

# Promoting the Quality of Medicines (PQM) Program

FY 2016 Fourth Quarter Report  
July 1–September 30, 2016

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**About the Promoting the Quality of Medicines Program (PQM)**

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The Promoting the Quality of Medicines (PQM) program is a Cooperative Agreement between the United States Agency for International Development (USAID) and the United States Pharmacopeial Convention (USP). Since 1992, USP has worked cooperatively with USAID to help developing countries address critical pharmaceutical challenges. The earliest program, the Rational Pharmaceutical Management Project, implemented and evaluated country-specific drug information resource programs in selected developing countries. Subsequently, the Drug Quality and Information program focused on medicines quality control and quality assurance systems. The PQM program (2009–2019) provides technical assistance to strengthen medicines regulatory authorities and quality assurance systems and supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

As of September 2016, USAID supports PQM's work in 20 countries, two Regional Missions, one Cross Bureau program, and four core health programs.

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# Executive Summary

The Promoting the Quality of Medicines (PQM) program provides technical assistance in partnering countries to strengthen medicines regulatory authorities (MRAs) and quality assurance systems in four Intermediate Result areas. It supports the manufacture of quality-assured priority essential medicines for malaria; HIV/AIDS; tuberculosis; neglected tropical diseases; and maternal, newborn, and child health (MNCH). The United States Agency for International Development supports PQM's work in 20 countries and in two regional programs in Asia and Latin America. This report summarizes results achieved during the fourth quarter of FY16, from July 1 to September 30, 2016.

The first Intermediate Result area of the PQM program aims to strengthen national regulatory systems. In pursuit of this goal, PQM provides technical assistance to strengthen pharmaceutical policies, legislations, and regulations to address critical quality assurance topics and enhance the ability of local MRAs to execute policy. Major accomplishments under the first result area include the development of national law and strategic plans, improvement of the effectiveness of medicines registration systems, and contributions toward university-level pharmaceutical curriculum. During this quarter, a review of Mozambique's pharmaceutical law resulted in recommendations for new regulations to strengthen the capacity for medicines quality assurance. PQM conducted a regulatory quality assurance (QA) and quality control (QC) systems gap assessment and provided advocacy for the incorporation of quality assurance priorities into the multi-year national-level strategic plans in Bangladesh, which served as a foundational document for the National Health Sector Plan (2016–2020). In the Philippines, PQM developed terms of reference for a consultancy to propose QA/QC components within the development of the regulatory authority's strategic plan (2017–2021). Finally, PQM advanced its commitment to improve the regulatory workforce in Nigeria and Ethiopia. PQM worked alongside a committee to incorporate quality assurance topics into the pharmacy degree curriculum in Nigeria; the committee submitted the draft Pharmaceutical Quality Assurance curriculum to the National Universities Commission for ratification. In Ethiopia, PQM supported the curriculum for the Masters of Science degree in Medicine Regulatory Affairs at the Addis Ababa University, which admitted the first cohort of students during the quarter.

The availability of quality medicines is PQM's second Intermediate Result area and encompasses broad technical assistance for the manufacturing of quality-assured priority essential medicines. PQM provides support to manufacturers to comply with Good Manufacturing Practices standards necessary for the supply of quality medicines. Significant accomplishments from the quarter include extensive technical assistance to manufacturers to pursue World Health Organization (WHO) Prequalification or stringent regulatory authority approval for six priority tuberculosis (TB) medicines, four essential MNCH medicines, and two neglected tropical disease medicines. During this quarter, technical assistance resulted in WHO Prequalification of the active pharmaceutical ingredient for the TB drug Rifampicin and support to 51 manufacturers of priority medicines.

Improving the capacity to detect poor-quality medical products is PQM's third Intermediate Result area. In collaboration with a country's MRA and national health program, medicines testing is conducted at a variety of sites in an effort to continuously monitor the quality of medicines present in a country. Field staff are trained in sampling and testing methods while national laboratories handle samples requiring advanced confirmatory testing. During the quarter, samples were collected and tested in the majority of PQM supported countries. In Ethiopia's medical device laboratory, an alarmingly high number of condoms failed quality testing (39/60 batches). The manufacturer has accepted the results and all of the 141 total imported batches, worth approximately \$2 million, have been banned from distribution. In Indonesia, PQM supported the revision of national regulation, known as 'Menkes 33/2016,' to ensure coordination between the ministry of health and regulatory authority on results stemming from post-marketing surveillance.

The fourth Intermediate Result area is global advocacy and technical leadership to enable the use of product quality information for decision making. Results this quarter highlight PQM's contributions to advocacy efforts to eradicate falsified and substandard products. PQM participated in various workshops and meetings on topics relating to TB eradication, sharing information on detection tools, developing competency for pharmacists, and supporting regional medicines surveillance. In the area of enforcement, PQM Indonesia's monitoring efforts resulted in a Food and Drug Agency advisory notice to healthcare professionals and the general public regarding poor-quality Isoniazid TB products. PQM also documented new reports on global incidents of poor-quality medicines; results were shared on the PQM webpage.

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# Acronyms

API	Active pharmaceutical ingredient
ARV	Antiretroviral
BBPOM	Balai Besar Pengawas Obat dan Makanan (Provincial QC Laboratory, Indonesia)
BPOM	Indonesian National Agency of Drug and Food Control
CAPA	Corrective and preventive action
CDL	Central Drug Laboratory (Pakistan)
CPHL	Central Public Health Laboratory (West Bank/Gaza)
DFDA	Department of Food and Drug Administration (Burma)
DGDA	Directorate General of Drug Administration (Bangladesh)
DNME	Divisão Nacional de Medicamentos e Equipamentos (Angola)
DNPL	Direction Nationale de la Pharmacie et des Laboratoires (Guinea)
DRAP	Drug Regulatory Authority of Pakistan
EAC	East African Community
EFMHACA	Ethiopian Food, Medicine and HealthCare Administration and Control Authority
FDA	Food and Drug Administration or Authority
FDC	Fixed-dose combination
FDQCC	Food and Drug Quality Control Center (Laos)
FMOH	Federal Ministry of Health (Nigeria)
FPP	Finished pharmaceutical product
GDP	Good Documentation Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HPLC	High-performance liquid chromatography
HVAC	Heating, ventilation, and air-conditioning
IEC	International Electrotechnical Commission
IR	Intermediate Result
ISO	International Standardization Organization
LMHRA	Liberian Medicines and Health Products Regulatory Authority
LNCM	Laboratoire National de Contrôle des Médicaments (Senegal)
LNCQ	Laboratoire National de Contrôle Qualité (Benin)
LNCQM	National Quality Control Laboratory (Mozambique)
LNS	Laboratoire National de la Santé (Mali)
LNSP	Laboratoire National de Santé Publique (Burkina Faso)
MNCH	Maternal, newborn, and child health
MOH	Ministry of Health
MQDB	Medicines Quality Database
MQM	Medicines quality monitoring
MRA	Medicines regulatory authority
NAFDAC	National Agency for Food and Drug Administration and Control (Nigeria)
NHQC	National Health Products Quality Control Centre (Cambodia)
NOMCoL	Network of Official Medicines Control Laboratories
NQCL	National quality control laboratory
NTD	Neglected tropical disease
NTP	National TB Program (Indonesia)
ORS	Oral rehydration solution
PD	Pharmaceutical Department (Mozambique)
PMI	President's Malaria Initiative
PMS	Post-marketing surveillance
PQM	Promoting the Quality of Medicines
PTBB	Produk Terapeutik dan Bahan Berbahaya (Therapeutic Product and Hazardous Substances, Indonesia)
QA	Quality assurance
QC	Quality control

