

**Promoting the Quality of Medicines (PQM) Program
Quarterly Reports: FY 2012 Activities (October 1, 2011–September 30, 2012)**

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Common Agenda	K. Chibwe				
Raise the profile of the PQM program and increase awareness about the importance of medicines quality					
Attend and present at national, regional, and international conferences	P Lukulay	P. Lukulay and V. Coignez attended the 3 rd ICIUM conference in Turkey; 3 PQM-related abstracts and posters were exhibited.	K. Chibwe presented at New Partnership for Africa's Development (NEPAD)'s African regulators roundtable in Tanzania.	A. Smine presented on the PQM program at the USG Supply Chain Meeting in Johannesburg, South Africa. He also spoke at the Africa Pharmacovigilance Meeting in Kenya on "The Link between the Quality and Safety of Medicines." V. Pribluda presented results of a case study PQM conducted in Indonesia testing the quality of oxytocin at the Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care in Bangladesh.	P. Lukulay presented "Understanding the Cause for Poor Quality Medicines in Developing Countries" at AEI in July.
Use available media outlets to advocate the need for medicines quality assurance	P Lukulay	In December, USP issued a PQM press release "Commitment to Quality Medicines Strengthened in Ethiopia with International Laboratory Accreditation"	In March, USP issued a PQM press release "Making Affordable, Good-quality Tuberculosis Medicine a Reality"	In April, the PQM program in Ghana was highlighted in a USP press release "Reducing the Threat of Counterfeits, Investing in the Future of Safe Medicines"	P. Lukulay gave a radio interview in September to Voice of America on "Health Chat" for the African Health Network. USP issued four PQM press releases: --Jul: "New Technology Represents Next-Generation Tool for Detecting Substandard and Counterfeit Medicines" and "National

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					Laboratory for Medicine Quality Testing Inaugurated in Mozambique” --Aug: “New Research Reveals Extent of Poor-Quality Antimalarial Medicines in South American Countries” --Sep: “Collaborative Focus on Fight against Counterfeit, Substandard Medicines in Greater Mekong Sub-region”
Produce up-to-date information about current issues in medicines quality and appropriate use					
Collect and publish reports on incidents of poor-quality medicine use	M McGinnis	Added 30 reports to the <i>Media Reports on Medicine Quality</i> ; received 364 website hits	Added 27 reports; received 428 hits	Added 37 reports; received 510 hits	Added 31 reports; received 746 hits
Maintain and update PQM website	M Foster	Added 8 stories, 9 photos, and 8 new or updated resources	Added 5 stories, 6 photos, 3 new or updated resources	Added 8 stories, 8 photos, 6 new or updated resources	Added 5 stories, 6 photos, 3 new or updated resources
Explore improved tools to ensure quality control or increase the knowledge base about quality assurance					
Support research to improve the accuracy and reliability of field-based quality control technologies	K Chibwe	The student from Boston Univ. working on “PharmaCheck” visited USP HQ; PharmaCheck completed design stage and was presented at the ICIUM conf.	PharmaCheck has reached Proof of Concept (POC) stage. Professor Zaman will visit USP in May for a formal status update.	Professor Zaman and his student presented to USAID (Tony & Maria) at USP’s Rockville site.	Carver press obtained; will be used for further demonstrative POC work.
Tuberculosis (TB) A. Hong					
Increase the supply of quality-assured second-line TB medicines					
Continue to provide TA to FPP mfrs from FY10		Visited Dong-A Pharmaceutical in South	• PQM continues to	• PQM continues to	• PQM continues to

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seeking WHO PQ		Korea to perform assessments on GMP capabilities for Cycloserine Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP).	support 17 manufacturers in different stages of compliance with WHO PQ including Farmanguinhos, Svizera, Simpex, Abbott, Shalina, Phapros, Indofarma, Dong-A, Ahn-Gook, Ildong, Deurali Janta, Lloyd's, Sintez, Shelys, TP Drug Lab, General Drug House, Arterium <ul style="list-style-type: none"> • Dong-A Pharma has passed inspection by WHO and expects to be prequalified within the next few months • Additional TA visits are scheduled for the following manufacturers in the next quarter: Farmanguinhos, Svizera, Simpex, Abbott, Shalina, Phapros, Indofarma, Dong-A, Ahn-Gook, Ildong, Deurali Janta, and Arterium 	support manufacturers in different stages of compliance with WHO PQ including Phapros, Indofarma, Dong-A, Ahn-Gook, Ildong, Deurali Janta, Arterium, <ul style="list-style-type: none"> • Concept Pharma, Sintez, • Additional TA visits are scheduled for the following manufacturers in the next quarter: Enzychem, Dong-A, Ahn-Gook, Ildong, Deurali Janta, and Arterium 	support manufacturers in different stages of compliance with WHO PQ including Phapros, Indofarma, Dong-A, Arterium, Zhejiang Hisun Pharma, Kilitch/Akorn, Shalina, Deurali Janta Pharma, Akrikhin <ul style="list-style-type: none"> • Additional TA visits scheduled for next quarter: Korea United Pharma, Arterium, Abbott, Simpex, Kilitch/Akorn, Phapros, Indofarma, Varichem
– To mfrs now in PQM pipeline			PQM pipeline increased after Korea and South Africa workshops to a total of 39 – in addition to 17 above: Zhejiang Hisun, Shaghai	Currently PQM pipeline includes 40 companies: Abbott, Akrikhin, Biotech, Chon Kun Dang, Concept, DJPL, Dong-A, Enzychem, Fuxin,	Currently in PQM pipeline: Concept Pharma, Macleod's, Arterium, Zhejiang Hisun, Kilitch/Akorn, Dong-A Pharma, Varichem,

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			Fosun/Guilin, Wuhan Purepac, Kunming, Zhejiang Jingxin, Nanning Sinotech, Zhejiang Xinhua, Zhejiang Starry, Concept Pharma, Bliss Pharma, Chong Kun Dang, Yuhan, Korea United, Swiss Pharma Nigeria, Hizon Labs, Akrikhin, Varichem, MCEPA Chemical, Biotech Lab, Universal Corp., Biodeal Labs, Skylight Chemicals	General Drug, Hebei Shengxue, Hizon, Humanwell, Indo Farm, Kilitch, United, Lloyd, Lomus, Macleod's, Nexgen, NAPC Huasheng, Phapros, Shalina, Qi-lu, Fosun, Hefeng, Shelys, Simpex, Sintez, Svizera, Swiss, TP Drug, Universal, Varichem, Yuhan, Hisun, Dankong, Jinxin, Xinhua, Yongning	Simpex Pharma, Deurali Janta Pharma, Shanghai Fosun Pharma, Korea United Pharma, Abbott, Lloyd Labs, Hizon
- To new mfrs on dossiers		Visited Novartis/Sandoz in Bangladesh to perform assessments on GMP capabilities and dossier review for Clarithromycin and Levofloxacin 500mg tablets.	Dossier assistance is provided to 4 manufacturers (review of dossier or providing query response to WHO) – Shalina, Dong-A, Sintez, Phapros	Dossier assistance is being provided to 7 companies: Zhejiang Hisun, Shanghai Fosun, Zhejiang Yongning, Zhejiang Dankong, Zhejiang Xinhua, Shandong Qi-Lu, Humanwell/Puracap,	Dossier assistance is being provided to Arterium, Zhejiang Hisun, Kilitch/Akorn, Shalina, DJPL, Hizon
- With GMP audits and support until products are PQed			2 – Dong-A, Shalina	6 – Zhejiang Hisun, NCPC Huasheng, Shandong QI-LI, and Akrikhan were audited. TA to Hebei Shengxue Dacheng's CAPA and Second Pharma CAPA was provided.	
With GDF, conduct workshops in a country with a high burden of TB; identify additional mfrs not yet in PQM			2 – South Korea (attended by 47 manufacturers), South Africa (attended by 23 manufacturers)		

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		Q1	Q2	Q3	Q4
pipeline					
Identify and provide TA to key SL-ATB API suppliers for WHO PQ			4 API manufacturers from Korea and China have been Identified and TA was provided – Fuzhou (CAPA completed), Dong-A, Enzychem, North China Pharma-Hebei Huasheng	Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, NCPC Huasheng,Zhejiang. Second Pharma	Zhejiang Hisun Pharma, Fuzhou Fuxing Pharma, North China Pharma, Hebei Shengxue Dacheng Pharma, Zhejiang Xinhua Pharma
– To API mfrs now in PQM pipeline			6 manufacturers have been added: Zhejiang Hisun, Shanghai Fosun/Guilin, Shandong Qi-lu, Zhejiang Yongning, Zhejiang Neo Dankong, Hebei Shengxue Dacheng	Total is now 11: Zhejiang Hisun, Shanghai Fosun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua,Fuzhou Fuxin, NCPC Huasheng,Zhejiang Dankong, Dong-A, Enzychem,Shengxue Dacheng	
– To new mfrs on dossiers			North China Pharma-Hebei Huasheng – dossier preparation (air flow TA)		Zhejiang Xinhua Pharma
– With GMP audits and support until products are PQ			Fuzhou – corrective action plan implementation assistance provided		EnzyChem, Zhejiang Hisun Pharma, NCPC Huasheng, Hebei Shengxue Dacheng'
Organize a forum for donors and partners to align efforts to avoid duplication		Drafted a letter of agreement to be signed by WHO PQ, GDF, and PQM to formalize the working relationship of supporting manufacturers interested in participating in the WHO PQ and/or GDF initiatives as interim			

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		Q1	Q2	Q3	Q4
		suppliers of priority ATB medicines.			
Participate in GDF and WHO meetings with mfrs to discuss PQ		Met with manufacturers in the Philippines (Hizon, Lloyds, Pascual, and Amherst/Unilab) to introduce and discuss PQM's technical assistance towards WHO PQ	2 workshops held – South Korea and South Africa		
Develop pharmacopeial monographs for PAS Acid Tablet, Ofloxacin tablet, Amoxicillin/Clavulanate tablets, Kanamycin; develop additional Minilab [®] methods for two SL-ATBs			Method validation in progress		Method validation in progress
Obtain comparator products and assist select mfrs with funding for BE studies/capital investments			AhnGook, Deurali Janta, Phapros	Shanghai Fosun, Zhejiang Yongning Pharma, Hisun Pharma' Humanwell	Zhejiang Hisun, EnzyChem
Update current literature on PQM TA and post on website	M. Foster	Updated TB webpage	Updated TB flyer		Updated TB flyer to reflect 11th Invitation for EOI
Reduce the prevalence of substandard and counterfeit SL-ATB medicines					
Conduct quality surveys; develop a database of GMP-compliant API mfrs and GCP-compliant CROs			Currently providing TA to API manufacturers – will continue to gather API mfr information; Working with one CRO in India, working on establishing more CROs globally to perform BA/BE studies	Database of GMP-compliant API manufacturers is under development.	One CRO was identified and audited in South Korea.

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		Q1	Q2	Q3	Q4
Encourage regulators to develop guidelines that expedite registration of WHO-PQ'ed SL-ATBs in their countries			Regulator Summit held in South Africa to engage them to work on fast track registration of companies that are Prequalified for second line ATB medicines		
Malaria		P Lukulay			
Conduct study in three countries to assess diversion of antimalarial medicines from public to private sector					
Develop study protocol for AM monitoring study		<ul style="list-style-type: none"> Developed a protocol to start monitoring the diversion of Coartem from the public sector to the private sector in two Nigerian cities (Kaduna and Port Harcourt). Protocol was shared with the Malaria team and consensus obtained. Discussed the details of results obtained from the previous study in Kaduna and Port Harcourt and, with USAID assistance, identified pharmacies that will be monitored in future diversion studies Discussed diversion results and next steps with USAID Inspector General Office 	Diversion studies have been conducted in Cameroon and a second follow up study concluded in Port Harcourt and Kaduna. Spreadsheet containing location of pharmacies and batch numbers identified is being shared with the malaria team at USAID/Washington. The Kaduna and Port Harcourt cities are now being used as sentinel sites to assess diversion over a period of time.		Additional diversion study was conducted in Benin and data shared with USAID/Washington.
Train country samplers in proper methods and documentation for			A good mechanism has been put in place for the monitoring and reporting		Study teams are well versed in conducting the studies

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collecting AM meds			of results.		
Develop report and disseminate results			Results have been disseminated to USAD/Washington		Report was shared with USAID/Washington.
Perform baseline study of two country markets for presence of antimalarial monotherapies					
Select 2 countries to conduct survey for monotherapies		<p>The protocol was drafted with the main questions:</p> <ul style="list-style-type: none"> • How widespread is the use of first-line antimalarial treatment? • Are first-line antimalarial medicines available and affordable in public and private health facilities? • What are the public perceptions about the geographical access and the quality of antimalarial medicines? • What are the most commonly used antimalarial medicines in public and private health facilities? 	Two countries were selected: Liberia and Mali. Due to political reasons, work in Mali is on hold and another country is being selected.	<ul style="list-style-type: none"> • PQM supported additional antimalarial medicine monitoring studies in two cities in Nigeria: Kaduna and Port Harcourt. These cities now constitute sentinel sites in Nigeria. • PQM supported antimalarial medicine monitoring studies in five cities in Cameroon 	Protocol was developed and consent sought from the Ministry of Health in Liberia. The study is underway and will be completed in FY 13. The Mali study, which was well on its way to starting, was halted due to the political unrest in the country.
Develop sampling strategy and protocol; identify locations			Protocol developed and finalized with partners in Mali, but work in Mali is now on hold due to political issues.		Protocol fully developed.
Travel to sites and conduct survey					Team travelled to Liberia to discuss the study with

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					USAID and country stakeholders
Procure samples and generate reports					Sample collection for the study is in progress and will be completed in FY 13
Develop NAMCOL into a full-fledged network					
Study other networks and learn best practices			Literature review on other networks conducted		
Develop bylaws and supervise election of officials; help set priorities			Draft bylaws are being developed. All countries agreed to meet to discuss NAMCOL's future.		At the Maputo meeting, Network members decided to register the network as an association in Ethiopia and elected a Chair, Vice-Chair, and Secretary to coordinate activities.
Bring country reps together to discuss vision and establish scope of work				NAMCOL now called NOMCOL (Network of Official Medicines Control Laboratories) meeting planned for September in Mozambique to discuss charter that has been drafted by PQM.	<p>Second Annual Meeting of NAMCOL held in September. Seven additional African countries—Kenya, Nigeria, Senegal, Sierra Leone, Tanzania, Zambia, and Zimbabwe—attended the meeting and joined the Network.</p> <p>The meeting participants agreed upon the following draft FY13 objectives:</p> <ul style="list-style-type: none"> • Finalize NOMCOL-Africa charter • Conduct one inter-laboratory testing scheme and training • Commit to supporting

