



PROMOTING THE QUALITY OF MEDICINES

Promoting the Quality of Medicines (PQM)

**Quarterly Report on Activities
October 1, 2013 – December 31, 2013**

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ACRONYMS

AMRH	African Medicines Regulatory Harmonization
ANEQAM	Asian Network of Excellence in Quality Assurance of Medicines
API	Active Pharmaceutical Ingredient
ATB	Anti-tuberculosis
BA	Bioavailability
BE	Bioequivalence
BINFAR	Pharmaceutical and Medical Production and Distribution Services
BREMERE	Building Regional Expertise in Medicines Regulation, Information-sharing, Joint Investigation, and Enforcement
CAPA	Corrective and Preventive Action
CAP-Malaria	Control and Prevention of Malaria
CDC	U.S. Centers for Disease Control and Prevention
CHD	Center for Health Development
CHX	Chlorhexidine
CRO	Contract Research Organization
DAV	Drug Administration of Vietnam
DDF	Department of Drugs and Food
DF	Pharmaceutical Department
DOH	Department of Health
DOMC	Division of Malaria Control
DPM	Direction de la Pharmacie et des Medicaments
DPML	National Medicines Regulatory Authority of Burundi
DQI	Drug Quality and Information Program
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FMHACA	Food, Medicine and Health Care Administration and Control Authority
FPP	Finished Pharmaceutical Product
GCP	Good Clinical Practices
GMP	Good Manufacturing Practices
GMS	Greater Mekong Sub-region
HCMC	Ho Chi Minh City, Vietnam
IMC	Inter-Ministerial Committee
INSP	National Institute of Public Health
IPT	Inter-laboratory Proficiency Testing
LAC	Latin America and the Caribbean
LGU	Local Government Unit
LMHRA	Liberian Medicines and Health Products Regulatory Authority
LNCM	National Laboratory for Medicine Quality Control
MDR-TB	Multi-Drug Resistant Tuberculosis
MOC	Memorandum of Collaboration
MOH	Ministry of Health
MQCL	Medicines Quality Control Laboratory
MQDB	Medicines Quality Database

MQM	Medicine Quality Monitoring
MRA	Medicines Regulatory Authority
MSH/SIAPS	Management Sciences for Health/Systems for Improved Access to Pharmaceuticals & Services
NA-FDC	National Agency of Food and Drug Control
NHQC	National Health Products Quality Control Center
NIDQC	National Institute for Drug Quality Control
NIMPE	National Institute for Malariology, Parasitology and Entomology
NOMCOL	Network of Medicines Control Laboratories
NQCL	National Quality Control Laboratory
NTP	National Tuberculosis Program
OI	Opportunistic Infection
OMCL	Official Medicines Control Laboratory
ORS	Oral Rehydration Salts
PAC	Provincial AIDS Committee
PAHO	Pan American Health Organization
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PNILP	Programme National Intégré de Lutte contre le Paludisme
PPB	Pharmacy and Poison Board
PQ	Prequalification
PQAD	Product Quality and Assessment Directorate
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RDMA	Regional Development Mission for Asia
SL-ATB	Second-Line Anti-Tuberculosis
SOP	Standard Operating Procedure
SSFFC	Substandard/spurious/falsely-labeled/falsified/ counterfeit
TA	Technical Assistance
TAP	Technical Assistance Program
TB	Tuberculosis
TWG	Technical Working Group
UCAD	University of Cheikh Anta Diop
UN	United Nations
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WB	World Bank
WHO	World Health Organization

Promoting the Quality of Medicines (PQM) Program FY13 Quarterly Report on FY14 Activities

Project Update for Q1: October 1 – December 31, 2013

Since 2009 the Promoting the Quality of Medicines (PQM), implemented by the United States Pharmacopeia (USP), has worked cooperatively with the United States Agency for International Development (USAID) to help developing countries effectively address critical issues related to poor quality medicines. PQM provides the needed technical leadership to build local capacity in medicines quality assurance systems, increase the supply of quality-assured medicines, combat the availability of counterfeit medicines, and advocate for medicines quality worldwide. Through these initiatives, PQM serves as a primary mechanism to help assure the quality, safety, and efficacy of medicines essential to USAID priority health issues, particularly malaria, HIV/AIDS, and tuberculosis (TB).

Core Funding

CROSS BUREAU

Background

In order to play a technical leadership and advocacy role, and to be in a position to influence national and international medicines quality assurance agendas, PQM plans to attend selected international meetings and participate in the design of proposed activities relating to medicine quality issues. PQM also produces up-to-date information about current issues in medicines quality. In an effort to improve tools to ensure quality control and increase the knowledge base about quality assurance, PQM will develop a field-based quality control tool with increased accuracy, sensitivity, and reliability.

Key Activities

Increase awareness about the importance of medicines quality

Dr. Mustapha Hajjou presented at the SciX 2013 Conference in October in Milwaukee, WI, and Dr. Kennedy Chibwe presented at the ASTMH Global Health Conference in November in Washington, DC.

USP issued three press releases related to PQM. These promoted PharmaCheck, the PQM program extension, and USP's membership in the "Fight the Fakes" campaign.

PQM submitted an editorial to the Bulletin of the World Health Organization about the Medicines Quality Database (MQDB); it will be published in the January 2014 issue.

Produce up-to-date information about current issues in medicines quality

On PQM's website, 4 new stories, 5 photos, 2 videos, and 3 new or updated resources were added; 38 new reports were included with the *Media Reports on Medicine Quality*, which received 1,980 hits.

Support regional approaches and networks to improve QA/QC of medicines

Dr. Karim Smine participated in a meeting of the African Medicines Regulatory Harmonization Technical Working Group, held in November in South Africa.

Explore improved tools to ensure quality control or increase the knowledge base about QA

Boston University is working with the design firm, Fikst, to develop an Alpha-prototype (field-ready). The prototype is expected to be ready by the end of January 2014. Artesunate and tetracycline are expected to be used for the initial field tests in Ghana. Boston University is working with PQM to finalize the protocol for the field studies and carrying out validation work as well.

** Core HIV/AIDS funds also contribute to PharmaCheck prototype preparations and field studies.*

Challenges

The PharmaCheck project with Boston University is facing some funding challenges as preparations to enter the field for pilot studies get underway. One funding source (U.S. Fellowship) did not materialize for FY2013/2014.

MALARIA

Background

PQM has provided support for the President's Malaria Initiative (PMI) objectives using core funds by developing public standards to test existing medicines where standards did not exist before. PQM then established a network of country quality control laboratories to teach chemists about the use of the standards in compliance with Good Laboratory Practices standards. More recently, PQM has been involved in obtaining information at country levels on the extent of diversion of malaria medicines from the public to the private sector. The information obtained will be used by the respective donors to identify risk areas for diversion and take the necessary actions to address the problem.

Key Activities

PQM completed testing on one sample of Sulfadoxine-Pyrimethamine from Kenya. In addition, Artemether-Lumefantrine from Kenya and Mefloquine from Burma were received and are currently undergoing testing.