QMS	Quality management system
RDMA	Regional Development Mission for Asia
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	Standard operating procedure
TA	Technical assistance
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeial Convention
UV	Ultraviolet
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification

## Program Background and Framework

Since 1992, the U.S. Pharmacopeial Convention (USP), a scientific nonprofit organization, has worked cooperatively with the United States Agency for International Development (USAID) to help developing countries address critical issues related to pharmaceuticals. The Promoting the Quality of Medicines (PQM) program was established in 2009 with a mission to help ensure the quality, safety, and efficacy of medicines essential to USAID priority diseases—particularly malaria, HIV/AIDS, tuberculosis (TB), and maternal and child health. The PQM program is USAID’s response to the growing development challenge posed worldwide by falsified and substandard medicines. There is increasing evidence of the threat that poor-quality medicines poses to populations and public health systems, especially in low- and middle-income countries. Falsified and substandard medicines can cause treatment failure and adverse reactions, increase morbidity and mortality, and increase 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.

The PQM program has presence in four countries (Ethiopia, Indonesia, Nigeria, and Philippines) and programs in 34 non-presence countries.



Figure 1: PQM Program Reach Worldwide

PQM's work is based on four **strategic objectives**:

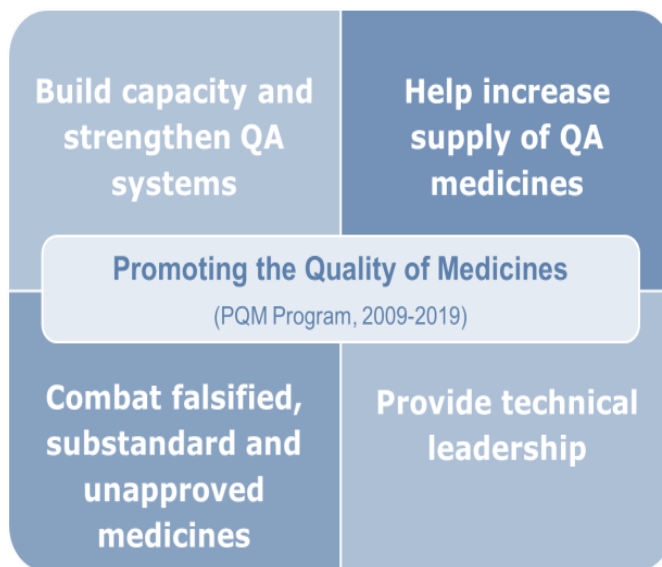


Figure 2: PQM Strategic Objectives

In order to achieve these strategic objectives, PQM's activities are guided by the following four Intermediate Result (IR) areas depicted in the PQM **Results Framework**

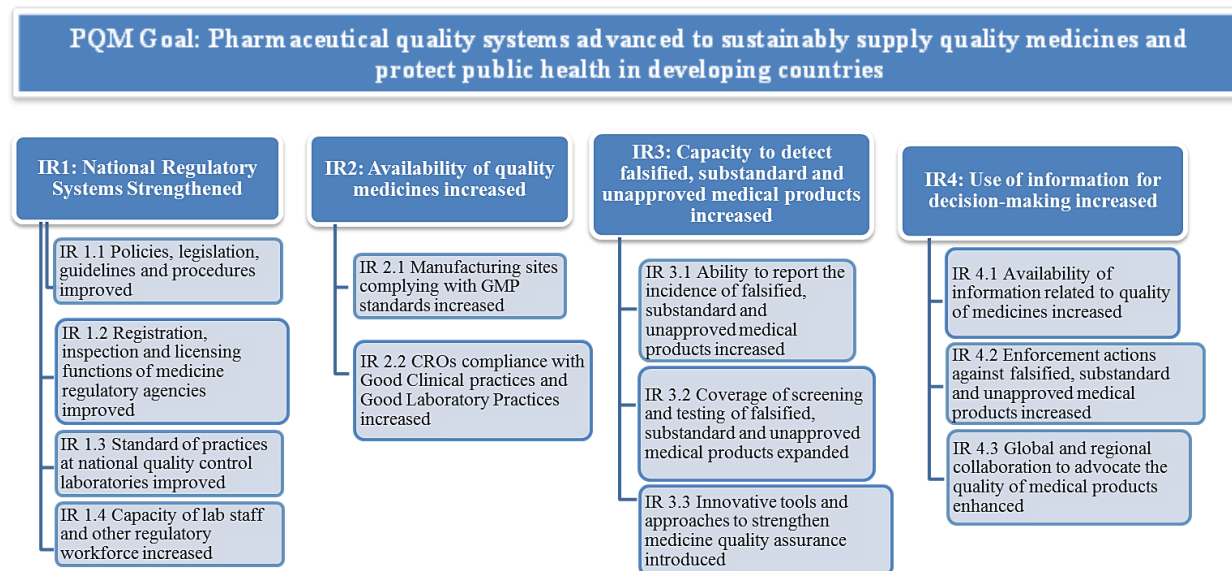


Figure 3: PQM Results Framework

PQM is able to achieve its strategic objectives by providing technical assistance in the four key IR areas using a health systems–based approach. The globally designed systems-based approach is tailored to fit the needs of individual countries or regions and includes all stakeholders throughout the health system. Activities include building the capacity of medicines regulatory authorities to review and approve quality essential medicines and strengthen their ability to protect their own population from poor-quality medicines. PQM works with national and regional regulatory authorities to build sustainable capacity for medicines evaluation, manufacturing inspection, and surveillance. PQM supports national quality control laboratories (NQCLs) through hands-on training and technical assistance to improve laboratory standards, and potentially attaining internationally recognized certifications such as International Standardization Organization (ISO) accreditation and/or World Health Organization Prequalification (WHO PQ).

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

PQM's systems-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 dossiers to submit to the WHO PQ program.

This report presents highlights of PQM activities organized by Intermediate Result area, representing multiple countries where the program works, as well as by global, regional, and country portfolios for the July–September 2016 period.