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					the Medicines Quality Forum to share information
Hold meeting of new officials & hand over mgmt to countries		Letters have been sent out informing participating countries about the formation of the network	Meeting will be hold in Q3 in Mozambique.	Directors of SSA laboratories will attend NOMCOL meeting; there will be an election to hand over management of NOMCOL to the countries.	Network members elected a Chair, Vice-Chair, and Secretary to coordinate activities.
Develop Minilab[®] methods for Coartem[®] Dispersible tablets and pharmacopeial monograph for DHA-PP					
Develop Minilab [®] methods for Coartem [®] Dispersible Tablets		Process to start working with GPHF in developing a method for Coartem initiated.	Minilab method development in progress.		
Develop monograph for DHA-PP			Sigma Tau, the maker of DHA/PP, has shared their analytical methods with USP. Reference standards are being generated along with the documentary standard	Monograph development for DHA/PP is near completion at the USP site in India. Reference standards are being sought from Sigma Tau to go with the monographs.	
Maternal Health and Child Survival		E Toledo			
Support selected zinc manufacturers for WHO Prequalification					
Conduct quality control and GMO assessments of zinc salt mfrs.		<ul style="list-style-type: none"> • Contacted Cosmos Pharmaceutical in Kenya and Hindustan Laboratories in India to assist them in the process of becoming UNICEF suppliers • In Ghana, worked with Abt Associates and FDB to draft EOLs for inspection of local 	<ul style="list-style-type: none"> • Visited Shelys and Zenufa in Tanzania in Feb to conduct GMP assessments • Reviewed WHO queries regarding Shelys zinc dossier • Cosmos Pharmaceutical assessment is scheduled for May 	<ul style="list-style-type: none"> • Visited Cosmos Pharma in Kenya in May to conduct a GMP assessment • Provided TA to Cosmos on requirements for zinc sulfate prequalification and UNICEF tenders. • Continued to support Shelys toward PQ in GMP correctives 	<ul style="list-style-type: none"> • Performed GMP assessments for 3 zinc manufacturers in Ghana for local procurement in support of USAID-funded Strengthening Health Outcomes through the Private Sector (SHOPS). • Provided USP

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		<p>manufacturing sites of zinc products to assess compliance with GMP. Assessment will begin Q2</p>	<ul style="list-style-type: none"> Ghana EOI was issued in Feb to manufacturers; deadline for submissions is Apr 30. 3 manufacturers have replied; Phyto- Riker Pharma, La Gray Labs, and Amponsah-Efah Pharmaceuticals Ltd. After April 30, a trip to Ghana will be planned for GMP assessments of interested manufacturers 	<p>actions plan.</p> <ul style="list-style-type: none"> Scheduled a visit to assess Ghana manufacturers' GMP capabilities July 16-20. 	<p>reference standards to Amponsah-Efah Pharmaceuticals Limited in Ghana</p> <ul style="list-style-type: none"> Prepared CAPA for Cosmos and followed up on implementation. UNICEF will audit them after the CAPA is completed. Continued to support Shelys and Zenufa toward WHO PQ
Complete zinc acetate syrup monograph			Proposed monograph submitted March 30 for PF 38(4) to be published in [July-Aug. 2012] for comments	Proposed monograph was published in PF 38(4) and will be published after comments in <i>USP36-NF31 2S</i> .	
Conduct medicine quality testing of zinc and pediatric amoxicillin dispersible tablets			Three samples were received from UNICEF and tested; report will be submitted by end of April	1 sample from Cosmos was tested.	4 samples from India, Kenya, and Ghana were tested
Strengthen DDA and NMQCL capacity					
Train Nepal DDA and NMQCL in audit GMP audit, GLP, & analytical method validation		Communicated with DDA to begin planning a GMP/GLP workshop. PQM will work with DDA and NMQCL by Q2 to develop training modules	PQM and DDA agreed on training modules for: method validation, setting specifications for pharma products, and HPLC. PQM's assessment of the lab is scheduled for June; the workshop will be held in August.	Lab assessment has been rescheduled for August; the workshop will be held in September.	Due to changes in Nepal DDA management (new director), this activity was cancelled.

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SUB-SAHARAN AFRICA					
Benin	M Hajjou				
Strengthen the capacity of the National Medicine Quality Control Laboratory					
Provide laboratory supplies for training		PQM provided reference material and standards and laboratory supplies to NMQCL			
Train staff on HPLC, UV-vis, Dissolution		<ul style="list-style-type: none"> • Lab staff received refresher training in Good Documentation Practices and Dissolution tester calibration (Performance Verification Test) • PQM trained three lab staff in UV-vis, Dissolution, and HPLC applied to the testing of antimalarials and other medicines following pharmacopeial methods. The medicines used in the training included amodiaquine hydrochloride, sulfadoxine-pyrimethamine, and artesunate. • PQM helped the lab staff with troubleshooting the HPLC and the 			

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		spectrophotometer. The two instruments were not functioning properly prior to the training.			
Evaluate the three trainings		To evaluate the training, PQM assigned work to the trainees consisting of testing two medicines (SP and artesunate) using HPLC and Dissolution.	NMQCL will submit a report to PQM in May.	Several requests to send the full report were left unanswered.	PQM received and reviewed the data on the testing of SP. Comments and recommendations will be sent to the lab by the end of October 2012.
Ethiopia	Eshetu W.				
Strengthen and maintain operational USP office in Addis Ababa					
Recruit additional office staff		Three technical staff and an office manager hired	Office cleaner hired		Invitation to participate in tender to audit the USP office announced in the Ethiopian Herald; documents submitted by bidders sent to HQ for assessment, and auditor selected. Contract signed with HST.
Purchase vehicle for travel					
Operational costs for supplies & salary			Made available		
Strengthen the organizational, quality assurance and regulatory capacity of FMHACA					
Review regulatory and QA capacity/systems and identify gaps			PQM consultant assessed FMHACA and submitted draft report. The report was discussed with Minister of Health. Final report expected to be submitted soon.	PQM consultant submitted official report to FMHACA, USAID/ Ethiopia, USP PQM USP Ethiopia office carried out a partial and informal assessment and submitted it to USP PQM	FMHACA entered into an agreement with the Ethiopian Management Assessment Institute to study the organizational structure and salary scale of FMHACA using the reports from the PQM consultant and the USP-

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			Study tours arranged for three teams of FMHACA management members to USA FDA, India DRA and Malaysia	and USAID/Ethiopia.	Ethiopia office as the basis for their study.
Address gaps identified with recommended solutions			FMHACA to take action based on the report.		
Improve/strengthen the registration and licensing system to ensure that medicines, foods and other regulated products are of good quality, safe, effective and perform as per standards					
Improve capacity and skills of registration & licensing staff		<p><i>Guidelines for Registration of Medicine</i> has been revised and submitted to the Authority in November. A consultative workshop is planned for January.</p>	<ul style="list-style-type: none"> Conducted consultative workshop on the revised guidelines on medicine registration and others ToT on vaccines registration was conducted for two staff of the Authority in Kenya Supported participation of one FMHACA staff in the regulatory summit held in S. Africa PQM staff also participated in the regulatory summit 	<ul style="list-style-type: none"> Purchased and installed shelves for storage of dossiers Dossier assessment tools were developed for the staff of FMHACA. These are included in assessment report templates used during evaluation of product registration applications. Through USP PQM regulatory affairs for QA and supervision of dossier assessment, two QA sessions have been conducted for Product Registration and Licensing Directorate staffs. More than 15 staff members participated in the two QA sessions which reviewed about 40 dossiers. The newly developed CTD guidelines were used as 	

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				a pilot test during the QA sessions. <ul style="list-style-type: none"> Developed strategic plan of action for risk-based assessment of dossiers and introduced an SOP for expedited registration of products accepted by Stringent Regulatory Authorities, including products registered with US FDA, Japan, EU, WHO/PQP, and other ICH observers and associate members. 	
Develop tools for smooth & effective functioning of the product registration & licensing system			Initiated Quality Assurance System for dossiers evaluation		
Obtain software & infrastructure for registration dept		Computers and printers were provided	Finalized acquisition of hardware (computers & sliding shelf) which is a prerequisite to develop the MIS		
Strengthen inspection systems–good manufacturing practices (GMP) good distribution practices (GDP) and good clinical practices (GCP)– to improve the quality of medicines and improve compliance by stakeholders					
Improve capacity & skills of inspectors				<ul style="list-style-type: none"> Conducted consultative workshop on GMP guidelines and the guideline for establishing licensing Provided ToT on GCP for two staff of the Authority in Saudi Arabia 	

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				<ul style="list-style-type: none"> Conducted GMP training for the staff of FMHACA, branch offices, and industries 	
Develop inspection guidelines & templates				Developed inspection templates and provided them as an annex to the licensing guidelines	
Strengthen the various FMHACA laboratories (physico-chemical, microbiological, toxicological, condom testing, etc.) to make them ISO Accredited and WHO prequalified					
Improve capacity of staff in analytical techniques and lab management		<p>The physicochemical laboratory was accredited with respect to seven tests in November and is valid for two years. GF has included the lab in their list of ISO17025 certified QC labs. PQM has been working with lab mgmt to expand the scope of accreditation to the remaining physicochemical tests, microbiological lab, and condom testing lab. Contacts have been made with institutions that can provide training on food analysis and microbiological testing. The microbiological testing will take place in February at USP India.</p>	<ul style="list-style-type: none"> Three analysts trained in USP/India lab on microbiological methods of analysis Twelve staff trained on advanced HPLC 	<ul style="list-style-type: none"> Nine HPLC instruments of PQAD underwent corrective and preventive maintenance. PQM conducted practical training to three PQAD analysts on how to perform preventive maintenance for the HPLC instruments. PQM consultant provided corrective and preventive maintenance and calibration for Valendor's condom testing equipment parts: Inflation tester; Electronic hole tester; Leaker tester; Tensile strength tester; and Thickness-measuring caliper. PQM provided practical and lecture-based training for seven PQAD 	USP PQM contracted RTC, an American PT provider, for PQAD PT of HPLC.

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				staff members on: <ul style="list-style-type: none"> - Preventive maintenance and calibration of condom testing equipment - Requirements of ISO 4074 - Requirements of WHO 2010 for male condoms • Enresol engineer provided maintenance and calibration of Enresol condom machines. • Three PQAD staff members were sent to Ghana FDB to attend a nine-day training on food testing. 	
Build quality systems at all levels of QC lab			<ul style="list-style-type: none"> • Assisted FHI 360 to assess the lab • Four SOPs on condom testing were prepared 		
Provide maintenance & servicing of equipment					
Provide equipment, RS, materials & lab supplies			One Karl Fischer titrator and log books supplied		
Establish/strengthen lab data management & info systems					
Support lab staff in regional QA activities					USP/PQM sponsored PQAD's participation in the NAMCOL workshop in Mozambique.

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Assist QC lab move to new facility and make operational					<ul style="list-style-type: none"> • Invitation for tender to move the lab to a new site announced in the Ethiopian Herald; bids assessed (none met requirements). • Direct negotiations were held with Shimadzu agent; contract drafted and submitted to FMHACA, USP/PQM, and Shimadzu agent
Assess the quality of ARV and OI medicines circulating in the market by undertaking post-marketing surveillance (PMS) activities					
Establish task force		Established		<ul style="list-style-type: none"> • Finalized report on ARV and OI PMS. • All laboratory supplies for testing ARV and OI medicine samples to be collected were delivered to PQAD laboratory. 	
Update protocol for PMS					
Select sentinel areas		Seven sentinel areas chosen			
Train sample collectors and analysts					
Provide budget for collecting and testing samples					
Collect samples		In FY11, post-market surveillance of ARV and OI medicines was conducted and about 124 samples of ARVs and OI medicines were collected from seven			

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		sentinel areas covering the whole country.			
Purchase lab supplies necessary for the testing		A list of chemicals and supplies required for PMS of ARV and OI medicines for FY 12 was prepared and sent to USP headquarters for procurement. Some of the items requested have been shipped while the remaining supplies have been ordered and are in the pipeline.	Most of the lab supplies required for testing the collected samples were procured and supplied.		
Test samples		Out of the 124 samples, 91 representing 5 brands of preparations manufactured by 5 manufacturers were subjected to lab testing and analysis; these were also investigated as to their registration status.			
Write report based on information gathered and data generated		A draft report was prepared by the PMS task force in Dec and submitted to FMHACA for action. The report will be submitted to USAID and other relevant partners after getting the consent of FMHACA.			
Assess the quality of antimalarial medicines by conducting post-marketing surveillance					
Establish task force					
Update protocol for PMS					

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		Q1	Q2	Q3	Q4
Select sentinel areas					
Provide supplies and instruments needed for PMS			Most of the lab supplies required for testing the collected samples were procured and supplied.		
Train sample collectors and analysts		A one-day training for sample collectors was held.			
Collect samples		In FY 11, 262 antimalarial samples were collected from 6 sentinel areas.	Samples of antimalarial medicines collected from five of the six sentinel areas.		
Test samples		Ongoing		Collection of samples from the 6 th site was finalized and all of the collected samples were delivered to the PQAD laboratory for testing	Testing of the collected samples was finalized.
Write report based on information gathered and data generated					Draft report was prepared and was circulated for comments.
Use results of PMS to create public awareness and to take administrative & legal measures					
Improve capacity and skills of local OI medicines manufacturers to ensure that their products and manufacturing sites comply with GMP					
Using results of GMP audit, identify gaps that local mfrs face in GMP compliance		A reminder letter to comply with the GMP audit report has been sent by FMHACA to all eight of the companies audited in December. One company has responded to the letter.		<ul style="list-style-type: none"> Developed a plan of action for GMP Road Map of Ethiopian pharmaceutical manufacturers. A total of eight manufacturers are expected to participate in the second 	<ul style="list-style-type: none"> Detailed inspection of all local manufacturers to critically review the deficiencies of the industries with regard to meeting cGMP requirements completed and report finalized.

