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PROMOTING THE QUALITY OF MEDICINES

Promoting the Quality of Medicines (PQM) Program

Highlights and Success Stories
April 1–June 30, 2015

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PQM discusses BA/BE studies at joint FDA/ASEAN workshop

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally.

Recommended Citation

PROJECT SUMMARY

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Agreement Officer's Technical Representative	Mr. Anthony Boni, Pharmaceutical Management Specialist Ms. Elisabeth Ludeman, Pharmaceutical Management Advisor
PQM Responsible Staff and Position	Mr. Jude I. Nwokike, Director
Quarterly Report Period	April 1–June 30, 2015

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ACRONYMS

AOR	Agreement Officer's Representative
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
BA/BE	Bioavailability/Bioequivalence
CHX	Chlorhexidine
DQI	Drug Quality and Information Program
FPP	Finished Pharmaceutical Products
GDF	Global Drug Fund
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPHF	Global Pharma Health Fund
HPLC	High Performance Liquid Chromatography
ISO	International Organization for Standardization
MCH	Maternal and Child Health
MOH	Ministry of Health
MQM	Medicines Quality Monitoring
MRA	Medicine Regulatory Agency
NMCP	National Malaria Control Program
NOMCoL	Network of Medicines Control Laboratories
NQCL	National Quality Control Laboratory
NTD	Neglected Tropical Diseases
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SCMs	Substandard and counterfeit medicines
SOP	Standard Operating Procedure
TA	Technical Assistance
TB	Tuberculosis
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	U. S. Pharmacopeial Convention
WHO	World Health Organization

Program Background and Framework

Since 1992, the U.S. Pharmacopeial Convention (USP) has worked cooperatively with the United States Agency for International Development (USAID) to help developing countries address critical issues related to poor quality medicines and their appropriate use. PQM serves as a primary mechanism to help ensure the quality, safety, and efficacy of medicines essential to USAID priority diseases, particularly malaria, HIV/AIDS, tuberculosis, and concerns related to maternal and child health. The PQM program is USAID's response to the growing development challenge posed worldwide by substandard and counterfeit medicines (SCMs). Their availability is increasingly recognized as a serious public health threat, especially in low- and middle-income countries. SCMs can cause treatment failure and adverse reactions, increasing morbidity and mortality, and they may contribute to antimicrobial resistance. They represent not only a waste of scarce resources but also a substantial risk to public health. They further risk undermining decades of health investments, including those made by USAID.

PQM's work is based on four strategic objectives:

Global Overview of Activities

Using a systems-based approach, PQM offers technical assistance (TA) in several arenas to achieve its strategic objectives. Many of these approaches are replicated globally, but tailored to fit the needs of individual countries or regions. These approaches include building the capacity of medicine regulatory authorities' (MRAs) national quality control laboratories (NQCLs) through hands-on training and technical assistance to improve laboratory standards, with one goal being to assist those labs to attain internationally recognized certifications, such as ISO accreditation and/or WHO prequalification.

PQM also helps NQCLs implement, or improve, post-marketing surveillance (PMS) programs. One aspect of PMS is field-based medicine quality monitoring (MQM), which involves laboratory staff collecting medicine samples at sentinel sites. These samples are screened in the field using Minilabs®, and subsequently, undergo confirmatory testing in the laboratory.

PQM's system-based approach also extends to medicines manufacturers. PQM experts in Good Manufacturing Practices (GMP) travel to manufacturing sites to help companies improve their GMP compliance and develop the dossiers they need to submit to WHO to become prequalified.

The following table provides highlights of PQM's accomplishments in these areas during Q3:

Area of Technical Assistance	Achievements for Q3
Quality Control (QC) trainings	12 training workshops held in 5 countries
Quality Management Systems (QMS)	20 labs in 13 countries assisted; USP/Ghana lab received ISO 9001 certification
Medicines Quality Monitoring (MQM)	136 active sentinel sites in 16 countries
Good Manufacturing Practices (GMP)	61 companies in 17 countries assisted

PQM Publications

In Q3, three articles co-authored by PQM staff were published in a special supplement to the *American Journal of Tropical Medicine and Hygiene (AJTMH*) that provided analyses of data collected through medicines quality monitoring programs in Africa, Southeast Asia, and Latin America. The supplement, "The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives," draws attention to 17 studies on the global proliferation and burden of ineffective, potentially toxic, substandard and falsified medicines.

USP Contributions

USP sponsored a laboratory analyst from the Indonesian national lab to participate in the Network of Official Medicines Control Laboratories (NOMCoL) meeting held in India. In addition, USP donated a Gas Chromatograph to Guinea Conakry's national lab and 20 copies of the USP-NF to labs and manufacturers in Indonesia.

Management Overview

The PQM Program Management Team meeting was held on June 15, 2015. As a first-of-its-kind meeting, it provided an opportunity for the new PQM Management Team to discuss how PQM would work together as a team, discuss new changes in the management of the program, and provide ideas for the strategic direction of the program. (See Annex 1 for organization chart.)