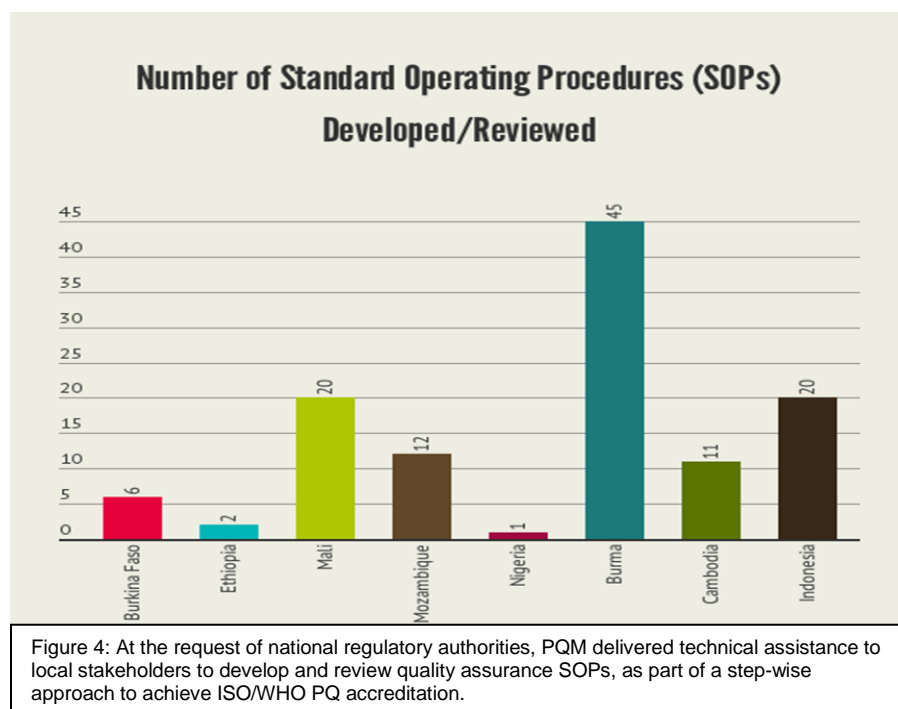
# Quarterly Progress by Result Area

## IR 1: National Regulatory Systems Strengthened

PQM strengthens the capacity of medicines regulatory authorities (MRAs) to review and approve quality-assured essential medicines and thus protect their populations from poor-quality medicines. PQM works with national and regional regulatory authorities to build sustained capacity for medicines evaluation, manufacturing inspection, and surveillance.

### Quality Assurance Policies, Legislation, and Regulatory Guidelines and Standard Operating Procedures (SOPs) Improved

Improving policy is fundamental to ensuring the quality of medicines and improving health systems; without effective policies, the illegal trade of poor-quality medicines would become rampant. PQM offers technical assistance to MRAs to develop adequate quality assurance measures against falsified and substandard medicines and to enable MRAs to adopt accepted international standards of Good Regulatory Practices.



**Bangladesh** PQM finalized and submitted a technical assessment report to the USAID Mission and the Directorate General of Drug Administration (DGDA). The report presents a gap analysis of medicines regulatory quality assurance and quality control systems of Bangladesh aimed at determining the needs for capacity strengthening with the main focus on DGDA and its quality control laboratories, namely the National Control Laboratory in Dhaka and the Drug Testing Laboratory in Chittagong. The assessment was carried out in close consultation and cooperation with DGDA and other key stakeholders, including Management Sciences for

Health, Systems for Improved Access to Pharmaceuticals and Services (SIAPS), WHO, and the USAID Country Office. The findings of this report will be used for the development of the PQM work plan (FY17, FY18, and beyond) in alignment with the 5-Year Road Map (developed by WHO-led Partners Consultation Meeting in March 2016), and for DGDA’s Annual and Strategic Plans and the National Health Sector Plan 2016–2020 document (currently being drafted). In each of the observations, PQM suggested “the what, the how, and the when” for DGDA and other stakeholders to consider and appropriate short-, medium-, and long-term corrective and preventive action. Certain gaps will be addressed by the country’s own existing capacity and resources while others will be addressed with external technical assistance agencies. This represents a major collaboration for partners across the health system (public, private, nonprofit), and will have broad-reaching impacts on the future quality of medicines in Bangladesh.

**Burkina Faso** In its effort to prepare the quality control laboratory for ISO 17025 accreditation, the Laboratoire National de Santé Publique (LNSP) recently revised its SOPs and other quality management system (QMS) documents. During this quarter, PQM reviewed the LNSP Quality Manual and the following SOPs: Management Review, Document Management, Internal Audit, Corrective Actions Follow-up, and Records Control. These QMS documents apply to all LNSP services.

**Guinea** PQM had a discussion with representatives from the USAID-funded SIAPS program and the Direction Nationale de la Pharmacie et des Laboratoires (DNPL) on the next steps of planning a review of the country's pharmaceutical law documents. Participants agreed to complete the planning phase of two to three workshops before the end of 2016. The workshops will be conducted in partnership with SIAPS, DNPL, and a review committee to be established by DNPL and PQM. The main goal of the workshops will be to finalize the first draft of the revised pharmaceutical law documents.

**Mali** In this quarter, PQM completed a review of 20 SOPs that the Laboratoire National de la Santé (LNS) submitted to PQM. The SOPs cover routine lab operations such as the use of pH meters, balances, spectrophotometers, and dissolution testers, as well as solution preparation, laboratory notebook, equipment logbook, and lab security. The review revealed the need for more support for LNS to develop SOPs needed for its quality control services.

**Mozambique** In July, PQM reviewed Mozambique's pharmaceutical law to strengthen the technical capacity of the Pharmaceutical Department (PD). PQM also facilitated the setup of a national technical working group to strengthen pharmaceutical legislation. In support of the objectives of the technical working group, PQM collaborated with the PD to involve key stakeholders such as WHO, SIAPS, local manufacturers, and key Ministry of Health (MOH) staff from legal, regulation, pharmacy council, central medical store, and secretariat to vice minister, and the National Quality Control Laboratory (LNCQM). The purpose of the working group was to establish appropriate and practical regulations detailing the roles and responsibilities of the PD. PQM provided support to the first meeting in September and presented a list of 24 recommended regulations based on a review of the national pharmaceutical law. The next steps are for the PD to review the recommended regulations and determine which are attainable and enforceable in Mozambique. PQM will also work with the technical working group to ensure timely actions are taken based on the time frame allowable by the government.

**Philippines** PQM is providing an expert in medicines policy, regulatory, and quality assurance (QA)/quality control (QC) systems to assist the Food and Drug Administration (FDA) in conducting a gap assessment and developing its next five-year strategic plan for the period of 2017–2021. The terms of reference for this five-year strategic plan have been recently revised to incorporate the vision of the new FDA director general who assumed position in August 2016. The new director general aims to align the strategic plan with the thrusts of the current administration as defined in FDA's vision, mission, and core values. The strategic priorities for strengthening the FDA include processing registration applications within 72 hours, zero backlogs, and strengthened enforcement.

