

**Promoting the Quality of Medicines (PQM) Program
Quarterly Reports: FY15 Activities (October 1, 2014–September 30, 2015)**

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
CORE					
Cross Bureau	M. Hajjou				
FY 15					
Objective 1: Increase awareness about the importance of medicines quality					
Attend and present at national, regional, and international conferences			PQM gave a seminar on the importance of medicines quality and technical leadership entitled "Why Is Medicine Quality Important?" at the University of Boston School of Public Health. This was part of the School's Pharmaceutical Program Spring Seminar Series; there were over 50 student and faculty attendees, mostly MPH and PhD students, including the Global Health Department Head.		
Use available media outlets to advocate the need for medicines quality assurance			The article "Monitoring the Quality of Medicines: Results from Africa, Asia, and South America," was revised and resubmitted to the American Journal of Tropical Medicines and Hygiene. The article will be published in a supplement on falsified and substandard malaria medicines, which will		

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		Q1	Q2	Q3	Q4
			launch at a press conference on April 20.		
Objective 2: Produce up-to-date information about current issues in medicines quality					
Collect and publish reports on incidents of poor-quality medicines	M. McGinnis	33 new reports were included in the <i>Media Reports on Medicine Quality</i> ; updated version was added to the website	32 new reports were included in the <i>Media Reports</i> ; updated version was added to the website		
Maintain and update PQM website	M. Foster	Updated 2 webpages	Added 10 articles and photos; updated 3 webpages; added 10 resources/links		
Objective 3: Support regional approaches and networks					
Participate in NEPAD's Technical Working Group on "Institutionalization of Regulatory Training Programs in Africa using Existing Regional Structures"		The next meeting is scheduled for February.	PQM attended a meeting in Feb in Cape Town and provided technical input for the "Grant Scheme" developed, which is aimed to increase African regulatory personnel expertise in regulatory activities related to clinical trials, registration of medicinal products, and technologies for human use. The following activities will be prioritized: <ul style="list-style-type: none"> • Review of clinical trial applications • Regulatory inspections 		

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		Q1	Q2	Q3	Q4
			<ul style="list-style-type: none"> Product registration processes Pharmacovigilance and related post-registration regulatory interventions <p>The call for proposals is ongoing. 5-10 fellowships are expected.</p>		
Objective 4: Demonstrate functionality of PharmaChk to screen for medicines quality in resource-constrained field settings in anticipation of potential Agency investments to bring PharmaChk to scale					
Develop a field-based quality control tool with increased accuracy, sensitivity, and reliability (continuing activity)		PQM worked with Boston Univ on budgeting and project description details for the new contract to refine the functionality of PharmaChk and develop, validate, and test new probes. Existing probes that were not validated will be validated as well.	Fixed Obligation Grant was established between Boston Univ and USP. Progress report on the optimization of SELEX system for isolating aptamers for oxytocin and cotrimoxazole, development of probe for amodiaquine, and testing of the probe on amodiaquine-artesunate tablets was received and reviewed. Comments were provided to BU. PQM met with BU and discussed the project.		
Core Malaria	L. Evans, III				
FY 14 – Carried Over Activities					
Objective 1: Monitor antimalarial medicines quality and the extent of diversion from the public to private sector					
Conduct studies to assess the diversion of antimalarial		Completed diversion study reports for Malawi	Completed diversion study report for DRC.		

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		Q1	Q2	Q3	Q4
medicines from public to private sector		and Tanzania.			
Objective 3: Increase the availability of standards and testing methods for selected antimalarials					
Develop monographs for pyronaridine API and pyronaridine-artesunate FDC			Monograph development process put on hold because of new USP initiative to develop monographs for products not marketed in the US. The manufacturer is reluctant to assist in developing the monograph.		
FY 15					
<i>Core Malaria FY15 workplan has not been approved, thus no activities have been completed</i>					
Core Maternal and Child Health - L. Evans, III					
FY 14 Carried Over Activities					
Objective 1: Monitor newborn health medicines quality					
Develop chlorhexidine gel monograph for USP Medicines Compendium		Laboratory work and the initial draft were completed at the end of FY14. Comments and recommendations were provided for the initial draft monograph.	PQM participated in a meeting with FDA and provided information regarding the inclusion of the monograph into the USP-NF. Comments were provided for the briefing section of the final monograph being prepared for publication in the <i>Pharmacopeial Forum</i> .		
Objective 3: Support USAID medicine quality initiatives related to UN Commission					
Participate in UN Commission Activities/Meeting		Completed for FY14			

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		Q1	Q2	Q3	Q4
FY 15					
Objective 1: Increase the supply of quality maternal, newborn and child health medicines					
Increase the supply of quality assured newborn health medicines -chlorhexidine.		Work plan approved in Dec 2014. Initial assessment was conducted for ACI (Bangladesh manufacturer) using UN Commission funds via USP-PATH agreement.	Two assessment reports (summarized public version and confidential version) were prepared and disseminated. Provided feedback to ACI to address observations from assessment conducted in Dec 2014. Will evaluate chlorhexidine manufacturing line in May; that was not on line in Dec 2014		
Increase the supply of quality assured newborn health medicines - injectable antibiotics		Work plan approved in Dec 2014.			
Objective 2: Provide technical leadership and advocacy on maternal, newborn and child health medicine quality					
Provide technical leadership and advocacy for quality newborn health medicines		Participated in chlorhexidine working group teleconferences and provided update on CHX production in Uganda and Kenya. Reports were prepared and submitted to PATH (These were not PQM supported activities but are relevant to USAID).	Participated in chlorhexidine working group teleconferences and provided updates on CHX monograph development.		
Objective 3: Increase the supply of quality maternal, newborn and child health medicines					
Increase the supply of quality assured child health medicines - amoxicillin DT		Initiated discussions with manufacturers in Kenya (Regal Pharmaceuticals)	PQM GMP staff performed a rapid assessment of Regal		

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		to determine their interest in manufacturing amoxicillin DT.	Pharmaceuticals to evaluate the company's readiness to receive PQM TA and to determine the status of the development of their Amoxicillin DT product. Based on the assessment, Regal was found to be ready to receive TA. A baseline GMP assessment of Regal's amoxicillin DT manufacturing line is tentatively scheduled for May-June 2015.		
Increase the supply of quality assured child health medicines - zinc tablets			Kilitch (India) completed QOS/QIS forms for WHO PQ and palatability study. The company will be sending WHO PQ dossier for PQM final review in May. LaGray-Vibrer received a no-cost extension for the quality validation work being done at LaGray.		
Objective 4: Provide technical leadership and advocacy for quality child health medicines					
Provide technical leadership and advocacy for quality child health medicines		Participated in Pneumonia and Diarrhea working group teleconferences. Provided overviews of manufacturer selection process and common issues to CHAI as related to zinc			

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		Q1	Q2	Q3	Q4
		production.			
Objective 5: Increase the supply of quality maternal, newborn and child health medicines					
Increase the supply of quality assured maternal health medicines - (oxytocin, misoprostol, magnesium sulfate)			In April-May 2015, Galychpharm will start up a new site for infusion solutions, and in June 2015 they will have a license inspection of this new manufacturing site. PQM is tentatively planning an assessment for July-August 2015. Travel to the company has been previously canceled because the company is located in the Ukraine.		
Objective 6: Provide technical leadership and advocacy for quality maternal health medicines					
6.1 Provide technical leadership and advocacy for quality maternal health medicines (Bangladesh)		Work plan approved in Dec 2014.	Developed agenda for MCH medicines quality meeting in Q3. Finalized logistics for workshop and identified collaborating organizations and attendees.		
6.2 6.1 Provide technical leadership and advocacy for quality maternal health medicines (East Africa)		Work plan approved in Dec 2014.	Followed up with initial discussions with Pharmacy and Poisons Board (PPB) to determine appropriate venue and collaborators to hold MCH workshop in Kenya. PQM has contacted potential speakers from UNICEF Supply Division and		

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			Concept Foundation to participate in the workshop. Topics to be covered by the mentioned speakers have been developed with their consultation.		
Core Neglected Tropical Diseases		T. Bedane			
FY 15					
Objective 1: Collaborative research on alternative bio waiver for NTD products					
Desk research on principles of BE/BW related to NTD products and Development of Plan of Action		Developed the concepts and plan of action on the approaches to be followed; translated the concept paper in the RFA	RFA responses were reviewed; University of Minnesota was selected to conduct the bio-pharmaceutical classifications characterization for Praziquantel (PQZ)		
Interviews with the key opinion leaders (SRA, research organization, and academia)		Established an NTD working group/team (see Objective 5)	The NTD working team conducted monthly discussions on PQZ while the study team (Univ. of Minn/PQM) conducted biweekly discussions on the progress of the study		
Review and analysis (may include lab analysis)					
Report organization and consultative workshops (1-2trips)					
Final report, recommendations and follow-up					
Objective 2: Increase in the supply of quality-assured NTD medicines					
Identify major manufacturers of NTD products		Potential manufacturers for NTD products	Potential NTD manufacturers include:		

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		Q1	Q2	Q3	Q4
		identified and contacted to determine interest	Mebendazol API (Yabang/China); Mebendazole FPP (Galenica/Moroco)		
Provide technical assistance to identified API and FPP manufacturers of NTD medicines seeking to obtain WHO PQ		Praziquantel API/FPP (Nanjin/China, Minsheng/China); Albendzole (Glomed/Vietnam, Nobel/Kazakhstan) have been identified as potential manufacturers	Praziquantel Drug Master File (DMF) from Nanjin/China reviewed. Comments provided to manufacturer for update as per WHO submission requirements		
Continue to provide TA on CAPAs, WHO PQ dossiers, and GMP compliance of API/FPP		Nanjin and Minsheng provided samples for the BCS characterization	PQM is providing continuous support for the PQZ API DMF and FPP dossier preparation		
Objective 3: Capacity-building through incentive and non-incentive support to promising companies					
Supply of reference standards and chemicals		Praziquantel reference standard for API and impurities provided to Univ of Minn for study			
Provision of comparators product					
Support for the conduct BW/BE study			The BW study protocol from Univ of Minn was reviewed and updated		
Objective 4: Engaging partners for expansion of NTD product in the essential medicines list and EOI					
Identification of key stakeholders and partners for engagement					
Identification of meeting venue and topics of discussions					
Conduct the workshop (may include trip)					
Implementation of the recommendation					

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Objective 5: Capacity-building through incentive and non-incentive to CRO for BE study					
Identify products near to acceptance except for BE study		The USAID NTD team, WHO NTD team, and the PQM GMP team are the key stakeholders identified	Established NTD working team composed of USP/PQM, WHO NTD department, and USAID NTD team		
Conduct baseline assessment of CRO site (1-2 trips)					
Provide funding support for the conduct of BE study					
Evaluation of the BE data					
Core Tuberculosis A. Hong					
FY 14 Carried Over Activities					
Objective 4: Support research to improve quality and yield of Kanamycin through genetic engineering					
Support scale-up of technology to API manufacturer			The selected applicant could not accept the sub-award due to health issues. Will be reassessed and republished.		
Objective 7: Conduct structural elucidation of impurities in Active pharmaceutical ingredient of Kanamycin and Capreomycin					
Conduct literature review of impurities in Kanamycin and Capreomycin			No new updates. Several standards were run on various columns by LC-Mass Spectrometry to understand the signature fragmentation exhibited by related antibiotics. MSU is still waiting to receive samples from PQM.		
Develop analytical methodology to profile impurities in Kanamycin and			Kanamycin API samples to be available upon completion of Genetic		

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Capreomycin			Engineering Study of Kanamycin.		
Characterize the impurity profile (structural elucidation) for select products produced by select Chinese companies for all impurities at levels of 0.5% or above					
Quantitate the levels of the impurities at or above 0.5%					
Objective 8: Conduct studies to assess the potential to increase the shelf life of certain second line TB medicines (Cycloserine, PAS Sodium, and PAS Acid)					
Identify select second line medicines with short shelf life			Cycloserine was selected to conduct the stability study, due to its high price and short shelf life (24 months).		
Conduct literature review of the establishment of shelf life for these medicines			Kick off meeting scheduled for April.		
Conduct accelerated stability studies using the ASAP software and suggest appropriate shelf life					
Validate the predicted shelf life using real time studies					
Suggest appropriate packaging for the medicines necessary to increase shelf life					
FY15					
Objective 1: Increase the supply of quality-assured second-line anti-TB medicines					
Continue to provide technical assistance to identified CRO, API and FPP manufacturers of second-line anti-TB medicines seeking to obtain		The following companies received WHO Prequalification approval in Quarter 1: NCPH Huasheng for	The following achievements took place during Quarter 2: Hizon Laboratories submitted the FPP		

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WHO Prequalification		<p>Capreomycin API; Hisun Pharma for Capreomycin FPP; and HEC Pharma for Azithromycin FPP</p> <p>China/Hong Kong: Fuzhou: working on implementing CAPA from WHO inspection; also submitted second APIMF for non-sterile kanamycin API Jinxin Pharma: WHO inspection conducted for Levofloxacin API Silver Eagle Pharma: Process validation completed for PAS Sodium API Hebei Xingang Pharma: Process validation completed for Rifampicin API Excel Pharma: Process validation in progress for Cycloserine API Reyoung Pharma: Early stage product development for Cycloserine, Clofazimine, and PAS Sodium FPPs Pen Tsao Pharma: Terizidone API development in progress NCPA Pharma: WHO inspection conducted for</p>	<p>dossier which was accepted for review; Hisun Pharmaceutical submitted their FPP dossier which was accepted for review, and their API and FPP facilities were inspected by WHO PQ. The outcome of the inspection is still pending.</p> <p>China/Hong Kong: Silver Eagle Pharma: dossier assistance provided for PAS Sodium API Hebei Xingang Pharma: GMP assessment and dossier assistance provided for Rifampicin API Excel Pharma: Process validation in progress for Cycloserine API Reyoung Pharma: assistance on dossier and stability program provided for Kanamycin FPP Asta Tech Inc.: site GMP assessment conducted for Linezolid API Baush Pharma: preliminary discussion held for Clofazimine and PAS Na FPP</p>		