Promoting the Quality of Medicines (PQM Program)
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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				round assessment to be conducted during August 2012 as part of technical assistance for future compliance with the cGMP. • USP PQM regulatory affairs staff participated in the training for local manufacturers on product dossier preparation that was sponsored by WHO. More than 30 participants took part, mainly staffs from manufacturers and from FMHACA.	• Supported the development of a roadmap for the local pharmaceutical industry; document is under discussion.
Select gaps most easily addressed w/PQM TA					
Provide TA to address select gaps & promote GMP compliance					
Establish/strengthen regulatory management information system					
Develop information tools and database					
Procure computers and accessories					
Develop software and network					
Train staff on MIS software					
Launch and sensitization of RMIS					
Monitor and evaluate program implementation					
Develop monitoring & evaluation tool					

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY12 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct monitoring & evaluation of program implementation					
Ghana	R. Okafor				
Support post-marketing surveillance program for antimalarial medicines and encourage FDB to take enforcement actions based on results					
Conduct medicines quality monitoring in five sentinel sites		Samples have been collected for the next round of testing; FDB will start testing in Q2	Round 1 MQM was completed and results sent to PQM.		MQM testing completed at sentinel sites. PQM is awaiting results from FDB.
Conduct confirmatory testing at the FDB lab			Testing has been completed and sent to PQM.	Reference standards ordered for confirmatory testing. Confirmatory testing currently in progress.	Confirmatory testing completed. Results to be sent to PQM.
Promote enforcement actions based on data					Report on results to be forwarded to FDB.
Strengthen the capacity of the FDB national QC lab and assist toward ISO 17025 accreditation and WHO prequalification					
Implement action plan to reach ISO 17025 accreditation in FY12		PQM conducted a working session with key FDB staff to identify the primary scope of accreditation, establish priorities, and develop an ISO 17025 and WHO prequalification implementation plan. PQM delivered training to all FDB staff on ISO and WHO standards, external audit expectations, auditee behavior, internal audit procedures, etc.	PQM conducted training on various techniques in January. List of equipment needed for ISO 17025 was provided to FDB CEO and lab director.	Manufacturing of furniture for new facility is ongoing. Upon completion of move to new facility, PQM will conduct a pre-audit for ISO 17025 accreditation.	Manufacturing of furniture with local company still ongoing.
Provide any needed TA to establish lab in new facilities		FDB will move to the new facility in March/April 2012.	PQM visited the new facility and made suggestions to correct safety issues.	PQM provided FDB with a move qualification plan.	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Develop a plan for equipment qualification & validation after move to new facilities		Following the move, PQM will assist in instrument qualification and scheduling of the pre-audit for ISO accreditation.	PQM discussed the plan for FDB to move to new facility. A move and qualification plan was developed and provided to FDB.	PQM has provided FDB with a qualification plan. Upon move to the facility PQM will schedule a trip to assist in the qualification of equipment.	FDB will employ local vendors to qualify equipment with a service contract. PQM will assist with others upon move.
Develop a list of SOPs needed for ISO 17025 & assist FDB to develop			PQM reviewed SOPs during the January visit. Suggestions were made to QA Officer on SOP additions and audit plan. PQM is helping with SOPs.	12 SOPs have been revised based on the suggestions made during the PQM visit.	PQM to train QA manager at Rockville site in FY 13.
Develop a GMP Road Map for local manufacturers of essential medicines					
Draft a GMP Road map document and share with FDB and UNIDO			Draft GMP Roadmap completed.		Draft GMP Roadmap completed.
Help FDB convene a meeting of local mfrs and share <i>Road Map</i>				Meeting of stakeholders to discuss Roadmap rescheduled twice due to unavailability of key stakeholders from Ministry of Health.	Meeting of stakeholders to discuss Roadmap rescheduled twice due to unavailability of key stakeholders from Ministry of Health. Meeting will be revisited in Q1 FY 13.
Support inclusion of FDB data in the PQM MQDB					
Support data entry and develop statistics using MQM data		PQM has provided assistance on MQM data and results were forwarded to PQM.			Ongoing, pending results from FDB.
Sensitize the public to the dangers of substandard and counterfeit medicines					
Assist to develop educational materials about SCMs			PQM discussed helping with SCM documents with CDC in January.		Ongoing, pending results from FDB.
Provide FDB resources for materials to raise awareness about SCMs			PQM and CDC agreed that PQM can help to provide wording.		

Promoting the Quality of Medicines (PQM Program)
Quarterly Reports: FY12 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Provide resources to FDB to develop educational materials					Resources to be provided upon receipt of completed results.
Ghana MCH	R. Okafor				
Monitoring the quality of uterotonic medicines					
Develop a protocol for the study of uterotonic medicines quality					Protocol was provided.
Train Laboratory staff on compendia testing of oxytocin			Lab staff was trained on oxytocin and technique errors; storage conditions were discussed.		Correct standards provided to correct mistakes.
Conduct sampling at selected sites and testing at the FDB laboratory				Sampling plan prepared. Training to be conducted in Q4 for field staff who will perform sampling to ensure cold chain is maintained for samples.	Samples collected. Testing ongoing at FDB.
Promote enforcement actions					Upon completion of testing, results will be forwarded to FDB for actions.
Kenya	L El Hadri				
Continue to strengthen antimalarial medicines quality monitoring					
Conduct one round of sampling & testing in collaboration with DOMC and PV Dept		QC testing of the 2011 round is nearly completed (80%). The MQM report, including the results of round 1 and 2, was shared with the relevant stakeholders.	Reagents and RS provided to NQCL; round of sampling and testing planned for Q3	Confirmatory testing for 2011 round completed. 530 samples of antimalarials were collected from 5 sentinel sites and tested using Minilab basic tests.	Verification testing of samples collected during round 3 completed at NQCL. Confirmatory testing on 28 samples completed at NQCL. The breakdown of the confirmed samples is as follows: SPs - 8, Quinine- 10, AL - 7 and

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY12 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					DHAP - 3. All samples passed QC testing.
Continue to support enforcement action by PPB on poor-quality medicines and strengthen NQCL					
Monitor MQM activities and provide supporting evidence to PPB		PPB recalled expired samples, sent warning letters to unlawful companies selling nonregistered medicines, closed one pharmaceutical company, and withdrew nonconforming lots.	Supporting data provided to PPB for regulatory actions	<p>Provided PPB with evidence-based data to take enforcement action against seller of counterfeit quinine tablets. (Seller arrested and jailed.)</p> <p>Conducted monitoring and evaluation visits to two sentinel sites. Gaps were identified and recommendations were provided.</p>	
Provide technical assistance to NQCL		TA to NQCL to complete the QC testing of the 2010 round has been provided.			Assisted NQCL in gathering all information needed to submit their application to undergo an external ISO 17025 assessment by SANAS (an international accrediting body)
Raise awareness on SCMs and share evidence-based data with PPB, DOMC, and other relevant partners		Shared enforcement actions taken by PPB with relevant partners.	Results of round 1 and 2 presented at round table meeting	Shared lab test results of failed quinine sulfate with PPB, DOMC, and USAID.	Provided PPB with an article from USP's newsletter <i>The Standard</i> -- "Pharmacy and Poisons Board in Kenya Partners with PQM, Tracks Source of Fake Antimalarial Medicine"-- to be posted on the PPB website and in their newsletter.
Liberia	L El Hadri				

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 Quarterly Reports: FY12 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Continue to assist the LMHRA in strengthening its regulatory capacity					
Facilitate transition of LMHRA management				<ul style="list-style-type: none"> • Managing Director (MD) position advertised and interviews for potential candidate are being conducted. • Developed an implementation plan for LMHRA, including: <ul style="list-style-type: none"> – creating awareness-raising activities; – standards for accreditation of medicines stores; – appointment of an MD; and, – planning a hands-on training workshop on registration and dossier evaluation. 	
Provide inspection training to LMHRA and NDS staff				Provided training on Medicines Regulatory Inspections to 13 staff members.	
Strengthen medicines quality control capabilities					
Provide theoretical training in USP General Chapters for compendial quality control of medicines		Completed training materials for theoretical training on USP General chapters; used it to train 6 LMHRA QC lab staff.			
Provide basic lab supplies, RS, chemicals, reagents, and equipment for the dissolution tester		Provided basic lab supplies, RS, chemicals, reagents, HPLC, and equipment for the dissolution tester.		Provided additional RS, chemicals, and 3 columns in addition to other consumable lab supplies.	Provided one set of Minilab TLC chemicals; 6 pipette bulbs; Minilab RS for antibacterials, antimalarials, antituberculars, antiasthmatics,

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
					antiallergics, analgesics, and ARVs and OIs.
Provide hands-on training using pharmacopeial standards and GLP, as well as hands-on training on HPLC		Conducted hands-on training using pharmacopeial standards and GLP on: use of UV software program; performance verification testing for Dissolution tester; calibration of pH meters; and dissolution of amodiaquine hydrochloride tablets		Conducted hands-on training on HPLC to 6 staff from LMHRA QC lab.	
Supervise the quality control for confirmatory testing of medicines				Supervised QC testing of selected medicines during HPLC training.	
Support NDS and LMHRA in testing of antimalarial and HIV medicines by providing new resources					
Conduct one round of antimalarial and antiretroviral medicines quality control study				One round of testing antimalarial samples completed. A total of 110 antimalarial samples were collected.	A total of 80 samples of ARVs and medicines to treat OIs were collected; one round of testing using Minilabs was completed. Confirmatory testing is pending the repair of the HPLC, UV, and dissolution tester.
Draft and share reports with stakeholders				Preliminary report shared with stakeholders.	
Assist LMHRA in taking appropriate enforcement actions based on medicines quality data and inspections				<ul style="list-style-type: none"> Failed antimalarial recalled from the market. Evidence-based data provided to LMHRA to initiate banning use of monotherapy treatment. T 	

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY12 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				<ul style="list-style-type: none"> Ministry of Health officially banned monotherapy treatment based on data provided. Materials created for public education and awareness-raising were reviewed. 	
FY11 Workplan Activities using FY12 Forth Funds					
Support the LMHRA In establishing priority medicines regulations					
Complete PQM initial draft guidelines for: - Premises licensing & registration - Pre-registration of medicines and health products - Priority guidelines and standards of practices to supplement LMHRA		A revised draft with new policies and regulations was submitted to LMHRA for review.	Guidelines have been reviewed and completed for: <ul style="list-style-type: none"> Premises licensing & registration Pre-registration of medicines and health products Priority guidelines and standards of practices to supplement LMHRA 	Finalized LMHRA guidelines and priority medicines regulations.	
Introduce regulations to importers and wholesalers				Regulations Guidelines presented to importers and wholesalers.	
Establish principles for memos between the Pharmacy Board, Customs, and Standards Laboratory				Completed.	
Establish principles for memos between the Pharmacy Board, Customs, and Standards Laboratory				Training provided to 13 staff.	
Develop human resources capacity					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Train LMHRA staff		Facilitated the hiring and training of 3 lab staff	3 permanent staff hired for LMHRA QC lab.		
Establish human resources plan			Established plan.		
Present 3-year LMHRA strategic plan that defines roles of Governing Board				Completed.	
Build quality control capacity by providing new resources					
Assess LMHRA QC lab equipment & consumables			Lab equipment and consumables assessed.		
Procure HPLC and other lab equipment		Provided basic lab supplies, RS, chemicals, reagents and procured HPLC, and equipment for the dissolution tester.		Provided additional RS and chemicals needed by lab.	
Conduct hands-on training of LMHRA QC lab staff		Provided hands-on training using pharmacopeial standards and GLP on: use of the UV software program; performance verification test for Dissolution tester; calibration of the pH meters; and dissolution of amodiaquine hydrochloride tablets			
Establish LMHRA QC laboratory documentation			Established critical laboratory documents for analytical reporting and data management.		
Install HPLC, needed electrical power stabilizers, and window blind		Ensured installation of HPLC, water purification system, and air exhaust hood.	Completed, except for power stabilizer and window blind due to limited budget.		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Madagascar	M Hajjou				
Improve medicines quality control and monitoring of ACTs in Madagascar					
Develop a sampling and testing protocol		Developed a protocol for the sampling and testing of ACTs available in the market. The total number of samples to be tested is 300.			
Sort samples, validate sampling, code samples, and organize information collected			330 samples received were verified, coded, and logged in USP database. The samples were sorted for testing.		
Identity, assay, and test samples for impurities per pharmacopeial monographs			Ongoing	Testing of 205 samples completed. Testing of remaining samples will be completed by end of July 2012.	Testing of all samples has been completed.
Develop detailed report and recommend actions					PQM Lab Services is drafting the final report. PQM shared a summary of the testing results with USAID/Madagascar.
Mali	M Hajjou				
Strengthen the capacity of the National Laboratory of Health (LNS) to attain ISO 17025 accreditation					
Strengthen technical capacity of lab & staff					
Strengthen quality system capacity with SOPs and QMS		14 SOPs were developed and reviewed. LNS staff will be trained on the SOPs.	8 new SOPs developed and reviewed.	All activities are on hold	All activities are on hold
Evaluate each training with exercises					
Support LNS in NAMCOL participation					
Provide refresher					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
training in GLP					
Support pre- and post-marketing quality monitoring of antimalarials and insecticides					
Prepare and facilitate new round of sampling and testing			60 samples were collected and tested using basic tests. An additional 320 samples were collected. Testing is on hold due to political issues in the country.		
Monitor and evaluate MQM activities					
Facilitate sampling and testing of ADRs					
Strengthen the National Pharmacovigilance Program					
Stimulate ADE reporting		A protocol for conducting continuous reporting of ADEs at one hospital was developed and is under review.			
Publicize CNRP activities nationally and internationally			First CNRP information bulletin issue developed and will be shared with health professionals.		
Mozambique	R. Okafor				
Strengthen the capacity of the National Laboratory for Medicines Quality Control					
Assist LNQCM to become fully operational in temporary facility		Floor plan was developed and included in contract between PD and the construction company; construction is to begin in Jan	New QC lab was refurbished and all work completed. PQM provided and installed equipment and two AC units and trained staff.	The Permanent Secretary inaugurated the temporary lab. PQM provided training on HPLC, UV, pH, Disintegration, Lab Safety, Volumetric and weighing techniques, Karl Fischer (theory), how to read and understand USP monographs, and Good	Provided reagents and reference standards to LNCQM. In September, provided PVT training, Dissolution training – theory and hands-on, Karl Fischer training – hands-on. Also conducted follow-up training on Disintegration,