MATERNAL AND CHILD HEALTH

Background

Since 2009, PQM has been involved in the efforts of the World Health Organization (WHO), UNICEF, and USAID to roll out zinc tablet and oral rehydration salt (ORS) supplementation in the management of children's diarrhea, especially for those children under the age of five. The technical assistance PQM has provided has largely been through quality control testing and good manufacturing practices (GMP) assessments of manufacturers to increase the availability of quality zinc and other maternal and child health (MCH) products, such as chlorhexidine. In 2012, the UN Commission on Life-Saving Commodities for Women's and Children's Health was formed as part of the Every Woman Every Child movement to increase access and use of essential medicines, medical services and health supplies that effectively address causes of death during pregnancy, childbirth and into childhood. Many of the recommendations that evolved from the commission overlap with key USAID priorities being addressed by PQM therefore the assistance PQM has provided is effectively meeting the goals of both initiatives. In order to help increase the global supply of quality assured MCH medicines, PQM will make recommendations to manufacturers to strengthen their quality assurance systems and GMP programs to subsequently achieve WHO prequalification (PQ) status

Key Activities

PQM participated in quarterly face-to-face meetings and teleconferences for each of the following UN Commission Commodity Technical Reference Teams: 1) chlorhexidine working group; 2) injectable antibiotics; 3) diarrhea and pneumonia working group; and 4) oxytocin, magnesium sulfate and misoprostol. In these meetings, PQM gave updates to partners on manufacturers of MCH medicines and provided technical advice and information on medicine quality.

PQM performed quality control analysis of zinc sulfate tablets, ORS, and vitamin A products submitted by UNICEF as well as other USAID programs and manufacturers receiving technical assistance.

Challenges

The number of MCH medicine samples submitted for QC analysis has increased tremendously, requiring more resources.

NEGLECTED TROPICAL DISEASES

Background

More than 1 billion people—one-sixth of the world's population—suffer from one or more Neglected Tropical Diseases (NTDs). These diseases are called “neglected” because they have been eradicated in most developed areas of the world and persist only in less developed regions.

The aim of the most recent invitation from WHO is to focus on four medicines used in the treatment of NTDs: albendazole, mebendazole, diethylcarbamazine, and praziquantel. These four single ingredient medicines have been shown to be effective in the treatment of lymphatic filariasis, soil-transmitted helminthiasis (STH), and schistosomiasis and have been included in the WHO Model List of Essential Medicines. With this funding from USAID, PQM plans to perform Good Manufacturing Practices (GMP) assessments of manufacturers to ensure that their products are of high quality. In order to help manufacturers achieve WHO PQ status, PQM provides recommendations to strengthen their quality assurance systems and GMP programs.

Key Activities

Manufacturers of mebendazole, albendazole, and praziquantel active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs) have been identified as potential candidates for future technical assistance. Additional activities will take place once a work plan has been finalized.

TUBERCULOSIS (TB)

Background

PQM provides support to the Global Drug Facility and the Green Light Committee in their efforts to increase the availability of good quality second-line anti-TB medicines (SL-ATBs). PQM assists SL-ATBs manufacturers to ensure an increased supply of quality-assured medicines globally.

Key Activities

Increase the supply of quality-assured second-line TB medicines

Technical assistance is continuously provided to finished pharmaceutical product (FPP) and active pharmaceutical ingredient (API) manufacturers.

There are 14 FPP companies in the pipeline, some with multiple products: Hisun Pharma, HEC pharma, Arterium, Chong Kun Dang, DJPL, Abbott, Dong-A, Shalina, Beijing Yabao Pharma, Hizon Labs, BC World Pharm, Peili, Sintez, Macleod's, and Yuyu Pharma. There are 15 API companies in the pipeline, some with multiple products: Zhejiang Hisun, Zhejiang Yongning, Zhejiang Shangyu Jinxin, Zhejiang Xinhua, Fuzhou Fuxin, NCPC Huasheng, Zhejiang Dankang, Dong-A, Enzychem, HEC, Suzhou Kaiyuan Minsheng, Dandong Beiqi, Zhejiang Excel Pharma, Shenxue Dachen Pharma, and Zhejiang Second Pharma.

Develop OEM for at least two critical second-line and/or third-line anti-TB medicines

Work is being performed to carry out the contracts between API and FPP manufacturers.

Provide support through capital investment to promising companies to obtain WHO Prequalification

Comparator products were provided to TheragenEtex, Hisun, Peili, and Zenith Pharma.

Challenges

Better market forecasting is needed for second-line ATB products in order to encourage manufacturers to participate in WHO PQ. Another major hurdle is that common technical document (CTD) product dossier compilation is a long process since it is a new concept to most manufacturers.

Africa

ANGOLA

Background

Implementation of large-scale malaria control activities in Angola faces serious challenges because the country's health infrastructure was severely damaged during the civil war. It has been estimated that only about 40% of the population has access to government health facilities. Malaria is a major health problem, accounting for an estimated 35% of the overall mortality in children under five, 25% of maternal mortality, and 60% of hospital admissions for children under five. Malaria transmission is highest in northern Angola, while the southern provinces have highly seasonal or epidemic malaria.

PQM was selected to provide technical, strategic, and operational assistance to strengthen medicines quality assurance in Angola, beginning in 2013. PQM was asked to assist the MOH develop and implement a post-marketing surveillance system for antimalarial commodities in the country.

Key Activities

An assessment of the MOH has been scheduled for January 2014. Upon completion of the assessment, a work plan will be drafted and agreed upon with USAID.

BURUNDI

Background

Beginning in 2012, PQM was selected to provide technical, strategic, and operational assistance to strengthen medicines quality assurance in Burundi. PQM was asked to propose interventions that will help ensure the adequate quality of antimalarial medicines in the country. In 2013, the President's Emergency Plan for AIDS Relief (PEPFAR) obligated funding for PQM through USAID/Burundi to contribute to the improvement of the quality of HIV-related medical products in the country.

Key Activities

PQM and USAID/Burundi have agreed on the activities to be carried out in 2014. However, discussions are still ongoing to finalize the work plan and prepare for a field visit. Activities for FY14 will include:

- Strengthen the capacity of the National Institute of Public Health (INSP) laboratory
- Support improved governance capacity of the national medicines regulatory authority (DPML)
- Support the creation of a national medicines quality monitoring system

ETHIOPIA

Background

PQM receives funding from PEPFAR through USAID/Ethiopia to strengthen the capacity of the Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA). The Product Quality and Assessment Directorate (PQAD) laboratory of FMHACA, through the technical and financial support provided by PQM, obtained ISO 17025 accreditation with respect to seven tests in 2011.

PQM also receives funding from PMI to provide technical, strategic, and operational support to strengthen antimalarial medicines quality assurance in Ethiopia. In order to monitor the quality of the country's antimalarial medicines, a medicine quality monitoring (MQM) program has been established, and PQM has supported the program by providing training to technical staff on sampling, testing of medicine samples, evaluation of medicine quality, and other activities.