PQM staff met at USP headquarters on July 20-24, 2015, to develop FY16 work plans. The Work Planning and Implementation Lifecycle approach introduced during the meeting comprised the following:

1. Weeklong (No-fly Week) preplanning meetings dedicated to the new fiscal year's work plans;
2. Refection on implementation of past year's activities and lessons learned that can be incorporated into the next fiscal year's work plans;
3. Thorough design, development, review, and internal management approval of proposed work plans;
4. Planning for timely submission of work plans to meet the requirement of the PQM cooperative agreement;
5. Establishing routine review of work plan implementation through monthly/bimonthly portfolio review meetings;
6. Capture of work plan implementation results, to be discussed during quarterly review meetings;
7. Annual review of implementation and consolidation of lessons learned.

The PQM program will continue to monitor the impact of the President's Emergency Plan for AIDS Relief (PEPFAR) Core/near-Core/non-Core designations on the program. A value proposal on the PQM program in product development and pharmaceutical quality of HIV/AIDS medicines is currently being developed.

During the period under review, PQM was informed that several in-country counterparts had expressed interest in receiving the technical assistance and support from the program. PQM will communicate these discussions to the Agreement Officer's Representative (AOR) accordingly. To further strengthen management of the program, the organizational structure of the program is revised to better align the work of the PQM program and improve support to program implementation and to the field offices. The staffing structure of the country offices is also being reviewed. In an effort to achieve operational excellence at the country office level, PQM is developing a field office manual that describes how to establish a field office and make them operational.

Highlights for Q3: April 1 – June 30, 2015

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 attends selected international meetings and participates in the design of proposed activities relating to medicine quality issues. PQM also produces up-to-date information and provides technical leadership 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 is developing a field-based quality control tool with increased accuracy, sensitivity, and reliability.

Highlights

Three articles co-authored by PQM staff and published in a special supplement to the *American Journal of Tropical Medicine and Hygiene (AJTMH*) provide analyses of data collected through medicines quality monitoring programs in Africa, Southeast Asia, and Latin America. The supplement, "The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives," draws attention to 17 studies on the global proliferation and burden of ineffective, potentially toxic, substandard and falsified medicines.

In a live webinar at the University of North Carolina-Chapel Hill Gillings School of Global Public Health that launched the supplement, the pervasiveness of fake and substandard medicines, particularly in developing countries, was highlighted, using statistics from studies included in the supplement and techniques available for detecting falsified products.

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.

Highlights

PQM continued to work closely with PMI to refine the FY15 Core Malaria work plan document, which has been revised and resubmitted to PMI for approval.

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 diarrheal disease, especially for 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).

A component of the USAID Ending Preventable Child and Maternal Deaths (EPCMD) initiative is the scale up of proven solutions in newborn health. Chlorhexidine digluconate 7.1% — an effective and inexpensive WHO-recommended treatment for umbilical cord infections in neonates for use in the first week of life — is one of those proven solutions. EPCMD overlaps with strategic objective 1 of the Every Newborn Action Plan (ENAP) to strengthen and invest in maternal and newborn care during labor, birth, and first day and first week of life. By providing manufacturers technical assistance to produce quality 7.1% chlorhexidine digluconate to meet global demand, PQM is effectively contributing to the achievement of the goals of EPCMD and ENAP.

Highlights

PQM performed a GMP assessment of the Advanced Chemical Industries Limited (ACI) to produce chlorhexidine according to internationally recognized GMP standards. With support from PQM, ACI has completed implementation of more than 90% of the recommendations from the initial visit. By September 2015, ACI will have collected additional data for PQM to complete its assessment of the company's capabilities to manufacture chlorhexidine solution.

The PQM Core MCH and TB teams, in collaboration with the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program in Bangladesh, conducted a workshop on MCH and TB medicine quality. Approximately 45 participants from the regulatory authority, national quality control laboratory, manufacturing sector, and other NGOs participated in the workshop that included medicine quality case studies and MCH and TB medicine manufacturing considerations. The workshop was the first held by PQM in Bangladesh, a country that was strategically selected for two reasons: 1) Bangladesh is one of the ten countries with the highest number of newborn deaths (76,800 in 2013), of which 13% are due to neonatal sepsis; and 2) the country has a fast growing pharmaceutical manufacturing sector.

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.

WHO’s Third Invitation for Expression of Interest (EOI) focused 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 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.

In its 4th EOI to manufacturers of products for the treatment of NTDs, WHO added Ivermectin 3 mg tablet for product evaluation to the WHO PQ program, which is an opportunity for the expansion of the NTD product list.

Highlights

The Biopharmaceutics Classification System (BCS) characterization study for praziquantel (PQZ) drug substance aimed at four objectives (characterize, isolate, identify, conduct solubility and permeability study) to improve the knowledge and the quality of the drug substance is currently ongoing. The study will continue to explore the possible alternative route of synthesis to improve the drug substance and drug product palatability and reduce tablet size. The study will be completed by the end of August 2015.