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				Lab Practices. Provided additional supplies to the lab: reference standards, reagents and solvents shipped, current USP monographs, lab supplies- air conditioning unit for reagent room, printers for equipment in lab and office, electrical supplies for lab, and parts for dissolution system and disintegration system. Also serviced refrigerator/freezer for storage.	HPLC, UV, and LOD. Provided lab consumables, replaced water pump to allow for proper operation and use of water purification system.
Assist LNQCM to refine plan to become ISO accredited/WHO PQ'ed within 2 years of moving to new facility			Training of LNQCM started with GLP and ISO 17025 as standards.	Assisting with evaluation of SOPs required for ISO 17025 accreditation is ongoing.	Discussed ISO accreditation plan with LNCQM management; pre-selected scope of accreditation. Discussed QA Manager visit to USP for intense training on ISO in FY 13.
Provide TA to USAID on construction, fitting & furnishing new QC lab			PQM recently met with USAID and agreed on a timetable to work together on a budget and a plan for QC lab with a US-based engineering company and USAID/Mozambique	Met with AECOM to discuss requirements for lab and later held a teleconference to discuss AECOM blueprint.	Provided revisions to AECOM on the blueprint, electrical requirements for equipment, and equipment and furniture cost estimates.
Provide support to LNCQM and PD as requested by USAID					Facilitated PD hosting NOMCOL meeting in September.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Establish and implement an MQM program for selected essential medicines in four sites (North, North West, Center, and South)					
Finalize and approve sampling & testing protocol and budget		Protocol developed and distributed			
Perform two rounds of sampling and testing according to protocol		Minilab training conducted in Oct	First round of MQM was partially completed; PQM reviewed the work done in three sites and urged PD QC lab to complete the work	MQM Round 1 completed. Testing at LNCQM completed. Confirmatory testing by PQM is ongoing. MQM Round 2 began at provincial sites.	LNCQM completed MQM round 2 and provided results to PQM.
Develop report for each round of MQM				LNCQM to provide results of Rounds 1 and 2 in Q4.	PQM to provide a report to USAID by the end of October.
Share reports w/stakeholders and promote enforcement efforts based on data		PD director agreed to share future MQM data in PQM's medicines quality database (MQDB)			LNCQM provided reports to PD on MQM results. LNCQM staff visited the medicine warehouse to instruct distributors to remove failed samples and expired medicines from inventory.
Formally include LNCQM in NAMCOL activities and encourage their participation					
Participate in NAMCOL annual meeting		PQM received approval from PD to formally include the LNCQM in NAMCOL	PD agreed to host upcoming NAMCOL meeting in Q3	Date set for NAMCOL meeting and invitation sent to participants. Logistics for location ongoing.	PD hosted NOMCOL meeting in September. PD is an official member of NOMCOL Africa.
Participate in NAMCOL lab training(s)					
Participate in NAMCOL inter-laboratory testing					NOMCOL members selected monographs and tests for inter-laboratory comparative testing. Medicine has not been distributed to members.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Participate in the Medicines Quality Virtual Forum					PD was informed about participating in Virtual Forum.
Hire a local consultant to serve as in-country coordinator for PQM activities					
Post job description; select candidate; and train consultant hired on PQM activities			Candidates were identified.	Interviewing candidates.	LNCQM informed PQM and USAID they prefer PQM visits instead of an in-country consultant. USAID agrees.
Rwanda	A Smine				
Assess Rwanda's existing medicine quality control systems and capacity and recommend possible improvements		All of Rwanda's activities are on hold because the MCP has prevented PQM from visiting the country. PQM developed QA procedures to control RDTs but never received any feedback.			
Equip and ensure repairs of NUR Faculty of Pharmacy QC lab and provide reagents needed to test antimalarial medicines					
Train NUR QC Lab staff, MOH-PTF pharmacists, and a local manufacturer in key QC methods					
Build capacity through QC testing of antimalarials from private and public sectors by NUR QC Lab and PQM evaluation					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Senegal	L El Hadri				
Ensure continued post-marketing surveillance of antimalarial medicines quality and promote corrective actions					
Conduct one round of MQM for AMM meds at 9 sentinel sites		QC testing of 2010 round was completed. QC results of antimalarial, anti-TB, antiretroviral medicines, and contraceptives were submitted to DPL. QC testing for round 2011 has been delayed because of the lab's transition to new management.	Minilab RS, reagents, chemicals provided to LNCM	List of samples to be collected and sources of collection completed.	For 2012 round, 430 samples including antimalarials, ARVs, and contraceptives were collected from 5 sites and tested using Minilabs. Confirmatory testing on failed samples is ongoing at LNCM. Sample collection and testing at the remaining 4 sites will be completed by November 2012.
Train new staff from Louga and Ziguinchor and LNCM on sampling strategies, Minilab [®] basic tests, and reporting.				Trained 4 staff from 2 new sentinel sites (Louga and Ziguinchor) and 11 staff from LNCM.	
Organize a meeting of MQM partners DPL, UCAD, LNCM and PNLP to review the role of each party; finalize, and approve the planned MQM activities for this round.				Planned MQM activities shared with stakeholders and approved.	
Facilitate one-day refresher training for five team leaders of nine sites on sampling, testing, data management, and travel logistics				Provided refresher training on supervising Minilab activities in the field to 9 staff from DPL, LNCM, and PNLP	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Monitor and evaluate MQM activities at 9 sentinel sites				Planned for Q4.	M&E visits completed at 2 sites: Ziguinchor and Louga.
Present MQM results and promote regulatory action by DPL		Shared with relevant stakeholders the regulatory actions taken by DPL on each category of failed samples. DPL took regulatory actions on failed, expired and non-registered samples. on 2011 round		Results of 2 previous rounds (2010 and 2011) presented to major stakeholders at roundtable meeting.	Present the prelim results of round 2012 (5 completed sentinel sites) to DPM and PNLN as well as the MCRs of Ziguinchor and Louga.
Support enforcing regulatory action by DPL					
Organize two-day workshop for DPL and customs agents		To strengthen the collaboration between DPL and customs, PQM initiated communication with the DPL director to discuss the content of the workshop and the presentations.		Discussed workshop planning and logistics with DPL director. Workshop agenda presented by DPL director to the customs director/	Activity still pending response from the customs general director.
Strengthen the capacity of DPL					
Provide TA to improve the registration processes at DPL				New software installed and 9 staff from DPL trained on its use.	
Strengthen the capacity of LNCM					
Improve the technical capacity of LNCM staff through NAMCOL				Invitation letter sent and travel arrangements made for LNCM director to attend NOMCOL meeting in Mozambique in Q4.	NOMCOL charter and the report from the meeting were shared with the lab director. Provided information needed to the lab to start the next inter-laboratory proficiency testing.
Prepare LNCM for ISO				Reviewed results of	Assessment of LNCM

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
17025 accreditation				previous mock audit conducted by TUNAC. Provided guidance on starting the process of implementing CAPAs.	<p>QMS and technical capacity conducted, scope of accreditation defined, and tasks assigned to lab personnel.</p> <p>20 SOPs developed</p> <p>10 LNCM staff trained on: management review, internal audit, and CAPAs; 2 lab staff trained on basic lab inspection</p> <p>Consolidated the LNCM roadmap toward ISO 17025 accreditation</p> <p>Organized a meeting at MOH with partners and presented the ISO 17025 accreditation processes as well as the list of needed lab supplies, training, and equipment.</p>
ASIA					
RDM-A Mekong Malaria	S. Phanouvong				
Conduct comparative studies on availability of antimalarials, their quality and source (country of origin, name of manufacturer/supplier, health facility and/or retailer) at existing MQM sites and non-MQM sites of Laos, Cambodia, Vietnam, and Thailand using random sampling methodology to determine the differences, if any, of the antimalarials' quality and availability, and source.					
Conduct a comparative survey between existing MQM and non-MQM sites using random sampling to obtain evidence-based data on quality,			Communication is ongoing with national partners to identify sites to include in the survey	Preliminary survey design and methodology has been discussed with all country partners. A draft survey design and methodology document is planned for July.	A training workshop on the comparative study is scheduled in October.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
availability, and source of antimalarials in hot-spot zones.					
Strengthen national & regional capacities in medicines regulation, enforcement and QA/QC systems, building on the success of ANEQAM					
Implement the BREMERE initiative: A regional Task Force will be established to prompt information sharing and investigation, and promote collective enforcement actions at inter-country and regional levels by involving MRAs, police, customs, prosecutors, WHO and the INTERPOL.			In discussions with national MRAs on defining roles and responsibilities of the BREMERE and identifying suitable dates in Q3-Q4 to hold a BREMERE meeting	<ul style="list-style-type: none"> • PQM introduce idea of BREMER meeting with Thailand, Laos, Cambodia, and Vietnam NQCLs; Laos MOH/FDD expressed strongest willingness to help PQM organize it. • Meeting is tentatively scheduled for Aug 28-29 or Sept 4-5 in Vientiane, Laos. 	Regional BREMERE meeting was held Aug 28-29 in Bangkok. Representatives from authorities in Cambodia, Laos, Thailand, Vietnam, Philippines, and Indonesia and from international and scientific/academic organizations participated. Timeline of activities and preliminary TOR were agreed upon.
Intensify collaboration and data-sharing with relevant partners, such country MRAs in the region, and the scientific communities for collective action and improve the work performance in the region		PQM exhibited at the 7th Indochina Conference on Pharmaceutical Sciences in December. Dr. Phanouvong gave a plenary lecture titled "ASEAN Harmonization & Regional Strategy for Quality Assurance and Quality Control of Pharmaceutical Products."	Engaged MRAs to use PQM's medicine quality database (MQDB)	No update to report for this reporting period	In addition to engaging partners in BREMERE, PQM distributed an article, on the counterfeit artesunate found, in Lancet 2012; 380:1120 to all GMS countries' MRAs and NMCPs to investigate if the products are still available in their markets.
Conduct ANEQAM regional GMP training for Thailand, Burma, Cambodia, Laos, and Vietnam with Mahidol University			Planning meeting was conducted for preparation of the training with Mahidol to identify suitable dates and location	Ongoing discussion with country and ANEQAM partners	Attempts made to re-engage Mahidol staff and discussed with one professor preparing for a workshop for Philippines' FDA staff on PV in November.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct ANEQAM regional training with Chulalongkorn University			Planning meeting was conducted for preparation of the training with Chula to identify suitable dates and location	Ongoing discussion with country and ANEQAM partners	Ongoing discussions with countries (China and Myanmar) and ANEQAM partners.
Provide direct TA to country level quality control labs towards ISO:17025 and WHO-PQ			Continued working with Vietnam NIDQC lab, Cambodia NHQCL, Laos FDQCC, and Thailand BDN lab	PQM informed the countries about PQM's new manager for ISO work at PQM. See Vietnam and Cambodia sections for plans made.	With the new Quality Management System Manager onboard at the HQ, this work will be resumed in FY13. Discussing with WB to leverage funds for Cambodia NHQCL. (See Vietnam and Cambodia sections for further information)
Maintain office at Chulalongkorn University laboratory to continue providing training and research on development of pharmacopeial monographs for anti-malarial medicines and fingerprints for profiling the counterfeit AMLs in the region		Worked closely with Chulalongkorn University, Faculty of Pharmaceutical Sciences, to agree on a new Memorandum of Collaboration which includes: office space and administrative support for the local consultant at the Faculty of Pharmaceutical Sciences; expansion of method development project for Atovaquone/Proguanil; and, as an ANEQAM partner, Chula will be a Center of Excellence and will provide trainings on QA/QC of medicines	Reference standards and columns were provided. MOC is in the renewal process.	<ul style="list-style-type: none"> • MOC has been signed with Chula Faculty of Pharmaceutical Sciences. • Chula will continue to provide PQM office space at their premise for 2-3 staff and agreed to assist in obtaining the work permit visa for the new PQM consultant. 	<ul style="list-style-type: none"> • Ongoing discussions with Chula on assistance for work permits and housing a consultant on Chula premises/payroll. • Chula completed method for AVQ/PNG; will start validation once comparators shipped. • Chula served as co-host of regional BREMERE meeting. • Ongoing discussions on future research collaborations (additional method, fingerprint library).

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Develop targeted communication tools and activities to raise public awareness about the dangers of counterfeit and substandard medicines					
Collaborate with US Embassy Public Affairs Office and Drug and Food Department MOH of Laos conduct a survey to determine public awareness level of pharmacists and consumers in Vientiane and develop and distribute awareness raising materials to pharmacists to educate consumers on danger of counterfeit medicines. Evaluate level of awareness after 6 months intervention i.e., after leaflets have been distributed to gauge the impact of the program on levels of awareness			Concept document, activities, and budget were agreed upon and approved. Contract is under review by Laos MOH/FDD and U.S. Embassy Public Relation Division	<ul style="list-style-type: none"> PQM received the revised time line for implementing this activity from the MOH/FDD and U.S. Embassy Public Relation Division, as requested. The MOC is being finalized by USP and is expected to be signed in July 2012. 	Review of draft survey questionnaire by PQM team completed. Awaiting final version of questionnaire after FDD incorporates relevant comments.
Contribute to the finalization of the regional documentary film on counterfeit medicines			Funds were wired to Soho Films and final filming will be completed in Q3	Editorial process has been completed; final filming in Vietnam and interview with USAID is planned for Q4.	Final version completed. No clearance was obtained for interview with USAID.
Contribute to the French Embassy-funded "Pharmacide Arts Project" expansion for the GMS			No financial contribution has been made, but PQM provided inputs on process and exhibition location (Vientiane, Laos and Hanoi, Vietnam)	Pharmacide Arts catalogue was produced by Soho Films and partners. PQM received 10 copies of catalogue which are being distributed to key stakeholders (USAID, USP Media Relations).	<ul style="list-style-type: none"> 20 additional copies of Pharmacide Arts catalogue obtained. Pharmacide Arts exhibition schedule finalized. Exhibitions in several Indonesian cities scheduled.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Support the outreach activities at the local level in high-risk areas to raise awareness about counterfeit/ fake medicines through public gathering/meetings, and dissemination of posters, brochures, bulletins, radio spots, PSAs. Awareness raising materials developed in collaboration with the US Embassy Public Affairs Office in Laos (under Activity 1 above) will be also adapted for this outreach activity in Cambodia, Thailand and Vietnam.			Under discussion with partners	Draft MOC being revised.	Three party MOC was signed between PQM, US Embassy to Laos, and MOH/FDD to conduct survey on knowledge and skills of pharmacy retailers in private sector in Vientiane on poor-quality medicines. Survey questionnaire developed, revised, and completed. Survey implementation is ongoing.
Draft and submit articles for peer-reviewed journals and popular media			Continued follow up on the manuscript submitted to TropMed Journal in Thailand on the Cross-border Study of AML quality in Thailand site. Similar manuscript on Cambodia site is in draft.	PQM contributed to draft article on medicines quality in Mekong Subregion; draft is in collaboration with a Mahidol professor, formerly PSyRiC Director, who helped DQI develop MQDB in 2003-2006. (IRASEC, Observatoire FSP Mekong Project of the French Ministry of Foreign and European Affairs, funded the Chula professor's time for writing this article.)	<ul style="list-style-type: none"> Continued follow up of the manuscript focusing on Thailand; fast-track requested. Submitted manuscript and requested fast-track for the manuscript focusing on Cambodia.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Other Activities					
		<ul style="list-style-type: none"> Participated in CAP-malaria project planning workshop with URC in December Coordinated with local Thai partners on continued MQM projects -- Sample collection for 2011 has been completed in 12 of 13 sentinel sites (total 503 samples). The samples included antimalarials, antituberculars, and antibiotics. -- Major delays were caused by widespread flooding in central Thailand during October-December PQM and Kenan Institute Asia successfully helped the Thai Bureau of Vector-Borne Disease to submit an application and receive Global Fund R10 malaria funding which was consolidated with earlier funding and 	<p>Planned with Kenan, Thai BVCD and FDA to conduct training on MQM for 22 provinces under the GFATM R10 support, which PQM was sub-contracted as technical assistance provider to help implement the MQM activities.</p>	<ul style="list-style-type: none"> Successfully conducted training workshop for 22 provinces under GFATM R10 support with Kenan, BVBD, and Thailand FDA on April 2-3; action items for implementation were developed and agreed upon. Recruited new consultant to represent the PQM program in Mekong Subregion and coordinate activities. 	<ul style="list-style-type: none"> Participated in CAP-Malaria meeting on cross-border collaborations in Cambodia. Coordinated with Thai partners on the progress of the GFR10 antimalarial quality project. Started recruiting for a country consultant in Myanmar. Explored potential collaboration with Save the Children Myanmar on MQ survey. Prepared TOR for recruitment of pharmacy interns to review the QA/QC curricula in Cambodia, to start in FY13 Q1. Consultant Siv Lang participated in high-level LMI meeting in Phuket, Thailand.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		renamed "Global Fund SSF-M". PQM contributed mainly on the Quality of Medicines element of the application. <ul style="list-style-type: none"> One Minilab (including manuals and reference tablets) has been obtained for the PQM office in Bangkok. This will be used to facilitate trainings, demonstrations, exhibitions, and rapid dispatching to sentinel sites throughout the region when needed. 			
BURMA		S. Phanouvong			
Obtain baseline data through household and health facility survey using random sampling on quality, availability, and source of antimalarials in targeted areas					
Collect general info on current QA/QC systems in supply & distribution of AMMs, and how they are supplied in public and private sectors.			Ongoing communication with National Malaria Control programs for relevant information	Completed.	
Design survey protocol and procedures			In conceptualization phase on study design and methodology development	Survey protocol developed, reviewed by country partners, and finalized.	
Train field staff on sampling methods			Will take place in Q3	Completed on May 12	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Train select QC lab staff from Nay Pyi Taw & Mandalay on compendial testing methods for AMMs			Will take place in Q3	Completed. Training was conducted May 7-11 for 11 participants from Burma FDA QC labs of Nay Pyi Taw and Mandalay, and for Dept. of Medical Research-Lower Burma (DMR-LB).	
Sample and collect data from survey sites			Will take place in Q3-Q4	Scheduled for Q4.	<ul style="list-style-type: none"> • Itemized budgets for survey obtained from DMR-LM, VBDC, and FDA. • List of samples (MARC project) sent to USP for review and to determine if all samples have compendial monographs. • Letter sent by WHO to IHD at MOH Myanmar for approval to start sample collection. • Collection started by VBDC in 11 townships (Mid Sep).
Analyze samples at Nay Pyi Taw & Mandalay labs; may need to confirm test sub-set at NIDQC, VN			Will take place in Q4	Scheduled for Q4. Samples collected for baseline survey will be analyzed at ISO-17025 accredited QC labs in the region (and/or at USP lab).	Coordinating shipping of samples (MARC project) to India USP lab or GMS lab.
Analyze data and write a technical report			Will take place in Q4		Delayed due to slow progress in Myanmar.
With WHO country office, establish a pilot MQM program for early detection of poor-quality antimalarials to strengthen the post-marketing					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
surveillance activities of FDA and local health agencies					
Meet with key stakeholders to plan set-up of 5 sentinel sites; engage local partners to implement			Completed in February		
Train Burmese FDA QC lab analysts in Nay Pyi Taw & Mandalay; staff selected sentinel sites; place Minilabs® at Division health facilities			Will take place in Q3	Completed. Training was conducted May 7-11 for 25 participants from the Burma FDA, VBDC, and DMR-LB.	
Collect samples from wholesalers, retail pharmacies, national malaria warehouses, and health facilities in targeted areas including Yangon & Mandalay			Will take place in Q3-Q4	Scheduled for Q4.	<ul style="list-style-type: none"> Itemized budgets for MQM obtained from DMR-LM, VBDC, and FDA. Letter sent by WHO to IHD at MOH Myanmar for approval to start sample collection.
Confirmatory test at FDA QC in Nay Pyi Taw and in regional reference lab (NIDQC or BDN)			Will take place in Q4	Scheduled for Q4.	Delayed; will need to be postponed to FY13. Additional QC lab identified (IDQC in Ho Chi Minh City)
Analyze data and report findings to relevant agencies for action			Will take place in Q4	Scheduled for Q4; may need to postpone until FY13.	Delayed; will need to be postponed to FY13.
Produce end-of-year baseline analysis & report for presentation to partners			Will take place in Q4	May need to postpone until FY13.	Delayed; will need to be postponed to FY13.
Disseminate findings at meeting and survey to plan for scale-up and			Will take place in Q4	Postponed until FY13.	Delayed; will need to be postponed to FY13.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
intervention					
Strengthen technical capacity of Nay Pyi Taw and Mandalay quality control laboratories for medicine quality analysis meeting international standards through training on select priority essential medicines					
Train nat'l and regional QC lab staffs hands-on in GLP, equipment maintenance, proper use, and advanced analytical methods for essential medicines, including antibiotics			Will take place in Q3	Planned for Q4.	Training workshop is planned for November; training will be provided by USP HQ staff.
CHINA S. Phanouvong					
With WHO, re-engage Chinese State and Yunnan FDAs to conduct survey on quality, availability, and source of antimalarials in targeted prefectures of Yunnan					
Support PQM travel to meet with MOH, SFDA, WHO, CDC to re-establish MQM			** Due to bureaucratic procedures the activities in China may be delayed Planned for Q3	Submitted request to PMI to consider allowing PQM to reprogram activities for China to:	Reprogramming approved by RDMA-PMI
Train Yunnan field staff on sampling, testing, and data reporting			Planned for Q4	1. Use funds to buy essential lab equipment for Burma, or , 2. Support one selected manufacturer of AMLs toward WHO PQ.	
Provide FDQC supplies; train lab staff on advanced HPLC methods for AMMs			Planned for Q4		
Conduct baseline survey of availability, quality, and source of AMMs in Dehong and Nujiang			Planned for Q4	See note above.	
Cambodia E. Yuan					
Continue to support the Cambodian MOH to take action against poor-quality medicines circulating in the Cambodian market					
Support existing PMS; apply new protocol w/DDF & NHQC		Supported the existing PMS program and implemented a new sampling and testing	Regular drug inspections and field visits are conducted by DDF/MoH drug inspectors	Regular drug inspections and field visits are conducted by DDF/MoH drug inspectors.	Continued sampling at 9 new provincial sites as a special investigation on medicine quality.

