (This activity is also funded by RDM-A TB)	
Support outreach activities in grass-roots community organizations to raise awareness about counterfeit/fake medicines.	S. Phanouvong	No progress	In Cambodia, a project to engage local Khmer artists to create a national poster campaign is underway. Meta House has hired the artists and had initial consults.	Pharmacide Arts Project of Cambodia exhibition opened in June at Meta House Cambodia Discussion of project expansion to Laos, Vietnam, and Thailand with support by PQM, US Dept of State, French Min. of Foreign	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Affairs, and private donors	
Submit an article on Cambodia/Thailand cross- border antimalarial medicines quality study to a peer-reviewed journal	S. Phanouvong	Completed rough draft of abstract, introduction, and methodology of article on Thailand	Revised the draft manuscript on Thailand. Request for countries' approval to disseminate and publish data on cross-border study was submitted and approval from Thailand was obtained. Awaiting approval from Cambodia.	Drafted, in partnership with the Thai study investigators, a manuscript for final internal review on Thai results for potential publication in peer review journal. Still awaiting formal clearance from Cambodia.	
Improve PQM regional approach and activity implementation through program review and information sharing with key stakeholders					
Organize a regional meeting of key partners in GMS countries to share medicines quality data; discuss lessons learned; revise sampling techniques as needed; and report recommendations for effective regional cooperation to combat SCMs	S. Phanouvong	Meeting is scheduled for March in Vientiane, Laos	Completed. A meeting was held March 29-31, with 55 representatives. A document on improving MQM in the region was drafted.	Disseminated trip report from meeting including drafts of "5-year strategy for GMS MQM program" and "Guidance on Enforcement" for country partners PQM regional activities presented in 'counterfeit and substandard medicines' session at the Lower Mekong Initiative meeting with partners, chaired by Admiral T. Ziemer of PMI. (This activity is also funded by RDM-A TB, OPHT and AI)	
Provide technical assistance to ensure the quality of all antimalarial medicines to be used in RDM-A funded clinical trials in the Mekong Subregion					
Collect and test antimalarial samples from study investigators or suppliers before (and 8 months thereafter) they are introduced to the USAID/RDM- A supported clinical trials	S. Phanouvong	Collected and completed tests of 4 antimalarials (arthemether and artesunate) from Cambodia's western border to support URC's efficacy trials in malaria containment zone in Cambodia	Requested by Clinton Foundation in Cambodia to test ACTs (artemisinin + piperquine) made by Holley Pharmaceuticals. These will be widely distributed near the Cambodia-Thai border. Communicating with Clinton how/when this can be carried out.	Identify antimalarial products of priority for analytical method development: DHA/PIP; and Atovaquone/Proguanil to be jointly developed by ANEQAM/Chulalongkorn Univ/NIDQC and PQM Consultant.	
Strengthen PQM technical leadership and collaboration with partners in the region through hiring new staff and south-south collaboration					
Recruit a lab technical	S.	Job advertisements placed	Held phone interviews	Asawin Likhitsup, PhD, was	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
consultant, based in the Mekong Sub-region to work closely with the existing Regional Consultant in Southeast Asia	Phanouvong	in Thailand; of 30 applicants, 3 were shortlisted	with 3 candidates. One candidate selected for in person interview in Thailand and Laos. Decision to be made in early Q3	selected and has been working since May. His office and lab space will be located at partner institution Chulalongkorn Univ. in Bangkok. (This activity is also funded by RDM-A TB, OPHT and AI)	
Support the Vietnam NIDQC in providing technical assistance to Laos National QC Lab (FDQCC) towards ISO 17025 accreditation	S. Phanouvong	Held Initial discussions	Arranged a visit to FDQCC by a NIDQC representative who participated in the Regional Meeting March 29-31 to lay out plans for assistance, including a visit of two QA personnel from NIDQC in June	NIDQC and FDQCC are working on a detailed action plan for TA. NIDQC to send experts to FDQCC in August to determine specific activities to be performed and guide FDQCC to compile necessary dossiers required by ISO. (This activity is jointly funded by RDM-A TB)	
Review and improve drug quality indicators for pharmacies to ensure the quality of medicines during the process of acquisition, storage, and handling					
Review most suitable pharmaceutical guidance documents, develop consolidated platform with indicators to ensure appropriate attention to medicines quality assurance	S. Phanouvong	Collected selected WHO materials to review for adapting and developing appropriate platform and indicators	Reviewed selected WHO materials and Laos Pharmacy “10 Indicators to evaluate retail pharmacy practice for ensuring the quality of medicines to be procured, stored, and dispensed.”	No progress	
RDM-A Tuberculosis S. Phanouvong					
Obtain data on anti-tuberculosis medicines through a regional monitoring program					
Continue evidence-based data collection through existing medicine quality monitoring to support regulatory actions in the region	S. Phanouvong	8 ATB samples collected and tested in Laos, 5 in Vietnam	625 TB samples were collected and tested from 2005-2009. The results were examined and discussed at the Laos regional meeting.	Laos contract agreement finalized. Thailand and Vietnam to finalize MOC for continuing MQM activities with collaboration between reg authority, national QC lab, and disease programs with PQM support	
Organize a regional Training-of-Trainers on new Minilab methods for second-line ATBs for	S. Phanouvong	Completed training materials of relevant second-line ATBs (levofloxacin, moxifloxacin,	Initial communication and discussion took place in Laos (during the regional meeting) with Thai and	Training completed at the NIDQC in Hanoi, Vietnam for 11 participants from Laos, Vietnam, Cambodia, and	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
participants from Cambodia, Laos, Thailand, and Vietnam		and prothionamide); training scheduled for Q2 or Q3	Vietnamese partners to hold this workshop. Awaiting decision.	Thailand on new Minilab methods for 2nd-line TB medicines (Levofloxacin, Moxifloxacin and Prothionamide)	
Support country trainers to conduct a national training workshop for their sentinel site personnel	S. Phanouvong		Discussed with Thai and Vietnamese partners as above	Budget proposals created following training in Hanoi, countries to submit proposals for training workshops in Q4	