TUBERCULOSIS (TB)

Background

PQM provides support to the Global Drug Facility (GDF) 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 and supports GDF in its efforts to increase the availability of quality-assured second-line medicines at an affordable price. To expedite the process of prequalification with WHO, and thereby expand the pool of viable manufacturers, PQM provides technical assistance to interested companies. PQM supports manufacturers to prepare product dossiers for submission to the WHO PQ program and guides companies to comply with GMP principles and guidelines. Since 2012, PQM has supported prequalification of six ATB active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP).

PQM exhibited on MQM and the GPHF Minilab at a TB World Day event

Highlights

During the period under review, PQM supported one company to submit dossiers for Kanamycin 0.5 g and Kanamycin 1.0 g FPPs to the WHO PQ Programme which have been accepted for review. PQM will continue to support manufacturers to address the global need for kanamycin as a critical medicine for the management of TB.

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.

Highlights

Note: In May, the Mission and MOH met to discuss PQM's proposed activities, and Minilab® training is now being planned for Q4.

BENIN

Background

In 2014, USAID/Benin determined that more support is required from PQM to assist the NQCL, National Malaria Control Program (NMCP), and Direction de la Pharmacie, du Médicament et des Explorations Diagnostiques (Department of Pharmacy, Medicines, and Diagnostics Explorations (DPMED)) speed up procedures for testing artemisinin-based combination therapies (ACTs) procured by PMI as well as increased ACT testing in the markets and private health facilities in the Cotonou area.

PQM conducted a consultation visit to Benin to gather updated information on the medicine QA situation, identify gaps, and propose priority activities. Based on the outcome of the visit and the level of funding, PQM proposes to support pre- and post-market quality control of antimalarial medicines by strengthening the capacity of NQCL and DPMED. The NMCP will benefit from the outcomes of these interventions.

Highlights

PQM trained 10 lab staff on sampling and screening antimalarial medicines. Following the training, the lab staff collected 172 antimalarial samples from public and private sectors, as well as the informal market in Cotonou. PQM assisted the lab in screening 65 artemether-lumefantrine samples; testing of the remaining samples is underway.

BURKINA FASO

Background

PQM was selected by USAID/Burkina Faso to strengthen the capacities of the National Drug Authority (DGPML), the National Quality Control Laboratory (LNSP), and other major health programs with the main goal of improving QA/QC systems in Burkina Faso.

Highlights

A workplan is being developed in consultation with various stakeholders.

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 (EFMHACA). 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. In FY15, PQM also received funding for Maternal and Child Health activities, to carry out post-marketing surveillance, enhance the registration processes of MCH medicines, and support MCH medicines manufacturers to improve GMP compliance and enable them to manufacture new children's formulations.

Highlights

PQM has supported EFMHACA to improve its regulatory functions by building staff capacity in basic dossier assessment and bioequivalence (BE) data assessment. Showing initiative in taking responsibility for its own institutional capacity development, EFMHACA financed a dossier assessment training that PQM conducted in Q3.

PQM provided technical support to develop science-based tools for EFMHACA, for instance, strategy for enhanced market authorization, inspection manual, and guidelines on biowaivers, variation, good distribution practices, good storage practices, and product recalls.

In the QC area, with the aim of improving the lab's quality management systems, PQM has supported EFMHACA's participation in proficiency testing (PT) programs, and the lab has passed all PTs. In addition, hands-on training on basic analytical test methods was provided at four EFMHACA branch laboratories, and two EFMHACA staff members were sent to India for training on microbiological test methods. Supervisory visits were also carried at two branch labs, and sample collection from all sentinel sites is complete.

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 NQCL toward the goal of ISO 17025 accreditation and WHO prequalification.

Highlights

In May, 2015, the FDA Ghana physico-chemical lab was audited by ANAB with minor findings. With the assistance of PQM, the findings were promptly corrected, and in June ANAB granted the FDA lab maintenance of its accreditation status. FDA Ghana also received ISO 9001:2008 certification in June.

FDA Ghana promptly takes regulatory actions against suppliers of substandard or counterfeit medicines in the West African region. As a result of the antimalarial post-marketing surveillance conducted by PQM, FDA Ghana issued several regulatory actions, including, but not limited to, blacklisting and fining companies, seizing products, and recalling products from the market at the expense of the manufacturer/vendor.

facilitated by FDA Ghana for local manufacturers—have included stability studies, process validation, batch manufacturing records development, specifications for APIs and FPPs, analytical method validation, labelling and variation filing, container closure system requirements, and analytical method validation.

GUINEA CONAKRY

Background

PQM was selected to provide technical, strategic, and operational assistance to strengthen medicines quality assurance in Guinea. In January 2014, PQM conducted a rapid assessment of the QA/QC capabilities of the country and met with key stakeholders involved in the regulation, control, management, and distribution of medicines. The outcomes of the QA assessment revealed the immediate need to begin introducing initiatives in support of strengthening the capacity of the Laboratoire National de Contrôle de la Qualité des Médicaments (LNQCM) and the Direction Nationale de la Pharmacie et des Laboratoires (DNPL).

Highlights

Though still impacted by the Ebola crisis, technical capacity of the lab was enhanced by USP's donation of a Gas Chromatograph to LNQCM.