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		Q1	Q2	Q3	Q4
		<p>protocol with DDF and NHQC; replenished Minilab reference standards and replenished some QC lab supplies for the 12 sentinel sites.</p> <p>Due to the delay of GFR6 budget disbursement in FY11 Q4, sample collecting and testing activities at sentinel sites were postponed, but with PQM's support, DDF inspectors have conducted regular field visits to sentinel sites.</p> <p>DDF plans to do sampling and testing in 9 provinces not currently included in regular surveillance.</p>		<p>GFR6 budget for DDF's field visit will finish at the end of September 2012. So far, drug inspection and field visits are jointly supported by PQM and GFR6. If the GFR6 budget ends, it will also affect these routine activities.</p> <p>Sampling and testing in 9 new provincial sites, not currently included in regular surveillance, will be conducted in Q4 because of current DDF's workload.</p>	<p>MoH removed registration numbers of 2 products (resulting from MQM activities) : (1) Cloxa-MS 500mg/Cap (cloxacillin 500mg) Box/10x10 Capsules, Reg#: CAM 09L-692, manufactured by Medical Supply-Cambodia; and (2) Cloxa-EPHAC 500mg/Cap (cloxacillin 500mg) Box/10x10 Capsules, Reg.#: CAM 09L-666, manufactured by EPHAC-Cambodia.</p>
Coordinate with GFATM, JPMA, WHO to streamline PMS			In discussion		No decision reached
Establish a mechanism to collect from partners suspected medicines samples for testing			In discussion		Other partners have a lack of interest because they collect a different set of medicines/samples.
Strengthen authorities for timely regulatory action & enforcement, including 12 ISCs			The DDF destroyed 3 tons of counterfeit, expired, banned, & unregistered medicines and drugs to treat animals which were collected from drug		Through collaboration among the police of the Ministry of Interior, prosecutor, MoH, and local authorities, 2 raids of counterfeit and unregistered medicines

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		Q1	Q2	Q3	Q4
			outlets around the country. This destruction event was attended by MoH police, chief of Registration Bureau of DDF/MoH, and others. This event resulted from the MQM program		were conducted in September: (1) First raid was Sep 22 where 42 items--around 2 tons--were seized; (2) Second raid was Sep 30 where around 3 tons of counterfeit and unregistered medicines were seized.
Attend annual meeting of Inter-Ministerial Committee		E. Yuan attended the IMC annual meeting held in December to assess progress in eliminating counterfeit medicines and illegal outlets in Cambodia during 2011.			DDF organized a quarterly meeting in July in Kampong Cham province to evaluate MQM activities and provincial inter-sectoral committees (ISC) from 12 sentinel sites.
Build capacity of the NHQC and DDF					
Work w/WHO & DDF to find funding for NHQC and develop GF R11 proposal & application			PQM developed activities with WHO, DDF, and NHQC into the EOI to respond to GF R11 for additional funding. Unfortunately The GF R11 was cancelled.	No longer relevant since GF R11 has been cancelled; however, new funding mechanisms might be rolled out soon.	
Continue TA to NHQC toward WHO PQ and ISO accreditation			World Bank required the MoH to resubmit the revised concept design of NHQC's new building to comply with international standards. MoH requested PQM assistance to review the architectural re-design and provide comments. PQM plans to send a	The Oversight Construct Committee has been created with its roles to monitor, communicate, and advise the action, and Dr. Souly Phanouvong has been nominated as a member to represent PQM.	MOH (HSSP2), NHQC management team, and WB had several meetings after visits from WB's architect group. The WB recommended that NHQC/MoH hire a consultant expert on lab furniture and equipment to provide assistance to NHQC. However, MoH

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		Q1	Q2	Q3	Q4
			consultant from Arc2Lab in April to develop a detailed action plan.	<p>Mr. Christian Schnitzer, Arc2lab Architecture, visited NHQC lab April 30–May 4, 2012, meeting with key staff from the MoH working on NHQC building construction, the construction firm “ILI”, and NHQC management team. He conducted architectural re-design work to make changes in the air handling systems and other mechanical and electrical laboratory designs in order to comply with ISO 17025 requirements. Redesign is under World Bank’s review for approval. Dr. Phanouvong met with Dr. Pema of World Bank on:</p> <ol style="list-style-type: none"> 1) Status of newly submitted concept design to WB for approval. 2) After its approval, the new concept design and action plan with its time line will be disseminated immediately to all parties including MOH’s regulatory and technical authorities, USP and USAID Mission. 3) USP will not be able to 	and NHQC management team strongly expressed their need for USP/PQM continuous TA. USAID has been informed of this situation and USP is looking for solutions to identify the funding source and clearly identify responsibilities.

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		Q1	Q2	Q3	Q4
				fund Mr. Schnitzer's further activities including visiting national lab for the rest of FY12. 4) Need to increase the transparency among all parties.	
Update curriculum in QA/QC & meds regulations for graduate pharmacy students			In discussion	In process of hiring 5 graduate students as summer interns to review current pharmacy curricula and provide feedback for planning future curriculum changes.	Proposal for evaluation of the medicines QA/QC and regulation syllabi at Cambodian universities was submitted for ethics review and approval.
Assist DDF to strengthen pharmacy practices program through trainings		DDF and PQM discussed how to improve Good Pharmacy Practices through training workshops, and PQM is now waiting for the results of DDF's internal discussions.	Waiting for the results of DDF's internal discussions	Guidelines for GPP has been drafted and reviewed by DDF team. DDF is now working to target the training area.	<ul style="list-style-type: none"> – Guidelines for GPP were approved by MoH-Cambodia – Budget plan for training on GPP to target area was approved by PQM. – Training modules on GPP are being prepared by DDF-MoH.
Maintain local PQM consultant for success of activities			Local consultant actively involved in implementing PQM activities; has attended local meetings and events to represent the program	Local consultant helped arrange travel for Christian (Arc2lab) and PQM HQ staff to Cambodia to conduct all needed activities.	Local consultant actively involved in implementing PQM activities; has attended local meetings and events to represent the program.
Raise awareness about medicines quality issues and disseminate information among regulators, health care professionals, and the public					
Develop materials and effective tools to disseminate at grass roots level		To better collaborate with USAID-funded partners about medicines quality issues, PQM met with URC,	<ul style="list-style-type: none"> • PQM supported the purchase of 200 t-shirts and 15,000 posters for CNM for World Malaria Day in 	<ul style="list-style-type: none"> • PQM supported and participated in URC/CAP-Malaria "Malaria Week" project and World Malaria Day 	<ul style="list-style-type: none"> • In collaboration with URC/CAP-Malaria project, a poster was completed and approved. Printing is

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		Q1	Q2	Q3	Q4
		PSI, RHAC, RACHA, and KHANA to share PQM's new workplans, specifically the activities related to raising awareness at the grassroots and community levels.	April. <ul style="list-style-type: none"> • PQM also supported the purchase of 200 t-shirts and 250 hats for the URC/CAP Malaria program. These materials, including posters and radio spots produced last year, will be used for Malaria Week activities from March to May. • In collaboration with URC/CAP-Malaria program, a poster about counterfeits was created and displayed in the libraries of 10 elementary schools (covered by CAP-Malaria program). 	on April 25 in Cambodia. Some 15,000 flyers and 400 T-shirts were distributed during the events. <ul style="list-style-type: none"> • PQM team met with USAID implementing partners to seek opinions on producing IEC/BCC materials to raise public awareness at community level; shared with them leaflet on counterfeit medicines created by DDF, and asked for their feedback. • PQM is working closely with USAID's implementing partners to effectively distribute IEC/BCC materials through partners' established networks. • PQM supported and participated in raising public awareness on dangers of counterfeit medicines through Pharmacide Arts project. The exhibition presents works by 34 artists from Cambodia, Indonesia, Laos, Thailand, and Vietnam. As a travelling exhibit, the art will be shown in 	expected to be done in October 2012. <ul style="list-style-type: none"> • In collaboration with DDF, leaflets on basic facts about counterfeit and substandard medicines were printed. Distribution will begin in October 2012.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
				each of the represented countries in Southeast Asia, as well as travelling to France.	
Collaborate with PAC to promote actions against SCMs		Two workshops were conducted (Oct and Dec) and a bulletin is being prepared for dissemination in early 2012.	1 bulletin was issued and disseminated to all 24 provinces in Cambodia. An additional issue of the bulletin is being prepared.	1 bulletin was issued.	1 workshop was conducted in August 2012.
Facilitate local and regional collaboration among DDF, health programs, media & enforcement authorities about impact of SCMs			In discussion		
Strengthen IMC to improve regional enforcement against SCMs through BREMERE activities			In discussion	In the preparation for inaugural meeting of BREMERE being held in August in Laos, informed DDF/IMC of the event.	3 Cambodia delegations (2 from DDF and 1 from customs) attended the BREMERE meeting in Thailand. All participants agreed to work closely with PQM to finalize the action plan before the end of 2012. Cambodia delegates have agreed to host a meeting to kick off BREMERE in January 2013.
Indonesia		S Phanouvong			
Assist Indonesian TB medicine manufacturers to obtain WHO prequalification for selected TB medicines					
Support first-line ATB mfrs (Indofarma, Phapros, and Kimiafarma) toward WHO PQ		<ul style="list-style-type: none"> Continued support to Phapros and Indofarma on dossier compilation and bioequivalence (BE) studies for WHO 	Phapros <ul style="list-style-type: none"> CAPA implementation is on target for both GMP and dossier aspect. Stability studies are 	Phapros <ul style="list-style-type: none"> PQM provided Comparator products (Rifadin, Isoniazid) needed for pilot of BE studies. 	Phapros: <ul style="list-style-type: none"> Based PQM's recommendation, Phapros has already done reformulation with the result of 4