Key activities

Strengthen the performance of the Product Registration and Licensing Directorate of FMHACA

Illegal trade of medicines and foods is becoming a serious problem in Ethiopia. To help FMHACA address these problems, PQM prepared a proposal for the establishment of a national taskforce—composed of government organizations, private pharmaceutical associations, and civic societies—as well as the creation of an inter-country working group composed of the regulatory authorities of countries sharing borders with Ethiopia. The proposal has been submitted to FMHACA, USAID/Ethiopia, and PQM for consideration.

Rapid review of the GMP inspection system of FMHACA showed that the Authority does not have essential written materials to guide the GMP inspection program carried out by FMHACA. Consequently, in December 2013, four draft guidance materials were drafted and submitted to FMHACA for review and discussion:

- Guidance on Training and Qualification Requirements for GMP Inspectors
- Guidance on Inspection of Foreign Pharmaceutical Manufacturers
- Guidance for Foreign Manufacturers Inspection Application Form
- Guidance on GMP Inspection Report Writing

Strengthen FMHACA's Product Quality Assessment Directorate (PQAD)

Re-assessment of the PQAD laboratory was completed in October 2013, and the laboratory was found to be compliant with ISO17025:2005 requirements for seven physico-chemical test methods. Hence, the accreditation has been extended for an additional two years.

Preparations for the laboratory to become WHO prequalified have begun, and the Laboratory Information File (LIF) and expression of interest were prepared and submitted to WHO.

PQM assisted the Laboratory in participating in a proficiency testing program organized by RTC-sigma-Aldrich Corporation for six physico-chemical test methods.

Strengthen post-marketing surveillance of the quality of antiretroviral (ARV) and opportunistic infection (OI) medicines circulating in the country

The Post-Marketing Surveillance (PMS) Protocol was prepared for conducting PMS of ARV and OI medicines circulating in Ethiopia. USP reference standards required for testing these medicines were procured and supplied to FMHACA. A PMS Guideline was prepared and submitted to FMHACA.

Strengthen FMHACA branch laboratories

In order to identify the type of support that the four branch laboratories need to enable them to monitor the quality of medicines found in their respective areas, it is necessary to conduct an assessment at each laboratory. PQM developed a laboratory assessment tool to be used by assessors.

Strengthen regional/city administration medicine regulators

A rapid assessment tool to assess regional/city administration medicine, food and healthcare regulatory bureaus was prepared and tested.

Assist Ethiopian Pharmaceutical Fund Supply Agency (PFSA) in establishing internal quality control laboratory

An assessment of the PFSA quality control laboratory was carried out, and a detailed work plan was prepared based on the assessment results. Organizational structure, job specifications, and job descriptions for the laboratory were prepared and submitted to PFSA for approval.

GHANA

Background

PQM has focused on providing technical assistance to the Food and Drugs Authority (FDA) to establish a functional medicine quality monitoring program throughout the country and to strengthen the capacity of the FDA's national quality control laboratory (NQCL) toward the goal of ISO 17025 accreditation and WHO prequalification.

Key Activities

Support round 6 of post-marketing surveillance of antimalarial medicines at the 7 sentinel sites in Ghana and encourage the FDA to take enforcement actions based on the results of MQM data

PQM procured the necessary reagents and supplies for the FDA to sample and test the MQM samples collected during FY12 Q4. The samples are undergoing confirmatory testing at the FDA, and PQM is waiting for the final results and report.

Strengthen the capacity of the national Food and Drugs Authority laboratory and assist them toward ISO 17025 accreditation

Preparations for ISO 17025 were put on hold due to delays with the FDA moving to their new site. In September 2013, FDA moved to the new site, and PQM assessed the lab's QMS in preparation for the ISO 17025 audit. Throughout Q1, PQM provided consumables that were needed for the accreditation. In November, PQM also helped install key equipment for the scope of accreditation and conducted training on key topics like Good Documentation Practices, Safety in the Lab, Karl Fischer, FTIR, and ISO 17025 training. A confidential report was forwarded to FDA senior management to work on corrective actions to remediate the observations. PQM has also been assisting the staff with correcting the findings. In January, a trip is planned to follow-up on the November trainings.

Provide training for more FDA staff involved in GMP inspections in the use of the risk-based compliance module as well as capacity building for strengthening the GMP Inspectorate Quality System

This activity is in progress and being planned for Q2-Q3.

Include MQM data into the PQM database and analyze trends to provide a basis for informed decision making

PQM is waiting for the final confirmatory testing results from the FDA.

Collaborate with the Maternal Health Channel of Creative Storm Network to develop public sensitization programs

This activity is in progress and being planned for Q2-Q3.

GUINEA CONAKRY

Background

PQM was selected to provide technical, strategic, and operational assistance to strengthen medicines quality assurance in Guinea.

Key Activities

An assessment of the country's QA and QC will be carried out in January 2014. The outcomes of the assessment and the work plan will be submitted in Q2.

KENYA

Background

PQM started working in Kenya in 2009 with the support of PMI through USAID/Kenya. PQM created a sustainable protocol for MQM in Kenya, and five sentinel sites for monitoring antimalarial medicines were established. PQM initiated the first round of MQM activities in 2010 by training representatives of

the Pharmacy and Poison Board (PPB), the National Quality Control Laboratory (NQCL), and others in sampling strategies, Minilab® basic tests, and reporting and managing medicines quality data. Second and third rounds were carried out in 2011 and 2012. Based on MQM findings, PPB has been instrumental in taking regulatory actions by jailing the sellers of counterfeit antimalarials, closing a manufacturer for selling poor quality and unregistered samples, recalling non-conforming samples, and destroying expired antimalarials.

The NQCL obtained WHO PQ status in 2008. In 2011, the NQCL started the process of ISO 17025 accreditation with PQM assistance. In addition to assisting the lab toward ISO 17025 accreditation, and as part of reinforcing the capacity of the NQCL, PQM has been providing technical assistance to lab staff through the Network of Medicines Control Laboratories (NOMCOL). The primary objective of this network is to provide a forum for sharing best practices at the national level on medicines quality; it provides the participating laboratories the opportunity for South-South collaboration on quality control of medicines. Kenya is a charter member of NOMCOL.

Key Activities

Continue strengthening medicines quality monitoring (MQM) of antimalarial medicines at the existing sentinel sites and expand it to new sites

In collaboration with the Division of Malaria Control (DOMC) and PPB, PQM expanded the MQM program to include four counties and two ports of entry. With the local MQM focal point, PQM has begun planning a Minilab training for the staff at the six new sites.

Continue encouraging regulatory actions by sharing MQM evidence-based data with relevant stakeholders and by raising awareness about poor-quality medicines circulating in the Kenyan market

Continue strengthening the NQCL laboratory capacity and assist it to improve its quality management system (QMS) and to reach ISO 17025 accreditation

PQM was able to review some lab documents needed by the accrediting body, SANAS. The lab is scheduled for audit during Q2.