Strengthen national, provincial and district authorities to provide timely reporting and share the medicines quality data that is routinely collected for in-country enforcement and regional action against violators					
Strengthen national, provincial and district authorities for effective regulatory action and enforcement in Laos, Thailand, and Vietnam	S. Phanouvong	Completed review of relevant regulatory enforcement current practices to develop SOPs	Drafted guidance document for taking regulatory and enforcement action against poor quality medicines and collected PQM input. Presented the document at the Regional Meeting and requested country input.	Incorporated comments into draft guidance document. Drafted 5-year strategy document on MQM (resulting from Laos regional meeting in Q20 Worked with Thai FDA Director of Drug Control division and BVBD Malaria Cluster, and BDN to finalize MOC for PQM-supported program, incl. MQM and taking effective action. Worked with Vietnam DAV, NIDQC, and NIMPE to finalize MOC for PQM-supported program, incl. MQM and taking effective action. (This activity is also funded by RDM-A TB)	
Intensify collaboration and data-sharing with relevant partners in the region for collective action	S. Phanouvong	Data is being compiled by country	At the Regional Meeting in Laos, concrete ideas were discussed regarding information sharing. A timely report on failed samples should be	Concept for regional mechanism for enforcement action among national authorities discusses at Lower Mekong Initiative conference in Vietnam.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			shared among relevant MRAs. Confirmed cases should be shared with WHO Rapid Alert System, and Interpol. PQM is creating a publicly accessible medicine quality database on the USP website which will be ready for internal review and testing by Q3.	Received USAID clearance to collaborate with INTERPOL and other enforcement agencies on counterfeit and substandard medicines	
Raise public awareness about the dangers of counterfeit and substandard medicines					
Re-edit PSAs to meet the country broadcast requirements (Laos, Cambodia, and Vietnam) and get clearance from relevant in-country authorities; finalize regional documentary	S. Phanouvong	– Documentary film proposal developed; budget awaiting approval from PQM. – Re-edits of PSAs completed. Cambodia PSA on hold indefinitely due to political issues. – Completed filming and editing *Combating counterfeit medicines on the frontlines in SE Asia*	- Revised proposal with budget sent to PQM for final approval. -Approval for PSAs to be broadcast in Laos and Thailand given by FDD and FDA. -Awaiting further funding sources to begin documentary -Awaiting further review of PSAs by Vietnam DAV	Written clearance from Laos authority obtained to broadcast PSAs in Laos. Verbal approval given by Director of DAV Vietnam contingent on contract agreement with O2 TV, which can then expand to other stations as part of a national campaign. Verbal approval given by the FDA Drug Control Division to broadcast PSA in Thailand. (This activity is also funded by RDM-A Malaria, OPHT)	
Support outreach activities in grass-roots community organizations to raise awareness about counterfeit medicines	S. Phanouvong	No progress	In Cambodia, a project to engage local Khmer artists to create a national poster campaign is underway. Meta House has hired the artists and had initial consults.	Pharmacide Arts Project of Cambodia exhibition opened in June at Meta House Cambodia Discussion of project expansion to Laos, Vietnam, and Thailand with support by PQM, US Dept of State, and French Min. of Foreign Affairs, and private donors.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				(This activity is also funded by RDM-A Malaria)	
Improve PQM regional approach and activity implementation through program review and information sharing with key stakeholders					
Organize a regional meeting of key partners in GMS countries to share medicines quality data; discuss lessons learned; revise sampling techniques as needed; and report recommendations for effective regional cooperation to combat SCMs	S. Phanouvong	Meeting scheduled for March in Vientiane, Laos	Completed. A meeting was held March 29-31, with 55 representatives. A document on improving MQM in the region was drafted.	Disseminated trip report from meeting included drafts of "5-year Strategy for GMS MQM Program" and "Guidance on Enforcement" for country partners PQM regional activities presented in 'counterfeit and substandard medicines' session at the Lower Mekong Initiative meeting with partners, chaired by Admiral T. Ziemer of PMI (This activity is also funded by RDM-A Malaria, OPHT and AI)	
Strengthen PQM technical leadership and collaboration with partners in the region through hiring new staff and south-south collaboration					
Recruit a lab technical consultant, based in the Mekong Sub-region to work closely with the existing Regional Consultant in Southeast Asia	S. Phanouvong	Job advertisements placed in Thailand; of 30 applicants, 3 were shortlisted	Held phone interviews with 3 candidates. One candidate selected for in-person interviews in Thailand and Laos. Decision will be made in early Q3.	Asawin Likhitsup, PhD, was selected and has been working since May. His office and lab space will be located at partner institution Chulalongkorn Univ. in Bangkok. (This activity is also funded by RDM-A TB, OPHT and AI)	
Support the Vietnam NIDQC in providing technical assistance to Laos National QC Lab (FDQCC) towards ISO 17025 accreditation	S. Phanouvong	Began initial discussions	Arranged a visit to FDQCC by a NIDQC representative who participated in the Regional Meeting March 29-31 to lay out plans for assistance, including a visit of two QA personnel from NIDQC in June	NIDQC and FDQCC are working on a detailed action plan for TA. NIDQC to send experts to FDQCC in August to determine specific activities to be perform and guide FDQCC to compile necessary dossiers required by ISO. (This activity is also funded by RDM-A Malaria)	
Develop drug quality indicators for pharmacies to ensure the quality of medicines during the process of acquisition, storage, and handling					
Review most suitable	S.		Reviewed selected WHO	No progress	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
pharmaceutical guidance document to ensure appropriate emphasis on medicine quality assurance indicators for pharmacies to guide proper acquisition, storage, and sale of good quality medicines	Phanouvong		materials and Laos Pharmacy "10 Indicators to evaluate retail pharmacy practice for ensuring the quality of medicines to be procured, stored and dispensed."		