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		Q1	Q2	Q3	Q4
		<p>Streptomycin FPP</p> <p>Georgia: Introductory visit to GM Pharma in October 2014; Reviewed WHO inspection observations and CAPAs implemented; API source to be changed.</p> <p>India: Shalina: Reviewing dossier using Langhua API; dossier completed with Langhua API; dossier scheduled for submission to WHO in March 2015; tentatively planning to visit in April; anticipating facility upgrade by middle of next year.</p> <p>Indonesia: Zenith: Follow up visit for CAPA implementation Sanbe: Follow up visit for CAPA implementation Kalbe: GMP assessment conducted for Levofloxacin FPP</p> <p>Korea: Dong-A: Terizidone BE study initiated and</p>	<p>Hisun Pharma: provided assistance on WHO inspection CAPA for Moxifloxacin API & FPP and Linezolid API & FPP; provided dossier assistance for cycloserine API & FPP and PAS Na API & FPP</p> <p>India: Sangrose: GMP Assessment conducted for Clofazimine API Shalina: dossier compilation assistance provided for Levofloxacin FPP</p> <p>Indonesia: Kalbe: GMP CAPA assistance provided for Levofloxacin FPP</p> <p>Korea: Dong-A: Awaiting Terizidone BE study report; initiated technical assistance discussion for clofazimine API & FPP CKD: met to discuss timelines and path forward for the WHO PQ – including the facility renovation schedule for Linezolid FPP Enzychem: held meeting</p>		

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		<p>scheduled for completion in December 2014 Enzychem: Query received from WHO PQT regarding starting material. KUP: Provided comment on Site Master File. Ildong; Provided comments on process validation protocol. Hanmi Fine Chemicals: Received CAPA for review from assessment in August 2014. JW Pharma: new manufacturer with potential interest in Linezolid API</p> <p>Philippines: Hizon: conducted facility assessment; CAPA plan received and reviewed – 90% implemented; dossier sent to PQM for review and comments sent to Hizon; Hizon to update the dossier by end of January 2015 Unilab: site assessment conducted</p> <p>Taiwan: Peili: Dossier received for review. General layout and format to be</p>	<p>to discuss dossier screening queries received from WHO and path forward Hankook Korus Pharma: CDA and dossier documents sent to initiate the dossier for Cycloserine FPP KUP: Provided review on utility drawings and revised SMF Hanmi Fine Chemicals: visited in February 2015 to discuss the final dossier review comments and GMP assessment; API MF scheduled to be submitted in May 2015 JW Pharma: QOS and API MF guidelines sent; QOS and CDA in progress</p> <p>Philippines: Hizon: dossier submitted to WHO PQ in March 2015 and accepted for review Unilab: dossier compilation assistance provided for Amikacin FPP</p> <p>Taiwan: Peili: awaiting for reformatted dossier for</p>		

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		Q1	Q2	Q3	Q4
		corrected and QOS to be completed and submitted for review. Vietnam: Imexpharm: CAPA received for review. STADA: New manufacturer with interest in TB medicines. Already prequalified for ARVs. Zimbabwe: Varichem: Safety and Efficacy part approved by WHO PQT; working on response to WHO queries for Quality part of the dossier – to be submitted by end of January; tentative visit scheduled for end of March.	review Vietnam: STADA: GMP assessment conducted for Levofloxacin FPP Glomed: GMP assessment conducted for Levofloxacin FPP OPV: GMP assessment conducted for Levofloxacin FPP Savipharm: preliminary meeting held to discuss WHO PQ for Levofloxacin FPP Zimbabwe: Varichem: dossier assistance provided		
Provide translation assistance on required dossiers/documents for WHO Prequalification		No translation assistance provided	Translation services for Shanghai Harvest/Interpharma were provided		
Collaborate with GDF and WHO PQT to conduct in-depth technical workshops		No workshops held	No workshops held		
Continue to collaborate with GDF and WHO PQT and participate in their meetings with/without manufacturers		No meetings attended	No meetings attended		
Attend any other meetings/conferences as necessary for technical		No meetings attended	No meetings attended		

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		Q1	Q2	Q3	Q4
assistance					
Objective 2: Provide support through capital investment to promising companies to obtain WHO Prequalification					
Obtain comparator products for use in in-vitro dissolution studies or bioequivalence (BE) studies		Reyoung: Cycloserine and PAS Hizon: Levofloxacin Shalinas: Levofloxacin Varichem: Levofloxacin Kalbe: Levofloxacin Pharmis: Moxifloxacin RS	No comparator products purchased		
Provide financial support for BE studies		No BE study support provided	No BE study support provided		
Objective 3: Clofazimine API Technology					
Initiate transfer of API technology to a manufacturer based in the US		No activity	No activity		
SUB-SAHARAN AFRICA					
Benin	M Hajjou				
FY 15					
Objective 1: Assess the Medicines Quality Assurance System in Benin					
Conduct a consultation visit		PQM conducted a consultation visit with local partners; following the visit a work plan was developed	Work plan developed and submitted to the Mission for approval.		
Objective 2: Strengthen Antimalarial Medicines Pre- and Post-market Quality Control					
Improve the quality management system of the National Quality Control Laboratory (NQCL)					
Improve the analytical capacity of the National Quality Control Lab					
Establish a Medicines Quality Monitoring program for antimalarial medicines			Quote for one Minilab and additional supplies obtained. Procurement is pending the approval		

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		Q1	Q2	Q3	Q4
			of the work plan		
Burkina Faso	L. El Hadri				
FY 15					
<i>An initial assessment of QA/QC systems in Burkina Faso was conducted in February. A work plan will be developed.</i>					
Burundi	M. Hajjou				
FY 14					
Objective 1: Establish a medicines quality program					
Implement the use of basic tests as first step of Quality Control program of antimalarial medicines			No funding is available to complete FY14 or FY15 activities		
Objective 2: Strengthen the medicines quality control laboratory of INSP					
Equip the QC lab and train staff according to the first phase of the implementation plan		Two lab staff completed a two-week training at CePAT in Ghana. The training covered Good Lab Practices, Good Weighing Practices, lab safety, pH measurement, Karl Fischer titration, disintegration, dissolution, and High Performance Liquid Chromatography Assay.			
Objective 3: Strengthen the capacity of the medicine regulatory authority (DPML)					
Assist DPML to build its medicines regulatory capacity					
FY 15					
Objective 1: Support establishing a national quality assurance system for Health Programs					
Assist Health Programs and DPML in developing a quality assurance policy			No funding is available to complete FY14 or FY15 activities		
Assist the National Council for Fight Against AIDS in					

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		Q1	Q2	Q3	Q4
developing procedure manual relating the QA assurance of ARVs					
Objective 2: Strengthen DPML Regulatory Functions					
Improve Drug registration processes					
Objective 3: Strengthen pre- and post-market Quality Control of Medicines					
Improve analytical capacity of the Medicine Quality Control lab					
Improve the quality management system of the Medicine Quality Control lab					
Support Medicines Quality Monitoring Program					
Objective 4: Strengthen the capacity of the Central Medical Store (CAMEBU)					
Develop a quality management system					
Ethiopia	T. Nwogu/E. Wondemagegnehu				
FY14					
Objective 1: To strengthen the performance of Product Registration and Licensing Directorate of FMHACA					
To train staff to operate and manage the information and data system					
To strengthen FMHACA's Product Quality Assessment Directorate(PQAD) (Drug Quality Control Laboratory)					
Objective 2: To strengthen FMHACA's Product Quality Assessment Directorate (PQAD) (Drug Quality Control Laboratory)					
To train staff in microbiological test methods in Ethiopia					
To move the condom laboratory to new site and ISO accredit					

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		Q1	Q2	Q3	Q4
To move the microbiological laboratory to new site and calibrate and qualify equipment					
To make additional physico-chemical test methods ISO accredited					
To train staff in physico-chemical test methods & QMS in Ethiopia					
Objective 5: To improve GMP knowledge and skills of local medicine manufacturers					
To local manufacturers of OI products to get their OI products quality assured					
FY15					
Objective 1: Management and program effectiveness of FMHACA improved and the new government changes on FMHACA institutionalized					
Assist FMHACA to develop regulatory frame work		Participated in the review of the draft FMHACA Proclamation and supported the translation of the draft copy to national language. Participated in the development of service charges for FMHACA services			
Assist FMHACA in review of legal instruments"					
Arrange experience sharing programs with developed and developing countries regulatory authorities for FMHACA		Participated in the first meeting of the Task Team to facilitate the establishment of the African Medicine Agency, held in Nov.			

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Support the participation of FMHCA by African medicine regulatory authorities harmonization groups		Participated in the First Conference of African Medicine Regulators of Sudan and Neighboring Countries, held in Khartoum in Dec			
Support FMHACA to initiate IGAD member countries medicine regulatory harmonization			Meeting held with FMHACA to review activities performed and progress made towards harmonization of Ethiopia with IGAD countries MRAs.		
Objective 2: FMHACA Product registration and licensing system made effective, efficient and transparent					
Assist FMHACA in capacity building of staff in dossier assessment		Training on basic medicine dossier assessment was given to 35 FMHACA staff in Dec	Continued participating on technical working group of FMHACA database development		
Development and printing of tools guidelines, procedures, sops necessary for the operation of the marketing authorization		<p>Guideline for Registration of Medicines printed and distributed; Guideline for Registration of Medical Devices in printing.</p> <p>Development of Guideline for Variation Medicine Application and Strategy for Enhanced Market Authorization is in progress.</p> <p>Participated in TWG meeting on FMHACA data and information</p>	<p>Printed and distributed guideline for registration of medical devices</p> <p>Enhanced marketing authorization strategy discussed with FMHACA</p> <p>Guideline for medicines applications discussed with FMHACA</p> <p>Guidance on Biowaiver medicines application discussed with FMHACA</p> <p>Guideline for registration of biological products is</p>		

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		software development	in development		
Objective 3: Inspection and market control system of FMHACA strengthened					
Capacity building on GMP inspection			Provided training on basic GMP inspection for 22 FMHACA staff Participated in GMP conference organized by Ethiopian pharmacy association Assisted in the development of a risk-based GMP inspection plan.		
Capacity building on inspection of distribution chain		Performed on-the-job training for 7 new medicine inspection directorate staff on inspection and coaching of inspectors on onsite GMP inspection.			
Support FMHACA in establishing national task force for combating illegal trade of medicines					
Support FMHACA in establishing IGAD inter-country task force for combating illegal trade of medicines					
Support FMHACA in developing science based tools relevant for inspection and market control systems		Good Storage Practices Guideline and Good Distribution Guideline drafted. Inspection Manual is in	Inspection manual is being reviewed Good Storage Practices Guideline under review		

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		progress.	Good Distribution Practices Guideline under review Pharmaceutical products recall guideline under review.		
Objective 4: Product quality testing system of FMHACA (the national medicine quality control laboratory and branch laboratories) strengthened					
Support FMHACA to sustain/maintain the physico-chemical test methods already ISO accredited		Procured lab instruments (dimension testing and water purifier system).	10 temperature/RH loggers to monitor temp and RH of refrigerators and one pH-Conductivity meter procured. PT samples for seven physico-chemical test methods procured.		
Assist FMHACA to make additional PQAD test methods ISO accredited		PQAD condom lab ISO accredited.	Awareness training on ISO17025:2005 and WHO PQ of laboratories was given for 30 PQAD technical staff in March.		
Support FMHACA so that the ISO accredited physicochemical test methods will be WHO pre-qualified		Prepared CAPA plan for ACLASS findings and are uploading the CAPAs. PQAD quality manual was revised as part of the action plan for WHO PQ. SOPs for proficiency testing (PT) and for data integrity drafted as part of the WHO PQ action plan.	15 QMS documents were revised as per WHO PQ recommendations. Procured laboratory supplies/apparatus to prepare the PQAD lab for WHO PQ.		