### **Key Regulatory Functions of National Regulatory Agencies Improved**

**Ethiopia** PQM helped the Ethiopian Food, Medicine, and HealthCare Administration and Control Authority (EFMHACA) to distribute and promote the utilization of various guidelines—Good Manufacturing Practice Guideline for Pharmaceutical Products, 2014; Guidelines for Registration of Medicines, 3rd Edition, 2014; and Guidelines for Good Storage Practice, Good Distribution Practice, Pharmaceutical Product Recall—at the Ethiopian Pharmacists Association annual meeting in Addis Ababa in July 2016. Two thousand copies of the three guidelines were printed, 300 of which were distributed during the meeting. PQM also supported the training of 13 EFMHACA staff on process validation and analytical method validation. The training will enable staff working on medicines dossier evaluation to be more analytical in the assessment process.

With PQM's assistance, a national workshop was conducted to review the annual performance of the health regulatory sector transformation plan. The workshop was attended by 72 individuals from EFMHACA, branch laboratories, regional/city administration regulatory authorities, and other stakeholder organizations. The workshop presented an opportunity to review the annual performance at each level, identify problems, and recommend solutions. Agreement was reached to harmonize planning and reporting systems that will help to create synergy between the different actors of the regulatory system.

**Ghana** Maternal mortality remains a major health challenge in Ghana, where postpartum hemorrhage is listed as a major cause of maternal mortality. Postpartum hemorrhage can be managed using uterotonics such as oxytocin, ergometrine, and misoprostol. The outcome of the FY15 MQM report on the quality of uterotonics indicated that a high percentage available on the Ghanaian market do not meet the required standards of quality, which could have serious implications for maternal mortality. PQM is providing technical assistance to FDA Ghana to monitor the quality of uterotonic medicines. During the fourth quarter, PQM followed up with FDA Ghana's registration unit concerning the status of the annual report of the uterotonics study and the implementation of the proposed action plan. PQM will also play a major role in arranging and facilitating a stakeholders meeting with the goal of disseminating the results of the uterotonics study and emphasizing the

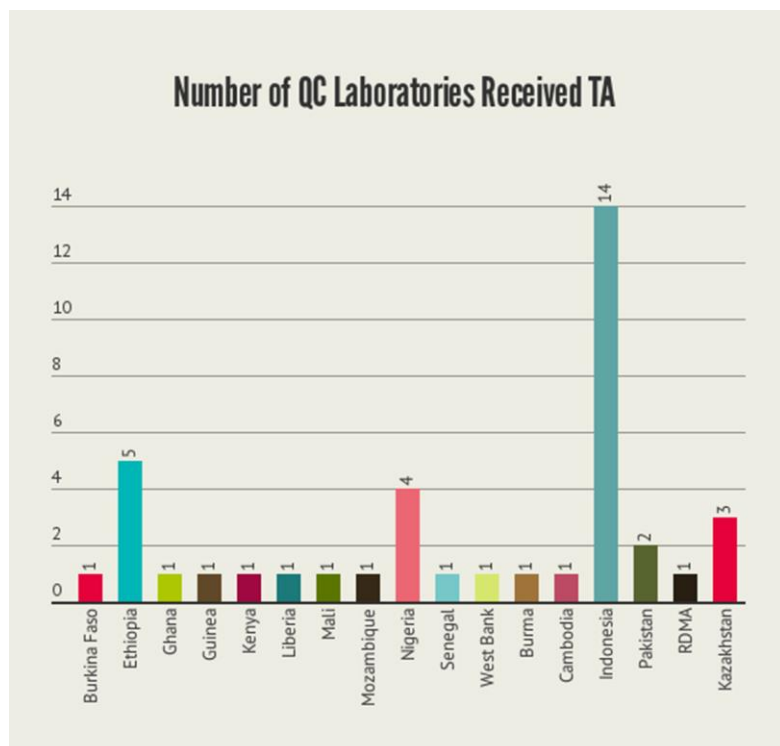


Figure 5: Through the continuous technical assistance (TA) of PQM:  
 -Four labs were supported toward maintaining accreditation in Ethiopia, Ghana, Kenya, and Nigeria.  
 -Twenty-one labs were supported in progress toward ISO 17025 accreditation.  
 -Fourteen labs in Indonesia and one lab in Laos were supported toward changing product-based accreditation to method-based accreditation.

roles and responsibilities of the manufacturers in ensuring the quality of medication within the country. It is especially important to include manufacturers to discuss aspects that affect the quality of the uterotonics, such as proper storage, manufacturing practices, the intricacies of the various tests, the outcome of improper storage on the quality of test results, the role of poor manufacturing practices and not utilizing good quality active pharmaceutical ingredients, and the effect on the purity and efficacy of the final product.

**Pakistan** PQM, in collaboration with the Drug Regulatory Authority of Pakistan (DRAP) and WHO Country Office, conducted a two-day workshop gathering the DRAP's chief executive officer and 15 staff in the Division of Pharmaceutical Evaluation and Registration and the Department of Biological Registration to present the current medicines registration process and practices and collectively identify areas for improvement. The output of the workshop was a draft outline roadmap for the DRAP to improve its medicines registration system. One of the key components to be improved is

the regulatory information management system, which, in the short term, entails developing data standards, and the basic prerequisites for the DRAP to move from a manual to semi-manual registration system. The DRAP's long-term goal is to introduce an integrated regulatory information management system connecting all key functions.

### Standards of Practice at National Quality Control Laboratories Improved

PQM builds the capacity of NQCLs to improve laboratory standards through hands-on training and technical assistance. Internationally recognized certifications, such as ISO accreditation and/or WHO PQ, are just one possible result of this increased capacity. ISO accreditation signifies that a laboratory is technically proficient to produce consistently valid results; MRAs and medicines manufacturers typically accept test results only from accredited or WHO-prequalified labs. WHO PQ aims to increase the supply of quality priority medicines by applying unified standards of acceptable quality, safety, risk, and efficacy to guide procurement decisions of UN agencies and other entities involved in procuring bulk medicine.

**Angola** A proposal to strengthen the technical capacity for conducting quality control testing was submitted to the head of the Drug Regulator Authority. The ultimate goal is to support the MRA, Divisão Nacional de Medicamentos e Equipamentos (DNME), and Inspector General Staff to be able to conduct quality control

compendial testing in-country rather than sending the collected samples for quality control testing abroad. The proposal is awaiting a final decision from the Mission and DNME.

**Benin** One of the challenges that the Benin NQCL faces is the lack of adequate laboratory equipment. For more than two years the Benin Laboratoire National de Contrôle Qualité (LNCQ) did not have a functioning high-performance liquid chromatography (HPLC) system, a piece of equipment critical for conducting quality control testing of medicines. Due to lack of sufficient funding to purchase a new HPLC system, PQM planned to replace a deficient detector in the existing HPLC system. However, the HPLC manufacturer discontinued the series and it was impossible to replace the defective part. PQM was able to secure additional funding from USP; this, along with a donation from Agilent and a steep discount from the manufacturer, meant that an advanced HPLC model was procured and the system will be shipped to LNCQ in October. Arrangements are being made for the installation and qualification of the equipment.