RDM-A Other Public Health Threats S. Phanouvong					
Utilize ANEQAM's technical expertise to support GMS countries in manufacturing, inspection, quality control, and dossier evaluation for drug registration					
Mahidol University's Faculty of Pharmacy will conduct 2 follow-up GMP trainings on-site in Cambodia and Laos building upon the needs and requests from these countries during a joint training at Mahidol in August 2009.	L. Krech	Awaiting final approval of RDM-A work plan to approach Mahidol about proposed activities in Q3-Q4	RDM-A work plan approved, initial discussions have begun.	Following a meeting with Mahidol Faculty of Pharmacy Dean and professors, 2 experts from Mahidol will conduct GMP on-site visits to Laos and Cambodia in Q4	
Chulalongkorn University will perform a 3-day training on advanced compendial analyses of oseltamivir for participants from Thailand, Laos, Vietnam, and Cambodia.	L. Krech	Awaiting final approval of RDM-A work plan to meet with Chulalongkorn about proposed activities in Q3-Q4	RDM-A work plan approved. Activity plan sent to Chulalongkorn; awaiting their response.	Due to political instability in Bangkok, the training was carried out at the NIDQC in Hanoi by PQM, Chula, and NIDQC. 11 participants from 4 countries were trained. This training was carried out jointly with the Minilab training on 2nd line tuberculosis medicines (see RDM-A TB activities): 3 days on compendial testing of oseltamivir and 2 days on Minilab testing of second-line TB medicines.	
Re-engage UST CeDRES as an ANEQAM partner	L. Krech	Will communicate with CeDRES in Q2-Q3.	No progress	No progress.	
Contribute to the costs of organizing the Regional Meeting on Medicines Quality, and strengthening PQM program leadership and collaboration in the region					

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Contribute to the cost of organizing a Regional meeting to review and share medicine quality data and lessons learned (as described in Malaria Obj. 4/1 and TB Obj. 4/1 funding earlier)	S. Phanouvong	Began meeting planning of meeting scheduled for March in Vientiane, Laos	Meeting completed	Disseminated trip report from meeting including drafts of "5-year Strategy for GMS MQM Program" and "Guidance on Enforcement" for country partners PQM regional activities presented in 'counterfeit and substandard medicines' session at the Lower Mekong Initiative meeting with partners, chaired by Admiral T. Ziemer of PMI (This activity is also funded by RDM-A Malaria, TB and AI)	
Contribute to the salary cost of the Technical Consultant	S. Phanouvong	Scheduled short-listed candidates for telephone interviews	Held phone interviews with 3 candidates. One candidate selected for in-person interviews in Thailand and Laos. Decision will be made in early Q3.	Asawin Likhitsup, PhD, was selected and has been working since May. His office and lab space will be located at partner institution Chulalongkorn Univ. in Bangkok. (This activity is also funded by RDM-A TB, OPHT and AI)	
Contribute to support of Laos FDQCC toward ISO accreditation	S. Phanouvong	Began Initial discussions	Arranged a visit to FDQCC by a NIDQC representative who participated in the Regional Meeting March 29-31 to lay out plans for assistance, including a visit of two QA personnel from NIDQC in June	NIDQC and FDQCC are working on a detailed action plan for TA. NIDQC to send experts to FDQCC in August to determine specific activities to be performed and guide FDQCC to compile necessary dossiers required by ISO. (This activity is also funded by RDM-A Malaria, and TB)	
RDM-A Avian Influenza					
Strengthen the quality control systems of MRAs in the GMS and monitor AI product quality.					