Challenges

The NQCL is still facing major challenges with their management, which drastically affected the performance of confirmatory testing for the samples collected during last MQM round. This challenge is coupled with the slow reaction from DOMC in getting the QC testing contract signed by NQCL.

LIBERIA

Background

PQM helped Liberia to establish the Liberian Medicines and Health Products Regulatory Authority (LMHRA), which was the result of a bill signed into law in 2010. PQM continues to support LMHRA in its efforts to establish priority medicines regulations, manage its regulatory functions, and strengthen the quality control of antimalarial and antiretroviral medicines.

Continue building the capacity of the LMHRA Quality Control Laboratory

The goals for the QC lab include ensuring that lab equipment is fully functional, analysts are able to conduct their routine activities, and that the lab might become ISO 17025 accredited within two to three years. PQM is planning a consultant visit during Q2 to start training lab staff in preventive maintenance.

Continue strengthening the LMHRA's regulatory capacities

A new registration system was installed at LMHRA, and 15 staff were trained on its use. With the new system in place, the number of applications for marketing authorization increased tenfold. To continue strengthening LMHRA functions, a PQM consultant will travel to LMHRA in Q2 to work with the staff and develop a new training module for the inspectorate department.

Strengthen antimalarial medicines quality monitoring at sentinel sites and promote regulatory actions

PQM completed the previous round of sampling and testing of antimalarials at Bomi site. The report of this round is under review.

For the subsequent round (round 5), PQM, the national malaria control program (NMCP), and LMHRA selected two new sites that will be added to the two existing ones.

PQM drafted a media report and shared it with LMHRA for publication. The report highlighted the official visit of the US delegate to the LMHRA QC lab and the 20 regulatory actions that LMHRA has taken as part of regulating the pharmaceutical market in Liberia.

Challenges

Limited funds are the major hurdle for PQM to accomplish the planned activities. In addition, the lab is still facing power outages, and their routine work is impeded by the lack of a continuous supply of lab consumables. Additionally, there is a need to buy a new dissolution tester and another HPLC.

MALI

Background

PQM has been assisting the MoH of Mali since 2008 in strengthening their medicine quality assurance systems. Activities focus on strengthening the capacity of the Direction de la Pharmacie et du Médicament (DPM) and Laboratoire National de la Santé (LNS) in pharmacovigilance (PV), drug registration, medicine quality control (QC) and monitoring, and providing assistance the National Malaria Control Program.

Key Activities

Strengthen the capacity of LNS to attain ISO 17025:2005 accreditation

In collaboration with PQM, the QA unit and technical staff of LNS finalized 22 standard operating procedures (SOPs). PQM conducted a quick audit of the LNS physical-chemical lab focusing on equipment usage and maintenance. The findings were discussed with the QA team to address the gaps identified and define the training needs.

Support MQM program

PQM reviewed the data from the previous round of sampling and testing of antimalarial medicines that was conducted in 2012. A draft report on the MQM results obtained from the two rounds of sampling and testing conducted so far was submitted to USAID/Mali for review.

PQM drafted a new MQM protocol for Mali; the draft was shared with local partners for review. PQM will organize a workshop to finalize the protocol with the partners. This workshop is scheduled for January 30, 2014.

Because PQM activities were put on hold for almost two years, PQM will organize training on sampling and screening antimalarial medicines using Minilab[®] methods. PQM procured laboratory supplies and reagents needed for the training, as well as to replenish existing Minilab[®] kits. The training workshop will take place February 3-7, 2014.

Support coordination of PQM activities

PQM developed a job description for a local consultant who will coordinate program activities in the country. LNS agreed to publish the position in a local newspaper, and the successful candidate will be hosted at LNS. PQM is collaborating with LNS in collecting and reviewing applications for this position.

MOZAMBIQUE

Background

PQM has been working in Mozambique since 2010. Activities have focused on strengthening the quality control (QC) and quality assurance (QA) capabilities of Mozambique's medicines regulatory authority, the Departamento Farmacêutico (DF).

Key Activities

Strengthen the capacity of the National Laboratory for Medicines Quality Control (LNCQM)

PQM provided technical assistance in October 2013 on HPLC trouble shooting to LNCQM staff. In December, PQM traveled to Mozambique to provide additional training of 2 new staff at LNCQM, evaluate the QC testing lab, assess the situation at LNCQM regarding key staff changes, and meet with SWISS cooperation to discuss possibilities for future collaboration. Due to the staff changes, PQM retrained/refreshed on techniques like UV/Vis, HPLC, USP General Chapters, Karl Fischer, and calculation of Dissolution and HPLC results. PQM also procured items for the lab such as lab notebooks, centrifuge tubes, light bulbs for the main laboratory space, filters for the water purification system, parts for the proper installation of the water distiller and other consumables. PQM also prepared staff for a meeting/training that took place in Ghana to discuss inter-laboratory comparison testing.

Strengthen the capacity of DF

During the December 2013 trip, PQM discussed the status of the decree that the DF and Medicamentos e Artigos Medicos (CMAM) are drafting that will allow DF more autonomy to be able to take regulatory actions. PQM offered to assist with drafting the document since PQM has assisted other countries with similar documents. Further discussions will be held during a visit planned tentatively for March 2014.

Support MQM program by expansion to the ports of entry

This activity will take place in Q2-Q3. Minilabs will be procured for the ports of entry.

Challenges

PQM faced challenges due to the abrupt change of a staff member who was a key in implementing activities at LNCQM and that PQM had invested time in training. Consequently, activities were left undone and are still not complete due to the transitional period and insufficient training of the new staff by the previous staff. PQM will have to spend time to retrain at least one-third of the staff due to shuffling of activities/responsibilities at LNCQM. Additionally, due to late receipt of funds in 2013, some activities were on hold until forward funding was approved.

NIGERIA-Malaria

Background

In 2012, USAID/PMI-Nigeria selected PQM to provide technical support to the National Malaria Control Program (NMCP) and the National Agency for Food and Drug Administration and Control (NAFDAC).

Key Activities

Strengthen NAFDAC regulatory capacity

Following the assessment of the NAFDAC lab in Yabba in 2013, PQM submitted a report on the gaps identified and proposed corrective actions. In Q1, PQM reviewed the quality manual of the lab and proposed modifications. PQM drafted a comprehensive two-year implementation plan for helping the lab to attain ISO 17025-2005 accreditation. The implementation plan describes the support that PQM will provide to the NAFDAC laboratory in Yabba, with timelines. The implementation plan has been approved by NAFDAC, and several trainings will take place in January to strengthen the quality management system of the Yabba lab, followed by training in analytical methods that are in the proposed scope of accreditation.