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.

Highlights

In April, NQCL received accreditation from the South African National Accreditation System (SANAS) for five pharmaceutical testing

methods—HPLC, ultraviolet spectroscopy, Karl Fischer titration, pH, and loss on drying—assuring that the lab's quality management system, administration, and technical operations are functioning at the highest internationally recognized levels.

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.

Highlights

Five stakeholders meetings were held at five sites to promote MQM activities using the newly developed protocol and, with support from the in-country consultant and PQM HQ, MQM for antimalarials is ongoing. The LMHRA has taken at least four regulatory actions based on MQM findings during this quarter. In addition, the LMHRA QC lab scored high in inter-laboratory testing.

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 to the National Malaria Control Program.

Highlights

During this quarter PQM commenced of the verification and confirmation testing, a dissemination workshop is planned for August 5.

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).

Highlights

As a result of country elections, a number of high level staff changes occurred at the Ministry of Health, including Ms. Tania Sitoie, the Head of the Pharmaceutical Department (PD). PQM and USAID/Mozambique staff met briefly with Ms. Sitoie at the MRA facility and learned from her a bit about the department's plans to reinvigorate the regulatory agency.

Additionally, PQM conducted technical trainings on standard operating procedures, high performance (HPLC) analysis, and data processing, which enables the lab to test medicines found during MQM and confirm any suspected of being substandard or counterfeit. In fact, during the training, analysts confirmed that one lamivudine 150 mg-zidovudine 300 mg tablet sample failed assay tests according to the current USP monograph.

NIGERIA

Background

In 2012, USAID/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). USAID/Nigeria also 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.

Highlights

The PQM-Nigeria office is now operational. The Chief of Party (COP) and support staff began work June 1, and the official office opening is scheduled for Q4.

Forty staff of the Registration and Regulatory Affairs Directorate received training in advanced dossier evaluations, and 30 staff of the Drug Evaluation and Research Directorate received training in Advanced GMP facility inspections.

PQM provided technical assistance to one manufacturer to support local manufacturing of oral rehydration salts. USAID is in discussions with the manufacturer regarding possible local procurement.

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 antiretroviral, anti-tuberculosis, 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 with international quality management system (QMS) standards.

Highlights

N/A

Asia

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, 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.

Highlights

During Q3, PQM support focused on engaging the countries (Burma, Cambodia, Laos, and Thailand) to collect antimalarial samples in border areas. A total of 88 samples were collected from the four countries. Samples will be analyzed at the Chulalongkorn University Pharmaceutical Technology Services Center Lab in Thailand. Some key observations:

The road to sample collection sites at border areas

Gathering information from a villager prior to sampling

- Artesunate oral monotherapy tablets are still used in Thailand public health facilities and are available in the private market in Burma, which can be bought by all who cross the border without any medical prescription.
- Antimalarials combined with other medicines (such as vitamins, antipyretics, antibiotics, and others) were sold at the discretion of the sellers.
- Antimalarials were sold in amounts according to what buyers could afford, not necessarily the full recommended course/regimen.

Borderer crossing between Laos and Cambodia

Overt sample collection at a health center in Steung Treng, Cambodia

Sample collection at a private clinic in Steung Treng province, Cambodia where very poor dispensing, storage, and treatment practices were observed by the joint sampling and inspecting teams

Overt sample collection at a health center near Burma border, in Kanchanaburi province of Thailand

In addition to taking part in the sampling, PQM's role was to provide supervision and monitor the medicines quality monitoring activities in specific provincial sites in these countries. The team also provided technical guidance to country partners to improve their sampling methodology and techniques as well as their post-marketing surveillance practices.

Oral artemisinin monotherapy is still in use in the public sector in Thailand. This product is manufactured by Guilin Pharm Co. Ltd and repackaged by Thailand Atlantic Labs Co. Ltd; purchased and distributed by the National Malaria Program

Oral artemisinin monotherapy is available in the private sector in Burma. Shown is a product collected near the Burma/Thai border produced by Mediplantex in Vietnam and distributed by Liberty Group Trading Ltd, a local distributor in Burma

In addition to the MQM activities, PQM developed and submitted a regional strategy entitled "PQM Five-Year Strategy (2016-2020): Assuring Medicines Quality in Response to Artemisinin-Resistant Malaria in the Greater Mekong Subregion" for USAID/RDMA and the PMI MOP team's consideration.

BURMA

Background

The presence of poor quality antimalarials are among the many drivers contributing to antimalarial drug resistance in Burma, and the Mekong region in general. The PQM program in Burma provides a unique set of services to stakeholders that manufacture, test, and regulate medicines with the goal of reducing both the prevalence of poor quality medicines and the risks of spreading resistance in the region.

PQM provides technical assistance to the Department of Food and Drug (DFDA) to address medicine quality gaps in the country to increase the supply of quality-assured medicines and increase the capacity of the national medicine regulatory system. This includes providing tailored support to the regulatory agency and national laboratory as well as engaging key players. PQM also aims to raise public awareness of the issues of poor quality medicines and streamline the DFDA's efforts in tackling poor quality medicines, in collaboration with collaborating partners.