Continue evidence-based data collection through existing medicine quality monitoring to support	C. Raymond	No oseltamivir collected during MQM in Q1	Will begin collecting in Thailand in Q3.	Delays in contract finalizing have postponed this activity to Q4 in Thailand and Vietnam.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
regulatory actions in the region				Approval for sampling and testing oseltamivir from stockpiles was given in Thailand (BVBD) and in Vietnam (with NIDQC and DAV)	
Establish a mechanism to support regulatory decisions and communication regarding extension of AI products shelf-life	C. Raymond	Contacted two Deputy Ministers of Health of Vietnam to provide oseltamivir TA	BVBD agreed to do pilot study on oseltamivir. Short protocol training course to be held in Q3; will begin collecting samples after	DAV and NIDQC of Vietnam agreed to allow TA from PQM to implement protocol of sampling and testing following meetings in June BVBD will sample and test following MOC	
Provide technical assistance to ASEAN to test quality and monitor stockpiled AI products in Singapore and/or at any other regional warehouses	C. Raymond	Offered assistance to ASEAN secretariat; will follow up in Q2	Teleconference with ASEAN secretariat scheduled for Q3.	No progress in Q3	
Cambodia					
Improve detection of poor-quality medicines circulating in the Cambodian market.					
Support existing post-marketing surveillance program, together with the Department of Drugs and Food (DDF), the Global Fund (GFATM) and the National Health Product Quality Control Center (NHPQ)	L. Krech	– Inter-Ministerial Committee to Eliminate Counterfeit Medicines and Illegal Health Services met to discuss actions taken in the provinces – PQM drafted a report for release in Q2	IMC end-of-year report distributed. Drafted joint press release (PQM and Cambodian MOH) to be released in Q3 on drop in illegal outlets. Sampling and testing of antimalarials and antibiotics continues in collaboration with the Global Fund. Local consultant has visited 4 of the 12 sentinel sites.	– Joint press release (PQM and Cambodian MoH) was issued on action taken to close down illegal pharmacy outlets. – PQM Director and Consultant visited Cambodia and meet with PQM partners to strengthen partnership. – Cambodia DDF/MoH drafted a new protocol and workplan for sampling and testing in Cambodia. – MoC between PQM and MoH is signed	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Strengthen the NHPQ	L. Krech	TA assessment of the NHPQ lab facility and site and blueprints for future lab facility will be conducted in Q2-Q3.		– Comment on NHQC Blueprint sent to NHQC Director to discuss with MoH and Architect Company to make necessary modification – 2 NHQC staff attended training on compendial testing of Oseltamivir and Minilab testing of TB medicines held in Hanoi	
Hire and train new PQM local consultant	L. Krech	– Consultant hired and being trained – Consultant attended meetings on behalf of PQM in Cambodia	Consultant has been trained on basic testing techniques and attended PV, Malaria Task Force, and WHO QA/QC protocol meetings, among others. Consultant coordinated communication between NHPQ and DDF to produce the 5-year country report and poster for the Regional Meeting in Laos.	Consultant attended training on compendial testing of Oseltamivir and Minilab testing of TB medicines held in Hanoi	
Expand and improve pharmacovigilance in Cambodia					
Continue to operationalize the Cambodian Pharmacovigilance Center (CPC)	L. Krech	PQM, the Cambodian MOH, WHO, and the Cambodian Pharmacovigilance Center worked with a healthcare communications consultant from Uppsala Monitoring Center to conduct a one-day pharmacovigilance strengthening meeting.	PQM has completed all planned PV activities for the fiscal year. PQM follows the development of the CPC, work plans with AMFm, and PV activities directed towards ACTs.	Due to staff changes, this activity is on hold.	
Raise awareness about medicine quality issues and disseminate information among regulators, health care professionals, and the public					
Produce and distribute regional documentary film on counterfeit medicines	L. Krech	Film proposal, sequence list completed; awaiting budget approval	Budget finalized and approved; revised proposal submitted for final review	Proposal finalized and pre-production completed with indication of additional funding from WIPO.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Production to begin in Cambodia and Laos in Q4	
Collaborate with the Pharmacists' Association of Cambodia (PAC) on activities to promote actions against counterfeit and substandard medicines	L. Krech	One workshop completed on 1) Use of capillary electrophoresis for the quality control of Drugs (Mr. Ing Ho, pharmacist, Geneva, Switzerland); and 2) Development process from molecule to marketing of finished medicinal products (Yimeng Lune, Geneva, Switzerland)	Planned for Q3 and Q4	– Workshop on Accredited Pharmacy and Good Pharmacy Practice held; another workshop is planned for Q4 – PAC Newsletter is being prepared by PAC	
Philippines					
Ensure continued postmarketing surveillance of tuberculosis medicines at the 6 pilot sites and examine status of project implementation.					
Trained CHD and LGU staff will perform testing and sampling according to the Department Order protocol PQM will monitor sampling and testing at selected sentinel sites, and provide technical assistance/training as necessary	L. Krech	Drafted end-of-the-calendar-year report on TB MQM activities which will be released to USAID Mission in Q2	Report distributed. Consultant has performed site visits to reinforce basic testing techniques and correct reporting of results.	Consultant resigned and PQM, with the help of the Philippines FDA, is currently looking for a new consultant. Previous consultant is still assisting PQM to implement activities	
PQM will visit two sites in FY10 together with FDA/DOH staff	L. Krech	Site visits planned for Q3-Q4	Site visits planned for Q3-Q4	Site visits planned for Q4.	
Organize a meeting in Manila to: (1) examine pilot site TB data and actions taken over the past 1-1/2 years; (2) discuss successes and challenges of pilot program; (3) through shared decision-making, come to a conclusion regarding how DOH-FDA-NTP can continue	L. Krech	Planned for Q3-Q4	Planned for Q3-Q4	Meeting planned for Q4 for 28 attendees (3 staff members from each of the 6 sentinel sites, FDA, and PQM)	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
the MQM project when USAID funding ends and the roles of each institution; and, (4) discuss if and how TB medicine quality monitoring can be integrated with FDA-in-a-suitcase/Quality Basket initiative.					