**Burma** The Department of Food and Drug Administration (DFDA) national QA/QC laboratory in Nay Pyi Taw is actively improving its standards of practice while progressing toward ISO/International Electrotechnical Commission (IEC) 17025 accreditation through PQM's technical assistance. During this quarter, PQM was able to leverage contributions from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) under a Regional Artemisinin Resistance grant of approximately \$40,000 to cover the costs of DFDA Nay Pyi Taw Pharmaceutical Chemistry lab equipment/instruments. PQM contributed funding to the staff and consultant associated with this activity. PQM also coordinated the calibration process with a certified calibration services provider (OTS Calibration Lab) in Bangladesh and provided assistance to ensure that all equipment was calibrated to the standards required by ISO 17025. The OTS Calibration Lab team visited the laboratory, and 47 pieces of equipment and instruments were calibrated successfully. PQM is also providing assistance to the laboratory to participate in a proficiency testing scheme. Proficiency testing samples arrived during the second week of September and the laboratory is waiting for test results to be released in October 2016.

PQM is in close discussion with DFDA management on the design and configuration of new laboratory construction projects in both Nay Pyi Taw and Mandalay. PQM, in collaboration with ARC2LAB Germany and DFDA Burma/Myanmar, is providing technical advice to these two new construction projects to ensure the laboratories are built according to international standards and will be suitable to transfer the ISO 17025 accreditation from the old facilities to the new ones once they are completed.



Technical Training on Eight Scopes of ISO Accreditation, Nay Pyi Taw Laboratory, Burma, July 2016

PQM conducted six refresher and two new hands-on trainings on the scopes of ISO 17025 accreditation of Nay Pyi Taw laboratory. The trainings on HPLC, dissolution, Karl Fischer, UV, IR, loss on drying, pH, and uniformity of dosage unit were delivered to 26 laboratory analysts from three QC labs of Nay Pyi Taw, Yangon, and Mandalay. The knowledge and expertise on all eight scopes of accreditation were enhanced, and the laboratory analysts are more prepared than ever to demonstrate their skills and competency during the ISO 17025 pre-assessment audit scheduled for early October 2016.

**Cambodia** In efforts to improve the standard of practice of the National Health Products Quality Control Centre (NHQC), PQM provided technical assistance to develop required QMS documents. During this quarter, the NHQC created and approved 11 new SOPs for a combined total of 64 SOPs for FY16. These SOPs covered procedures for the use analytical techniques used to analyze medicines and key laboratory procedures. During this quarter, NHQC conducted 11 trainings on approved SOPs. Given the limited funding, the PQM program has begun engaging stakeholders and partners to leverage financial sources for the technical assistance (TA) needed to support NHQC's progress toward ISO/IEC 17025 accreditation. NHQC will leverage the support from

(1) WHO (\$10,000) to conduct trainings on Compendial Techniques for NHQC analysts; (2) the Global Fund (\$20,300 per year over two years [2016 and 2017]) to calibrate laboratory equipment; and (3) the government budget (\$6,000) to send its key managers and technical staff to the laboratories that obtained ISO 17025 accreditation to learn best practices via a south-south collaboration. By leveraging up to 50 percent of the total budget, PQM has successfully mobilized partners to build on the USAID catalytic investment to support NHQC to progress toward its goal of ISO 17025 accreditation.

**Ethiopia** PQM technical consultants provided support to EFMHACA in the calibration of 55 laboratory instruments at the Medicine Quality Assurance Directorate laboratory. The calibration is mandatory for the laboratory to maintain ISO 17025 accreditation. PQM's plan in the near future is to build in-country capacity in order to save costs incurred by employing consultants from abroad to calibrate the instruments. PQM also provided technical assistance for the maintenance and calibration of a condom quality control machine.

**Ghana** The ISO 17025 accreditation audit was completed in the third quarter with microbiology and medical devices added to the scope. During the fourth quarter, PQM continued to support these units by providing key technical assistance to address gaps identified during the third-quarter visit and ISO assessment. A training plan was also prepared for all three ISO 17025 accredited units for FY17. Key equipment and consumables were procured and shipped to the laboratory to support technical capacity and to continue to meet the ISO 17025 requirements. Key equipment procured during this quarter included a disintegration tester, which is needed for testing zinc sulfate tablets. The equipment will allow the laboratory to meet all the compendial testing necessary to adequately evaluate the quality of zinc for FY17 activities.. For the microbiology unit, an autoclave was procured, as the stability of the temperature of the three autoclaves was not satisfactory or suitable to meet the compendial testing during the assessment. PQM has also continued to provide remote guidance on documents, such as a road map to the next ISO 17025 assessment in FY17, and established a training plan for FY17 accredited work.

**Indonesia** The Produk Terapeutik dan Bahan Berbahaya (Therapeutic Product and Hazardous Substances) (PTBB) laboratory made progress toward WHO PQ, including submission of three sections of the Laboratory Information File to PQM for internal review following extensive support by the Indonesian Field Office. In addition, facility upgrades for safety and environmental control were made to the PTBB, which is able not only to better control temperature and humidity in the laboratory, but also to have a dedicated sample storage room under proper storage conditions. The PQM Indonesia team worked extensively with the laboratory to follow up on the corrective and preventive action from last year's PQM QMS audit. In addition to the documentation and practices support, PQM provided analytical training for the PTBB and national reference standards laboratories on quality control testing for impurities and related substances according to the United States Pharmacopeia and The National Formulary (*USP-NF*). This training, attended by 32 participants (three males and 29 females), is important to begin both developing analytical skills as well as building overall understanding of the importance of testing impurities throughout the National Agency for Drug and Food Control's (NADFC or BPOM in the local language) national system of laboratories. Impurities and related substances in medicines are often indicators of either poor quality of manufacture or storage conditions that are outside the acceptable limits for temperature and humidity. Since Indonesia does not currently have the capacity to test for impurities, PQM is aiming to increase buy-in from senior officials to prioritize this type of testing, as well as support the capacity to do so via PQM and Global Fund projects.

An important achievement during the fourth quarter was the agreement by the Denpasar Balai Besar Pengawas Obat dan Makanan (Provincial QC Laboratory) (BBPOM) to embark officially on a WHO PQ project for the provincial QC laboratory, with support from the national laboratory. This represents incredible buy-in from BPOM, and advocacy and technical support efforts by PQM during the past year at this laboratory. PQM will help to establish a project timeline during FY17 with expected outputs and milestones, as well as a commitment agreement to achieve WHO PQ within a reasonable time frame.