Highlights

In a national effort to secure areas at high-risk of antimalarial resistance, PQM staff and local partners went in teams to 6 sentinel sites to collect antimalarials from outlets and map risky vendors. The activity took the teams over a month; over 150 antimalarials were collected and will be tested for quality.

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).

PQM has three objectives in Cambodia: 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.

Highlights

During the quarter under review, the Cambodia Department of Drugs and Food (DDF) was able to collect 30 samples. There were 7 failed samples including 5 samples of Prednisolone 5mg and 2 samples of Dexamethasone 0.5mg. In June, the Secretariat of the Inter-Ministerial Committee (IMC) met to evaluate these 7 failed samples and decided to remove the registration number of DexLife 0.5 mg (Dexamethasone 0.5 mg) manufactured by Eurolife-India and re-test the remaining 6 samples.

In order to strengthen cross-border collaborations in the Greater Mekong Sub-region (GMS), Cambodian and Lao drug inspectors conducted joint drug inspection on antimalarial samples collected in hospitals/health centers in Steung Treng (Cambodia) and Veunkham and Nakrassin (Laos) in April 2015.

In collaboration with the Department of Hospitals, DDF organized a Technical Meeting in June 2015 to discuss the elimination of counterfeit medicines and illegal health services. There were 93 participants from 25 provincial health departments.

DDF completed 14 trainings for pharmacists and drug sellers from 18 provinces, focusing on Good Pharmacy Practices (GPP) with an emphasis on maintaining the quality of medicines throughout acquisition, storage, dispensing and handling. In total, 945 participants were trained on GPP from July 2014 to June 2015. DDF created a GPP certificate to be provided to any pharmacy that complies with Cambodia's GPP Guidelines. Meanwhile, DDF also produced a poster to advise people to buy medicine from pharmacies with this certification.

Following the QMS assessment performed in December 2014, a PQM QMS expert conducted training on SOP writing for the NHQC management team in April 2015. As a result, 10 SOPs—including the Quality Manual—have been completed. An additional 20 SOPs are being drafted.

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 NA-DFC 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.

PQM received new funding from PEPFAR to scale up treatment of HIV and STIs in Indonesia. PQM will begin engaging key partners, including the National AIDS Control Program at the Ministry of Health, international NGOs such as the Clinton Health Access Initiative, JSI, WHO, UNAIDS, and others on a national and local level to strengthen the quality assurance of antiretrovirals, STI medicines, and medicines used in the treatment of Opportunistic Infections associated with HIV infection. In addition, PQM will help develop and implement projects and provide technical input into the development of grant proposals under the New Funding Mechanism of the Global Fund, especially with a focus on HIV and TB joint proposals. PQM will also work with the primary manufacturer and importer of antiretrovirals in Indonesia, Kimia Farma, which is producing the majority of these medicines under a compulsory license granted under a Presidential Decree as part of the TRIPS agreement.

Highlights

Support to manufacturers and WHO PQ and international workshops

PQM supported three BPOM officers from the BE evaluation section to attend BE training in the Philippines. In addition, PQM supported representatives from each of the Contract Research Organizations receiving technical assistance toward successful recognition in the WHO Public Inspection Report (WHOPIR).

PQM supported two BPOM GMP registration officers to participate in the 7th Annual WHO Medicines Quality Assessment Training in May. This training was aimed specifically at staff that is responsible for assessing the quality part of generic dossiers submitted for registration in accordance with WHO recommendations. The training will help to build capacity of inspectors by providing first-hand knowledge of WHO requirements as well as enable the participants to advise peers on the job. A follow up knowledge dissemination seminar was held after the trainees returned to BPOM.

PQM supported one staff from BPOM (responsible for reviewing BE study data for registration purposes) to attend the international BA/BE consultation in Geneva in June/July. Dissemination and knowledge sharing from this event was subsequently arranged and supported by PQM for other colleagues within BPOM under Deputy 1.

Support to GLP and QC activities
A weeklong on-site assessment and training was conducted at the PPOMN official National Reference Standards laboratory in Jakarta by senior scientists from PQM. Stemming from the initial assessment and training, and after identifying priority areas in need of strengthening, a two-week follow-up QC training will be conducted in August.

PQM conducted a national advanced HPLC training at the PTBB laboratory for partcipants from 20 provincial BPOM QC laboratories, using nevirapine as the case study medicine sample.

PQM facilitated a national forum, for BPOM laboratory supervisors from 30 provincial BPOM institutes, at PPOMN. PQM also facilitated a workshop for 120 participants from all BPOM institutes nationwide on standardizing and harmonizing a Method Verification and Validation SOP for BPOM in accordance with international standards.

A regional workshop on medicines sampling from public facilities was conducted in Sorong, West Papua province in June. This workshop was attended by Maluku, North Sulawesi, Papua, NTT, and West Papua provinces represented by both the Ministry of Health and the BPOM provincial institutions. Also in attendance were national directors from BPOM and the Head of the Provincial Health Office of West Papua. The workshop was brought MOH and BPOM together to discuss challenges in sampling and testing medicines from government-provided stocks, especially from the provincial and district warehouses. This was an opportunity to learn methodologies for sampling and PMS, which is not currently implemented via the national post-marketing surveillance system employed by BPOM.