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		Q1	Q2	Q3	Q4
		<p>prequalification</p> <ul style="list-style-type: none"> • USAID/Indonesia will contribute 50% of BE study costs, and PQM provided comparator products to be used in the BE studies. • Reviewed BE protocol and made recommendations. • Conducted an audit at two Contract Research Organization (CRO) laboratories to develop in-country capabilities. 	<p>planned for the re-formulated 2FDC and 4FDC. <i>In vitro</i> dissolution (IVD) studies for both 2 and 4 FDCs to be completed. BE studies for both 2 and 4 FDCs to be conducted in Q4 after the bio-batch production completed.</p> <ul style="list-style-type: none"> • PQM to visit Phapros in June to evaluate facility CAPA and IVD studies • PQM reviewed BE study protocol and Phapros will sign final agreement with Accutest (CRO) for BE study • Phapros will send MOC with PQM to be revised by Legal and signed • PQM will contribute first amount of BE cost to Accutest in order to expedite the process <p>Indofarma</p> <ul style="list-style-type: none"> • Working with CAPA plan and <i>in vitro</i> dissolution studies • PQM will send comparator tablets to Indofarma 	<ul style="list-style-type: none"> • Finalizing contract agreement with Accutest of India to conduct BE studies; PQM will contribute 50% of costs. • Phapros submitted progress report on CAPA implementation to PQM for review. <p>Indofarma</p> <ul style="list-style-type: none"> • According to progress report, WHO PQ CAPA preparation is 50% to 60% complete. • Validation Process: FDC 4 and FDC 2: in process →50%, TOC parameter may still need validation. • IVD test: First experiments against Rifamat capsule has been completed→ Calculate result F1 and F2, and report for all three media. • New experiment of IVD against the tablet to be conducted. • Review HVAC Main Production Building: In Process →80 % done. • Water System qualification in Process→60% done. 	<p>FDC at 2 pHs (1.2 and 4.5) is similar, but at pH 6.8 is not similar; and for 2 FDC at 3 pHs are not similar, neither Rifampicin nor INH, so they need to reformulate</p> <ul style="list-style-type: none"> • Will do comparisons with the new comparators which have been received together with Myambutol (in Oct) • Plans to do BE test of 4 FDC first. • Since the solid facility renovation has been postponed, the production of biobatch will be in Jan/Feb • Planning to conduct pilot of BE study at Equilab (before full BE study at Accutest – India), so the BE study will begin in June 2013. • As soon as Phapros gets the pilot BE study results from Equilab, they will submit the dossier to WHO <p>Indofarma:</p> <ul style="list-style-type: none"> • Validation Process:

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		Q1	Q2	Q3	Q4
			<ul style="list-style-type: none"> Organizational change occurred in Indofarma and a new focal point was assigned to WHO PQ project with PQM. Indofarma slowed down due to new election and the possibility of merging with Kimiafarma. 	<p>Kimiafarma:</p> <ul style="list-style-type: none"> PQM team met with QA and production mgrs of Kimiafarma in June for update. Kimiafarma is in initial steps of designing a new facility close to its compound that will be dedicated to producing ATBs, primarily first-line, some second-line solid dosage form products. 	<p>4FDC and 2FDC in process - TOC parameter made still needs validation. New formulations are in final stage of dissolution property profiling against WHO recommended comparator products.</p> <ul style="list-style-type: none"> Instead of continuing to address CAPA plan in the existing plant, Indofarma has decided to invest in building a new plant for manufacturing their FDCs. This will delay dossier submission, but is a good investment for long-term achievement. <p>Kimiafarma:</p> <ul style="list-style-type: none"> Will be reviewed by the government on all preparations for WHO PQ of ATBs. PQM stopped its TA to Kimia as it did not commit to addressing critical observations recommended in the CAPA, which are prerequisites to complying with WHO requirements.

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		Q1	Q2	Q3	Q4
Continue to engage 2nd-ATB mfrs of levofloxacin tabs and, possibly, kanamycin powder to participate in WHO PQP			PQM submitted two letters to propose approach and convene a high-level meeting for key stakeholders to DGs in MOH (Diseases Control and Pharmaceuticals Services)	PQM has not received any feedback from two DGs, despite series of follow ups by PQM in-country consultant.	Since August, NTP has been receiving Sandoz's applications for ATBs for WHO PQ; now processing for "approval for recommendation" from DG.
Assist two local contract research organizations (CROs) toward compliance with Good Clinical Practices (GCP) for bioequivalence studies of ATB medicines					
Follow up progress of Equilab Int'l and San Clin-EQ Lab on CAPA implementation and provide TA as needed			<ul style="list-style-type: none"> Equilab continues to work with CAPA. PQM noted good progress toward compliance with WHO and international guidelines for CROs during March visit CAPA implementation on both GCP and GLP and quality systems is in progress and report received. PQM verified the implementation. Improved schematic layout of the building for sampling and recreation rooms to be submitted to PQM. Improved GCP/GLP training records and documentation to be completed in Q3. SanClin started working with CAPA plan 	<p>Equilab:</p> <ul style="list-style-type: none"> Remaining CAPA items and additional feedbacks have been implemented by to improve compliance to good documentation of the new SOPs and renovations of the subject receiving, dining, specimen collecting, and recreation rooms. Updated report was received. A few pieces of equipment still need validation & calibration Equilab has been trying to find appropriate service provider(s) to affordable insurance premium for subjects in the trials. <p>San Clin EQ:</p> <ul style="list-style-type: none"> First CAPA 	<p>Equilab:</p> <ul style="list-style-type: none"> The issues of renovating the sampling room, adding a recreation room, and improving GCP/GLP training records and documentation have been completed. GCP training to help with equipment calibration is still needed. In process of seeking an appropriate insurance service provider for subjects enrolled in the BE trials <p>San Clin EQ:</p> <ul style="list-style-type: none"> GCP ASPECT (58 corrective actions): 34 corrective actions already implemented (complete), 24 corrective actions not yet completed (waiting for proof of

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		Q1	Q2	Q3	Q4
				implementation report was received by PQM. There have still been a lot of items to complete from both GLP and GCP aspects.	implementation). <ul style="list-style-type: none"> GLP ASPECT (32 corrective actions): 14 corrective actions already implemented (complete), 8 corrective actions not yet completed (waiting for proof of implementation).
Establish and support a post-marketing TB medicines quality monitoring network of targeted sentinel sites throughout Indonesia					
Procure equipment, provide training, and establish MQM sentinel sites for TB & selected antibiotics		Met with BPOM officials regarding the status of the Letter of Agreement (LoA) between USP and NA-DFC, which will allow for establishing the MQM program in Indonesia, once signed. In December, BPOM sent a request for changes to the LoA. PQM will review and follow up in Q2.	LoA signed in Feb, a significant breakthrough after several months of efforts with assistance from USAID. Action plan was developed; will begin implementation in April. Training workshops on compendia analysis of ATBs will be held in Q3 for 5 sentinel sites.	<ul style="list-style-type: none"> Two training workshops were completed successfully for participants from 5 provincial and national levels: Establishing MQM for ATBs in selected provincial sites (14) and Compendial analysis of ATBs (16). PQM, NA-DFC/NQCL-DF and NTP jointly developed action items. Extensive efforts have been put forth to clear 5 Minilabs from customs; this has slowed progress of MQM work. 	<ul style="list-style-type: none"> Minilabs transported to PPOMN office from custom's storage; scheduled for transport to the sentinel sites ASAP. Once Minilabs have been delivered to sentinel sites, sentinel site visits will be scheduled. Cost for Minilab transport to sentinel sites will be covered by the fund balance from the June 2012 training.
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 existing regs & technical guidelines on ATB mkt authorization and licensing of health clinics and pharmacies; identify strengths, weaknesses and gaps			Discussed with relevant departments of the MOH (Pharmaceutical production & distribution, Pharmaceutical & Medical Devices Control, & NTP)	Further discussions have taken place in Q3; a face-to-face meeting among key stakeholders is planned for Q4.	A meeting will be held October 18, 2012.

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		Q1	Q2	Q3	Q4
Ratify revised regs and technical requirements (proper authorities) for implementation					
Open an office to increase program visibility, improve communications with national and local partners, and improve program performance					
			Initiated discussions and consulted with all relevant authorities (USP legal, Finance, USAID and USAID implementing partners, NA-DFC, NQCL-DF, NTP, BINFAR, YANFAR, and potential service providers).	<ul style="list-style-type: none"> Office location identified and quotes received. Service providers (tax and admin/support arrangement) identified. Under final discussion; decision anticipated in Q4. 	Initiated discussions with the head of the Indonesian University Community Medicine Residency Program regarding office space.
Philippines E. Yuan					
Ensure continued post-marketing surveillance of TB and other essential medicines at six established and three new sentinel sites and examine the status of MQM project implementation					
Continue to support MQM at 6 existing sites; replenish supplies		Minilab data has been collected and the report updated Processed Minilab replenishment order for the sentinel sites in need	Two Minilabs and supplies were ordered for two newly added sentinel sites (Region IV-A and Region V) and lab supplies have been requested to replenish the existing Minilabs.	<ul style="list-style-type: none"> Participated in promoting advocacy of TB DOTS center at the sentinel sites. Supported “No Prescription, No Dispensing” policy on ATBs and antibiotics in all pharmacies. 	Communicated effectively with the sentinel sites.
- Expand MQM to 3 new sites in IV-A, V, and Nat’l Capital regions		Started the expansion process for two new sentinel sites (Regions 4A and 5)	Region IV-A sentinel site will be located at CHD for Southern Tagalog Quirino Memorial Medical Center Compound, and Region V Sentinel Site will be located at CHD for Bicol Bagtang, Araga, Legaspi City	GPHF Minilabs arrived on June 18, 2012; PQM is waiting for their release by Philippines Bureau of Customs.	PQM/FDA visit to region IV-A planned for November 2012 to formally launch the sentinel site.

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		Q1	Q2	Q3	Q4
- Expand MQM to include some 2nd-line TBs			FDA and other partners agreed to include 2 nd line ATBs & antibiotics in FY12; implementation will be in FY13	Expansion has been moved to FY13	
- Expand MQM to include some antibiotics			Expansion has been moved to FY13	Expansion has been moved to FY13	
Monitor sampling & testing at select sites, provide TA & training as needed; visit 2 sites w/FDA and DoH staff			Updated Minilab testing data was reported to PQM HQ. In-country consultant conducted supervisory visits to Cebu and Malolos sentinel sites in March.	The following sentinel sites were visited: <ul style="list-style-type: none"> • Zamboanga (Apr 19-20) • Iloilo (Apr 25-27) • La Union (May 2-4) • Davao (tentative visit planned for July) Trained two staff members from each site of Region IV-A and Region V (4 staff total) on Thin Layer Chromatography testing at the Philippines FDA.	Sentinel site visits to Davao and Malolos City planned for October 2012.
With FDA, form Quality Monitoring Technical Working Group w/defined roles		Identified key stakeholders (FDA, WHO, NTP, USAID/PQM, DOH-NCDPC and DOH-MMD, NCPAM, etc.) to form TWG. Continued working with the FDA to finalize the agreed-upon commitments/activities. FDA elaborated on a TWG draft action plan and disseminated it to	In collaboration with FDA, an action plan for the TWG for strengthening MQM in the Philippines was developed; FDA Lab Chief to join the sentinel site visit in Iloilo and discuss TWG action plan	Scheduled for Q4.	In discussion; the scope of this task might change.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		each partner for feedback. FDA will incorporate comments and finalize the action plan			
Identify gaps and needs in MQM; develop training modules for annual refresher training of all site staff			<p>In-country consultant and FDA lab analysts conducted PMS and provided technical advice for Minilab (Disintegration and Basic Testing) during sentinel site visits.</p> <p>The Minilab staff assigned for Region IV-A and Region V will receive technical assistance & orientation on TLC in April</p>		Based on routine site visits to all 6 existing sentinel sites, results indicate that all MQM activities are performed according to SOP and protocols. There are no obvious gaps.
Consultant serves as Project Secretariat to monitor progress, supplies & equipment			Communicated with sentinel sites on Minilab replenishment of reagents, supplies, etc.	<ul style="list-style-type: none"> • Provided TA to Minilab staff to perform quality testing. • Provided waste management training. • Collaborated with Systems for Improved Access to Pharmaceutical and Services (SIAPS) program of Management Sciences for Health (MSH) and FDA to assess performance of pharmacovigilance systems in Philippines by providing requested information and sharing 	

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		Q1	Q2	Q3	Q4
				data from MQM on quality of medicines.	
Strengthen the capacity of the FDA and its QC lab for regulatory oversight of pre-marketing medicines registration and post-marketing surveillance					
Improve pharmaceutical mgmt and QA systems at nat'l and local levels			In discussion	In discussion	After F2F discussions with FDA deputy director and the chief of laboratory services, it was decided that TA and training on pharmaceutical management in TB medicines and antibiotics storage and dispensing are needed.
Provide training on areas identified through gap analysis and request from FDA			In discussion	In discussion	Hands-on Training on the Compendial Analysis of Anti-TB Medicines and Introduction to Good Lab Practices is scheduled for October. Manufacturing Process Validation training for Food and Drug Regulation Officers (FDROs) is scheduled for November.
Purchase needed lab equipment and reference materials not included in DOH or other budgets		New USP35 NF30 2012 has been delivered to FDA; the Food Chemical Codex has also been requested.	FDA received a copy of the Food Chemical Codex from USP. Reference substances (rifampicin, ethambutol, pyrazinamide, isoniazid, and prednisone) were ordered from USP and are awaiting shipment. They will be used by	PQM sent the following: <ul style="list-style-type: none"> • USP35 NF30 2012 3-volume set and 1st and 2nd supplements • Mettler Toledo MT5 Balance • USP RF Standards for Amoxicillin, Levofloxacin, Rifampicin, Pyrazinamide, and 	FDA received the USP Catalog and USP RS (Ethambutol, Rifampicin, Pyrazinamide, Isoniazid) and Prednisone Calibrator Tablets for FDA Davao Sat Lab Training.

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		Q1	Q2	Q3	Q4
			FDA and CEBU and DAVAO sat lab for confirmatory testing	Isoniazid, and Prednisone Tablets	
Support meetings of multisectoral groups to discuss finalizing and implementing RA9711 rules & regs			Planned for Q3	Planned for Q4.	Sent 2 scientists (from FDA Central Lab) to USP for 3 months of BA/BE training. Sent 2 scientists (1FDA Central lab and 1FDA Davao Sat Lab) to USP for a 4-week training.
Obtain quality data on selected generic anti-infective meds			Planned for Q3	A tentative list of generic anti-infective medicines was submitted to FDA management for finalization.	Generic medicines quality checking and the comparative studies with branded medicines have been planned for FY13, per FDA suggestion.
Vietnam S. Phanouvong *Covered by FY10 funding					
Conduct GMP assessment of two selected manufacturers for local production of methadone					
* Make formal request to conduct GMP compliance and dossier review of manufacturers to determine capacity and competency for producing methadone locally w/PQM TA		Two PQM consultants attended the National Conference on Methadone in December and gave a presentation on PQM's technical assistance to local methadone production. The Deputy Prime Minister supports the acceleration of local production of methadone, and PQM will work with relevant departments: Ministry of Health (Drug	PQM worked with PEPFAR and USAID/Vietnam to issue an introductory letter for the PQM team who will work with MoH on the TA of Methadone production. The letter was sent to DAV and VAAC. PQM is still waiting for MoH response.	PQM met with key contacts at MOH/DAV to discuss progress of the local methadone production. The GVN has not allocated national budget for the methadone production project 2011-2015 and TA to the local production is still delayed. MOH developed criteria for selection of potential manufacturers and, according to DAV, only one local manufacturer will be selected.	PQM again sent out the request letter to MoH and DAV to join the final assessment of six potential local manufacturers. PQM has not received responses from MoH and DAV.