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Assist FMHACA to qualify and calibrate the medicine Microbiological laboratory equipment in the new FMHACA laboratory					
Assist PQAD to participate in quality management system (QMS) related workshops and trainings					
Support FMHACA so that the ISO accredited physicochemical test methods will be WHO pre-qualified					
Train staff in condom quality management system (ISO 4074 and WHO requirement)					
Train staff in medicine microbiological test methods					
Train staff Of FMHACA branch laboratories in medicine analytical techniques					
Train staff Of FMHACA branch laboratories in medicine analytical techniques					
Provide laboratory equipment and supplies to FMHACA branch laboratories					

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Assist Supportive Supervision of FMHACA branch laboratories					
Provide training on QMS and WHO PQ					
Objective 5: Sustainable post-marketing quality surveillance system for medicines					
Train staff for testing samples of anti-malarial, MCH ARV and OI samples			26 PMS sample collectors were trained on the new and revised PMS protocols Procurement of lab supplies and Minilabs is underway.		
Assist FMHACA in finalizing the national guideline on PMS		First draft report of the FY14 PMS on ARV, OI, and antimalarial medicines prepared. Draft protocol for PMS of MCH medicines prepared.			
Train sample collectors for PMS					
Train regulators /inspectors on general principles of PMS					
Support and coordinate collection of PMS samples (ARV, OI, MCH and antimalarials)					
Support testing of collected PMS samples					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
(antimalarial, MCH ARV, OI)					
Support FMHACA in writing a consolidated PMS report			Report on PMS of ARV and OI medicines was drafted and submitted.		
Using PMS results, support FMHACA in the fight against illegal trade of medicines			Two awareness raising workshops were organized at Gonder/Amhara and Logia/Afar in March		
Objective 6: Medicine regulatory capacity of regional/city administration authorities improved					
Support in development of science-based tools relevant for regional/city administration medicine regulators					
Support regular discussion forum between FMHACA and regional/city regulatory authorities					
Provide desktop computers to regional/city administration medicine regulators					
Provide video cameras to regional/city administration medicine regulators					
Objective 7: Local medicine manufacturers made GMP compliant and their products WHO prequalified					
Assist local medicine manufacturers engaged in		Mock inspection carried out at Adigrat			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
manufacturing of OI and MCH medicines to be GMP compliant and their products WHO prequalified		Pharmaceuticals Factory (APF) and Cadila Pharmaceuticals. Meeting with Julphar Pharmaceuticals- Ethiopia on Neglected Tropical Disease (NTD) medicines WHO PQ was held. Participated in a High-level Capacity Building Workshop on Policy Coherence for Local Pharmaceutical Production and Access to Medicine in Ethiopia, organized by UNCTAD			
Objective 8: PFSA quality control laboratory able to conduct basic tests					
Train PFSA QC laboratory staff on analytical techniques					
Provide PFSA laboratory equipment and supplies					
Assist PFSA in installing, calibrating and qualifying lab instruments/equipment					
Objective 9: Training programs in regulatory sciences introduced/initiated based on MOU between FMHACA and school(s) of pharmacy					
Support the school of pharmacy in carrying out need assessment to start training program					
Provide technical					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
assistance to the school of pharmacy and FMHACA in curriculum development					
Support the development of training materials, availability trainers, and the conduct of the trainings			Discussed with school of pharmacy how to proceed with creating a pool of trainers.		
Objective 10: The laboratory of Addis Ababa University School of Pharmacy made functional					
Support Addis Ababa University School of Pharmacy in the preparation of the facilities of the teaching laboratory					
Support Addis Ababa University school of Pharmacy in installation, qualification and calibration of laboratory equipment					
Support the training of selected University staff in operating the laboratory equipment					
Ghana	R. Okafor				
FY14					
Objective 1: Support post-marketing surveillance					
Round 6 Cycle 2 antimalarial and round 2 uterotonics MQM		FY14 Uterotonic results were completed and results were forwarded to USAID/Ghana for review	Cycle 2 uterotonics will be collected at the same time as antimalarials in Q3		
Conduct confirmatory testing		Funds were wired for the	Minilab reagents,		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
– for Round 6 Cycle 1 antimalarial		continuation of sample collection	reference standards, and supplies were procured and shipped to FDA Ghana		
Conduct confirmatory testing – Round 6 Cycle 2 antimalarial and round 2 uterotonics			Sampling is slated to start in Q3		
Promote implementation of regulatory measure			Planned, after results are received in Q4		
Objective 2: Strengthen the capacity of the national Food and Drugs Authority laboratory and assist toward ISO 17025 accreditation					
Based on the outcome of the assessment appropriate QC training and technical assistance will be provided for an estimated 20 staff to improve competence					
Travel expenses (2 trips) in respect of PQM Technical Assistance for the period Nov 2013 – Feb 2014					
Facilitate accreditation assessment audit			Surveillance assessment scheduled in May		
PQM travel expenses (2 trips) in respect of ACLASS Audit			ACLASS is scheduled to travel with the program manager in May for the assessment		
Objective 4: Support the inclusion of FDA data into the MQM Database					
Support data entry and development of statistics on Ghana MQM data			Results were forwarded to the PQM consultant for inclusion in MQDB.		
FY15					
Objective 1a: PMI -Support round 7 of post-marketing surveillance of antimalarial medicines at the 7 sentinel sites in Ghana					
Conduct medicine quality monitoring at selected			MQM slated to start in Q3		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
sentinel sites for testing.					
Promote implementation of regulatory action					
Objective 1b: MCH - Conduct Round 3 of quality monitoring of uterotonic medicines (oxytocin and ergometrine) in Ghana to: 1) Determine source and registration (marketing authorization) status 2) Assess conditions of storage in the various distribution channels, 3) Determine the quality of these products.					
Conduct Round 3 of quality monitoring of uterotonic medicines (oxytocin and ergometrine)					
Purchase samples					
Purchase Minilab consumables					
Objective 1c: MCH - Conduct Round 1 of quality monitoring of Zinc formulations for diarrhea in children, this will include zinc tablet, in combination with Oral Rehydration Solution (ORS) in Ghana to: 1) Determine source and registration (marketing)					
Conduct Round 1 of quality monitoring of Zinc formulations					
Purchase samples					
Carry out Minilab screening for Zinc formulations					
Transport samples to lab for testing					
Objective 2: Strengthen the capacity of the national Food and Drugs Authority laboratory and assist toward maintaining and expanding their scope of ISO 17025 accreditation.					
Complement QMS by adding additional units and prepare for WHO prequalification			Training planned for Q3; procured and shipped reagents and consumables for maintenance of ISO accreditation; procured current USP under TAP agreement (required to comply with ISO accreditation)		
Provide technical assistance to FDA laboratory and continue support toward			Key documents were reviewed; provided assistance on technical		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
maintaining ISO 17025 accreditation			documents electronically		
Surveillance Assessment			Scheduled for May		
Objective 3: Support GMP Improvement					
Follow-up training with FDA Ghana and local manufacturers'					
Objective 4: Support inclusion of FDA data into PQM database, analyze and develop trends to provide basis for informed decision making.					
continue to include results/data from all PQM regions/countries including Ghana in the PQM global database subject to their consent			FY14 results were forwarded for inclusion in the MQDB.		
Guinea Conakry	L. El Hadri				
FY14					
Objective 1: Build the technical capacity of the National Quality Control Laboratory (LNQCM)					
Build the technical capacity of the National Quality Control Laboratory (LNQCM)		UV and GC donated to the lab			
Objective 2: Strengthen the capacity of the medicines regulatory authority (DNPL) to improve the existing registration system					
Strengthen the capacity of the medicines regulatory authority (DNPL) to improve the existing registration system			DNPL legal documents are under review. The first draft was submitted to DNPL.		
Objective 3: Establish a medicines quality monitoring program in collaboration with major stakeholders					
Establish a medicines quality monitoring program in collaboration with major stakeholders					
Objective 4: Create and develop an advocacy plan for the promotion of regulatory actions					
Create and develop an advocacy plan for the promotion of regulatory					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
actions					
FY 15					
Objective 1: Continue building the technical capacity of the national quality control laboratory (LNQCM)					
Improve the technical capacity of LNQM			Plans were made to send lab staff to be trained in an accredited lab		
Strengthen quality control of medicines					
Objective 2: Strengthening quality control of medicines					
Improve DNPL medicines registration systems			Plans for training are delayed due the Ebola outbreak.		
Improve DNPL inspection functions					
Kenya	L. El Hadri				
FY14					
Objective 1: Continue strengthening medicines quality monitoring at the existing five sentinel sites and expand it to six new sites					
Conduct one round of medicines quality monitoring at eleven sites		One round of sampling and testing using Minilabs was completed at 11 sites			
Conduct training on Minilab® basic tests ,sample collection, and reporting MQM data					
Conduct monitoring and evaluation visits to three sites					
Objective 2: Continue promoting regulatory actions by sharing MQM data with stakeholders					
Promote efforts to support enforcement actions taken by PPB based on MQM data		PPB took five regulatory actions based on the preliminary MQM results.			
Raise awareness about poor-quality medicines and share					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
data with PPB, DOMC, and relevant stakeholders					
Objective 3: Continue strengthening the NQCL capacity and assist it toward improving its QMS and toward reaching ISO17025 accreditation					
Improve technical capacity of NQCL staff on quality management systems		SOPs and QMS documents needed for ISO 17025 have been reviewed			
Prepare the lab to be audited by SANAS		Lab prepared for SANAS audit	SANAS lab audit was completed successfully, and CAPA plan was provided to make the necessary corrections in the lab; the lab should be officially accredited next quarter		
FY 15					
Objective 1: Continue strengthening the post-marketing surveillance of medicines in Kenya by improving the monitoring the quality of medicines program in its five sentinel sites, four counties, and two ports of entry					
Support the 11 selected sites to carry out one round of MQM activities.			Ongoing		
Improve Minilab [®] testing, sample collection, and results reporting					
Conduct monitoring and evaluation (M&E) visits to selected counties and support QC testing of failed samples					
Objective 2: Strengthening the quality control of medicines in Kenya by assisting the PPB in establishing its QC laboratory and advancing the NQCL to reach ISO 170025 accreditation					
Improve NQCL technical capacities			PPB lab design was reviewed and action items were sent to PPB.		
Improve PPB functions					
Objective 3: Strengthening quality assurance capacities by improving PPB registration and inspection systems and processes					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Improve PPB medicines registration systems					
Improve PPB inspection functions					
Liberia	L. El Hadri				
FY14					
Objective 1: Continue building the capacity of the Quality Control Laboratory					
Assess the lab Quality Management System (QMS) and technical capacity of the lab		Remote technical assistance provided to the lab			
Establish an action plan to prepare the lab toward the lab for ISO 1705 accreditation.			Action plan was prepared and provided to the lab. More than 50% of planned activities with the lab have been completed (a number of new SOPs were provided and 15 were reviewed, including work instructions)		
Objective 3: To Support the National Drug Services (NDS), LMHRA, and Malarial Control programs in monitoring the quality of medicines and promote regulatory actions					
Facilitate the sampling and testing of antimalarial (fifth round) based on the new MQM protocol in four sites: Margibi, Bomi and the two new sites.) 1. Note: other medicines will be selected if other health programs and LMHRA contribute financially to this activity			Workshop conducted with LMHRA, NDS, NMCP, and other stakeholders to initiate round 5 of MQM activities		
Monitor and Evaluate MQM activities 1. Supervisory visit to					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
sentinel sites to monitor the implementation of MQM protocol 2. Review and validates sentinel sites data 3. Review final report					
Share results of the final report with relevant partners and country MOH					
Raise public awareness by filming regulatory actions (confiscation of non-conform samples in the market) and through media as a part of strengthening regulatory actions					
FY15					
Objective 1: Continue building quality control of the existing lab and improving the design of the new LMHRA laboratory					
Facilitate training of QC manager at an accredited lab on all major lab equipment included in NQCL's ISO 17025 scope of accreditation; QC manager will then train NQCL analysts			Preparations are ongoing.		
Provide lab resources (chemicals, Minilab [®] supplies, and reference standards) needed to complete MQM Round 5 to the lab			Resources were provided to LMHRA.		
Provide advanced training on repair and preventive maintenance of lab equipment			Pending due to the Ebola outbreak		
Develop an action plan to monitor the lab's progress in			Completed		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
pursuit of ISO 17025 accreditation					
Evaluate implementation of ISO 17025 action plan			In progress		
Follow up on lab QMS findings and review the implementation of CAPAs			Ongoing		
Assist lab in developing, reviewing, and finalizing SOPs			Ongoing		
Review building design of the new LMHRA laboratory for compliance to ISO 17025 requirements and provide recommendations for improvements			Planned for Q3-Q4		
Assist in conducting/reviewing outcome of NOMCoL-Africa ILT exercises			In progress		
Objective 2: Continue strengthening MQM activities for antimalarial medicines and promote the LMHRA taking appropriate regulatory actions					
Complete MQM activities for Round 5 beyond Montserrado under supervision of the local consultant			Ongoing		
Review MQM results and generate report					
Promote LMHRA taking enforcement actions based on MQM data					
Promote LMHRA taking enforcement actions based on MQM data					
Share information on MQM results with key stakeholders					
Objective 3: Support coordination of PQM activities by hiring a locally-based consultant					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Hire PQM consultant to assist in implementing and supervising PQM activities in Liberia					
Mali		M. Hajjou			
FY14					
Objective 2: Support pre- and post-marketing quality monitoring of antimalarials					
Conduct quality monitoring of antimalarial medicines			Up to now, 455 samples have been collected and tested at 7 sentinel sites. Because of security concerns in Timbuktu, the Minilab was not delivered to the Regional Directorate of Health.		
Monitor and Evaluate MQM activities			Supervision of MQM activities was conducted in collaboration with LNS at Kayes and Sikasso. 45 samples were collected and screened during these visits. One fake Coartem was identified. LNS reported all failed samples to DPM for actions.		
Mozambique		R. Okafor			
FY14					
Objective 1: Strengthen the capacity of the LNCQM					
Strengthen Quality Management capacity			Strategic plan was drafted and translated and provided to DF and LNCQM		
Assist LNQCM in refining strategic plan for ISO 17025			LNCQM participated in NOMCOL ILT with		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