A two-week GLP and basic and compendial testing training was conducted in the two Papuan provinces of Balai POM Manokwari and Balai Besar POM in Jayapura. During those weeks, PQM assessed the QC labs and conducted on-site training on GLP, USP 101, Karl Fischer Titration, LOD, weights and balances, and HPLC.

PQM facilitated, and provided a module for, a national Training of Trainers (TOT) on ARV Care, Support, and Treatment in Jakarta aimed at providing clinicians and other health care providers with information on assessing medicines quality using basic visual and physical inspection of medicines and familiarizing participants with concepts related to medicines quality.

Three analysts (one each from the PTBB national QC lab in Jakarta, the Balai Besar POM Jakarta lab, and the Balai POM Manokwari of West Papua) participated in the regional Asia-Pacific Network of Official Medicines Control Laboratories (NOMCoL) meeting at USP India in Hyderabad.

Support for QMS and system improvement
PQM supervised and facilitated the completion and release of 42 SOPs (towards a goal of 55 SOPs) for the PTBB national QC laboratory and facilitated the completion of the draft PTBB Quality Manual, which was subsequently approved by the Head of PPOMN.

Increased PQM Country Office operations and management
PQM recruited two new staff for the Jakarta Office: an Operations Manager and a Senior Project Coordinator. PQM is in the process of recruiting a Finance Officer and a Procurement & Logistics Assistant. Existing staff were converted to official USP employees starting from July 1.

PHILIPPINES

Background
PQM has been actively providing technical and professional assistance to the Philippines Food and Drug Administration (FDA) to enhance its regulatory capacity in evaluation and registration of pharmaceutical products through the introduction and build-up of internationally accepted quality

standards, guidance, processes and procedures. Also providing technical assistance to the Department of Health (DOH) – National Center for Pharmaceutical Access and Management (NCPAM), National Center for Disease Prevention and Control (NCPDC) – National Tuberculosis Program (NTP), selected Local Government Units (LGUs) and Regional Offices (ROs) in an effort to strengthen medicine's 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 in the market of the Philippines, and local pharmaceutical manufacturers towards WHO Pre-Qualification (WHO PQ) program.

Highlights

On July 1, the PQM/Philippines field office was officially established. The office space is designed for 5 staff: COP, Deputy COP, two technical advisors (with expertise in QA/QC), and an administrative staff.

Joined by Philippines FDA and Association of Southeast Asian Nations (ASEAN), PQM convened a training workshop on bioavailability/bioequivalence (BA/BE) studies in Manila in May. The workshop was attended by around forty participants representing the Indonesia, Vietnam, Thailand and Malaysia, as well as the Philippines. The training was organized to benefit ASEAN's Pharmaceutical Harmonization Initiative through providing the participants with updates on BA/BE guidelines, tools to design their own studies, and techniques for method validation.

In June, after several meetings with USAID/Philippines on how PQM's MQM data can be made more useful to the national TB program and others, PQM created a database that tracks the number of TB medicines registered by the Philippines FDA and how many of them have been tested using the Minilab® and/or by compendial analysis. One can also use the database to check if the medicine collected was falsified or counterfeit. The database has been presented to USAID/Philippines for comments and suggestions.

In June, the PQM team attended the Annual Gender Action Planning Workshop at the U.S. Embassy, Manila. The purpose of this workshop was to help implementing partners gauge the gender responsiveness of their projects and identify strategies to prepare, update, and report on Gender Action Plans. A portion of the workshop was devoted to an orientation on disability and how that can be related to Gender Action Planning.

VIETNAM

Background

PQM has developed partnerships with key stakeholders including, the National Institute for Malariology, Parasitology, and Entomology (NIMPE), the National Institute for Drug Quality Control (NIDQC), the Drug Administration of Vietnam (DAV), and WHO-Vietnam. PQM has established nine sentinel sites for medicines quality monitoring (MQM), with three additional sites using leveraged funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). During FY15, PQM is providing technical

assistance under three main objectives: i) Deliver technical assistance and capacity strengthening support for expanding operations and impact of National Quality Control Laboratories; specifically, for HCMC IDQC towards WHO Prequalification; ii) Provide technical assistance and engagement on local methadone production and procurement to support the government to reach their national treatment targets, and iii) Providing technical assistance for integrated delivery of a quality monitoring reporting system in recording and responding to adverse events.

Highlights
As PEPFAR reduces funding, developing a local manufacturing sector that produces quality-assured ARVs and methadone will be crucial . In July, PQM collaborted with the Vietnam Pharmaceutical Companies Association to hold the first ever Good Manufacturing Practices training in the country. The workshop was attended by over 30 local manufacturers and 60 industry leaders in Vietnam.

PQM, in collaboration with NIDQC, held an ARV testing workshop for analysts from 8 provincial drug quality control centers and the IDQC. Trainees also were trained in Good Documentation Practices and other laboratory skills.