Monitor the quality of antimalarial medicines

PQM provided resources to the National Malaria Control Program (NMCP) for conducting one round of sampling and testing of antimalarial medicines. NAFDAC is responsible for carrying out most of the technical activities relating to the MQM program. PQM reviewed the sampling protocol to be used at the sentinel sites and provided suggestions. NAFDAC plans to complete training of sentinel site teams on sampling strategies before the end of January 2014. Sampling and testing using Minilabs is expected to start immediately afterward.

Support the NMCP in finalizing its quality assurance policy for anti-malarial medicines and diagnostics

Challenges

Transferring money from NMCP to other MQM partners delayed the start of activities. Improvement of this process will be discussed with NMCP.

NIGERIA-Maternal and Child Health

Background

USAID/Nigeria selected PQM to support strengthening the capacity of select Nigerian manufacturers that produce zinc sulfate tablets, chlorhexidine digluconate gel, and other maternal and child health (MCH) priority commodities for the United Nations (UN) Commission on Life-Saving Commodities for Women and Children.

In support of the UN Commission's goals, USAID/Nigeria is working to increase the availability of relevant MCH medicines in the country. Toward that end, PQM will provide technical assistance on GMP and quality assurance to local medicines manufacturers in collaboration with NAFDAC. PQM will also provide TA to NAFDAC to build its capacity to regulate these products.

Key Activities

PQM performed a gap analysis of Drugfield Pharmaceutical's chlorhexidine gel manufacturing line for compliance with GMP. During the visit, other manufacturers receiving PQM technical assistance for the production of MCH products were visited. Manufacturers submitting expressions of interest for the manufacture of amoxicillin dispersible tablets also underwent a rapid assessment to determine if they had the infrastructure and capacity to produce the product under GMPs.

SENEGAL

Background

Since 2002, USAID and USP have been providing technical assistance to Senegal to strengthen their medicine QA/QC systems. An MQM program was launched in 2002 at five sentinel sites to monitor antimalarials. In 2009, the program expanded to four additional sentinel sites and began covering antiretrovirals, antituberculars, and contraceptive products.

Senegal's official medicines control laboratory (LNCM) has been working to obtain ISO 17025 accreditation. An important component of PQM technical assistance has been to strengthen the lab's compliance of with international quality management system (QMS) standards.

Key Activities

Strengthen the monitoring of the quality of antimalarial medicines at nine sentinel sites and promote regulatory actions

Planned activities for this fiscal year have been shared with the PMI advisor and NMCP for review. In the meantime, PQM and LNCM completed the 2013 MQM round (sampling and testing using Minilabs) at nine sites and the preliminary report for this round was submitted to stakeholders. Confirmatory testing is ongoing at the lab.

In addition to antimalarial medicines, PQM managed to leverage funds from other health programs to include the sampling and testing of TB and HIV medicines as well as contraceptives.

PQM assisted LNCM in providing evidence-based data to Direction de la Pharmacie et des Medicaments (DPM) for regulatory actions to be taken on the five substandard Artemisinin-based Combination Therapies (ACTs) (Artemther-Lumefantrine) found last fiscal year.

Continue building the capacity of LNCM to reach ISO 17025 accreditation

PQM provided technical assistance to LNCM regarding the ISO 17025 action plan and provided a detailed report to the lab on lab qualifications (conducted by Zef-Sci).

PQM facilitated the U.S. visit of a Senegal delegate and meetings with USAID and USP. PQM prepared a presentation for the meeting with USAID in Washington DC.

Challenges

Reduction in funding has caused some delay in the implementation of this fiscal year activities.

Asia

REGIONAL DEVELOPMENT MISSION FOR ASIA (RDM/A), MEKONG MALARIA

Background

Malaria remains a disease of public health importance in the Greater Mekong Sub-region (GMS), the impact of which is compounded by increasing concerns about the emergence of artemisinin-resistant malaria in the GMS, which might have arisen from, among other factors, availability and use of poor-quality antimalarials. Although there have been some improvements, there continues to be sporadic incidences of such products in the region requiring intensified and coordinated efforts of intervention.

Key activities for Burma/Myanmar

Conduct sample collection of antimalarial (AMLs)—and highly suspected antibiotics (ABTs) with quality problems—in targeted areas of the country. In addition, collect information on the availability of oral artemisinin antimalarial monotherapies and report findings to the relevant agencies, including DFDA and VBDC

Additional Minilabs have been procured and placed at the additional sentinel sites. PQM worked with Myanmar DFDA, VBDC, and DMR-LM to outline sampling and testing protocols/procedures.

Purchase and replenish essential Minilab and some QC lab supplies to maintain surveillance activities and confirmatory analyses

PQM donated one dissolution tester to the DFDA laboratory in November 2013 which significantly strengthens the laboratory's capacity to perform compendial testing of antimalarial medicines as well as other medicines. Hands-on training according to USP standards was conducted in December together with a workshop on establishing MQM programs. The MQM training included the use of Minilabs to perform basic testing on medicines, procedures for sample collection, and generating quality reports. After the trainings, a Project Management Team (PMT) was formed and will oversee the progress of the MQM program.

Key Regional Activities covering Cambodia, Laos, Thailand, and Vietnam

Continue to strengthen the post-marketing surveillance capacity of Laos Food and Drug Department (FDD) and Bureau of Food and Drug Inspection (BFDI), Vietnam Drug Administration (DAV), and selected local authorities of Burma and Thailand

PQM continues to support the collection of samples and completion of analyses for the Comparative Study of the Quality, Availability, and Source of Antimalarial Medicines in Cambodia, Laos, Thailand, and Vietnam in PQM-MQM Covered and Non-Covered Areas in Mekong Sub-Region. Sample collection has finished in Laos and Cambodia, and is ongoing in Thailand. The target for completion of

testing and analysis is the end of FY14 Q2, with publication of sub-regional reports to follow later this year pending approval from the participating government agencies. This final regional report will provide information on how MQM has impacted antimalarial medicines quality at GMS area.

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

PQM provided some 100 reference standards for compendia analyses and reference products for Minilabs to FDQCC this quarter. These supplies will be distributed as needed to the sentinel sites to enable them to conduct effective MQM

After the visit to the Thailand BDN laboratory and Laos FDQCC by PQM's QMS team, PQM has been working with BDN to identify an appropriate accreditation body and reviewing the Quality Manuals and other reference documents from FDQCC. PQM attended the ISO 17025 accreditation ceremony in November 2013 where the Laos FDQCC received accreditation for two products (amoxicillin and paracetamol). PQM continues to actively support the completion of necessary documentation and quality control activities in anticipation of FDQCC reaching a level where methods-based accreditation will be possible.

Support in-country and inter-country efforts for cooperation and enforcement through the BREMERE initiative to enhance collective action along with the WHO-led substandard, spurious, falsely-labeled/falsified/counterfeit (SSFFC) medical products working group, INTERPOL-led Storm Enforcement Network, and ASEAN Post-Marketing Alert System (ASEAN PMAS)

The new regional PQM consultant participated in a Minilab training conducted in Myanmar in December 2013 to increase coordination across the region.