**Kazakhstan** – During the third quarter, PQM performed an initial assessment of three NQCLs of the National Center for Expertise of Medicines, Medical Devices and Medical Equipment (Kazakhstan FDA) in Karaganda, Pavlodar, and Kostanay for their compliance with WHO and ISO 17025 requirements and their capability to participate in the WHO PQ program. Toward the goal of reaching compliance, during the fourth quarter, PQM worked on the preparation of assessment reports, which provide individual observation details, objective evidence of the observations, suggested corrective and preventive actions, and a suggested timeline for implementation. PQM also discussed the next steps in technical assistance with the laboratories. The Kazakhstan FDA and PQM will work jointly to select the strongest laboratory and PQM will assist this laboratory





in development and improvement of QMS documents in order to share their documents with other laboratories. It has also been agreed that the Pavlodar laboratory will not participate in the program, as its current location on the first floor of an apartment building would not comply with the international standards and its relocation to a more suitable place in the short term does not seem feasible. Instead, PQM will work with the Astana laboratory. Therefore, the PQM technical assistance will be provided to three laboratories: Kostanay, Karaganda, and Astana.

**Laos** In the fourth quarter, PQM conducted a follow-up visit to Laos Food and Drug Quality Control Center (FDQCC) to review the QMS document, conduct a training on standard operating procedure writing, and

analytical method demonstration witnessing. Twenty (12 male and 8 female) participants were trained on how to write standard operating procedures. Self-assessment for the training session indicated a perceived increase in understanding of how to write standard operating procedures. FDQCC staff should be able to write operating procedures and work instructions needed for method-based accreditation.

**Liberia** In July 2016, PQM provided intensive TA to the Liberian Medicines and Health Products Regulatory Authority (LMHRA) QC Laboratory, which helped the lab improve its standards of practice for potential ISO 17025 accreditation. The TA included a QMS assessment and a review of technical and managerial documents pertaining to ISO/IEC 17025 accreditation and the evaluation of the implementation of existing SOPs. The development and implementation of SOPs is an integral part of building and sustaining the laboratory's performance. Additionally, training was provided to the laboratory staff on ISO/IEC 17025 requirements. The goal was to ensure that the laboratory has a QMS that accurately identifies the organizational structure, responsibilities, procedures, and resources required to deliver quality data for medicines testing. Subsequent to the assessment, the laboratory provided PQM with seven SOPs, nine working instruction forms, two summary documents, and the CVs of all laboratory staff. To enable the laboratory to conduct its routine work, PQM also provided assistance in repairing various equipment, including a water purification machine, a dissolution heating unit, and the HPLC.

In August 2016, PQM facilitated the travel of the LMHRA QCL manager to USP's laboratory in Rockville, Maryland, as a visiting scientist to be trained in quality control and quality assurance of medicines. During the fourth quarter, the LMHRA QCL manager has begun rolling out training to his counterparts at the laboratory.

**Mali** During the fourth quarter, PQM provided technical support to the LNS by assessing the status of laboratory equipment and determining parts and/or accessory items needed to maintain and/or repair the equipment. Among other activities, PQM conducted hands-on trainings (five laboratory staff on HPLC application software, one senior laboratory staff on preventive maintenance and use of laboratory equipment, three staff on pH, five staff on UV-Vis spectrophotometer, and five staff on dissolution tester), evaluated the condition and status of laboratory equipment (HPLC, dissolution, UV, Karl Fisher, oven, fume hoods, electrophoresis apparatus, and pH meter), and worked on equipment maintenance capacity (generated a list of assessed equipment with needed parts for repair and conducted troubleshooting and repairs on non-operational equipment with identified failures). The observations and recommendations provided in the final report will inform PQM's support in order to enhance the technical capacity of the laboratory in its preparation for ISO 17025 accreditation.

**Mozambique** During the fourth quarter, the national laboratory (LNCQ) participated in an ISO 17043 accredited proficiency study. PQM procured samples for the study from Sigma Aldrich and shipped them to the Mozambique national lab, which completed and submitted the testing before September 30, 2016. The results will be available in FY17 for PQM to evaluate and determine if there are any areas for improvement.

To continue maintaining Good Laboratory Practices, PQM contracted an ISO 17025 accredited calibration body to calibrate LNCQM's key equipment. Proper calibration and maintenance of the equipment ensures the quality of results from the lab. During the fourth quarter, key equipment was procured and shipped to LNCQM, including Fourier Transform Infrared Spectroscopy (FTIR), a centrifuge, a dissolution system, HPLC, and reagents and consumables needed to run the lab. Also procured but awaiting delivery is a glassware washer. Due to the electrical instability in the lab, PQM has contracted a locally certified electrical company to overhaul the electrical system to allow power stability. This contractor will be able to install a stabilizer and generator for the lab. Key trainings were provided to four key LNCQM staff by PQM on the proper reporting and processing of HPLC data.

**Nigeria** PQM continued work on activities toward achieving ISO 17025 accreditation to improve the technical capacity of two National Agency for Food and Drug Administration and Control (NAFDAC) quality control laboratories in Agulu and Kaduna and the pharmaceutical research laboratory in Abuja, National Institute for Pharmaceutical Research and Development. The capacity of 79 laboratory staff (53 males, 26 females) was strengthened through hands-on training on quality control of medicines in the areas of dissolution, water determination, IR, Good Weighing Practices, loss on drying, UV-VIS spectroscopy, and uniformity of dosage unit. At the quality control laboratory in Agulu Anambra State, calibration of 18 pieces of equipment was completed in preparation for an ISO audit. Following an audit, the ANSI-ASQ National Accreditation Board (ANAB) recommended the laboratory for ISO 17025 accreditation with eight minor findings and two opportunities for improvement reported. The ISO 17025 accreditation will be made official once the minor findings are addressed and the corrective and preventive actions (CAPAs) accepted by the



Agulu Laboratory Audit, Nigeria, September 2016

accreditation body. The managerial and technical staff of the NAFDAC quality control laboratory in Kaduna observed the ANAB assessment audit of the NAFDAC quality control laboratory in Agulu. Lessons learned were found to be helpful for the staff, as plans are underway in FY17 to prepare the Kaduna laboratory for accreditation.

**Pakistan** An initial quality management systems assessment and gap analysis of the Central Drug Laboratory (CDL), Drug Regulatory Authority of Pakistan, Karachi, was conducted during this quarter to identify deficiencies and opportunities for improvement within the quality systems and to assess the laboratory's readiness toward its application to ISO/IEC 17025:2005 accreditation. Based on the findings from the assessment, PQM has identified the gaps and made the recommendations on immediate needs in training, laboratory equipment supplies, personnel, and supporting material. PQM has developed a realistic timeline to build a robust quality management system and has identified areas for immediate training that can be complemented by other regional training providers such as the Pakistan National Accreditation Council.