accredited and WHO prequalification within one year of moving to new facility			passing results		
Participate in continuous improvement collaborative proficiency testing					
Objective 2: Sensitize the public of the dangers of counterfeit and substandard medicines by publicizing LNCQM and DF activities					
Assist DF/LNCQM in developing a quarterly Q & A session with local media on issues relating to quality of medicines and highlight activities of LNCQM and USAID support			This activity was put on hold by the MRA due to political sensitivity		
Establish a communications campaign to inform the people of Mozambique about the dangers of counterfeit and substandard medicines as approved by the director of DF (work with LNCQM management)					
Coordinate activities between LNCQM and ARV manufacturer (dependent on the status of activities at the ARV site, as of FY12, was not manufacturing yet, only packaging)			ARV is still not being manufactured; only packaging		
Objective 3: Support the MQM program					
Promote efforts to support enforcement actions taken by DF based on MQM data					
FY15					
Objective 1: Strengthen the technical capacity of the National Laboratory for Medicines Quality Control (LNCQM)					
Training of Quality Assurance			Quality assurance staff		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
staff(s)			hired in March; training scheduled for April		
ISO 17025 Accreditation evaluation of LNCQM			Potential calibration bodies were contacted; waiting for feedback		
Establish calibration system for equipment in the lab					
technical capacity of LNCQM staff by conducting trainings					
Procure equipment, reagents, reference standards, and lab consumables to ensure operation		Procured reagents and consumables and shipped them to the lab.	LNCQM provided a list of materials needed.		
Hire a consultant/in-country consultant			Consultant interviewed; will meet in-country during April trip; contract is being drafted		
Objective 2: Strengthen the capacity of DF activities					
Enforcement action by DF					
Coordinate activities between CMAM and PD/LNCQM			To be discussed with USAID during April trip		
Objective 3: Support MQM Program activities at all sites					
Support PD/LNCQM to carry out 2 rounds of testing and confirmatory testing at LNCQM			FOG in progress		
Replenish the Minilabs® by procuring supplies, reference standards, reagents, and/or consumables			List of Minilab supplies provided to program manager; procurement is in progress		
Objective 4: Encourage collaboration between PD/LNCQM with local universities for training					
1.1 Coordinate and sponsor a training workshop after PD/LNCQM has established a definite relationship with some local universities			Planned for Q3-Q4		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Nigeria		L. Evans, III & T. Nwogu			
FY14					
Objective 1: Monitor Antimalarial and Maternal Child Health Medicines Quality					
Monitoring of MQM activities			Draft report submitted to PQM for review and comments.		
Objective 2: Strengthen NAFDAC regulatory capacity					
Train staff in select competencies					
Train staff in select competencies					
Objective 3: Support NMCP in finalizing its quality assurance policy for anti-malarial medicines and diagnostics					
Assist NMCP in finalizing the draft QAP					
Assist NMCP in drafting and reviewing procedures needed to implement the QAP					
Objective 4: Build capacity in GMP of selected local manufacturers of Zinc sulfate, Chlorhexidine, and other MCH commodities for global and local supply					
Provide support to CHI ORS manufacturing activities to enable procurement by local organization including USAID					
PQM in collaboration with NAFDAC will issue an Expression of Interest to identify manufacturers of amoxicillin dispersible tablets					
FY15					
Objective 1: Strengthen NAFDAC Regulatory Functions					
Finalize QAP document for medicines			Draft QAP report submitted by NAFDAC to PQM for review and comments.		
Improve drug registration					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
processes					
Improve capacity of Inspectors			Trainings on dossier review and assessments scheduled for June.		
Support medicines quality monitoring			Draft 2014 MQM report submitted by NAFDAC to PQM for review. Discussions initiated with NAFDAC, but pending finalization of 2014 MQM report.		
Support NAFDAC Central Control Laboratory to obtain and maintain ISO 17025 accreditation			Reagents supplied for ILT testing.		
Build capacity of NAFDAC regional laboratories			Initial assessment visit conducted in March; the implementation plan is being drafted.		
Support in-country program implementation			Fixed award contract for OOC approved. Office set-up initiated. COP candidate identified		
Objective 2: Increase Supply of Quality-assured MNCH Medicines Manufactured Locally					
Build capacity in good manufacturing practices (GMP) of identified manufacturers of MNCH medicines			Visited Chi, Drugfield, Tuyil, and Nemel.		
Senegal		L. El Hadri			
FY14					
Objective 1: Strengthen the capacity of DPM and support enforcement of its regulatory actions					
Support DPM in enforcing its regulations			Plans are underway to conduct a workshop with DPM.		
Objective 2: Continue strengthening the capacity of LNCM and prepare the lab for TUNAC ISO 17025 accreditation					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Prepare the lab for TUNAC ISO 17025 Audit			Ongoing		
FY 15					
Objective 1: Continue strengthening the capacity of LNCM to reach ISO 17025 accreditation					
Review Equipment Documentation (certifications, calibrations, qualifications)			Ongoing		
Review Technical and QMS Activities			Ongoing		
SEA					
RDMA/Thailand	S. Phanouvong				
FY14					
Objective 2: Continue to strengthen the capacity of the national quality control laboratory of Laos Food and Drug Quality Control Center (FDQCC) toward ISO 17025 accreditation, and Support the Chulalongkorn University Pharmaceutical Technology Service Center (PTSC) toward compliance with WHO Prequalification					
Assist the FDQCC toward ISO 17025		Completed			
Conduct an assessment of Chula PTSC for WHO PQ		Completed			
FY15					
Objective 1: Strengthen post-marketing surveillance in key areas					
Conduct sample collection of antimalarials and highly suspected antibiotics to audit the region for quality problems			Sampling plan and logistical arrangements completed for Q3 sample collection with local partners in Cambodia, Laos and Thailand in malaria "hot spots" in selected border provinces		
Provide reference standards, comparator products, chemical reagents, solvents, essential lab supplies, and reference materials to			Conducted inventory of necessary chemical and reference supplies to be provided for Laos, Vietnam and Thailand		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
national QC labs and replenish Minilab® supplies					
Conduct supervisory and monitoring visits to the sites in the field by PQM country and/or regional consultant and local partners			Planned for Q3		
Data analysis and produce end-of-fiscal year technical reports by each country and by PQM			Planned for Q4		
Strategic Information: Streamline different alert systems to combat poor quality systems to create a coordinated response for the GMS.			<p>In communication with WHO-led FFSSC alert and ASEAN PMAS</p> <p>PQM Regional Manager for Asia has been in contact with key new initiatives (Emergency Response to Artemisinin Resistance coordinated by WHO, APLMA, and GFATM/Regional Artemisinin Initiative) responsible persons to identify areas for potential cooperation</p> <p>Final version of an article for the American Journal of Tropical Medicine was submitted. Publication is planned for April 2015. The article will show the efforts of USP globally, and the state of poor quality medicines.</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Objective 2: Improve capacity of national QC labs for support regional QC activities					
Support post accreditation activities and engagement with local sampling partners for the Laos Food and Drug Quality Control Center (FDQCC). and Ho Chi Minh City IDQC toward WHO PQ to help fill the gap of long-waiting results of analysis		PQM QMS staff conducted an assessment of IDQC	Assisted FDQCC improve its quality manual and develop additional SOPs Helped develop a proposal requesting financial support to help FDQCC staff with their English skills (for SOP writing and external communications) PQM QMS staff followed up with IDQC CAPA implementation after the assessment in Q1		
Objective 3: Revitalize collaboration and coordination of activities and advocacy across GMS					
3.1. PQM will help BREMERE countries implement their enforcement actions by providing specific cases of suspected counterfeit and/or substandard medicines, including oral artemisinin-derivative monotherapies of antimalarials found in the region through the MQM program and/or other sources, for joint investigation by the countries concerned and, if warranted, take appropriate action			A falsified artemether/lumefantrine Batch No. DYI402542 Mtg date: 07/2013 Exp Date: 06/2016 found in west Africa was alerted through BREMERE in the GMS		
Objective 4: Increase effective inspections of the supply and distribution chains and education exchange					
Conduct regional inspections			In planning phases to be		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
training workshop in the distribution chains			completed in Q4		
Engage pharmacy school students and faculty members in the reduction of counterfeit and substandard medicines in the GMS).			<p>In planning phases with universities in Cambodia and Laos to be completed in Q4</p> <p>The plan to re-print '<i>Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide</i>' in local languages for SOP development support, and to serve as a reference for pharmacy education, was launched at the end of FY14 and continues to evolve. This document—if translated into Lao, Vietnamese, Thai and Khmer—would prove very helpful to training in the region</p>		
Thailand					
Objective 1: Strengthen the provincial health authorities in post-marketing surveillance through MQM					
Conduct sample collection of antimalarial (AMLs) and highly suspected antibiotics with quality problems in targeted geographical areas in the country.			<p>Sampling plan and logistics arrangements completed for Q3 execution of sample collection with local partners (Bureau of Vector-Borne Diseases (BVBD) and provincial authorities in malaria hot spots in Thailand.</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Sampling to be conducted in Q3		
Provide reference standards, comparator products, chemical reagents, solvents, essential lab supplies, and reference materials to national QC labs and replenish Minilab® supplies			Inventory and needs identification completed. Supplies to be provided in Q3		
Conduct supervisory and monitoring visits to the sites in the field by PQM country and/or regional consultant and local partners			Planned for Q3		
Data analysis and produce end-of-fiscal year technical reports by each country and by PQM			Planned for Q4		
Objective 2: Support Chula PTSC toward WHO PQ					
A team of PQM Quality Management System (QMS) specialists will continue to provide technical assistance to support Chula PTSC toward WHO PQ by submitting the application by Q3 of 2015		PQM QMS staff completed an assessment of Chula PTSC	CAPA implementation was monitored after the assessment in Q1. Chula PTSC is translating the SOPs and quality manual into English		
Objective 3: Support in-country and inter-country action through BREMERE and other appropriate mechanisms/means					
Support the in-country and inter-country as well as regional BREMERE communication, coordination and joint investigation on all SCMs (with main emphasis on antimalarials).			Info was shared on the falsified Artemether/Lumefantrine Bureau of Drug and Narcotic submitted all 12 antimalarial cases that failed quality testing from the GFATM-supported		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			survey project conducted by Kenan Institute, BVBD and USP PQM with Thai FDA for appropriate action, but no feedback has been received from the Thai FDA		
Objective 4: Participate in meetings and share data and findings as appropriate					
1.1. As deemed necessary, PQM relevant staff/consultant and/or a country representative from the FDA or BVDC or BDN will participate and present PQM's work, progress, and achievements at regional or international technical AND scientific conferences / meetings and publication on medicines quality issues			A technical report on "Antimalarial Medicines Quality Evaluation in Selected Border Provinces in Thailand" (completed in 2014) was widely shared among partners		
Burma	G. Nayyar				
FY15					
Objective 1: Continue to strengthen the regulatory capacity with an emphasis on post-marketing surveillance for antimalarial and other essential medicines of Burma Department of Food and Drug (DFDA), and their provincial/state/division levels. Mobilize the data through improved medicines quality monitoring (MQM) program to obtain appropriate data to support enforcement action to support malaria control programs in Burma.					
Post-marketing surveillance, vendor mapping and provision of safety equipment and resources for sentinel sites			This activity is planned May 2015. In February, a meeting with DFDA was held on sentinel site selection and vendor mapping in each sentinel site.		
Provision of reference standards and supplies			Reference standards have been ordered and will be shipped in upcoming weeks.		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Field supervisory visits as part of MQM efforts			Planned for Q3		
Data compilation, report development and mobilization of the data to enforcement action			Results of the baseline study showing 22% of sample failure in Burma were shared with USAID and key implementing partners who assisted in completion of the study. Results were reported to DFDA for actions		
Objective 2: Increase awareness raising activities on poor quality medicines at various levels of the healthcare system; with a special focus on vulnerable communities in the village and remote areas.					
Awareness programming at sentinel sites in high risk settings in response to poor quality medicines detected (focused on supporting the DFDA)			This activity will be conducted after samples have been collected for post marketing surveillance in partnership with CAP-Malaria.		
Host a seminar on the issues of poor quality antimalarials in the country as well as in the GMS			This activity will be completed in conjunction with objective #5. Planning is underway and the regulatory agency has been engaged.		
Objective 3: Continue to strengthen the capacity of national quality control laboratory in Nay Pyi Taw: to become a proper functional lab and pave the way towards WHO Prequalification.					
Technical assistance in new lab construction			Due to the recent change in the leadership of the regulatory agency, the reconstruction has been put on hold. These funds may be reprogrammed		
Technical assistance in quality management in		The reconstruction of the lab has been	Completed		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
relocation of the lab		delayed. To support the temporary lab, recalibration of 4 HPLC machines and 3 dissolution testers in Nay Pyi Taw and Mandalay labs was completed with leveraged funding from WHO.			
Training of lab staff on compliance and safety			A meeting was held among PQM, WHO, DFDA, and UNOPS for potential collaboration to assist DFDA laboratory in Nay Pyi Taw.		
Objective 4: Provide technical assistance to increase compliance with Good Manufacturing Practices to manufacturing facilities producing antimalarials in Burma/Myanmar to ensure that good quality antimalarials are being produced and used locally.					
Assessment of current conditions and provide technical assistance			Planned for Q3-Q4		
Objective 5: Create a forum on Quality of Medicines to help support the DFDA, sharing of information and update each other on products with the quality issue and suggest collective intervention.					
Host a national forum for streamlining quality of medicines activities			Planned for Q3-Q4 after MQM testing data becomes available		
Cambodia	E. Yuan				
FY15					
Objective 1: Continue to strengthen the DDF post-marketing surveillance activities at national and local levels by implementing the enhanced medicines quality monitoring (MQM) program in the country to support enforcement action against the poor-quality essential medicines, with emphasis on antimalarials.					
Conduct sample collection and testing of antimalarial (AMs) and highly suspected antibiotics (ABTs) with quality problems in targeted geographical areas in the		On hold due to delay with funding from USAID-PMI; sampling and testing activities were not conducted within this period.	There were 15 samples collected in February 2015 and tested by Minilabs in Battambang site, using previous year's funding.		