In December, meetings were held in Thailand with BDN and FDA focal points to review progress for the year and provide an introduction to the regional PQM consultant. Joint site visits with USAID RDMA and local government partners are planned for Q2.

Two regional training programs including members from Myanmar, Vietnam, Laos, Thailand and Cambodia were conducted in Manila, Philippines in September and October 2013. Training in September (FY2013) focused on GMP training. In October, the BREMERE representatives from national testing laboratories were trained on Bioequivalence/Bioavailability testing methods. In November 2013, Thailand provided the final nominees needed to complete the BREMERE team.

Increase the availability of quality-assured antimalarials by improving inspections in supply and distribution chains, supporting selected manufacturing facilities to produce quality Artemisinin-based combination therapy (ACT) medicines, enhancing pharmacy practices, and engaging pharmacy school students and faculty in the reduction of counterfeit and substandard medicines in the GMS

Support for the pharmacy schools to improve their final-year pharmacy curriculum on medicines policy, quality assurance, and regulations has been held due to the political instability in Thailand; this activity is pending in Laos for Q2.

Through existing and proven means and tools, maintain the awareness-raising momentum about the dangers of using counterfeit and substandard medicines in the GMS

A journal article detailing the success of Cambodia's efforts in reducing counterfeit medicines was written and sent to Cambodian authorities for approval. Publication is expected in Q2.

A draft report was prepared describing the effects of IEC initiatives in Laos. The report will be finalized in Q2.

Challenges

Challenges in regional programs include:

1. Language barriers between regional government staff make sharing regional expertise more challenging.
2. Due to the volume of work and shortages of staff, government partners are often unable to allocate sufficient time to improve regulatory management and oversight.
3. Delays in identifying BREMERE team members and promotion/changes within government staff makes continuity within the program an ongoing effort.
4. Continuing political sensitivity in Burma and the escalating situations in Thailand and Cambodia have made planning and implementation more difficult.
5. The needs and demands of government partners for support do not match the limited budget and staff allocation available for covering all key components of the PQM program in the region.

CAMBODIA

Background

PQM provides technical assistance to the Royal Government of Cambodia in efforts to strengthen the country's medicines quality assurance program and quality control systems (QA/QC).

The PQM scope of work in Cambodia encompasses three objectives: Improving detection of poor-quality medicines and supporting the MOH to take action against counterfeit and substandard medicines and health products based on the results of testing; strengthening medicines QA/QC through building the capacity of the Department of Drugs and Food (DDF) and National Health Products Quality Control Center (NHQC); and raising awareness about medicines quality issues and improving access to medicines quality information among regulators, health care professionals, and the general public. To improve detection methods and QA systems, PQM helped establish an MQM program to support post-marketing surveillance of the quality of antimalarial and other infectious disease medicines in the marketplace.

Key Activities

Continue to strengthen the DDF post-marketing surveillance activities at national and local levels by implementing enhanced MQM programs in the country to support enforcement action against poor-quality essential medicines, with the emphasis on antimalarials

PQM revised and re-submitted a request to H. E Chou Yin Sim for his authorization to conduct Comparative Studies with the sample collection from the public sector in addition to the private sector which was already approved in late 2012. In October 2013, PQM's request was approved. The country study teams organized an orientation meeting and refresher training on testing with Minilabs in November. 12 provincial staff from 3 MQM sites and 3 non-MQM sites participated. Sample collection within those 6 provinces was completed. Basic testing with Minilabs is planned for January 2014. All related reference standards, reagents, and testing materials have been procured and replenished.

In order to take timely regulatory actions on the identified poor quality, substandard, and counterfeit medicines, the DDF-MoH created the Guideline for Recalls on Pharmaceutical Products (including poor quality, substandard and counterfeit medicines). This guideline has been reviewed by DDF's technical working team and submitted to H.E Chou Yin Sim for his approval for implementation.

Continue to strengthen the capacity of the National Health Product Quality Control (NHQC) toward compliance with ISO 17025

PQM provided technical assistance in reviewing the list of lab furniture and equipment. PQM is now waiting for final construction of the NHQC building in order to provide more technical assistance regarding installation of lab furniture and equipment.

Support in-country, inter-country, and regional coordination, cooperation and enforcement through BREMERE to enhance collective action at national and regional levels

PQM worked with the DDF director, who is also a Co-chair of BREMERE, to finalize the list of nominees for focal points.

Increase the availability of quality-assured antimalarials through enhanced inspections of distribution chains and pharmacy practices and involve pharmacy school students and faculty members in the reduction of counterfeit and substandard medicines in Cambodia

PQM has closely worked with DDF in establishing guidelines and developing training courses for Good Pharmacy Practices. The policy has been approved by the MOH and is available in Khmer and English. Training courses will be rolling out to train medicines inspectors in enhancing their capabilities in inspections of distribution chains and good pharmacy practices.

Participate in and present at meetings and conferences to share findings, achievements, and challenges encountered during PQM program activities in Cambodia, as well as in regional and international arenas

PQM helped financially support the Mekong Bio-Pharma conference held in Cambodia in October 2013. There were about 400 participants including pharmacists, physicians, and pharmacy students.

PQM submitted an article “Cambodia Takes Aggressive Action in Fight Against Substandard and Counterfeit Medicines” to the Journal of Tropical Medicine and Surgery.

INDONESIA

Background

The National TB Control program of Indonesia (NTP) faces many challenges in scaling up its efforts to control the spread of multi-drug resistant tuberculosis (MDR-TB) and extensively-drug resistant tuberculosis (XDR-TB). A multi-pronged approach has been developed by PQM in collaboration with the NTP and the National Agency for Food and Drug Control (NA-FDC) in support of TB control by increasing access to quality-assured anti-tuberculosis medicines from local and imported sources. PQM provides technical assistance to Indonesian manufacturers to support the submission of high-priority anti-TB medicines (1st and 2nd line) product dossiers for WHO Prequalification. PQM also builds the national and provincial capacity of NA-FDC through the development and implementation of medicines quality monitoring to enhance post-marketing surveillance of anti-TB and antibiotic medicines. In addition, PQM plays an important role by facilitating coordination among the NA-FDC national and provincial laboratories, the BPOM regulatory authority, the NTP, and local manufacturers to increase availability of and access to quality-assured, anti-TB and antibiotic medicines in Indonesia.

PQM sits on the Indonesian national Technical Working Group under GFATM and provides input into the overall leadership, management, coordination, and proposal development for the National TB Control Program and the Country Coordinating Mechanism (CCM), and under select Health Systems Strengthening grants. PQM has also been collaborating with the ASEAN Secretariat in Jakarta to develop regional programs for training and building capacity on GMP Inspection under PIC/S and on BA/BE studies under the auspices of the ASEAN Pharmaceutical Products Working Group in light of ASEAN harmonization in 2015.