PQM also conducted an initial quality management systems gap assessment of the Appellate Laboratory in order to identify deficiencies and opportunities for improvement in the quality systems. PQM also observed the Appellate Laboratory conducting compendial testing. As a result of this assessment, PQM made recommendations and advised immediate needs for training, laboratory equipment supplies, personnel, and supporting material. PQM also identified gaps in the quality management systems, which are outlined in the confidential report sent to the laboratory. From the observations, PQM will identify those areas that the laboratory is lacking and provide clear guidelines, develop a realistic timeline to build robust quality management systems, and conduct immediate training that can be complemented by other regional training providers such as the Pakistan National Accreditation Council.

The Appellate Laboratory at the National Institute of Health (in Islamabad) has a key role to play in the quality assurance of drugs. Therefore, strengthening the Appellate Laboratory's capacity is strategic and paramount as it serves as the country's last resource for all court cases related to the quality and safety of medicines and biological products. In addition, the improvement of the CDL and provincial quality control labs has the potential to support the monitoring of medicines in the market.

**Senegal** During this quarter, PQM continued its support to increase the technical capacity of the Laboratoire National de Contrôle de la Qualité des Médicaments (LNCM) by initiating the procurement process for a number of pieces of priority laboratory equipment, spare parts, and accessories. After the procurement and delivery of the lab equipment parts, PQM will provide the needed TA to install and/or repair the non-operational equipment and assist LNCM in conducting the calibration and validation of the equipment that will be used to perform analytical tests under the ISO scope of accreditation. These repairs are expected to make operational a defective water purifier, UV spectrophotometer, conductivity meter, and HPLC.

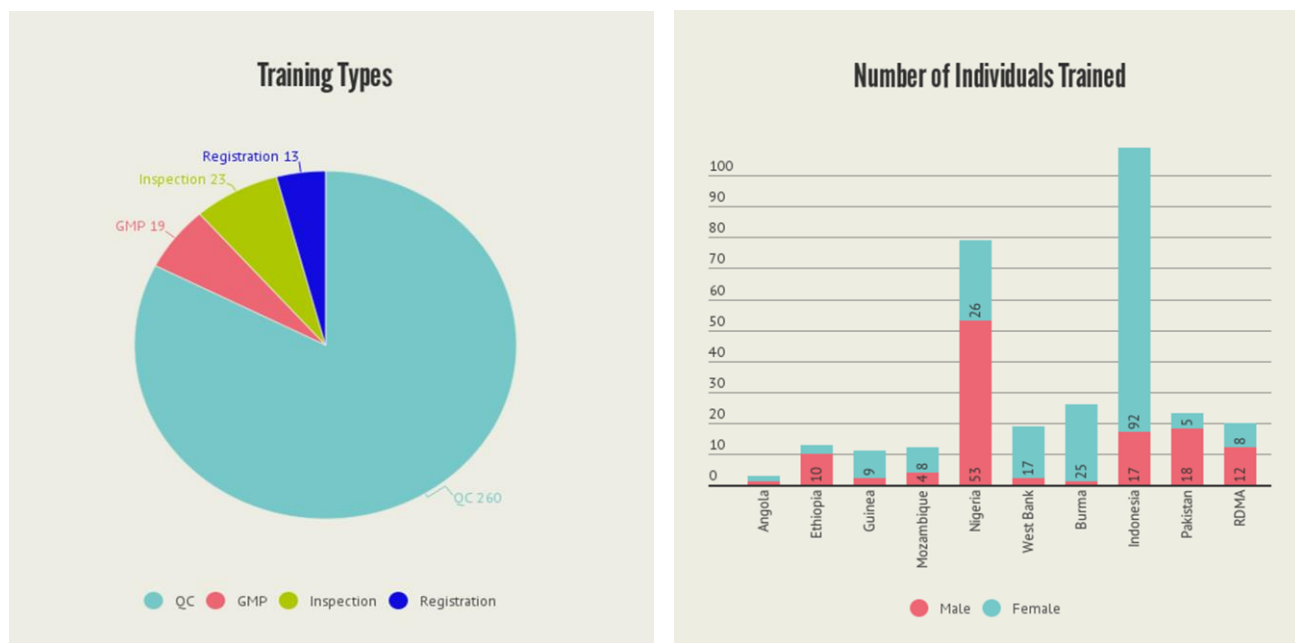
**Vietnam** PQM conducted a mock audit at the Institute of Drug Quality Control (IDQC), Ho Chi Minh City, Vietnam, in support of its preparation for the WHO PQ official inspection planned for October 2016. PQM conducted an audit of product traceability against WHO good practices pharmaceutical quality control laboratories, and an impromptu training on verification of forms and worksheets to ensure documentation of critical procedural parameters. Four of the seven analysis departments of IDQC participated in the audit. The laboratory staff were able to respond to inquiries related to quality, administrative, and technical operations of the department; provide documents in an efficient manner in relation to traceability of samples; and assign individuals with specific responsibility for inspection-related tasks such as information gathering as well as preparation and presentation of information to external inspectors. Steps were taken and a plan was put in place to address deficiencies in relation to record control, instrument maintenance, and internal procedures.

**West Bank/Gaza** Last year, a PQM Quality Control assessment revealed that the Central Public Health Laboratory (CPHL) is in a state where it could be ready to submit an application to an international accrediting body within a year. During the PQM team's visit this quarter, the head of CPHL confirmed that the Tunisian Accreditation Council was selected by the Ministry of Health to be the ISO 17025 accrediting body for CPHL. PQM has also assisted the laboratory to be part of the Middle East North Africa Network of Official Medicines Control Laboratories (NOMCoL) and facilitated one staff member's attendance at the NOMCoL meeting and training in Saudi Arabia. However, due to instability in the region, the staff member was ultimately unable to attend the NOMCoL training. Additionally, during this quarter, PQM enrolled the laboratory in the inter-laboratory testing scheme and submitted all documents, reagents, and reference standards needed to participate. Being a member of NOMCoL and conducting the inter-laboratory testing will help the laboratory continue to progress toward ISO accreditation.

### **Capacity of Laboratory Staff and Other Regulatory Workforce Increased**

PQM collaborates with the WHO, its regional and country offices, and national health authorities to conduct training courses on a broad spectrum of quality control test procedures and Good Manufacturing Practices. The courses, held onsite at national drug quality laboratories or at sentinel sites and local labs, focus on a wide range of topics related to various facets of medicines quality at the regional, national, and local levels.





Figures 6 and 7: PQM trained a total of 315 people (62 percent female and 38 percent male) during the quarter on the following topics: Good Manufacturing Practices (GMP), Quality Control (QC), Product Registration, and Inspection.