Support the Project Secretariat to coordinate, purchase necessary supplies and equipment, and report progress on postmarketing surveillance of TB medicines and other PQM-supported activities in the Philippines	L. Krech	Consultant visited Davao and participated in an FDA yearly strategic meeting; report will be ready in Q2	Consultant continues to purchase necessary supplies, communicate with the six sentinel sites, and report progress to PQM headquarters.	Consultant resigned in Q3, however until June she purchased necessary supplies and continues to communicate with the six sentinel sites and report progress to PQM headquarters (until a new consultant is hired).	
Participate in the Mekong Regional Meeting on medicines quality and share findings with the region and partners	L. Krech	This will occur in Q2	3 Philippines representatives participated in the Regional meeting and created a country presentation, report, and poster.	Completed in Q2	
Strengthen FDA and satellite laboratories					
Perform a comprehensive assessment of the FDA and how the new government laws to strengthen the FDA are impacting quality assurance regulatory actions	L. Krech	Planned for Q3	Planned for Q3	Planned for Q4	
Building on GLP training conducted in FY09, invite 2 FDA staff to become visiting scientists at USP Headquarters	L. Krech	– FDA selected two scientists – Schedule will be designed and approved by USP in Q2	10 week schedule has been designed. Visiting scientists will arrive at USP headquarters the beginning of Q4.	Visiting Scientists arrive Q4.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
USP QA and PQM staffs continue to review documents FDA submits to the PAO to identify gaps and provide recommendations	L. Krech	PAO performed an on-site assessment of the microbiology lab; FDA will share results with PQM in Q2	FDA provided PAO assessment results of 3 laboratories. PQM staff reviewed and provided recommendations. PQM is using this information to maximize the experience of the visiting scientists.	PQM drafted a press release on the FDA's success in attaining ISO 17025 accreditation; will be circulated Q4. Visiting scientists will have time to train with QA to explore areas for improvement for the Philippines FDA laboratories.	
Collaborate with FDA, EU* and WHO on the FDA Quality Basket initiative ***Technical Assistance for Health Sector Policy Support Program in the Philippines/EU Funded Programme managed by the DOH and EC.**					
FDA, WHO, and PQM will conduct a training for 16 regions on sampling and testing 16 essential medicines using protocols and similar equipment currently in use for TB quality monitoring	L. Krech	FDA trained 8 regions on only 4 essential medicines in November; PQM staff did not attend due to other commitments but plan to attend training planned for February/March	No other training performed this quarter. FDA will inform PQM when the next training is scheduled.	No other training has been scheduled by the FDA at this point. More information will be obtained in Q4.	
Europe and Eurasia					
Russia					
Conduct trainings for laboratory staff from Roszdravnadzor's national network of drug quality control and, possibly, for selected manufacturers of second line TB medicines in quality control of pharmaceuticals	K. Burimski	– Developed and sent to Roszdravnadzor the list of courses that could be conducted for its staff – Selected a Roszdravnadzor scientist to participate in USP Visiting Scientist program at USP Headquarters	– Developed and sent to Roszdravnadzor the preliminary program of courses that could be conducted for its staff and secured approval from Roszdravnadzor – Selected USP facilitators to provide the course – Began preparing materials for the course – Prepared visit of Roszdravnadzor scientist to USP Headquarters	Eight training courses were developed, tailored to suit the needs of the RZN staff, and translated into Russian. The trainings were held in May for 98 participants representing five regional/federal district labs, the Scientific Centre laboratory, and one medicine manufacturer from Kazakhstan.In a letter to USP Executive Director Roger Williams, Dr. E. A. Telnova, Acting Director of Roszdravnadzor, expressed appreciation to USP for preparing the trainings and conveyed their wish to collaborate in the future.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Dr. Andrey Korolev, a scientist at Roszdravnadzor's Scientific Center of Expertise of Medical Products who was selected by USP to participate in its Visiting Scientist program, started the internship, working on dissolution-related project. Pat, I asked Kirill about this part, because it does not fit into this activity (I checked the work plan, and there is no mention of an internship under this activity). Is this something that PQM is funding or USP? If it's USP, should I delete this? The second activity (below) mentions an internship, but I don't think this is the same thing.	