Key Activities

Continue to provide technical assistance to anti-TB medicines manufacturers to obtain WHO prequalification for selected medicines

Firm commitments have been observed from participating manufacturers, including state-owned manufacturers Kimia Farma (2FDC-RH & 4FDC-RHZE), Indofarma (2FDC-RH), and Phapros (4FDC-RHZE); and other companies in the private sector, including Zenith Pharmaceuticals for Levofloxacin, Sanbe Farma for Levofloxacin, and Sandoz Indonesia for R/H chewable tablet and R/H/Z chewable tablet. Some highlights are summarized below:

- Comparator products (Levaquin (levofloxacin) and Rafinah (Rifinah (Rifampicin /Isoniazid) have been provided to Kimia Farma for in vitro and BE pilot studies
- A site inspection at Zenith Pharmaceuticals manufacturing facility in Semarang was conducted

Continue to support implementation of MQM for ATB medicines at five pilot sentinel sites that completed training in June 2012

One round of sampling and basic testing was completed during FY13 for samples collected from 5 provincial sentinel sites labs (BBPOM) in Indonesia, with a second round planned for Q2. In round one, a total of 869 anti-TB and antibiotic medicines were screened from five provincial MQM sites at the BBPOM labs; confirmatory analysis is underway, with results expected in Q2. Preliminary results suggest that some samples are failing assays for content of API and dissolution. Two samples of streptomycin sulfate injection were analyzed at USP HQ, and one sample failed the assay for API content. For the failed samples, the results have been communicated to the relevant staff at PPOMN and Deputy 1 at BPOM for appropriate actions, and PQM will follow up with them directly.

PQM arranged an MQM sentinel site visit for the US Embassy, USAID, NA-FDC, and other interested officials to Medan, Sumatera to demonstrate the PQM MQM program activities on the ground.

Continue to assist two local contract research organizations (CROs) toward compliance with Good Clinical Practices (GCP) for BE studies of ATB medicines

Equilab International (Jakarta) and San Clin EQ (Bandung) have completed implementing CAPA recommendations from FY12 and FY13 to comply with GLP and GCP in response to audits conducted by PQM, WHO, and regulatory authorities in the region. Both are presently considered ready to conduct BE studies and will likely be audited by WHO when manufacturers submit their expressions of interest to apply for prequalification. PQM has been coordinating with both CROs to conduct BE studies for the 2FDC-RH and 4FDC-RHZE for Phapros, Indofarma, and Kimia Farma. Three staff from Equilab and San Clin were also supported by PQM to attend the 'USP PQM-ASEAN-Philippines FDA Joint Training Workshop on Bioavailability/ Bioequivalence Studies' to deepen their skills and experience in BA/BE study protocols as well as scientific, technical, and regulatory requirements.

Strengthen regulatory systems and measures of Ministry of Health and National Agency for Drug and Food Control to better control and regulate ATB medicines, particularly 2nd-line ATBs, to support the MDR-TB program

Supported two NA-FDC staff to participate in a regional workshop jointly organized by PQM, the Philippines FDA, and ASEAN Secretariat in October in Manila entitled 'USP PQM-ASEAN-Philippines FDA Joint Training Workshop on Bioavailability/ Bioequivalence Studies.'

A short-term consultant position will be advertised in Q2 to review regulations and availability in the private sector markets of anti-TB medicines and provide recommendations to key stakeholders (NTP, NA-FDC) to address the issue.

Per the request of the NA-FDC, PQM conducted a workshop in December in Jakarta on WHO PQ for manufacturers and for BPOM inspectors, co-sponsored by HSS GFATM. The workshop was attended by some 70 participants from regulatory agencies at central and provincial levels as well as manufacturers.

PQM also provided support for 5 staff from the NQCL-DF (PPOMN) to travel to USP HQ for training on compendial analysis of antiretrovirals and antimalarials, as well as quality management systems and other essential methods and procedures. The training was jointly sponsored by PQM and HSS GFATM.

Provide technical support to NQCL-DF toward renewing ISO 17025 accreditation with a process-based scope

PQM completed an initial QMS assessment of the lab, and training workshops were conducted covering key managerial and technical aspects of the QC labs.

USP issued a press release on the recent recognition NQCL-DF received from the Global Fund as an official ISO/IEC 17025-accredited laboratory to conduct quality testing on Global Fund-procured medicines used for the treatment of HIV, TB, and malaria.

Challenges

Many of the challenges in implementing the project in Indonesia include bureaucracy and logistics, including delays in receiving donated commodities, reference standards, and in sourcing comparator products for manufacturers and CROs. The NA-DFC and/or NQCL-DF seem not to have the capacity or capability to help address customs clearance issues.

In addition, the Ministry of Finance regulations were not well understood by the partners or by PQM, resulting in some delays in implementing the MQM sampling and testing. This issue should be resolved with the next Letter of Agreement to begin in January 2014 and may need discussion/consultation with key stakeholders at high levels.

Local staffing challenges for more than half of the fiscal year resulted in delays in a number of the work plan activities, as senior GMP or QC staff from USP headquarters were only on hand in-country as schedules permitted.

PHILIPPINES

Background

PQM has been actively providing technical and professional assistance to Philippines Food and Drug Administration (FDA), Department of Health (DOH), National Tuberculosis Program (NTP), selected Local Government Units (LGUs) and Centers for Health Development (CHDs) in an effort to strengthen medicines quality assurance and quality control system (QA/QC) with emphasis on post-marketing surveillance through medicines quality monitoring (MQM) for anti-tuberculosis and other essential medicines available on the market in Philippines; to enhance the FDA regulatory capacity in evaluation & registration of pharmaceutical products through the introduction and buildup of internationally accepted quality standards, guidance, processes and procedures.

Key Activities

Maintain and sustain MQM with continued post-marketing surveillance (PMS) at the eight sentinel sites

PQM replenished Minilabs, inventoried supplies/reagents, and forwarded expired medicines to the FDA laboratory for proper disposal.

PQM and FDA visited CALABARZON sentinel site to strengthen PMS of ATBs in the region.

Strengthen the FDA's capacity and its QC laboratory to enhance the medicine regulatory system in both pre-marketing medicine registration and PMS

PQM conducted "USP PQM – ASEAN – Philippines FDA Joint Training Workshop on BA/ BE Studies" with participants from the Philippines FDA, ASEAN Member States, and the Center for Drug Research, Evaluation and Studies, Inc. (CEDRES).

The PQM in-country consultant participated in the FDA's 3rd National Consciousness Week against Counterfeit Medicines and also attended "Ethics Rules for USAID Employees and USAID Partners" training at the U.S. Embassy in Manila and the Harmonization Workshop on TB Technical Assistance and Research Initiatives in Pasay City.

Collaborate with NTP and other TB partners on relevant disease control programs

PQM met with other implementing partners including the Innovations and Multisectoral Partnership to Achieve Control of TB (IMPACT) program manager and had a teleconference with SIAPS to discuss

program gaps in medicines quality assurance and opportunities to collaborate for PMS and QA/QC systems strengthening.