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		Administration of Vietnam, Vietnam Administration for HIV/AIDS Control and Prevention) to select two potential manufacturers from a shortlist of ten.			
Conduct GMP inspection on two manufacturers; provide recommendations to address GMP deficiencies			With introductions from the GVN office and USAID, a PQM team met with the Chemical and Biological Institute under the Ministry of Public Security. The CBI is studying the production of Methadone API. PQM will send an assessment questionnaire in April to assess the capacity of CBI prior to sending a GMP expert	PQM sent an assessment questionnaire to the CBI. So far, PQM has not received any feedback.	Among the six potential manufacturers, VIDIPHA is the most promising. The screening questionnaire for pharmaceutical manufacturers to determine eligibility for PQM's TA was sent to VIDIPHA and subsequently returned to PQM.
Strengthen national, provincial and district authorities to provide timely reporting and share medicines quality data that is routinely collected for in-country enforcement and regional action against violators.					
Involve DAV and law enforcement agencies in BREMERE activities by participating in the regional Task Force; promote collective enforcement actions			PQM is in contact with DAV, Ministry of Public Security, and Customs on the BREMERE meeting. Last year, the meeting was postponed due to flooding in Bangkok.	This activity is delayed. BREMERE meeting has been rescheduled for Aug/Sept.	The BREMERE meeting was held in Bangkok in August. Representatives from DAV, MPS, and customs participated the meeting.
Intensify collaboration and data-sharing with relevant partners and country MRAs for collective action.			PQM is re-enforcing data sharing and reporting on locally produced CSMs which were identified through	This activity is delayed due to other pressing priorities of some partners, e.g., NIDQC has been working on WHO	The TOR for the BREMERE mechanism has been shared with stakeholders for comment.

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		Q1	Q2	Q3	Q4
			the MQM program in FY11 between DAV, NIMPE, and NIDQC. NIMPE/National Anti-malaria program will send an information letter to DAV and NIDQC soon.	PQ re-qualification.	
Strengthen the quality assurance of medicines for the treatment of Opportunistic Infections (OI)					
Make formal request to carry out the baseline survey on the quality of OI medicines in HIV/AIDS treatment centers at PEPFAR funded provinces		PQM sent request letters to Vietnam Administration for HIV/AIDS Control (VAAC). Due to bureaucratic reasons, PQM has not received feedback from VAAC.	PQM sent a letter to NIDQC requesting collaboration on implementation of the baseline survey of OI medicines quality.	PQM country consultant assisted NIDQC in preparing the budget, planning and developing the protocol in the local language as well as compiling needed documents and submitting all to the VAAC prior to sampling. VAAC review has been delayed as the agency has numerous other pressing priorities.	Formal clearance has been received from the NIDDC, the key partner for this activity.
Organize a one-day training workshop on methods for sampling and testing of OI medicines			PQM experts and NIDQC collaborated to hold a one-day training workshop on sampling and testing methods for selected OI medicines in 25 PEPFAR provinces. More than 30 persons from Drug Quality Control Centers, PACs, CDC-LifeGap participated.	Completed.	
Sampling and testing of selected OI medicines				This activity has been postponed until Q4.	Sampling has begun.

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		Q1	Q2	Q3	Q4
Raise public awareness about the dangers of counterfeit and substandard medicines					
Help finalize production of a regionally-focused documentary film for global public broadcast about the problem of CSMs in the GMS	Tuan Anh		A request letter was sent to NIMPE/MoH to obtain formal clearance for the filming of "Pharmacide" series. However, due to bureaucratic and political reasons, this activity is still delayed.	After sending PQM request letter to NIMPE, PQM country consultant assisted NIMPE to send needed documents to MoH/DAV for formal clearance of the filming of the "Pharmacide" series. MoH approved the trip for Mark Hammond from SohoFilm in July-August.	Scenes about MQM sentinel site activities in Vietnam were filmed in August.
Discussion with NIDQC and Partnership for Safe Medicine (PSM), Vietnam Pharmaceutical Companies Association (VPCA) on raising public awareness about the danger of CSMs.	Tuan Anh		Local consultant met with VPCA and PSM and planned additional discussions for April.	Country consultant met and discussed with NIDQC, PSM, and US Embassy representatives (Low Mekong Initiatives). Next steps: PQM would co-fund NIDQC to implement IEC activities. PQM is waiting for funding approval from LMI.	NIDQC received \$5,000 from US Embassy in Hanoi to implement the video clip contest event and maintain the Safe Medicines website. Discussions are ongoing between PQM and youth unions of NIDQC, HUP, and schools of Public Health.
Maintain local consultant to support and coordinate project implementation, follow up progress and write timely report to PQM and USAID as needed					
Support local consultant salary and misc. expenses for FY12			Local consultant's salary and other expenses have been paid monthly. Local consultant actively involved in implementing PQM activities; attended local meetings and events to represent the program	Local consultant actively involved in implementing PQM activities; has attended local meetings and events to represent the program.	Local consultant actively involved in implementing PQM activities; has attended local meetings and events to represent the program, actively involved in preparation of new FY13 workplan.
Support office space, maintenance, utilities,			Office space has not been established due to	After discussions with USP/PQM headquarters,	

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		Q1	Q2	Q3	Q4
and admin support expenses			limited space NIDQC, PQM's main partner. The local consultant will seek other options, i.e. renting shared office space close to NIDQC and USAID.	country consultant is still working at home-based office.	
Provide furniture, laptop, and printer			A laptop and a printer have been purchased.		
Conduct a mock inspection of NIDQC prior to the WHO re-qualification inspection in April 2012					
Conduct a mock assessment of NIDQC facility and provide them with a CAPA report			PQM identified an experienced QM expert for NIDQC. The expert will conduct a mock assessment of NIDQC lab in April	A QMS expert was sent to NIDQC to conduct a mock-up inspection and assist the lab prior to the WHO PQ inspection. A report was disseminated to NIDQC with recommendations. In June, the WHO PQ inspection report was sent to NIDQC with deficiencies observed in 2 main issues: documentation and microbiological laboratory.	Local consultant followed up on the CAPA activities after the WHO re-assessment. NIDQC has submitted its CAPA report to WHO HQ; no response yet.
Europe and Eurasia					
Russia		K. Burimski			
Work w/Sintez to get Kanamycin & Levofloxacin WHO prequalified		After being translated into Russian, the template for the protocol on stability studies was sent to Sintez; consultations on the protocol were conducted.	Stability study started and study results for two months received.	Stability study results for five months received. Dossier on Kanamycin reviewed, started re-formatting into CTD format.	Stability study results for six months received. Re-formatting of dossier on Kanamycin into CTD format continues.
Work w/Pharmasintez				Pharmasintez informed	

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		Q1	Q2	Q3	Q4
to get PAS and Prothionamide WHO prequalified				PQM they are working on corrective actions.	
Work w/Obolenskoe to get Clarithromycin approved by GDF		Documents on Clarithromycin, which are required for GDF expert committee review, were received from JSC Obolenskoe and translated into English.	<ul style="list-style-type: none"> • Clarithromycin is in low demand by GDF. Obolenskoe will decide re: Clarithromycin approval by expert review panel. • Translated materials on Clarithromycin forwarded to Obolenskoe. 		
Work w/Akrikhin to get Prothionamide WHO prequalified (Akrikhin submitted a Letter of Interest to PQM)				Visit to Akrikhin by PQM GMP specialists conducted April 23-24.	Based on the audit results, recommendations were provided to Akrikhin. Workplan for WHO PQ discussed, drafted, and submitted to Akrikhin CEO for approval.
Translate WHO PQ documents into Russian		A person was selected to work on translating WHO Prequalification documents into Russian.	Files for translation prioritized and translation of WHO PQ documents started	First part of the documents translated.	Part of translated documents reviewed by WHO, recommendations provided.
Document and report medicines quality data in selected TB clinics using Minilabs [®]		The report on "Establishment of Anti-Tuberculosis Medicines Quality Monitoring in Selected TB clinics in Russia" was developed and includes data on 120 antituberculosis medicines collected and tested with Minilabs [®] .	<ul style="list-style-type: none"> • Training for six new Minilab[®] sites conducted in March • MQM protocol drafted and discussed with participants • Next steps for implementing the MQM program discussed 	<ul style="list-style-type: none"> • Minilabs delivered to the sites. • MQM protocol updated and agreed upon with Roszdravnadzor. • Template for contract with Minilab sites developed. 	Vladimir TB dispensary tested five medicines; all passed tests.
Conduct roundtable discussion on express		Dr. Hool, VP of Applied Compidual Research at	• Presentation on Raman method	• Dr. Long, President, Spectroscopic Solutions	Roszdravnadzor informed PQM that in 2013 it plans

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		Q1	Q2	Q3	Q4
methods of TB MQM for Roszdravnadzor labs		USP, presented at Roszdravnadzor's Science-Practical Workshop on the Issues of Drug Quality Control Using the Methods of Express-Diagnostics and Practical Aspects of the Work of Mobile Express Laboratories in Moscow. Dr. Hool an PQM Russia consultant, Dr. Oksana Dmitrenok, met with Roszdravnadzor staff to discuss cooperation in rapid methods of quality control, including Raman Spectroscopy and other rapid tests.	planned for April, presenter selected, presentation translated into Russian <ul style="list-style-type: none"> • Round table on Raman method of TB MQM for Roszdravnadzor labs appointed in April, possible participants discussed, and agenda drafted in cooperation with Roszdravnadzor 	LLC (PQM consultant) delivered presentation "Raman spectroscopy for pharmaceutical applications" at Roszdravnadzor's International Conference on the Quality of Medicines and Medical Devices on April 19-20. <ul style="list-style-type: none"> • PQM team attended a high-level meeting with Roszdravnadzor to discuss next steps for implementing the use of Raman spectroscopy in the MQCLs. 	to sample anti-TB medicines and screen them for quality; Roszdravnadzor is planning to complement current test methods by adding Raman spectroscopy and establishing a Raman spectral database for anti-TB medicines.
Provide two Raman spectrometers for Roszdravnadzor labs			Potential vendors of Raman spectrometers in Russia investigated	<ul style="list-style-type: none"> • PQM staff met with a representative of the company Enhanced Spectrometry, Inc., Russian vendor of the Enspectr® Raman spectrometer and other devices. • Two possible vendors of Raman spectrometers for Roszdravnadzor selected, negotiations begun. • Testing of Raman spectrometers by Enspectr® started; selected anti-TB medicines forwarded to 	<ul style="list-style-type: none"> • Testing of Enspectr® Raman spectrometer conducted – three spectra of anti-TB medicines obtained and reviewed by experts • Two Raman spectrometers purchased for Roszdravnadzor • Roszdravnadzor requested PQM to provide technical assistance on establishing the Raman spectral database for anti-TB medicines and conduct training on

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				Enspectr® for testing	Raman spectroscopy for MQCL staff
Conduct lab training courses for Roszdravnadzor regional NQCLs		The scopes of available pharmacopeial education courses (with brief descriptions) were developed and shared with Roszdravnadzor.	<ul style="list-style-type: none"> • Preliminary program for three rounds of lab trainings developed, in cooperation with Roszdravnadzor. • Trainers for first and second rounds of lab training selected, training materials for first round discussed 	<ul style="list-style-type: none"> • First round of lab training planned for July 9-14; second and third rounds planned for September-October at Saint Petersburg MQCL • Training materials for first round of lab training developed and translated into Russian; supplies and logistics prepared. 	<ul style="list-style-type: none"> • First round of lab training conducted at Roszdravnadzor's Saint Petersburg MQCL. Four training courses on validation of analytical methods, medicine sample preparation, atomic absorption spectroscopy, and identification of residual organic solvents were conducted. Thirty-four individuals representing ten regional/federal district labs participated. • Dr. Telnova, Acting director of Roszdravnadzor, thanked USAID for support of the training • Second round of courses (Microbiological aspects of medicines quality) planned for October 15-18. Trainers were selected, training materials were developed and translated into Russian, and all supplies and logistics prepared • Next round is planned for 2013
Provide TA to		Corrective action plans	<ul style="list-style-type: none"> • Answers to corrective 	<ul style="list-style-type: none"> • Dr. Ofelia Villalva, PQM 	<ul style="list-style-type: none"> • Audit of newly

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		Q1	Q2	Q3	Q4
Roszdruvnyadzor regional NQCLs in WHO PQ		<p>based on the audit of Roszdruvnyadzor's Rostov-on-Don quality control laboratory were provided to Roszdruvnyadzor.</p> <p>Mr. Adrian Barojas, Program Manager for Quality Management Services, delivered a presentation on <i>ISO 17025 and WHO GLPs: common pitfalls and strategic approaches to compliance</i> at the Pharmmedobraschenie Conference held in Moscow.</p>	<p>action plan based on audit received from Rostov-on-Don lab</p> <ul style="list-style-type: none"> • Kazan regional lab selected for participation in WHO PQ. Kazan lab submitted the questionnaire and submitted it PQM • Audits of two Roszdruvnyadzor regional labs (Rostov-on-Don and Kazan) planned for April • Papers on WHO PQ prioritized for translation into Russian, potential interpreters discussed 	<p>consultant, delivered a presentation on ISO 17025 Accreditation and WHO PQ for MQCLs at Roszdruvnyadzor's International Conference on the Quality of Medicines and Medical Devices in April.</p> <ul style="list-style-type: none"> • Conducted audits of two Roszdruvnyadzor regional labs (Rostov-on-Don and Kazan) in April. • Based on audit results, Rostov-on-Don is almost ready for ISO accreditation. • ACLASS was selected as the accreditation body for Rostov-on-Don; pre-audit by ACLASS planned in July. • Various lab SOPs and other documents were received from Rostov-on-Don, translated into English, and forwarded to ACLASS. 	<p>established Roszdruvnyadzor regional MQCL in Saint Petersburg conducted by PQM.</p> <ul style="list-style-type: none"> • ACLASS conducted a mock audit of Rostov-on-Don MQCL in July, accompanied by PQM GMP specialists. Based on the mock audit results, Rostov-on-Don MQCL is ready for ISO accreditation inspection planned for October 2012 • PQM provided assistance to the Rostov-on-Don lab in translating its SOPs, quality manual, and other documents into English so that they can be reviewed by ACLASS.
Train 5-6 Roszdruvnyadzor staff on key meds quality issues at USP HQ		<p>The agenda for the Roszdruvnyadzor staff training at USP headquarters was drafted in cooperation with Roszdruvnyadzor.</p>	<ul style="list-style-type: none"> • Program for the Roszdruvnyadzor staff training at USP headquarters was updated 	<ul style="list-style-type: none"> • Training for six Roszdruvnyadzor staff conducted in June. • In her letter to Mr. Slater of USAID/Russia, 	