PQM provided technical assistance to the Hanoi Center for HIV/AIDs Control (Hanoi PAC) to develop specifications for the largest national bid for methadone syrup. PQM provided input on five potential methadone manufacturers and legal narcotic distributors and also shared with Hanoi PAC some of the experience gained from Ho Chi Minh methadone procurement. Hanoi PAC was successful with its bid, at a value of 9.5 bil VND (430,000 USD) to procure 13.812 litters of methadone syrup 10mg/ml.

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.

Highlights
N/A

UZBEKISTAN

Background
According to WHO, Uzbekistan is among the 27 high MDR-TB burden countries. 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.

Highlights
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.

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 QA/QC systems to ensure the quality of antimalarials throughout the supply chain. During the few years, PQM's emphasis in LAC has been on sustainability, firstly through MRA institutionalization of the Three-level Approach for MQM activities, and secondly, through exploring sustainable mechanisms to facilitate south-south collaborations, in order to utilize the extensive human and technical resources existing in the region.

Highlights
The MRAs in Ecuador and Peru took total ownership of the "three-level approach" developed and implemented initially by PQM. Both countries established programs (for 6 months in Ecuador and bi-annually in Peru) that include field screening tests. The MRA in Ecuador (ARCSA) included the screening tests approach (Level 2) in their guidelines for post-marketing medicines assessment.

A Concept Note from the South-South Collaboration Sustainability Workshop held in 2014 was developed and delivered to participating LAC country stakeholders, for subsequent submission to their respective Ministries of Health. The Concept Note addresses OMCL and MRA capabilities and needs and includes recommendations for the implementation of sustainable mechanisms for South-South collaboration. Ministerial support at the country level will be essential to move this initiative forward.

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 (Guatemalan MoH)

To address some of those issues, USAID/Guatemala obligated funds for PQM from FY11 to FY14. Using remaining FY14 funds, PQM activities in FY15 will be to support the expansion of the OMCL's

ISO 17025 accreditation, from a product-based (acetaminophen) to a method-based accreditation. This expansion will require transferring the accreditation form the current grantor, the Guatemalan National Accreditation Body, to ANAB (ex-ACLASS), an international accreditation body.

Highlights
The Guatemala OMCL submitted all necessary documentation for the transfer of its current product-based (acetaminophen) accreditation to a method-based ISO 17025 accreditation. The current product-based accreditation had been granted by the Guatemalan Accreditation Organization, while the method-based accreditation, if successful, will be granted by ANAB, an internationally recognized accreditation body. If accredited, the lab will be eligible to provide services to the Global Fund in the four methodologies included in its scope.

Students who provided field support in 2014 in the implementation of the three-level approach for MQM in Huehuetenango were able to base their theses on their experience and attain their degrees in Pharmaceutical Chemistry. This is the first time that this type of collaboration between academia and the MOH was practiced. By utilizing technically-prepared students, this collaboration illustrates a potentially sustainable mechanism to address limitations in human resources for performing MQM in decentralized areas and also sets a precedent for students to utilize this type of experience to fulfill the academic requirements for graduation.

Middle East

WEST BANK and GAZA

Background
Beginning in FY14, PQM will provide technical support for manufacturers in West Bank/Gaza to meet Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standards.

Highlights
PQM staff conducted a rapid assessment of QA/QC capacity in Palestine and met with four medicines manufacturers to determine their goals for advancing their GMP status. The West Bank companies—Beit Jala Pharmaceutical Company, Birzeit Pharmaceutical Company, Pharmacare PLC, and Jerusalem Pharmaceutical Company Ltd—are interested in expanding their sales to a broader international market and, to do so, need to meet international standards. The PQM team visited the manufacturing facilities and collected critical documentation they will review to prepare the companies for full assessment to reach PIC/S standards. PQM will also provide technical assistance to strengthen the medicines regulatory authority and assist the country's Central Public Health Laboratory to pursue ISO 17025 accreditation or WHO Prequalification.

PAKISTAN

Background
USAID and other international agencies, including UNICEF and WHO, are supporting the Pakistani Government to reduce the morbidity and mortality of newborn infants caused by umbilical cord

infections. PQM will work alongside other implementing partners to help USAID introduce quality-assured chlorhexidine (CHX) in Pakistan. PQM is tasked with providing TA to potential manufacturers of CHX gel in improving their manufacturing quality standards. In addition, PQM will help strengthen the Drug Regulatory Authority of Pakistan's (DRAP) capacity, improving medicines registration processes and the standards of medicines quality control laboratories working under DRAP.

Highlights

PQM staff completed an gap assessment visit to Islamabad, Lahore, and Karachi and met with partners (USAID Mission, WHO, JSI-Deliver, and UNICEF) and stakeholders (DRAP officials and division chiefs, including registration, inspection, and QC lab, as well as QC lab directors at federal and provincial levels and selected manufacturing facilities (Remington, Getz, Friends, and Atco).

A draft assessment report has been submitted to DRAP, WHO, USAID, UNICEF, and JSI-Deliver for comments. The final revised report will be circulated in Q4.