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
country. This MQM activity is also aiming to collect information on the availability of oral artemisinin antimalarial monotherapies as well and report to the relevant agencies, including DDF, and National Center of Parasitology, Entomology and Malariaology (CNM).					
Purchase and replenish essential Minilab and some QC lab supplies (reference substances, comparator products, HPLC columns, UV lamps, etc.) to maintain the surveillance activities and confirmatory analyses.		Due to delay of funding from PMI, there was no Minilab replenishment			
Conduct at least 5 supervisory and monitoring visits to the sites in the field by PQM country and/or regional Consultant(s) with representative from DDF, NHQC and CNM.		Due to delay of funding from PMI, there were no field visits	Local consultant conducted one field visit to the Minilab site in Battambang province		
Data analysis and produce end-of-fiscal year technical reports by each country and by PQM.			Planned for Q4		
Streamline different alert systems to combat poor quality systems to create a coordinated response within Cambodia and linkage with GMS via bi-weekly alert or other programs					
Objective 2: Continue to strengthen the capacity of National Health Product Quality Control (NHQC) toward compliance with ISO 17025 international standards of performance and practices for reliable test results.					

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
A team of PQM Quality Management System (QMS) will continue to provide technical assistance to support the NHQC to implement the road map of achieving ISO-17025 which was jointly developed and agreed between PQM and NHQC in 2012. This activity will entail a visit to the meet with the NHQC management and verify the progress.		PQM continues to provide TA to NHQC's quality management system, on the lab's Quality Manual and SOP on document control. The submitted QM and Document Control SOP have been reviewed by PQM's technical expert and comments have been sent to the NHQC QA management.	Communication between the PQM QMS expert and NHQC team is regularly conducted. 5 SOPs have been reviewed, and the roadmap was developed.		
Provide technical guidance to the final stage of the new lab construction which may, and not limited to, include positioning the major lab equipment, their qualification and calibration; and determine the training needs for NHQC staff.			Lab construction is in process. The building is expected to be completed at the end of 2015 or early 2016.		
Objective 3: Support in-country, inter-country, and regional coordination, cooperation and enforcement through BREMERE (Building Regional Expertise in Medicines Regulation, Information-sharing, Joint Investigation and Enforcement) to enhance collective action at national and regional levels.					
Support the in-country BREMERE communication, coordination and joint investigation on all counterfeit and substandard medicines (CSMs) (with main emphasis on antimalarials) cases among the Inter-ministerial Committee (IMC) members as well the Provincial Sectoral Committee (PSC) members at the provincial		Official declaration was issued to remove the registration number, recall, and withdraw from the market 5 medicines: <ul style="list-style-type: none"> • Gentamycin 80mg, Liquid for Injection, Ampoul/2ml, from China (failed quality test) • Glibenclamide 5mg, Oral Tablet, from 	Ongoing		

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
level.		Pakistan (failed quality test) <ul style="list-style-type: none"> • Metformin Hydrochloride 500mg, Oral tablet, India. (failed quality test) • Amoxicillin 500mg, Oral tablet, from Cambodia (failed quality test) • Glibenclamide 5mg, Oral table, from France (smuggled) 			
3.2 Inter-country and regional BREMERE support and beyond, including ASEAN Post-marketing Surveillance Alert System on pharmaceutical products and the INTERPOL through timely information sharing, evidence data provision, joint investigation and enforcement.		Cambodia DDF-MoH shared information on the above 5 medicines with all BREMERE countries			
Objective 4: Increase the availability of quality-assured antimalarials through intensified inspections in the distribution chains and enhanced pharmacy practices. Engage the pharmacy school students and faculty members in the reduction of counterfeit and substandard medicines in Cambodia					
Improve inspection practices for inspectors in the supply and distribution chains through inspector training in key provinces and hands-on inspection exercises to support implementation of the oral monotherapies ban policy. This activity will occur in collaboration with the U.S. Lower Mekong Initiative and		Delayed due to delays with funding from PMI			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
other GMS countries' inspectors.					
Intensify the inspections in the distribution chains and the medicines dispense		Delayed due to delays with funding from PMI			
Technical support to Cambodia's center of Pharmacovigilance		Delayed due to delays with funding from PMI			
Engage pharmacy faculty members (5-6) and final year students (100) of two universities Faculties of Pharmacy in Phnom Penh in the PQM efforts to improve practices concerning pharmaceuticals in various settings through curriculum/syllabus improvement.		PQM team met with the Dean of the Pharmacy School of International University to discuss pharmacy education and to decide how to start this project in this fiscal year. Budget and activity plan were submitted to and approved by PQM.	GPP training for pharmacists and medicine sellers was conducted in Rattanakiri, Banteaymeanchey, Kampong Thom and Preah Vihear provinces.		
Education exchange of Pharmacy curriculum across key universities in the GMS.					
Objective 5: Participate in and present at meetings and conferences to share the findings and achievements of PQM program activities in Cambodia, as well as challenges encountered, in national, regional, and international arenas as necessary					
As deemed necessary, PQM relevant staff/consultant and/or a country representative from the DDF or NHQC or CNM to participate and present PQM's work, progress and achievements at regional or international technical/scientific conferences/meetings on medicines quality issues, publications in journals, and		Dr. Souly Phanouvong and the local consultant: Presented the PQM FY15 Work Plan at the PMI Partners' Meeting held in October Met with local partners and agencies to discuss and brief them on PQM FY 15 program objectives and activities	The local consultant attended: PMI partners meeting in January Meeting with PMI's Pre-MOP team in February to provide information on MQM activities and planned FY16 WP. Annual Conference		

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 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
improving MQDB database		<p>for their cooperation and support.</p> <p>Attended the Stakeholder Meeting on Pharmaceutical System Strengthening in the context of Emergency Response to Artemisinin Resistance (ERAR) for countries of the Greater Mekong Sub-region which was organized by WHO in November.</p> <p>Met with PSI malaria program to discuss how to assure the quality of antimalarials and rapid diagnostic tests which are distributed by PSI to private sectors in Cambodia.</p> <p>Met with the Office of the WHO Representative in People's Republic of China to discuss strengthening DDF-MoH's medicines quality surveillance. The local consultant attended:</p> <p>Seminar on Continuing Education for Pharmacists Project in December at the Faculty</p>	<p>organized by National Center for Malaria (CNM) in February in Siemreap province.</p> <p>Seminar on Capacity Building for Law Enforcement to counter counterfeit products which was organized by the Ministry of Interior in March in Siemreap province.</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		of Pharmacy of University of Health Sciences). Ceremony to launch new governmental committee against counterfeit products with high risk for health and public safety in November.			
Indonesia		C. Raymond			
FY14					
Objective 1: WHO-Prequalification Activities					
Continue to provide technical assistance to additional local manufacturers on WHO prequalification to increase availability of prequalified TB medicines in Indonesia			-Sanbe Farma is making progress towards submitting levo 500mg dossier this calendar year. PQM conducted site visit and provided comparators, review of dissolution data and assistance on API issues -Kalbe Farma is implementing CAPA from Nov 2014 PQM audit for levo 500mg, and timeline for PQ has been developed -Sandoz is under discussion on renewing its PQ project for pediatric FDCs -Zenith received TA for dossier, comparative dissolution, and product formulation/development		

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			for levo 500mg -site visit to Phapros manufacturing facility, they changed to 2FDC based on API challenges for eth and rif, and are developing levo500mg and moxifloxacin - Kimia Farma has decided to put the WHO PQ Program on hold until 2016. PQM will continue to support Kimia Farma on GMP compliance and technical assistance needs		
Specialized/tailored training for all manufacturers under PQM support on dossier compilation for Common Technical Document (CTD) format		Completed			
Continue to assist two Indonesian Contract Research Organizations (CROs) to enhance their compliance with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) for BA/BE studies on ATB medicines			Conducted follow up visit to San Clin Eq, which has closed their previous CAPA and is ready to be inspected by WHO in conjunction with the manufacturers submitting BE data from San Clin Eq under PQM support		
Objective 2: Quality Assurance/Quality Control Laboratory Activities (PPOMN and BBPOM QC labs)					
Provide initial TA to the BPOM PPOMN to improve its			Planned for Q3		

Promoting the Quality of Medicines (PQM Program)
 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
in-house reference substances development program					
Objective 3: Medicines Quality Monitoring Activities to Support Post-Marketing Surveillance					
Managerial support NTP's compliance with GFATM Quality Assurance requirements for TB medicines under SSF Phase II, with focus on 2nd-line			-convened two workshops on Guideline development for Public Sector Sampling between MOH and BPOM -secured \$980,000 in grant funding from Global Fund to support TB medicines testing		
Objective 4: Country office support and other activities					
Employ PQM Chief of Party in Indonesia			Ongoing		
Objective 5: Collaboration with ASEAN in key regional initiatives/activities for sustainability					
Strengthen ASEAN in its harmonization efforts in pharmaceutical technical requirements for registration, GMP audits and BA/BE			Planned for Q3-Q4		
FY15					
TB FUNDING					
Objective 1: Provide Technical Assistance to local Indonesian pharmaceutical manufacturers towards achieving WHO Prequalification for selected 1st line FDCs and 2nd line anti-TB medicines intended for the Indonesian markets					
Support Corrective and Preventive Action implementation following cGMP audit at Kimia Farma for 1st line 2FDC product for TB (RH) towards WHO PQ			PQM Indonesia met with the Production Director of Kimia Farma to discuss continuation of the WHO PQ Program in March 2015. Kimia Farma has decided to put the WHO PQ Program on hold until		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			2016. PQM will continue to support Kimia Farma on GMP compliance and technical assistance needs		
Support Corrective and Preventive Action implementation, API sourcing support, and BE study support, following cGMP audit at PT Phapros for 1st line 4FDC product for TB (ZRHE) towards WHO PQ			Followed up progress on 1st line and 2nd line TB Medicine toward WHO PQ. Current progress: explore for API source for Ethambutol and Rifampicin, dossier preparation for Levofloxacin, dissolution test for Levofloxacin, and product formulation development for Levofloxacin. On-site visit to Phapros TBK in Semarang, Central Java on March 2015 they will change to 2FDC based on API challenges for eth and rif, and are developing levo500mg and moxifloxacin		
Support on-site validation activities of the utilities, cleaning validation, packaging line validation, and others through cost-share with PT Phapros			Planned for Q3-Q4		
Provide PT Phapros with WHO-approved pharmaceutical comparator products for 2nd line anti-TB medicines product			Provided comparators for levofloxacin 500mg		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
development					
Support product dossier submission to WHO for PQ for Sandoz Indonesia's 3FDC anti-TB product (RZH)			Sandoz is discussing renewing its PQ project for pediatric FDCs, further development in Q3/Q4		
Support on-site validation activities of the utilities, cleaning validation, packaging line validation, and others through cost-share with Sandoz Indonesia			Planned for Q3/Q4		
Support on-site validation activities of the utilities, cleaning validation, packaging line validation, and others through cost-share with Sanbe/Caprifarmindo			Validation activities planned for Q3/Q4 Provided, monitored and followed up progress on 2nd line TB Medicine towards WHO PQ. Current progress: dossier preparation, comparative dissolution test, actual timeline on WHO PQ project drafted, method development activities. Follow up visit to Caprifarmindo/Sanbe Farma and SanClin Eq in Bandung, West Java on March 2015. Discussed and followed up on WHO PQ Progress and plan for upcoming activities. Report and a set of		