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		The training is tentatively scheduled for June.	<ul style="list-style-type: none"> List of training participants received, invitation letters to participants sent 	Dr. Telnova, Acting Director, Roszdravnadzor, thanked USAID for their support of the visit. She emphasized that the visit was fruitful, rich in practical events, and well-organized.	
Latin America and the Caribbean					
Amazon Malaria Initiative V. Pribluda					
Implementation of three-level approach (3LA) for sustainable MQM activities throughout the supply chain					
Follow up on countries' commitments from Three-level Approach workshop in FY10 WP		PQM conducted a workshop on the three-level approach for the quality control of medicines with 38 representatives from MRAs, OMCLs, and national malaria control programs.	<ul style="list-style-type: none"> Discussions held with key stakeholders in Guyana that are involved in quality monitoring activities to develop an MoU between them to coordinate the implementation of the three-level approach for all medicines in Guyana. Reviewed and returned new regulations that include the three-level approach from Ecuador's MoH. Revision currently under review by country authorities Reviewed and 	<p>Bolivia - Communications sent to new MRA Chief. No response received yet</p> <p>Ecuador - 3LA included in the revised version of the regulations (Reglamento De Control Post Registro De Medicamentos). Reviewed by PQM and returned to MoH</p> <p>Colombia - The 3LA has been included and it is part of the Strategy that the MoH is creating for the National Network of Labs, which includes the Departmental Medicines QC laboratories. Completed</p> <p>Peru - 3LA adopted and included in DIGEMID</p>	<p>Ecuador - A more advanced draft of the regulations that include the 3LA (Reglamento de Control Post Registro de Medicamentos), received, reviewed by PQM, and returned to MoH.</p> <p>Peru - The 3LA was included in the guidelines for MQM activities implemented by DIGEMID (Peru MRA) and Diresas (Regional Health Offices). A study using this approach was performed in the Madre de Dios region in September 2012.</p>

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		Q1	Q2	Q3	Q4
			<p>returned new regulations that include the three-level approach from Peru's MRA. Currently under review by country authorities.</p>	<p>(MRA) guidelines for post-marketing QC. Reviewed by PQM and returned to DIGEMID. Final version from DIGEMID has been completed and has been disseminated to country stakeholders and PQM for their final review</p> <p>Guyana - MOU between Ministerial departments defining roles and responsibilities, including TLA implementation. PQM completed and returned draft document to country with comments and recommendations.</p>	
Strengthen south-south collaborations, and facilitate communication and sharing of information					
Support collaborations between OMCLs for internships and technical assistance					
Support Peru OMCL in delivering one round of inter-lab proficiency testing scheme			<p>Peru OMCL sent invitation letter to participating countries. Due to programming timelines a malaria medicine has not been included. PQM will support AMI participating countries with RS upon request from the participating labs.</p>		
Continue to support				The following videos were	

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
internet-based Virtual Forum				added to the training session: 1. Dissolution Performance Verification Testing - Mechanical Calibration - How to measure wobble? 2. Dissolution Performance Verification Testing - Mechanical Calibration - How to measure level and height? 3. How to measure shaft centering (Distek dissolution tester). 4. How to measure shaft centering (Hanson and Vankel dissolution testers). Documents added – Three Level Approach Workshop resource documents Revised “News & Updates” page to include link to PQM news and resource center and links to both of the LAC papers accepted to Malaria Journal Revised “Online Resources” page include Global Health Impact Programs website	
Implementation of stringent Quality Management Systems					
Follow up CAPAs from PQM and CCCM QMS		Representatives of CCCM (Uruguay) visited	Reviewed CCCM evaluation on follow up	INVIMA is addressing observations.	

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		Q1	Q2	Q3	Q4
evaluations performed at Colombia OMCL		INVIMA (Colombia) to assess progress made addressing the CAPAs from the previous QMS evaluation. CCCM submitted the evaluation report to PQM.	on CAPAs. Final report sent to INVIMA lab (Colombia's OMCL).		
Assessment by CNCC of CAPAs for the OMCL in Bolivia			Two analysts from CNCC traveled to Bolivia's OMCL (CONCAMYT) to assess the lab and evaluate readiness for WHO prequalification on microbiological methods	Report from CNCC received and reviewed by PQM and PAHO. Will be delivered to CONCAMYT and USAID by end of July 2012.	Report with results of the assessment and recommendations for improvement sent to CONCAMYT July 2012.
Ensuring the availability of good quality malaria medicines					
Regional training on compendial testing for Coartem® (AL FDC) for Brazil, Suriname, and Guyana	L. Evans		Final dates for training (April 16-27) agreed upon with country stakeholders. A delegate from Brazil will also participate. (USP TAP program will support participation of one delegate each from Jamaica, Trinidad Tobago and Belize)	<ul style="list-style-type: none"> - Training delivered April 16-27, 2012 by PQM in Suriname at the BGVS Lab - The participants included Belize (1); Brazil (1); Jamaica (1); Suriname (22) & Trinidad Tobago (1) - Belize; Jamaica and Trinidad Tobago sponsored by Global Health Impact Programs (GHIP, USP) - Training report delivered to countries' stakeholders and USAID 	
Follow up on Farmanguinhos WHO prequalification of Artesunate/Mefloquine	V. Pribluda/ E. Toledo		Visit planned for July	Visit rescheduled for September 2012 following ANVISA visit (July-August)	Farmanguinhos received GMP certification from ANVISA in Aug 2012, which is a prerequisite for

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		Q1	Q2	Q3	Q4
(ASMQ) FDC Tablets					WHO PQ. The visit to assess readiness for the WHO audit is scheduled for November 2012.
Follow up on CAPAs based on case studies in private and informal sectors in Suriname and Guyana	L. Evans		Follow up with Suriname authorities planned to occur during visit for Coartem training in April	Met with Suriname MOH and PAHO during training visit to discuss awareness strategy. PAHO drafted and circulated initial draft for comment	PQM developed a strategy for implementing awareness campaigns, which will be provided to countries.
Coordinate and support training in Guyana on the basic QC tests of the most prevalent malaria medicines identified in case studies	L. Evans			<ul style="list-style-type: none"> – Training logistics coordinated with country's stakeholders – Training materials and lab supplies shipped to country 	Guyana Food and Drug Dept delivered training to 9 pharmacy assistants on basic QC tests for malaria medicines, with technical and financial support from PQM.
Develop and validate HPLC assay and dissolution procedures for antimalarial medicines identified in case studies	L. Evans	Assays and dissolution methods for sulphamethoxypyrazine and pyrimethamine tablets were developed and validated.			
Assist Colombia health authorities to develop CAPA plan based on AMM quality study in private and informal sectors			Report from sampling from COHAN received and reviewed. Waiting for final corrections to be made. Analysis of all chloroquine and primaquine samples finalized by CCCM, (Uruguay's OMCL). Reports of all chloroquine samples received and are currently under review.	<ul style="list-style-type: none"> – Report of all primaquine samples received – Reports reviewed and accepted by PQM – Final study report in preparation. Expected by end of August 2012 	Final study report will be delivered in November 2012.
Continue to support				Malaria medicine quality	

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NMCP's ongoing rounds of MQM				monitoring report received from Guyana and reviewed	
Train on compendial testing of selected AMM used in Brazil for: Amapá LACEN, INCQS & School of Pharmacy Laboratory at UFMG	L. Evans		NMCP and ANVISA requested the training to be done at the School of Pharmacy Laboratory at Federal University of Minas Gerais (UFMG). Currently coordinating with lab director. .	<ul style="list-style-type: none"> – The UFMG laboratory was assigned by the NMCP to provide the training. The activity was not implemented because of lack of response from the UFMG lab. – PQM and USP Brazil coordinated the participation of the latter to give a presentation on matters related to dissolution of anti-malarials at a NMCP meeting 	This activity, which was to be led by the laboratory at UFMG, was cancelled because no follow-up was provided by this institution. This activity will not be pursued in the future until a formal request and authorization is provided to PQM by the NMCP and ANVISA.
Develop basic tests methods for analysis of ASMQ FDC			Request letter sent to Farmanguinhos.	<ul style="list-style-type: none"> – Method development for Artesunate Mefloquine (in artesunate co-formulations) was completed. – Validation for Farmanguinhos' ASMQ FDC tablets will be completed by July 2012. 	The analytical method for assessing Artesunate & Mefloquine in artesunate co-formulations, which was developed by GPHF, was validated for Farmanguinhos' ASMQ FDC tablets (completed in July 2012)
Support PAHO's Strategic Fund to ensure that AMMs procured for AMI countries undergo QC before distribution					No follow-up provided by PAHO for this activity, which was cancelled.

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Dissemination of results on the quality of antimalarial medicines					
Maintain MQDB containing information of medicines assessed during MQM activities	L. Evans/ V. Pribluda		Guyana's results received. Under review. Carryover activities from FY11 WP: The following articles were submitted to Malaria Journal: a) Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname b) Implementation of basic quality control tests for malaria medicines in Amazon Basin countries: results for the 2005–2010 period	– Guyana data reviewed and available in MQDB – Two articles were accepted for publication in Malaria Journal on June 2012, a) Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname b) Implementation of basic quality control tests for malaria medicines in Amazon Basin countries: results for the 2005–2010 period	
Attend meetings					
Participate in AMI and other meetings w/in-country & tech partners	L. Evans/ V. Pribluda		Participated in and gave presentations at the AMI/RAVREDA and Steering Committee meetings held in Antigua, Guatemala in March		
Maternal and Child Health V Pribluda (continuing FY11 activities from FY10 budget)					
Dissemination of results from studies performed in Guatemala and Peru					
Share study results via conferences, & pubs to nat'l/int'l stakeholders		PQM gave a presentation at the Technical Forum "Advancing Newborn Health through Alliances" in Asunción,	Final report of study in Guatemala sent to USAID and delivered to the MoH. Data was presented to the Technical Vice Minister		Waiting for Guatemala MoH authorization to disseminate results before writing an article for submission to a peer-reviewed journal.

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		<p>Paraguay, in November. The information presented focused on the case studies performed in Guatemala and Peru assessing the quality of emergency obstetric and neonatal medicines in public primary care services in decentralized areas.</p> <p>PQM gave a presentation on “Quality of Emergency Obstetric and Neonatal Medicines: Results of Case Studies in Public Primary Care Services in Decentralized Areas in Guatemala and Peru” at the USAID Maternal Health Technical Series in Washington, D.C. in November.</p>	<p>and USAID representatives during the visit to Guatemala in March.</p>		
Follow up on studies to assess the quality of selected obstetric and neo-natal medicines utilized in primary care health facilities in decentralized regions in Peru and Guatemala					
Identify source of problems found in Peru & Guatemala studies; share with stakeholders			<p>Source of problems in Guatemala identified and discussed with the MoH and USAID. Follow-up activities will be performed with funds recently committed by the USAID mission.</p>		
Develop CAPAs with stakeholders & help implement			See above		

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If no critical issues from studies, expand to Peru or Guatemala or another country					No additional funding was provided. Remaining funds will be used to write an article (see above).
South American Infectious Diseases Initiative (SAIDI) V. Pribluda (continuing FY11 activities from FY10 budget)					
Medicine Quality Monitoring Activities in Macro Region Oriente – Peru					
Complete analysis of medicines sampled during FY10		Activity completed			
Introduction of SAIDI approach, focusing on AMR for TB, in one Department in Peru					
Assist SAIDI partners identify dept in Peru to introduce approach					
Develop Terms of Reference for base-line study on TB resistance					
Coordinate local workshop to disseminate results of base-line study and develop plan to combat AMR					
Coordinate with local stakeholders to implement activities		PQM collaborated with regulatory authorities in Peru to include the Minilab as part of the regular MQM activities in the Madre de Dios Region, Peru, the area where the SAIDI approach is being implemented by PQM and its partners.	Donated Minilab was received by the DIRESA (Regional Health Office) of Madre de Dios. Before training and quality study is performed, the DIRESA needs to get approval for the use of controlled reagents included in the Minilab. Permission has been requested by the DIRESA and is expected to be received in Q3.	<ul style="list-style-type: none"> – The first draft of guidelines for the use of the 3-level approach by DIGEMID for market surveillance activities was reviewed and edited by PQM. DIGEMID will deliver final version by the end of July 2012 – Coordinated activities with country's stakeholders for: <ul style="list-style-type: none"> a) Sampling (to be 	Training on the Three-level approach, Basic Tests, and use of Minilab delivered in September 2012 to 23 participants from DIGEMID, CNCC, PAHO, and the DRESAS of the Macro Región Oriente (Amazonas, Loreto, Madre de Dios, San Martin and Ucayali). - Guidelines for the use of the 3-LA, developed in collaboration with

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				<p>performed during August 2012) and b) Minilab training (to be delivered in September 2012) in collaboration with personnel from Antioquia Departmental Health Lab (Colombia)</p>	<p>DIGEMID, finalized. - Guidelines included in the protocol for a study initiated in the Madre de Dios region, in September 2012. The objective of the study is to assess the quality of anti-TBs, antimalarials, antibiotics and AINS in the DIRESA. Local and international partners that participated in the coordination of the study were DIGEMID, DIRESA of Madre de Dios, CNCC, MSH and PAHO/Peru. Sampling has been completed and medicines are currently being assessed at the Regional Medicine Office (DIREMID) of Madre de Dios and at the CNCC.</p>
Disseminate MQM activities performed in all SAIDI countries					
Develop w/DIGEMID & disseminate report of Madre de Dios study					
Publish report/article for MQM activities in SAIDI countries					<p>Since no more funds are available for SAIDI, no publication will be pursued. Articles were not produced beforehand because: a) There was no follow up by UNIMED (Bolivia MRA) b) There was no follow up by the Paraguay lab on data deemed</p>

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					questionable by DQI/PQM c) The quality data in Peru has been made publicly available at the DIGEMID (MRA) website.
Guatemala Mission V. Pribluda (FY12 activities from FY11 funds; <i>funding was not received until Q2, therefore activities will continue into FY13.</i>)					
Improve the processes of evaluation of medicines quality certificates for purchases made by MSPAS (Ministry of Public Health and Social Services)					
Workshop on quality certificate evaluation during the purchase and/or acceptance of medicines intended for those responsible on the central and regional levels.				Workshop coordination with MRA and key MoH personnel initiated (to be delivered in September 2012)	- A consultant was hired in August 2012 to help in the coordination of this and other activities in Guatemala. - Agenda finalized and participants identified. The workshop has been postponed until December due to delays in coordination with country stakeholders.
Strengthening the Quality Management System (QMS) at the UM-LNS					
PQM will provide assistance to support UM-LNS in attaining WHO prequalification. To do so, PQM will support training of LNS-QMS department staff and will follow-up on the implementation of Corrective and Preventive Action (CAPA) made during previous assessments.				Logistics for UM-LNS personnel to attend training at CNCC (Peru OMCL) in July 2012 finalized	The coordinator of the Quality Management Unit from the National Health Laboratory (LNS) received training in July 2012. The trip report will be delivered in October 2012.
Implementation of the three-level approach for the quality control of medicines					
Train staff of the Department of				Minilabs for training purchased and shipped	- Minilab received at the Medicines Unit (UM) from

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		Q1	Q2	Q3	Q4
Regulation, Monitoring and Control of Pharmaceutical and Related Products (DRVCPFA), for the Medicines Unit of the National Health Laboratory (UM-LNS), and staff from selected health areas.					the LNS. - Agenda finalized and participants identified. The training has been postponed until December due to delays in coordination with country stakeholders.
Evaluate the quality of medicines in the private and informal sector					
Pilot study to evaluate the quality of selected medicines sampled in the private and informal sector using the three-level approach.					Protocol currently being developed in consultation with country stakeholders. Sampling scheduled for November/December 2012.