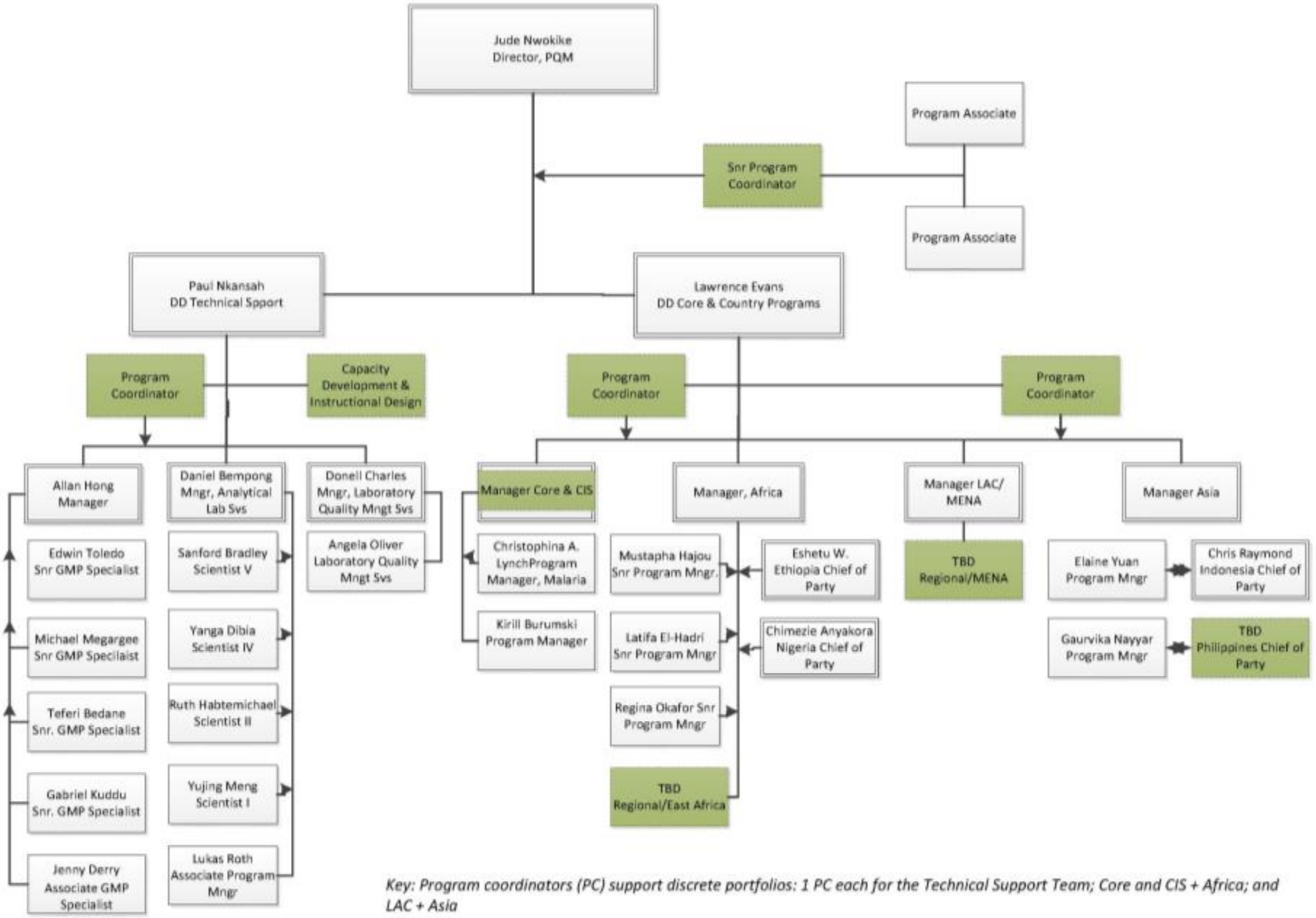
A draft FY15 work plan has been completed and submitted to USAID/Pakistan and DRAP for final review.

A country consultant, based in Islamabad, with expertise in product quality and safety evaluation as well as program management and coordination, has been successfully recruited. An additional technical consultant with GMP expertise is in the final stages of the hiring process.

Conclusion

During the third quarter of FY15, PQM was active in 30 countries, working with 24 MRAs and NQCLs, as well as academic institutions, other nongovernmental organizations, and a variety of stakeholders. Program activities cover all aspects of medicine quality – from manufacture and packaging to distribution to proper storage at a vendor's facilities – with the aim of increasing the capacity of a country's regulatory agencies and enabling improved functions to become institutionalized as permanent elements of quality assurance and quality control. PQM efforts result in stronger regulatory systems that have the ability to review and approve products for timely access to treatment, test medicines sampled from the market to detect falsified and substandard products, and enforce controls to ensure the country's medicines are protected throughout the supply chain.

ANNEX 1



Key: Program coordinators (PC) support discrete portfolios: 1 PC each for the Technical Support Team; Core and CIS + Africa; and LAC + Asia
Shaded positions are vacant.