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 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			recommendations were developed.		
Support Sanbe/Caprifarmindo to conduct full BE study for levofloxacin according to local BPOM regulations to allow for market authorization in Indonesia at 50% cost-share			Planned for Q4		
Provide Sanbe/Caprifarmindo with WHO-approved pharmaceutical comparator products for 2nd line anti-TB medicines product development			Provided WHO PQ comparator products (2 bottles @ 50 tablets, Levaquin 500) received by Caprifarmindo during Q2		
Provide Technical Assistance to BPOM to promote waiving of BE requirements for local market authorization of levofloxacin 500mg product			Planned for Q3/Q4		
Support Corrective and Preventive Action implementation, and dossier compilation support, following cGMP audit at Zenith Pharmaceutical Laboratories for Levofloxacin 500mg towards WHO PQ			<p>Provided reagent L-isoleusine for testing with USP NF monograph 37th edition (shipped by Sigma Aldrich as main distributor)</p> <p>Provided monitored, and followed up progress on 2nd line TB Medicine towards WHO PQ.</p> <p>Current progress : dossier preparation, comparative dissolution test, product formulation development</p> <p>Follow up on-site visit to</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Zenith Pharmaceutical in Semarang, Central Java on March 2015. Discussed and followed up on WHO PQ progress, plan for upcoming activities and did a site walkthrough. Report and a set of recommendations were developed.		
Support on-site validation activities of the utilities, cleaning validation, packaging line validation, and others through cost-share with Zenith Pharmaceutical Laboratories			Planned for Q3/Q4		
Provide Zenith Pharmaceutical Laboratories with WHO-approved pharmaceutical comparator products for 2nd line anti-TB medicines levofloxacin product			Provided WHO PQ comparator product (Levaquin 500), shipped from USP PQM HQ.		
Support on-site validation activities of the utilities, cleaning validation, packaging line validation, and others through cost-share with Kalbe Farma			Validation activities planned for Q3/Q4 GMP specialist senior USP PQM submitted an Audit Report to Kalbe. Audit was done on November 24-25, 2014 Provided reagent L-isoleusine for testing with USP NF monograph 37th edition (shipped by Sigma		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Aldrich as main distributor) Reviewed Corrective and Preventive Action (CAPA) document PQM Indonesia provided monitored, and followed up progress on 2nd line TB Medicine towards WHO PQ. Current progress : dossier preparation, comparative dissolution test, method development PQM provided draft of project realistic timeline template for dossier compilation.		
Support Kalbe Farma to conduct full BE study for levofloxacin according to local BPOM regulations to allow for market authorization in Indonesia at 50% cost-share			Planned for Q4		
Provide Kalbe Farma with WHO-approved pharmaceutical comparator products for 2nd line anti-TB medicines levofloxacin product			Shipped, to arrive during Q3		
Objective 2: Provide technical assistance to local Indonesian Contract Research Organizations to build capacity for conducting Bioavailability / bioequivalence studies under the WHO PQ program for Indonesian manufacturers of TB and HIV medicines					
Support new CRO Pharma Metric Laboratories to achieve WHO recognition to conduct BE studies (listing on			Q4 GLP/GCP audit planned		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
WHOPIRs)					
Follow-up on CAPA implementation and compliance with GLP and GCP with Equilab International to conduct BE studies in association with WHO PQ projects in Indonesia			Planned for Q3/Q4		
Follow-up on CAPA implementation and compliance with GLP and GCP with San Clin Eq to conduct BE studies in association with WHO PQ projects in Indonesia			Conducted follow up visit to San Clin Eq, which has closed their previous CAPA and is ready to be inspected by WHO in conjunction with the manufacturers submitting BE data from San Clin Eq under PQM support		
Objective 3: Provide Capacity-building Training/Workshops on GMP, BE and WHO PQ for regulators and manufacturers					
Conduct an advanced training workshop on validation and verification of analytical procedures for the local pharmaceutical industry and CROs		Conducted 2-day training on method validation for manufacturers, CROs, MRA, and academia (80 participants)			
Conduct an advanced training workshop on EMEA Guidelines on The Investigation Of Bioequivalence and drafting BE study reports according to international standards for Indonesian CROs [sub-award]			Planned for Q4		
Support Indonesian CROs to			Planned for Q3 in Manila		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
participate in regional ASEAN GLP and GCP training convened by USP PQM HQ					
USP PQM Support Central BPOM/BINFAR officers to participate in WHO PQ activities at manufacturers			Planned for Q3/Q4		
GMP registration officers to attend WHO 7th annual Medicines Quality Assessment Training (Copenhagen-Denmark)			Planned Q3 – 2 people sponsored by PQM		
Objective 4: Build QA/QC and regulatory capacity and strengthen technical expertise of the National Agency for Drug and Food Control throughout the national system (central and provincial) towards international standards to achieve WHO Prequalification					
Conduct national-level advanced analytical training on HPLC methods according to international pharmacopeial standards for analysts from across the BPOM QC lab system (PPOMN + Provincial BPOM QC labs)			Planned for Q3		
National training at PPOMN for provincial lab supervisors on method validation and development of harmonized, national SOP for method validation and verification			Planned for Q3		
Establish and execute an implementation plan with clear targets and timeline towards reaching WHO Good Laboratory Practices standards Accreditation of PTBB lab; support the PTBB lab to improve its facilities, safety policies and practices,			-PQM Indonesia supported the completion and release of 35 SOPs within the PTBB Laboratory, towards a final goal of 55 total SOPs. Socializations meeting were done on a weekly		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
and management systems and continuously monitor progress towards the agree-upon targets [PQM/internal audits]			basis, currently 21 SOPs have been socialized to PTBB laboratory staff and ready to be approved by the head of the laboratory. PQM Indonesia provided significant guidance, support and input into the SOPs to meet WHO criteria. -PQM Indonesia supported the completion of the PTBB Quality Manual Draft. Quality Manual was completed according to WHO criteria and is ready for review. -PQM Indonesia supported the calibration of laboratory equipment in the PTBB Laboratory. Currently 23 Shimadzu equipment are fully calibrated which includes: 15 HPLCs (High Performance Liquid Chromatography), 3 UV-Vis Spectrophotometer, 1 IR Spectrophotometer, 3 GC (Gas Chromatography), and 1 GC-MS (Gas Chromatography Mass Spectra). -PQM Indonesia		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			supported and assisted a new labeling format for calibrated laboratory equipment. The new label was designed to meet WHO criteria and has been approved by the PTBB Laboratory officer and quality assurance team for use. Currently all calibrated equipment and devices are attached with the new calibration label. -PQM Indonesia has supported PTBB Laboratory to develop a Master Equipment Inventory List and USP Reference Standard Inventory List according to GLP standard.		
QMS Audit of the PTBB lab in accordance with WHO PQ standards and training workshop at the central-level PPOMN labs to improve the QMS			Planned for Q3		
Provide analytical training on Global Fund-procured Dionex IC HPLC instruments and 2 days training on GC			\$980,000 funding was secured from Global Fund TB to procure equipment for BPOM provincial QC labs, to rollout during Q3/Q4		
Conduct a Workshop on Validation and Verification of Analytical Procedures for analysts and managers from		Conducted week-long advanced training on method validation and verification according to			

Promoting the Quality of Medicines (PQM Program)
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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
the PPOMN laboratories in Jakarta and Conduct initial Assessment of the BPOPM Reference Substances Laboratory		USP for 30 national BPOM laboratory analysts			
Under the WHO PQ project, USP PQM Indonesia will support the PTBB lab to improve its facilities, safety policies and practices, and management systems and continuously monitor progress towards the agree-upon targets (PQM/internal audits)			<p>Socializations meeting were done on a weekly basis, currently 21 SOPs have been socialized to PTBB laboratory staff and ready to be approved by the head of the laboratory. PQM Indonesia provided significant guidance, support and input into the SOPs to meet WHO criteria.</p> <p>-PQM Indonesia supported the completion of the PTBB Quality Manual Draft. Quality Manual was completed according to WHO criteria and is ready for review.</p> <p>Safety equipment and procurement planned for Q3/Q4</p>		
Conduct training workshops at provincial level on 1.) socialization and dissemination of the newly-adopted BINFAR-BPOM Guidelines on Sampling from Public Sector Facilities and 2.) practical training on			<p>Planned for Q3/Q4</p> <p>Initial meeting was conducted in Tanah Papua to discuss PQM support for quality control of medicines and other collaboration</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
sampling from public sector warehouses to implement Guidelines on Sampling from Public Sector Facilities (BINFAR-BPOM)for MOH (Province/District) participants together with BPOM (Provincial)			opportunities in Tanah Papua Pre-assessment of the quality control laboratories were conducted at the NADFC Jayapura Regional Office Initial meeting was conducted between the Provincial Health Office, District Health Office, NADFC Manokwari Regional Office, NQCLDF/ PPOMN and USP PQM Indonesia to discuss collaboration and activities to promote the quality of medicines in West Papua. Pre-assessment of the quality control laboratories were conducted at the NADFC Manokwari Regional Office		
Conduct two QMS Assessments according to WHO standards for provincial BPOM institutions in Java Barat and Sumatera Utara, with ongoing follow-up on CAPA implementation			Planned for Q3/Q4		
Regional technical training on advanced analytical methods (HPLC, etc.) and GLP, using USP, etc. and 2 day QMS Assessment in regional			Planned for Q3 Planning meetings conducted during Q2 in Bali and Kepri with BPOM and PQM		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
collaboration with Chulalongkorn University and USP QC experts					
Provincial BBPOM QMS Assessment and Provincial, on-site advanced testing training workshop for Tanah Papua capacity building on GLP and advanced testing of HIV and TB medicines			Planned for Q3 Planning meetings conducted during Q2 on-site in Papua and West Papua with BPOM and PQM		
Support for BPOM officials to attend regional and global meetings and conferences			Planned for Q3 in India for NOMCoL		
Objective 5: Provide Technical Assistance on collaboration and coordination for Ministry of Health partners (BINFAR, DITJEN PPPL programs) and BPOM for QA/QC activities of HIV and TB medicines, and introduction of new second-line TB medicines (e.g. Bedaquiline)					
Support the Government of Indonesia on Establishing a National Medicines QA Policy Team and a National Medicines QA Policy		PQM Indonesia spearheaded the proposal to form an interagency National Medicines QA Policy team, with an inaugural meeting held in December. This Team will be headed by BINFAR, and will include representatives from the CDC programs (P2PL), BINFAR, BPOM, and relevant partners including JSI, CHAI, WHO, PQM Indonesia, and others.	Follow up meeting planned for Q3		
Support coordination and collaboration efforts between MOH and BPOM on roll out of new post-marketing surveillance Guidelines for Sampling from Public Sector			PQM Indonesia in collaboration with WHO supported 2 workshops on the development and finalization of the Guideline for Sampling		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Facilities (BINFAR-DITJEN PPPL-BPOM)			<p>at the public sector in Indonesia. Coordination meetings between BINFAR, BPOM and other relevant partners were conducted since the end of 2014 and the draft guideline is completed.</p> <p>A coordination meeting was held in January with the Deputy 1 of the NA-DFC. Discussion included USP PQM programs in Indonesia and upcoming activities in collaboration with NA-DFC Deputy 1 and NQCLDF (National Quality Control Laboratory for Drug and Food). The meeting ended in a positive note and future meetings are expected to further develop collaboration in implementing the USP PQM-BPOM joint activities in FY15.</p>		
Conduct regulatory assessment and draft recommendations on restriction of Bedaquiline and other 2nd line TB medicines available without prescription or in private markets			Planned for Q3		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Objective 6: Providing technical inputs into Global Fund and National Strategic Action Plans for HIV and TB, and serving on Technical Working Groups (Bedaquiline introduction, etc.), participating in People that Deliver and other initiatives with MOH and BPOM, SMT meetings with Challenge TB, etc.					
Provide inputs into concept notes and activities, Participate in TWG meetings for grant implementation, Provide Technical Assistance as needed, Provide inputs into concept notes and activities related to GF and partner activities			-\$980,000 in Global Fund grants were secured to support PQM-led projects with BPOM provincial QC labs -PQM substantially contributed to the National TB Program's 5-year Strategic Action Plan by incorporating specific budgeted activities on Quality Assurance of TB medicines and support for local manufacturers into the MOH's strategy. -Under the SCM monitoring on ARV Decentralization activities, an initial meeting between USP PQM Indonesia with Provincial Health Office, District Health Office was conducted to discuss collaboration and activities to support quality control of medicines in Kepulauan Riau. -Initial meeting with the head of NADFC Batam Regional Office was conducted to discuss		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			collaboration and activities to promote the quality of medicines in Kepulauan Riau.		
Objective 7: Developing strategic media and messaging for advocacy and public awareness on issues related to medicines quality					
Re-version the current Pharmacide: Mekong documentary film on counterfeit medicines in SE Asia for use in Indonesia (subtitling, edits, overdubs)			Planned for Q3/Q4		
Objective 8: Provision of needed Supplies and Equipment for BPOM					
Supply of basic supplies, documentary and chemical reference standards, and laboratory equipment needed to control quality of HIV medicines and other antibiotics			USP-NF provided for manufacturers and 5 provincial QC laboratories -HPLC columns provided for national lab for training -USP RS \$250,000 order was placed, planned delivery during Q3 Other procurement during Q3/Q4 planned		
Equipment Qualification and Calibration for National QA			All HPLC equipment calibrated during Q2 to be monitored by PQM		
Objective 9: USP PQM Indonesia country office support					
USP PQM Indonesia Office Human resources and staff development		6 new staff hired for PQM Indonesia office	Ongoing		
Integrated M&E and office SOPs for Indonesian program			Planned for Q3		

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 Quarterly Reports: FY14 Activities

Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Project vehicle			Planned for Q3		
HIV FUNDING					
Objective 1: Support Kimia Farma on first- and second-line ARVs for cGMP and WHO PQ with the aim to ensure quality manufacture and storage of HIV medicines for the National AIDS Control Program in Indonesia					
Follow up on Corrective and Preventive Action implementation plan from FY2014 cGMP assessment at Kimia Farma's ARV manufacturing facility			PQM Indonesia met with the Production Director of Kimia Farma to discuss continuation of the WHO PQ Program in March 2015. Kimia Farma has decided to put the WHO PQ Program on hold until 2016. PQM will continue to support Kimia Farma on GMP compliance and technical assistance needs		
Objective 2: Provide technical assistance to local Indonesian Contract Research Organizations to build capacity for conducting Bioavailability / bioequivalence studies under the WHO PQ program for Indonesian manufacturers of TB and HIV medicines					
Support new CRO Pharma Metric Laboratories to achieve WHO recognition to conduct BE studies (listing on WHOPIRs)			Q4 GLP/GCP audit planned		
Follow-up on CAPA implementation and compliance with GLP and GCP with Equilab International to conduct BE studies in association with WHO PQ projects in Indonesia			Planned for Q3/Q4		
Follow-up on CAPA implementation and compliance with GLP and GCP with San Clin Eq to			Conducted follow up visit to San Clin Eq, which has closed their previous CAPA and is		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
conduct BE studies in association with WHO PQ projects in Indonesia			ready to be inspected by WHO in conjunction with the manufacturers submitting BE data from San Clin Eq under PQM support		
Objective 3: Provide Capacity-building Training/Workshops on GMP, BE and WHO PQ for regulators and manufacturers					
Conduct an advanced training workshop on validation and verification of analytical procedures for the local pharmaceutical industry and CROs		Completed			
Conduct an advanced training workshop on EMEA Guidelines on The Investigation Of Bioequivalence and drafting BE study reports according to international standards for Indonesian CROs [sub-award]			Planned for Q4		
Support Indonesian CROs to participate in regional ASEAN GLP and GCP training convened by USP PQM HQ			Planned for Q3 in Manila		
USP PQM Support Central BPOM/BINFAR officers to participate in WHO PQ activities at manufacturers			Planned for Q3/Q4		
GMP registration officers to attend WHO 7th annual Medicines Quality Assessment Training (Copenhagen-Denmark)			Planned for Q3 – 2 people sponsored by PQM		
Objective 4: Build QA/QC and regulatory capacity and strengthen technical expertise of the National Agency for Drug and Food Control throughout the national system (central and provincial) towards international standards to achieve WHO Prequalification					