Conduct an internship at USP HQ for Russian GMP experts with focus on WHO prequalification Requirements; Develop support capacity for second-line TB medicines TA in Russia by training qualified Russian scientists who would help with follow-ups and translation requirements	K. Burimski	– Discussed internship with Roszdravnadzor and Drug Safety Research Institute – Began selection of interns	Continued cooperation with Roszdravnadzor and Drug Safety Research Institute in selecting interns	Continued selection of specialists from Roszdravnadzor laboratories and manufacturers for internship	
Conduct a Symposium on WHO prequalification for Russian 2nd line TB medicine manufacturers	K. Burimski	– Developed program for the symposium – Identified co-chairs and key speakers	– Finalized the symposium program and list of invitees based on USAID/Russia	The symposium was held at the Man & Drugs Conference in Moscow in April. At least 40 people attended and 14	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		– Secured approval and support from Roszdravnadzor – Roszdravnadzor agreed to provide a list and contact information of Russian manufacturers of second-line TB medicines	suggestions – Sent invitation letters to manufacturers, Roszdravnadzor, Drug Safety Research Institute, etc.	firms from Russia, Ukraine, and Belarus were represented	
Provide technical assistance to manufacturers of second line TB medicines on WHO prequalification	K. Burimski	– Secured Roszdravnadzor approval and support – Roszdravnadzor agreed to provide a list and contact information of Russian manufacturers of second line TB medicines	Compiled a list, including contact information, of Russian manufacturers of second-line TB medicines and disseminated the list to interested parties	Continued reviewing Dossiers from Sintez on Levofloxacin 500mg tablets and Kanamycin powder for injection; sent comments to Sintez to implement correctives actions Translated Expression of Interest Questionnaire for SLD manufacturers into Russian and disseminated it to selected Russian and Ukrainian SLD manufacturers	
Disseminate results of the study "Assessing the Impact of the *Infectious Diseases Textbook* & the Distance Education Courses on Prescribing Patterns of Antimicrobial Medicines in Selected Health Facilities in Russia"	K. Burimski	Submitted report of study to PQM for editing	Prepared and sent draft version of final report for comment	– Continued reviewing the report addressing comments from interested parties – Discussed further steps of dissemination with interested parties	
Conduct training courses on basic tests using Minilabs; document and report medicines quality data and provide recommendations	K. Burimski	– Identified training participants and venue – Began translating training materials into Russian – Prepared draft of training program	– Received Minilabs – Finalized program of the training course – Translated training materials into Russian – Purchased necessary chemicals and other supplies for the training		
Latin America and the Caribbean					

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Amazon Malaria Initiative (AMI) V. Pribluda					
Evaluate and support accessibility and quality of malaria diagnosis and treatment facilities					
Strengthen QA systems and incorporate the three-level approach to ensure the quality of medicines throughout the supply chain, particularly in low transmission settings		– Received and reviewed first draft of Manual of Procedures for the Management of Malaria Medicines (MPMMM) and related SOPs from Guyana. – Reviewed version sent on January 2010 – Received final draft of the MPMMM and associated SOPs from Colombia; currently under review	Final draft of the of Manual of Procedures for the Management of Malaria Medicines and associated SOPs from Colombia was reviewed and returned with comments and recommendations	Contributed to AMI Strategic Orientation Document for 2011-2015. Developed section on Quality Assurance of Malaria Medicines in High and Low Incidence Conditions	
Establish sustainable south-south collaborations among OMCLs in AMI countries; follow up on FY09 workshop		– Provided Reference Standards for 8 countries (Bolivia, Brazil, Colombia, Ecuador, Guatemala, Guyana, Jamaica and Panama) to participate in the latest round of inter-laboratory proficiency testing sponsored by Peru OMCL (CNCC) – Six countries delivered results (Bolivia, Brazil, Colombia, Guyana, Jamaica & Panama) for three tests; 16/18 (89%) test results from AMI participating countries evaluated by CNCC as satisfactory – Sponsored two analysts Ecuador OMCL to participate in training on Biological and Microbiological Assays for Pharmaceutical	– Assisted CNCC in coordinating inter-laboratory proficiency testing rounds for 2010. There will be two rounds in 2010 and currently, 9 and 11 labs will participate in the 1st and 2nd round respectively. – The OMCL Virtual Forum Project Charter was drafted which describes the purpose, mission, and scope of the project. The document is in its final review before being forwarded to in-country partners.	– Sent RS to 9 labs (and coordinated for USP and PAHO to include a 10th lab – Uruguay's OMCL) for first round in 2010. – CNCC will send results of round in Q4. Sponsored CNCC personnel participation in QMS evaluation of Panama OMCL (see below under Support OMCLs to implement stringent Quality Management Systems) – Developed User Requirements Document for OMCL Virtual Forum to be submitted to an external consultant; currently under review by IT	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		Products sponsored and delivered by Peru's OMCL (CNCC); PAHO sponsored two analysts from El Salvador OMCL			
Strengthen MRAs' GMP inspection capabilities, specifically for local antimalarial medicine manufacturers			PQM and PAHO's HSS/MT team met to finalize institutional agreement to proceed with PQM activities aimed at strengthening MoH regulatory capabilities. – PQM developed draft of letter of intent and sent to PAHO for review – Final version finalized incorporating PAHO's suggestions.	Letter of Intent for collaboration on strengthening MoH regulatory capabilities sent to PAHO in April – Letter is still under review and no update has been provided – Due to the lack of response from PAHO, PQM contacted the Latin America office of FDA to develop a joint PQM/FDA training – FDA LA Office agreed and is currently assessing how to implement it	