Support local manufacturers towards WHO PQ for 1st and 2nd line TB medicines

PQM met with the FDA chief and representatives from the local manufacturer industry on how to provide technical assistance to improve their GMP and obtain WHO PQ. The PQM GMP team visited three manufacturers to perform assessments.

VIETNAM

Background

PQM has been active in providing technical assistance to Vietnam to improve the quality of essential medicines by building the capacity of National Institute of Malariology, Parasitology and Entomology (NIMPE), Drug Administration of Vietnam (DAV) and National Institute of Drug Quality Control (NIDQC) to improve the quality of medicines they register, supply, and use in the priority health programs. PQM has also been tasked with capacitating selected local pharmaceutical manufacturers to produce methadone according to internationally accepted GMP. In addition, PQM has helped set up an MQM program for anti-infective medicines and opportunistic infection (OI) products.

Provide technical assistance to local methadone production and procurement

PQM followed up with DAV, VAAC, and HCMC PAC on the final selection of 1-2 local manufacturers from a pool of 5 qualified ones. Procurement of methadone for the national HIV/AIDS program and HCMC still needs an open tender which will include both imported finished products and locally produced ones. HCMC PAC may prepare a budget in 2014 for procurement of methadone.

Increase capacity of the NIDQC and HCM IDQC quality control labs

PQM communicated with HCM IDQC and NIDQC to prepare needed documents for USP experts to review and helped the NIDQC comment on the design of the microbiological lab. Together with PQM, the WHO PQ program will provide technical assistance to HCM IDQC towards WHO PQ.

Provide technical assistance for ARV quality assurance through post-marketing surveillance in both the public and private sectors

With NIDQC, PQM discussed a tentative schedule for USP experts to visit Hanoi and for NIDQC staff to travel to USP HQ to learn technical monographs on ARV testing. An appropriate NIDQC staff has been selected and will travel to USP HQ in March 2014.

Challenges

The Vietnamese MoH's process of methadone procurement and selection of local manufacturers has been slow and bureaucratic.

Europe and Eurasia

KAZAKHSTAN

Background

According to WHO, Kazakhstan is among the 27 high multidrug-resistant tuberculosis (MDR-TB) burden countries in the world. TB control, and especially combating MDR and extensively drug-resistant TB (XDR-TB), is a priority in the Health Care Development Programme 2011–2015. The national budget for TB control has been increased to enable rapid scale-up of treatment for MDR-TB patients. Despite these efforts, universal access to treatment has not yet been achieved.

PQM began receiving funding from USAID/Kazakhstan in FY13 with the goal of improving the quality of anti-TB medicines produced by the major medicines manufacturers in the country. PQM's technical assistance will enhance the capacity of these manufacturers to comply with international GMP.

Key Activities

PQM visited Pavlodar Pharmaceutical Factory in October 2013. The manufacturer is in the process of building a new facility that will be GMP certified by the local regulatory agency. PQM reviewed the drawings for the new facility and the quality system documents and provided Pavlodar with recommendations for improvements. The manufacturer developed a corrective and preventive action (CAPA) plan per the recommendations.

Further work plan activities for FY14 are being discussed with USAID/Kazakhstan.

UZBEKISTAN

Background

According to WHO, Uzbekistan is among the 27 high MDR-TB burden countries in the world. Starting in 2015, the national government will assume greater responsibility for procurement of first-line TB medicines.

PQM began receiving funding from USAID for Uzbekistan in FY14. PQM's technical assistance will enhance the capacity of the local manufacturer to comply with international GMP and strengthen quality assurance systems of the country.

Key activities

Work plans are still under discussion. Possible activities include: assessment of the capacity of an ATB manufacturer and related technical assistance, strengthening quality assurance systems of the country (post-marketing surveillance of anti-TB medicines, registration, strengthening regional labs), initial assessment of the medicines QA/QC situation in the country.

Latin America and the Caribbean

AMAZON MALARIA INITIATIVE (AMI)

Background

AMI is an initiative whose primary role is to focus the USAID Latin American and the Caribbean (USAID/LAC) Bureau's financial assistance toward improving malaria control and decreasing national morbidity and mortality in LAC countries. Since its inception, AMI has provided assistance to six South American countries (Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname) and subsequently additional countries in Central America and the Caribbean were included. AMI is currently being implemented and coordinated by five international partners: The Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), Systems for Improved Access to Pharmaceuticals and Services (MSH/SIAPS), Links Media, and PQM. PQM's role in AMI is to strengthen country's QA/QC systems to ensure the quality of antimalarials throughout the supply chain.

Key Activities

PQM hosted two visiting scientists from the Suriname Drug Supply Company (BGVS) laboratory in for three weeks in November. The objective was to provide the visiting scientists with experience in QMS and hands-on analysis of malaria medicines utilizing HPLC and Karl Fisher analysis. Near the end of the training, the visiting scientists began developing a follow-up plan to ensure the knowledge obtained will be transferred to others in their lab to improve their overall capacity to test antimalarial medicines and strengthen the laboratory's QMS.

GUATEMALA

Background

PQM performed a two-country study requested and financed by USAID's Maternal and Child Health Latin American and the Caribbean (MCH-LAC) Bureau. The objective of the study, carried out in Guatemala and Peru in 2011, was to assess the quality of emergency obstetric and newborn medicines. The evaluation, performed in the Santa Rosa Health Area in Guatemala, uncovered several

quality issues and system deficiencies, including, (1) a 27% failure rate of the tested medicines; (2) inadequate storage conditions at central and peripheral facilities; (3) technical capability gaps at the Unidad de Medicamentos from the Laboratorio Nacional de Salud, Guatemala's Official Medicines Control Laboratory (OMCL); and (4) QC procedural and documentary deficiencies during procurement of medicines by the Ministerio de Salud Pública y Asistencia Social.

To address some of those issues, USAID/Guatemala has obligated funds for PQM since FY11. Using funds obligated in FY13, PQM will continue strengthening QA/QC systems in Guatemala by advancing some of the work addressed in previous years and expanding the scope of work.

Key Activities

Upgrade registration software (SIAMED) at the Dirección de Regulación y Control de Productos Farmacéuticos y Afines (DRCPFA)

The module for "renewal of registration without modifications" through the internet has been completed. In December 2013, selected manufacturers were invited to participate in a pilot to evaluate this module; however, manufacturers did not use the system because of the holiday season. After the pilot is completed, the official launch of this module will be announced to professional pharmacists associations.

Challenges

Changes in authority and delayed responses from official institutions continue to be major challenges for finalization of programmed activities in Guatemala.

Middle East

WEST BANK/GAZA

Background

Beginning in FY14, PQM will provide technical support for manufacturers in West Bank/Gaza to meet Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) certification, similar to the support being provided for manufacturers seeking WHO prequalification.

Key Activities

PQM has developed a concept paper containing possible strategic approaches for technical assistance; this has been forwarded to USAID for review. Activities will begin following USAID's decision and guidance.

Challenges

Regional political and economic instability, lack of regulations, and language barriers are some of the challenges. In addition, this is a new geographical region for PQM.