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
Conduct national-level advanced analytical training on HPLC methods according to international pharmacopeial standards for analysts from across the BPOM QC lab system (PPOMN + Provincial BPOM QC labs)			Planned for Q3		
National training at PPOMN for provincial lab supervisors on method validation and development of harmonized, national SOP for method validation and verification			Planned for Q3		
Establish and execute an implementation plan with clear targets and timeline towards reaching WHO Good Laboratory Practices standards Accreditation of PTBB lab; support the PTBB lab to improve its facilities, safety policies and practices, and management systems and continuously monitor progress towards the agree-upon targets [PQM/internal audits]			-PQM Indonesia supported the completion and release of 35 SOPs within the PTBB Laboratory, towards a final goal of 55 total SOPs. Socializations meeting were done on a weekly basis, currently 21 SOPs have been socialized to PTBB laboratory staff and ready to be approved by the head of the laboratory. PQM Indonesia provided significant guidance, support and input into the SOPs to meet WHO criteria. -PQM Indonesia supported the completion of the PTBB		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			<p>Quality Manual Draft. Quality Manual was completed according to WHO criteria and is ready for review.</p> <p>-PQM Indonesia supported the calibration of laboratory equipment in the PTBB Laboratory. Currently 23 Shimadzu equipment are fully calibrated which includes: 15 HPLCs (High Performance Liquid Chromatography), 3 UV-Vis Spectrophotometer, 1 IR Spectrophotometer, 3 GC (Gas Chromatography), and 1 GC-MS (Gas Chromatography Mass Spectra).</p> <p>-PQM Indonesia supported and assisted a new labeling format for calibrated laboratory equipment. The new label was designed to meet WHO criteria and has been approved by the PTBB Laboratory officer and quality assurance team for use. Currently all calibrated equipment and devices are attached with the new calibration label.</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			-PQM Indonesia has supported PTBB Laboratory to develop a Master Equipment Inventory List and USP Reference Standard Inventory List according to GLP standard.		
QMS Audit of the PTBB lab in accordance with WHO PQ standards and training workshop at the central-level PPOMN labs to improve the QMS			Planned for Q3		
Conduct a Workshop on Validation and Verification of Analytical Procedures for analysts and managers from the PPOMN laboratories in Jakarta and Conduct initial Assessment of the BPOPM Reference Substances Laboratory		Completed			
Under the WHO PQ project, USP PQM Indonesia will support the PTBB lab to improve its facilities, safety policies and practices, and management systems and continuously monitor progress towards the agree-upon targets (PQM/internal audits)			Socializations meeting were done on a weekly basis, currently 21 SOPs have been socialized to PTBB laboratory staff and ready to be approved by the head of the laboratory. PQM Indonesia provided significant guidance, support and input into the SOPs to meet WHO criteria. -PQM Indonesia supported the		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			<p>completion of the PTBB Quality Manual Draft. Quality Manual was completed according to WHO criteria and is ready for review.</p> <p>Safety equipment and procurement planned for Q3/Q4</p>		
<p>Conduct training workshops at provincial level on 1.) socialization and dissemination of the newly-adopted BINFAR-BPOM Guidelines on Sampling from Public Sector Facilities and 2.) practical training on sampling from public sector warehouses to implement Guidelines on Sampling from Public Sector Facilities (BINFAR-BPOM) for MOH (Province/District) participants together with BPOM (Provincial)</p>			<p>Planned for Q3/Q4</p> <p>Initial meeting was conducted in Tanah Papua to discuss PQM support for quality control of medicines and other collaboration opportunities in Tanah Papua</p> <p>Pre-assessment of the quality control laboratories were conducted at the NADFC Jayapura Regional Office</p> <p>Initial meeting was conducted between the Provincial Health Office, District Health Office, NADFC Manokwari Regional Office, NQCLDF/ PPOMN and USP PQM Indonesia to discuss collaboration and activities to promote the quality of medicines in West Papua.</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Pre-assessment of the quality control laboratories were conducted at the NADFC Manokwari Regional Office		
Conduct two QMS Assessments according to WHO standards for provincial BPOM institutions in Sumatra Utara and Jawa Timur, with ongoing follow-up on CAPA implementation			Planned for Q3/Q4		
Regional technical training on advanced analytical methods and GLP, in regional collaboration with Chulalongkorn University and USP QC experts			Planned for Q3; planning meetings conducted during Q2 in Bali and Kepri with BPOM and PQM		
Provincial BBPOM QMS Assessment and Provincial, on-site advanced testing training workshop for Tanah Papua capacity building on GLP and advanced testing of HIV and TB medicines			Planned for Q3 Planning meetings conducted during Q2 on-site in Papua and West Papua with BPOM and PQM		
Support for BPOM officials to attend regional and global meetings and conferences			Q3 in India for NOMCoL		
Objective 5: Provide Technical Assistance on collaboration and coordination for Ministry of Health partners (BINFAR, DITJEN PPPL programs) and BPOM for QA/QC activities of HIV and TB medicines					
Support the Government of Indonesia on Establishing a National Medicines QA Policy Team and a National Medicines QA Policy		PQM Indonesia spearheaded the proposal to form an interagency National Medicines QA Policy team, with an inaugural meeting held in	Follow up meeting planned for Q3		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		<p>December. This Team will be headed by BINFAR, and will include representatives from the CDC programs (P2PL), BINFAR, BPOM, and relevant partners including JSI, CHAI, WHO, PQM Indonesia, and others.</p>			
<p>Support coordination and collaboration efforts between MOH and BPOM on roll out of new post-marketing surveillance Guidelines for Sampling from Public Sector Facilities (BINFAR-DITJEN PPPL-BPOM)</p>			<p>PQM Indonesia in collaboration with WHO supported 2 workshops on the development and finalization of the Guideline for Sampling at the public sector in Indonesia. Coordination meetings between BINFAR, BPOM and other relevant partners were conducted since the end of 2014 and the draft guideline is completed.</p> <p>A coordination meeting was held in January with the Deputy 1 of the NA-DFC. Discussion included USP PQM programs in Indonesia and upcoming activities in collaboration with NA-DFC Deputy 1 and NQCLDF (National Quality Control Laboratory for Drug and</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			Food). The meeting ended in a positive note and future meetings are expected to further develop collaboration in implementing the USP PQM-BPOM joint activities in FY15.		
Integration of the USP PQM Indonesia's Visual Inspection component for Quality Control of Medicines into the Anti-Retroviral Care, Support, and Treatment curriculum training provided by Ministry of Health (SUBDIT AIDS) for Physicians, Pharmacists, Nurses and support staff.			Planned for Q3		
Objective 6: Providing technical inputs into Global Fund and National Strategic Action Plans for HIV and TB, and serving on Technical Working Groups (Bedaquiline introduction, etc.), participating in People that Deliver and other initiatives with MOH and BPOM, SMT meetings with Challenge TB, etc.					
Provide inputs into concept notes and activities, Participate in TWG meetings for grant implementation, Provide Technical Assistance as needed, Provide inputs into concept notes and activities related to GF and partner activities			- \$980,000 in Global Fund grants were secured to support PQM-led projects with BPOM provincial QC labs - PQM substantially contributed to the National TB Program's 5 year Strategic Action Plan by incorporating specific budgeted activities on Quality Assurance of TB medicines and support for local manufacturers into the MOH's strategy.		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			-Under the SCM monitoring on ARV Decentralization activities, an initial meeting between USP PQM Indonesia with Provincial Health Office, District Health Office was conducted to discuss collaboration and activities to support quality control of medicines in Kepulauan Riau. -Initial meeting with the head of NADFC Batam Regional Office was conducted to discuss collaboration and activities to promote the quality of medicines in Kepulauan Riau.		
Objective 7: Developing strategic media and messaging for advocacy and public awareness on issues related to medicines quality					
Re-version the current Pharmacide: Mekong documentary film on counterfeit medicines in SE Asia for use in Indonesia (subtitling, edits, overdubs)			Planned for Q3/Q4		
Objective 8: Provision of needed Supplies and Equipment for BPOM					
Supply of basic supplies, documentary and chemical reference standards, and laboratory equipment needed to control quality of HIV medicines and other antibiotics			USP-NF provided for manufacturers and 5 provincial QC laboratories -HPLC columns provided for national lab		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			for training -USP RS \$250,000 order was placed, planned delivery during Q3 Other procurement during Q3/Q4 planned		
Equipment Qualification and Calibration for National QA			All HPLC equipment calibrated during Q2 to be monitored by PQM		
Objective 9: USP PQM Indonesia country office support					
USP PQM Indonesia Office Human resources and staff development		6 new staff hired for PQM Indonesia office	Ongoing		
Integrated M&E and office SOPs for Indonesian program			Planned for Q3		
Project vehicle			Planned starting in Q3		
Philippines	E. Yuan				
FY14					
Objective 1: Sustain MQM to support PMS at 8 Sentinel Sites and establish new 4 additional sites.					
Expand the Sentinel Sites to: (a) Region II (b) Region IV-B (c) Region XII (d) Region X		In the process of requesting the procurement of 4 Minilabs	The survey and site study have been done for the expansion of the sentinel site		
Objective 2: Strengthen the FDA capacity and its QC labs to enhance the medicine regulatory system in both pre – marketing drug registration and PMS.					
Conduct hands-on training on Good Clinical Practice and conduct audits on the BA/BE Centers/ establishments		Planning underway	Part 1: Training scheduled in May Part 2: BA/BE center visit is scheduled for Q4 of FY16Q1 (location is to be determined; Malaysia		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			or Singapore)		
Provide technical and professional assistance in Quality Management System (QMS) to FDA Davao Satellite Laboratory for ISO17025 accreditation/ certification.		Preparation underway for the ISO 17025 certification	Met with Davao Sat Lab Staff at the FDA Alabang office regarding ISO 17025 certification 1 nominee from FDA Davao Sat Lab will participate at the 1 st Annual NOMCoL AP Workshop to enhance capacity in proficiency testing		
Objective 3: Provide technical assistance in medicines quality control to support the NTP in partnership with relevant TB Partners.					
Provide TA to the DOH-NTP, DOH-NCPAM and TB partners for activities relevant to drug quality		Planning underway for the Joint DOH-NCPAM, FDA and PQM project regarding “the study on the comparative quality of selected antibiotics between the government and private drug facilities in the Philippines.”	Met with NCPAM and FDA to discuss the TOR for the joint project TOR was forwarded to the stakeholders for comments; due April 30		
FY15					
Objective 1: Strengthen and sustain the MQM program through a focused and expanded scope to monitor where the quality of ATB medicines and selected antibiotics need to be quality assured in the Philippines					
Continue the routine sampling and testing to support FDA’s post-marketing surveillance by using advanced sampling & testing methods at PQM’s 12 sentinel sites (eight of well-established and four newly established but still under development / not operational		Checked the status of Minilabs. Collected expired medicine samples from sentinel sites for proper disposal. Processed and forwarded Minilab	Updated MQM data Submitted current MQM report to HQ Received GPHF reference standards for Minilab use: 1. Rifampicin – 9 tubes		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
yet)		replenishment to the sentinel sites. Monitoring and evaluation of sentinel sites conducted in October : 1. Davao 2. Zamboanga 3. Cebu 4. Iloilo 5. Bicol	2. Ethambutol – 5 tubes 3. Isoniazid – 5 tubes 4. Pyrazinamide – 9 tubes Attended Inauguration of new FDA-DOH building in Region 5 (Bicol) Certificate of appreciation was given to the regional director and FDA Minilab staff in Bicol in recognition of their contributions and commitment to PQM's progress		
Pre-distribution sampling from National Warehouse for TB medicine quality. (First point in the supply chain after medicines clear customs)		This activity is in line with FY14 Objective 3.1	Planning and preparation for the Joint DOH-NCPAM, FDA and PQM project is underway		
DOTS-center based sampling: Extend MQM to ensure TB medicines quality in 5 additional DOTS centers across Philippines (total =10 sites)		Inspected TB DOTS facilities within IMPACT project sites: 1. Caloocan - Bagong Barrio Zone 1 Health Center 2. Mandaluyong - E. Rodriguez Health Center 3. Pasay - San Juan De Dios Hospital 4. Quezon City - QC City Health Office (stockroom or buffer stocks)	Performed basic and disintegration test using the Minilab. The results were not conclusive; the samples were forwarded to FDA lab for confirmatory testing, where all samples passed. Inspection follow-up of TB DOTS facilities was conducted with the PQM managers in Caloocan City - Bagong Barrio		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		5. San Juan - San Juan City Health Office (stockroom or buffer stocks)	Zone 1 Health Center and Pasay City - San Juan De Dios Hospital to assess the performance of the TB centers for ATB quality used for TB patient treatment		
Objective 2: Continue to provide technical assistance to the Philippines FDA, especially the satellite offices/QC laboratories in Davao and Cebu, in order to build their organizational and regulatory capacity					
Conduct an M&E assessment on FDA's effectiveness in utilizing the knowledge gaining from PQM trainings on BA/BE and cGMP/dossier review (PICS, ICH) to conduct GMP inspections to local Filipino manufacturers.			The M&E indicators are being developed and will be shared with Philippines FDA inspection department for comments		
Lead FDA to apply the knowledge and skill-set gained from USP's trainings on GLP, GCP in relation to BA/BE to Bedaquiline's registration and marketing in the Philippines for treating the MDR-TB cases. The USP will provide the TA to FDA in Developing a regulatory mechanism to successfully introduce bedaquiline in the Philippines MDR TB programs, establish an expert advisory committee for market entry strategy for BD, develop the requirements for import, and subsequent in country quality control and pharmaceutical management, identify potential sites to pilot			PQM showed interest in collaborating with the National TB Program regarding 9 th month regimen, Bedaquiline; a meeting was held to plan for the project		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
introduction of BD, issue a MoH secular order to accelerate abbreviated use and scale in country.					
USP/PQM will assist FDA on the new drug safety and efficacy evaluation, which will develop and enhance FDA's capacity on the new molecule/innovation drug's development and registration for marketing. For the expertise that USP can't provide to, USP will provide Philippines FDA with the useful resource to connect with subject matters experts/institutions/regulatory agencies (U.S. FDA) to attend regulatory science training and workshop to enhance FDA's capacity.			In planning phases		
FDA scientists from satellite laboratories to participate in a three-week International Training or Visiting Scientist Program at USP headquarters. Philippines FDA scientists who previously participated in USP programs have successfully transferred their knowledge to help strengthen critical health systems operations		Coordinated planning	Nomination will follow once the scope of learning for this program has been established		
Training for laboratory testing that provides timely, reliable and robust results for			In planning phases		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
confirmatory testing is needed for Davao and Cebu. Currently reporting and testing is often delayed by months, further slowing regulatory action on the field					
Purchasing of laboratory resources aid essential laboratory equipment: laboratory supplies, and regulatory science reference publications and journals that may not be included in DOH or other donor's budgets		USP publications were sent to FDA as a part of USP's Technical Assistance Program (TAP)	<p>Received 8 bottles of complimentary USP Prednisone Calibrator Tablets; forwarded 2 bottles each to Central Lab Antibiotic Section and Drug Section, Davao Sat Lab and Cebu Sat Lab</p> <p>FDA central lab received their 1st and 2nd TAP order; PQM assisted FDA in the process of releasing the shipment in customs</p> <p>Purchased 17 HP laptops and Microsoft software for MQM use at 12 sentinel sites for data entry; the distribution of property is scheduled for April</p> <p>FDA Davao Sat Lab submitted their 1st TAP order to USP</p>		
Strengthen USP/PQM's local force and capacity by hiring a consultant as Chief of Party based in the Philippines to		Notice of vacancy for COP position has been posted at the FDA website	Hiring process completed for one administrative staff		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
lead team and performance.		Ongoing process (finalization of contract) for the hiring of a technical consultant	PQM managers conducted a panel interview of applicants for PQM-Philippines COP position		
Explore the possibility to open a country office for PQM in the Philippines to benefit PQM activities		Office quotes are being reviewed	Met with the candidate offices to discuss business proposals for opening an office in the Philippines; Regus was the chosen office center for PQM Philippines Ongoing process (finalization of lease agreement) between USP and Regus		
Objective 3: Provide technical assistance and resources to local, second-line TB manufacturers to achieve internationally accepted standards and requirements for producing quality assured medicines for PIC/S and ICH (ASEAN harmonization) or for the World Health Organization Pre-Qualification Program					
Provide TA in cGMP to local MFRs to achieve PIC/S, ICH standards under ASEAN harmonization umbrella.			In planning phases		
Conduct a site visit and gap analysis for selected local manufacturers to receive the technical assistance from USP			PQM helped Hizon company to complete CAPA plan implementation for both GMP and dossier on Levofloxacin 500mg tablets. Hizon submitted the EOI and application to WHO PQ and the dossier was accepted for review.		
Training to be developed and delivered to selected manufacturers towards			In planning phases		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
cGMP with involvement and guidance from the FDA (parallel to the Objective #2 activity 2.1)					
Continue support local SLATB medicine manufacturers towards WHO PQ: Hizon for levofloxacin tablets and Amherst for Amikacin parental injection			PQM visited Hizon Laboratories, Inc. and United Laboratories, Inc. (UNILAB) regarding WHO PQ Hizon Laboratories - Levofloxacin 500mg tablets dossier has been accepted by WHO		
Objective 4: Provide leadership on medicine quality driving sustainable development, technology solutions for health, and international collaboration					
Project review meeting for engaging regional partners and stakeholders			Met with Dr. Alex Golubkov at US Embassy (presented project status and updates) Submitted FY14 PQM annual report to USAID/Philippines Met with WPRO to discuss updates and potential activities for collaboration		
Technical assistance: Help develop specific monographs and compendial methods, if currently unavailable through any national or international pharmacopeia (i.e. bedaquiline), to meet the needs of the Philippines			Met with FDA to discuss PQM Work Plan FY15 objectives and activities/trainings for 2015 Visited FDA Laboratories facility		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
FDA's research and development efforts.					
Provide technical input and recommendations to Philippines FDA on the development and implementation of their business plan towards their goal of sustaining FDA operations.			In discussion phases		
Vietnam	G. Nayyar				
FY14					
Objective 1: Technical assistance to strengthen the capacity of Pharmaceutical Management Practices at the Peripheral Level for the ARV distribution system					
Technical assistance to 12 provinces			Reprogramming		
Objective 2: Provide administrative and program operation support					
Recruiting two technical staff, one admin support staff and one part-time accountant/consultant			Reprogramming		
Salary for additional job allowance to COP-Consultant and fringe benefits			Completed		
Office rental and other office expense (electricity, water, and maintenance cost)			Reprogramming		
Procurement of office equipment and other management costs			Reprogramming		
FY15					
Objective 1: Deliver technical assistance and capacity strengthening support for expanding operations and impact of National Quality Control Laboratories; specifically, for HCMC IDQC towards WHO Prequalification					
Provide technical Assistance to HCM IDQC toward WHO PQ and expansion of its			Providing intensive technical support to lab management remotely.		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
<p>current ISO-17025: initial assessment and distance technical support</p> <p>USP-PQM will also help HCMC IDQC develop a plan to leverage their PQ status to test more medicines locally and expand their services AND provide Quality support services to NIDQC for operational maintenance of their International Standards which were achieved via WHO PQ</p>			<p>Submission to the WHO PQ program is planned for August. An additional trip by a PQM QMS expert is needed prior to WHO submission which is currently being planned</p>		
<p>Conduct a 2-day workshop on ARV testing procedures, data management and adequate reporting in partnership with NIDQC for trainers occurring at IDQC tailored to the southern provinces</p>			<p>PQM has partnered with NIDQC based in the north and the IDQC in Ho Chi Minh City to plan for the ARV testing methods training (to be held in IDQC). The labs worked together with PQM on the scope and needs of the training to create a sustainable model for local human resources capacity building while strengthening the Southern Provincial Quality Control Labs (SPQCLs). Labs determined the biggest gaps were in Lamivudine, Zidovudine and Nevirapine (FDC) testing and applying the</p>		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			USP monograph. Training is planned for June.		
Objective 2: Provide technical assistance and engagement on local methadone production and procurement to support the government to each their national treatment targets					
Conduct a two-part series open workshop on good manufacturing practices targeted to local manufacturers determined by the DAV/MOH to attend on methadone production			PQM is working with DAV to plan a 3-day GMP workshop for five local methadone producers and a number of ARV manufacturers. The workshop will occur in May in Ho Chi Minh City.		
Continue to provide technical support on procurement standards and requirements to VAAC as tender needs arise			In March, PQM had a meeting with Hanoi Provincial AIDS Center (HN PAC) to determine technical assistance needed in 2015 methadone procurement and other needs.		
Objective 3: Providing technical inputs for integrated delivery of a quality monitoring reporting system					
Local meetings in Hanoi with National Pharmacovigilance and Drug Information Center			Postponed to Q3-Q4		
Technical assistance on questionnaire development on quality: Including topics such as poor quality products that may result in sub dosing and monitoring adverse reactions that may link to quality.			Planned for Q3		
Objective 4: Attend local meeting, publishing reports, and engaging					
Attending local implementer engagement meetings on			Ongoing		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
MMT and ARVs					
Europe and Eurasia					
Kazakhstan	J. Derry & K. Burimski				
FY15					
<i>Note: Workplan FY15 has not been approved by USAID/CAR. However, certain activities approved in FY14 are carried over for FY15.</i>					
Objective 1: Increase access to good quality anti-TB medicines and promote demand for participation in the WHO Prequalification Programme					
Conduct Regional Forum on WHO prequalification in Almaty as part of Central Asian Trade Forum held by USAID/CAR		Pharmaceutical plenary session of the IV Central Asia Trade Forum was held.			
Quality Consultant spends 2.5 months at the Kazakhstani factories with additional 5.5 months remotely and assists in setting up the documentation system to comply with GMP requirements and providing guidance on the implementation and training of procedures.		Contract with Quality consultant for the Kazakhstani manufacturers concluded.	Quality consultant spent 2 weeks at Pavlodar Pharmaceutical Factory and together with Validation consultant conducted a GMP assessment of the quality systems. An audit of facilities & documentation was conducted; trainings & technical assistance to the staff were provided. A confidential report was sent to the company.		
Validation Consultant spends 2.5 months at the Kazakhstani factories and 5.5 months remotely. The Consultant will assist in technical activities related to the construction and start up of the new manufacturing facility to ensure GMP compliance.		Contract with Validation consultant for the Kazakhstani manufacturers concluded.	Validation consultant spent 2 weeks at Pavlodar Pharmaceutical Factory and together with Quality consultant conducted a GMP assessment of the quality systems. An audit of facilities &		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			documentation was conducted; trainings & technical assistance to the staff were provided. A confidential report was sent to the company.		
Conduct a 2-day GMP baseline assessment of Nobel Almaty Pharmaceutical Factory, October 2014		GMP assessment of Nobel Almaty Pharmaceutical Factory was conducted. A confidential report was developed and sent to Nobel.	CAPA plan was developed by Nobel Almaty Pharmaceutical Factory and reviewed by PQM. Comments on the CAPA plan were provided to Nobel.		
Translation of 2 WHO Prequalification documents into Russian		The translator was identified and the contract signed.	Translation of 2 WHO Prequalification documents into Russian was completed.		
Uzbekistan		J. Derry & K. Burimski			
FY15					
<i>Note: PQM has been waiting for a formal request from the Uzbekistan Ministry of Health for technical support from PQM. Meanwhile the activities in Uzbekistan are on hold. Workplan FY15 was not submitted to USAID/CAR.</i>					
Latin America and the Caribbean					
Amazon Malaria Initiative		V. Pribluda			
FY14					
Objective 1: Strengthening Quality Assurance (QA) & Quality Control (QC) Systems					
Capacity to perform rapid testing					
Capacity to perform registration method testing		A workshop to explore sustainable mechanisms for south-south collaboration for medicines QA was held in Peru in November. Attendants included			