Expand Colombia's capacity to perform QC analysis of medicines by strengthening the National Network of Laboratories			PQM was requested to attend a meeting in May to promote the establishment of a National Network of Laboratories, organized by INVIMA. No final date has been established for this meeting	– Meeting date has been set for end of August – In consultation with the NMCP, two Departmental Health Laboratories were identified to receive Minilabs in order to support the implementation of the three-level approach in routine MQM	
Assist in antimalarial Medicine Quality Monitoring (MQM) activities		– Received medicines sampled in private and informal sector of Suriname; currently being analyzed at USP Lab – Ordered and sent Minilab supplies to Suriname NMCP analytical lab – Reviewed report of MQM Minilab activities	– Continued analysis at USP of the samples received from Suriname & Guyana – PQM met with Suriname NMCP representatives at the AMI/RAVREDA meeting in Bolivia regarding samples remaining in country – Waiting for approval	See below under 'Conduct study of QC of antimalarials at informal sites' – Suriname MoH approved shipment of remaining samples that were sent to PQM for analysis at USP lab – Provided Ecuador NMCP with Minilab manuals in Spanish to perform routine MQM in public sector	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		in Colombia; comments and recommendations sent back to NMCP	from Suriname MoH to send remaining samples for analysis at USP HQ. – Provided Ecuador NMCP with RS to perform routine MQM in public sector		
Support OMCLs to implement stringent Quality Management Systems (QMS) to comply with internationally recognized standards (WHO and/or ISO)		– Performed of Quality Management System (QMS) Assessment at Guatemala OMCL – Provided support to LNS for preparing Expression of Interest (EoI) to participate in WHO PQ Programme	– See comment under SAIDI CONCAMYT & CNCC sections	– Performed Quality Management System (QMS) Evaluation at Panama OMCL. Assessment performed in collaboration with personnel from CNCC (Peru OMCL). Interaction between Peru and Panama OMCLs has been continuous as Peru has provided TA for a variety of QC procedures, particularly microbiological methods – Assisted Bolivia & Peru OMCLs in developing Corrective and Preventive Action Report that was submitted to WHO Prequalification team. Awaiting final decision from WHO regarding including both labs in list of PQ labs. (See under SAIDI) – Sponsored translation of revised WHO GLPs into Spanish. Document will be harmonized and approved by the PANDRH GLP WG Meeting in Peru in July (PQM will attend meeting) – Visiting Scientist Program o Coordinated activities with USP personnel involved in training and logistics o Information submitted to	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				process the visa of the scientist that will be participating from the Caribbean Regional Drug Testing Laboratory in Jamaica. – Created with PAHO a joint work plan for OMCL activities performed by PQM, PAHO, & USP.	
Strengthen pharmacovigilance (PV) activities in selected countries		See comment below	See comment under cGMP section	Letter of Intent for collaboration on strengthening MoH regulatory capabilities sent to PAHO in April – Letter is still under review in PAHO and no update has been provided (See also Q2 comment under cGMP)	
Establish a LAC secondary standard program		Exploring potential approaches with PAHO for USP assistance and alternative approaches	PQM is evaluating the possibility of having OMCLs buy RS directly from USP at a reduced price. The objective is to increase the availability and reduce the cost of all USP RS. – To determine if this approach is feasible, PQM is compiling information from OMCLs in the region regarding the use and cost of the RS used. Additionally, PQM is compiling information regarding the logistical process of having OMCLs purchase RS directly from USP at a reduced price.	USP developed alternative approaches to strengthen this program in several regions of the world and support to the countries will not be managed through PQM. Further information will be discussed with region as it becomes available.	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct GMP assessment of Farmanguinhos; verify AS/MQ FDC quality (carry over from DQI)			– PQM reiterated to Farmanguinhos the intent of the GMP assessment and proposed to assist in PQ Process of this FDC. PQM is waiting final decision from Farmanguinhos regarding proposal. – Since carry over funds need to be utilized by the end of FY 10, if by the end of Apr/May Farmanguinhos does not respond to PQM or an action plan cannot be coordinated with them to complete this activity during FY 10, this activity will be discontinued and the funding reallocated.	Due to changes in the infrastructure of the factory and the manufacturing process, pre-qualification plans and TA by PQM have been postponed for 2011, until the validation of systems and processes in the manufacturing plant are completed	
Conduct study of QC of antimalarials at informal sites in locations with high prevalence of illegal commerce of medicines in Colombia & Guyana (carry over from DQI)		– All medicines sampled from the private and informal market in Guyana received and are currently being analyzed at USP and CNCC – Signed contract for study on medicines from the private and informal market in Colombia with country consultant (COHAN); study to start in January 2010 – See comment #1 in MQM activities (re: Suriname)	– Continued to analyze medicines from Guyana at USP and CNCC. Final results expected in Q3. – Study on the availability of antimalarials in the private and informal sector of three departments in Colombia has been initiated – See comments #1, 2 & 3 in MQM activities (re: Suriname)	– Continued analysis at USP of the samples received from Suriname & Guyana – CNCC completed 19 of 29 samples from Guyana – Remaining samples at CNCC delayed because of inability of local suppliers to deliver reagents. PQM is working with CNCC to find alternative suppliers. – Analysis at USP lab of samples received from Guyana and Suriname at final stages of completion	
Train health professionals of all levels in the diagnosis, appropriate management, and use of antimalarials					
Write an article with		– Drafted article outline	Began drafting	An early draft of completed	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
results of Minilab activities at sentinel sites (mostly public sector); submit to peer-reviewed journal		– Reviewing MQM data received since inception of program; additional related information being requested from countries	introduction section and analyzing basic tests (Minilab) data from Bolivia, Colombia, Ecuador, Guyana and Suriname	sections is under review	