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
		representatives from MRAs, OMCLs, and Schools of Pharmacy from 16 LAC countries. Two committees were assembled to develop two documents: 1. surveillance forms to collect info on country needs, and 2. concept notes to be presented to the MOHs of the countries.			
Implementation of three-level approach for sustainable Medicines Quality Monitoring (MQM) activities throughout the supply chain					
Objective 2: Combating Substandard & Counterfeit Medicines					
Develop an informatics tool to support Visual and Physical Inspections of medicines in the field.		The final scope of the tool was established with the contractor. Contract draft developed and submitted to contractor.	Contract under review by legal department at USP		
Objective 3: Provide technical leadership and global advocacy					
Attendance at meetings					
FY15					
Objective 1: Strengthening Quality Assurance & Quality Control (QA/QC) Systems					
Support sustainable implementation of the Three-level Approach (3LA) in decentralized areas			1. Activities in Brazil will not be continued; these will be performed through a collaboration of the NMCP and in-country partners. 2. Ecuador was identified as the		

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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			alternative country for PQM assistance: Initiated communication with country partners to identify areas of support and development of new regulations including the 3LA for post-registration surveillance of medicine quality. 3. Peru: While the new regulation that includes the 3LA awaits approval from the MoH, DIGEMID (the MRA) will develop a national surveillance plan utilizing the 3LA. This will be implemented in parallel with the existing OMCL surveillance. 4. Coordinated with DCPFA (Guatemala MRA) re: expansion of MQM utilizing the 3LA. Due to changes in authority at the MoH, work is on hold.		
Ensure sustainable south-south collaborations			Surveillance forms to assess MRA and OMCL capabilities and needs for medicines quality assurance were finalized and distributed to countries. 26 institutions from 15 countries returned their		

Promoting the Quality of Medicines (PQM Program)
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Activity	Staff Lead	Quarter			
		Q1	Q2	Q3	Q4
			forms. These noted that extensive regional resources exist and discussed how those resources may address needs if collaboration mechanisms are established.		
Objective 2: Combating Substandard & Counterfeit Medicines					
Develop tool to support Visual and Physical Inspection (L1) of medicines in the field		Contract development and approval were discussed	PQM discussed the scope of the tool with the MRAs of Colombia and Peru, the two countries proposed for initial deployment. Both will provide a list of priority medicines for the initial assessment.		
Build capacity to develop L2 methodologies to assess countries' medicines			Training (with USP scientists) on method validation for the OMCLs of Colombia and Peru will be delivered in July.		
Objective 3: Attendance at Meetings					
Attend semi-annual Steering Committee Meetings					
Annual RAVREDA Technical Meeting			Attended meeting in Rio de Janeiro, Brazil; presentations on PQM activities were delivered		
Other meetings with in-country and technical partners			PQM and all other AMI partners attended a meeting in the Loreto region, convened by USAID/Peru. The objective of the meeting was to discuss AMI support with local health		

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			authorities and other in-country local stakeholders, in light of the resurgence of malaria in the region.		
Guatemala		V. Pribluda			
FY14					
Support OMCL for expansion of scope, from product based to method based ISO 17025 accreditation		Completed purchase of a vacuum oven and Karl Fisher supplies. These will be donated to the OMCL to support accreditation expansion.	Coordinated shipment documentation with USAID/Guatemala. Coordinated (with PQM QMS manager and the OMCL) required documentation for ISO accreditation expansion.		
Middle East					
West Bank/Gaza		S. Phanouvong			
PQM conducted a baseline assessment of four Palestinian manufacturers, organized meetings with key stakeholders, visited the MOH Palestinian Authority and the NQCL, and conducted a rapid assessment of Palestine's QA/ QC capacities.					
Pakistan		S. Phanouvong			
An assessment of the country's QA/QC systems and an initial assessment of selected manufacturers producing Chlorhexidine get products both took place, March 27-April 12, 2015. A detailed report on the findings, as well as a workplan, will be distributed in Q3.					