Write an article with results of case studies in Colombia and Guyana on the quality of malaria medicines at the private and informal sectors					
Finalize concept paper on use of the Three-level approach for quality control of medicines in developing countries		Final draft finalized and is currently under internal review	Further revisions are being made to the draft and the final document is expected to be ready in Q3	Final draft of revised version has been completed and is currently under review by PQM team	
Develop an online database of information on the quality of antimalarial medicines in AMI countries. (Funded by USP)		– Finalized and approved user requirements document – IT programmers began constructing site; estimated completion Q3	– PQM and USP IT Department continued developing the database – Completion expected on Q3	– Development of the database software has been completed by IT, and assessed by PQM – Public access to database expected by mid-Q1 FY11 ○ Uploading of existing data is expected to be finalized throughout the next two quarters	
Promote and implement evidence-based decisions on accessibility, quality, and use of appropriate diagnosis and treatment					
Participate in the annual, steering committee, and other regional meetings with initiative countries and technical partners			Attended IX Annual AMI/RAVREDA and semi-annual steering committee meetings in Santa Cruz, Bolivia in March		
Maternal and Child Health V. Pribluda					
Assess the quality of selected obstetric and neonatal medicines used in primary care health facilities in decentralized regions of Peru and Guatemala					
Develop study protocol		– Identified partners and relevant stakeholders in Guatemala and Peru; project objectives presented and	Peru: – Protocol refined with in-country partners and includes sites and medicines to	Peru: – Protocol finalized Guatemala: – Proposal completed and	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		discussed – Debriefed USAID/ Guatemala on project – Currently developing protocol for Peru (to be shared with country partners in Q2)	sample. – Sampling is scheduled to be performed simultaneously with SAIDI study in two stages (2 regions in May and 3 remaining regions in June) Guatemala: – Proposal for Study to be presented to the MoH – Proposal developed by PQM is currently under review by in-country partners – Expected submission date to MoH: May 2010 Upon approval PQM will hire an in-country consultant to perform sampling and send samples to PQM designated lab.	sent to in-country partners for submission to MoH in April – A change in senior decision-making officials in the MoH and a national emergency delayed submission of the proposal to the end of Q3. Response expected in July. – Terms of Reference for consultant sent to in-country partners.	
Conduct sampling and QC testing				Peru: – Sampling completed in all regions and medicines sent to CNCC – USP Reference Standards sent to CNCC – Results expected by Q4	
Prepare and disseminate report					
South American Infectious Diseases Initiative (SAIDI) A. Barojas					
Increase breadth of evidence base for LAC PHN priorities increased regionally.					
Coordinate and institutionalize sampling and analysis of selected medicines (ABs, TB &		– Provided a 1-day course to UNIMED (Bolivia's MRA) on Appropriate Use of USP-NF	Peru: Third round protocol finalized; sampling will occur concurrently with MCH	Peru: – Sampling finalized in all regions and medicines sent to CNCC	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
NSAIDs) in Bolivia & Peru		standards – Peru–third round temporarily put on hold until MCH protocol is finalized – Both MCH and SAIDI activities will be performed in the same region for efficient use of resources	study to maximize funds. Sampling will occur in two stages (2 regions in May and 3 remaining regions in June).	– USP Reference Standards sent to CNCC – Results expected by Q4	
Cross-cutting activities related to QA/QC (to be implemented dependent on further developments) in Peru, Ecuador & Paraguay	PQM/DQI	Provided input to Links Media and other SAIDI partners on draft 'SAIDI Approach' document on expansion of SAIDI into Ecuador; Links Media finalizing draft	– 'SAIDI Approach' document is still pending approval by USAID. – PQM has received approval from USAID to assist Ecuador National TB Control Program (NTBCP) in MQM of common AB & TB medicines stored in decentralized public health centers. – PQM will provide RS to perform routine MQM	– 'SAIDI Approach' document is still pending approval by USAID.	
Communicate and use evidence base for LAC PHN priorities. **All participating countries collect, analyze, disseminate and evaluate information**					
Assist CONCAMYT (Bolivia) to establish a stringent QMS to comply with international standards (WHO & ISO) (carry over from DQI)			– Visited CONCAMYT to assist them in preparing for the WHO Inspection – WHO PQ Programme Inspection Conducted March 22-23 (Final report is pending)	– Assisted Bolivia OMCL in developing Corrective and Preventive Action Report that was submitted to WHO Prequalification team. Awaiting final decision from WHO regarding inclusion of CONCAMYT to list of PQ labs.	
Assist CNCC (Peru) to obtain WHO prequalification & expansion of ISO 17025		– Provided support to CNCC on EoI to participate in WHO PQ Programme	– CNCC expanded ISO 17025 scope to include 7 more tests. ACLASS audit	– ACLASS approved CNCC's expanded scope and the lab is now currently accredited for 12	

PQM Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
accreditation		– CNCC's EoI sent in October; WHO Headquarters accepted EoI Schedule of WHO audit TBD	conducted March 8-12 and final report pending. As a result 90% of work performed by lab is accredited and recognized internationally. – WHO PQ Programme Inspection Conducted March 25-26 (Final report is pending)	tests, which comprises approximately 90% of work performed by lab. – Assisted Peru OMCLs in developing Corrective and Preventive Action Report that was submitted to WHO Prequalification team. Awaiting final decision from WHO regarding inclusion of CONCAMYT to list of PQ labs.	
Promote more inclusive and better informed policy process. **All participating countries define and implement policies in conjunction with participation of all sectors, including the community**					
Publish article on MQM activities performed in all SAIDI countries		In progress	In progress	In progress	
Participate in all SAIDI meetings					