**Ethiopia** With PQM support, a medicines regulatory workforce development program leading to a Master’s of Science Degree in Medicine Regulatory Affairs was launched by Addis Ababa University’s School of Pharmacy to address the challenge of a shortage of trained and qualified staff that EFMHACA, other regulatory authorities, and medicines manufacturers are facing. This program is expected to help make Ethiopia self-reliant and sustainably increase much-needed human capital. The first cohort of students (four females, eleven males) was admitted October 24, 2016. PQM also arranged for and financed the study tour of two management team members from the School of Pharmacy to the Regulatory Affairs Professional Society and Association for Graduate Regulatory Affairs Educators meetings in Los Angeles and San Jose, California. In addition, the team visited Howard University, George Washington University, and the U.S. Food and Drug Administration. The team was able to identify teaching material and reference textbooks for the master’s program. The team identified areas of collaboration with the different institutions and advanced commitment to sign a memorandum of understanding with the University of Southern California, George Washington University, and the University of Washington in Seattle. Fly-in professors are scheduled to come to Ethiopia to teach relevant courses. PQM plans to continue support toward development of regulatory affairs skills in Ethiopia by providing the necessary financial support and technical review of the teaching material.

**Guinea** PQM provided refresher Minilab™ training for 11 LNCQM staff (two females, nine males). They had received their initial training in 2014. Emphasis was placed on efficient physical and visual inspection and high-quality spotting and pipetting to avoid false positive and/or negative results regarding a sample’s quality. The importance of Good Documentation Practices (GDPs) and Good Laboratory Practices (GLPs) was also highlighted, as these practices are also critical toward compliance with the ISO 17025 standard. PQM also organized a one-day workshop on launching the MQM program in Guinea. The workshop was chaired by the director of DNPL and attended by 26 individuals representing several organizations, including DNPL, LNCQM, MOH health programs, customs, and Lutte Contre la Criminologie Pharmaceutique au Guinée. In addition to providing an overview of MQM, the workshop served as a forum to develop a sample collection strategy for the purposes of an initial survey on the quality of medicines and to finalize a list of medicines to be sampled including the collection methodology. This will bolster the capacity of personnel working at the central level who will then train personnel working outside of Conakry.

**Indonesia** PQM partnered with BPOM to provide trainers for a national training on analytical methods by chromatography in which staff from 14 provincial BPOM quality control laboratories were brought to the national laboratory (PPOMN) to receive this training. Analyses of fixed-dose combination (FDC) TB medicines were used

for the training, and staff gained valuable skills on HPLC, dissolution, and GLPs for use in detecting counterfeit or substandard medicines in the market.

The QMS team provided training on CAPAs, root cause analysis, and document and record control (GDP) according to ISO/IEC 17025, and conducted follow-up assessments at the Jayapura (Papua), Denpasar (Bali), and Jakarta (Jakarta DKI) laboratories. These laboratories are making considerable progress in their overall compliance with ISO requirements. The assessments were part of the overall QMS implementation plans developed during the third quarter for the laboratories under PQM support.

PQM also worked closely with the MOH and BPOM on drafting a concept note and budget/procurement list for the National TB Program (NTP)-BPOM follow-on project to build BPOM laboratory capacity for TB and HIV medicines testing in 12 to 15 provinces. The final draft was submitted to the GFATM during the fourth quarter with the expectation of a new contract being awarded during the first quarter of FY17.

**Liberia** In July 2016, the quality control manager of the LMHRA quality control laboratory traveled to the USP's Rockville laboratory as a visiting scientist to be trained in quality assurance and quality control of medicines. PQM provided training on GLPs, GDPs, the Calibration of Dissolution Test, and HPLC. The purpose of this training was to build in-country capacity for the Liberia Medicine Control Laboratory to detect substandard medicines in the country in order to sustainably protect the health of the population. This initiative was part of an ongoing effort to build and sustain host country capacity beyond technical support provided to Liberia by PQM. To that end, the quality control manager will roll out this training to his counterparts at the laboratory.

**Nigeria** Results of proficiency tests (their first proficiency tests in dissolution and a UV-vis test) carried out by the Agulu laboratory toward the end of last quarter were received and indicated an excellent z-score. This achievement is traceable to the trainings and technical support provided earlier by PQM to the Agulu laboratory staff. Plans are underway to commence preparation for Kaduna laboratory accreditation next quarter.

As a follow up to implementation of strategies by PQM to strengthen the pipeline of skilled professionals in the pharmaceutical sector, the draft Pharmaceutical Quality Assurance curriculum was presented to the National Universities Commission for ratification. Response from the review team at the commission is expected before the end of in the first quarter of FY17.

**Pakistan** DRAP's Division of Licensing currently has no capacity to inspect and approve the heating, ventilation, and air-conditioning (HVAC) design. PQM conducted a four-day training of trainers for DRAP's Division of Licensing and Division of Quality Control (Inspectorate staff) on HVAC design, qualification, and validation to assist and improve compliance with international GMP approval and inspection of HVAC systems. This training was conducted in September by PQM Pakistan's technical team, quality assurance and GMP consultants, and some experts from the industry. As requested by DRAP's CEO, seven newly hired assistant directors participated in the training alongside 12 existing Federal Inspectors of Drugs. Participants acquired new knowledge and skills in HVAC system inspection. Recommendations from the training included that DRAP develop an inspection guideline that incorporates the HVAC system and that the Federal Inspectors of Drugs implement it as part of the overall inspection process.

**Regional Development Mission for Asia (RDMA)** Method-based ISO/IEC 17025 accreditation has been regarded by FDQCC as an important international norm that it must achieve. PQM has been working with the Laos FDQCC laboratory to move from product-based to method-based accreditation for over a year. In this quarter, PQM worked tirelessly on rectifying internal policy and procedural conformance CAPAs since the last visit in the second quarter. PQM also provided a training on standard operating procedure writing. As a result of PQM's work, the FDQCC wrote a quality manual and general procedures to comply with the requirements of ISO/IEC 17025, the Drug-Cosmetic Division had its major equipment calibrated by a local calibration provider, and 20 participants (12 males and eight females) were trained on how to write standard operating procedures.

## IR 2: Availability of Quality Medicines Increased

PQM Good Manufacturing Practice specialists travel to manufacturing sites in order to help companies improve their compliance with WHO standards and develop dossiers to submit to the WHO Prequalification of Medicines Program for certification. WHO Prequalification, and other stringent regulatory authority approval, helps ensure that medicines meet acceptable standards of quality, safety, and efficacy. WHO's list of prequalified medicines is used by procurement agencies and countries to guide their bulk purchasing of essential medicines. The goal of PQM's work in this area is to increase the supply of locally produced, quality-assured medicines, targeting USAID priority health programs. PQM delivers broad technical assistance to manufacturers to address GMP and other quality-related issues. By doing so, PQM helps increase access to a steady supply of essential medicines of assured quality, safety, and efficacy, thus improving local health systems. Technical assistance is provided throughout the application process for WHO Prequalification, Stringent Regulatory Authority, or local National Regulatory Authority approval, from early initiatives to the final submission of the application or dossier.

Manufacturers Received TA - Core Programs Vs Country

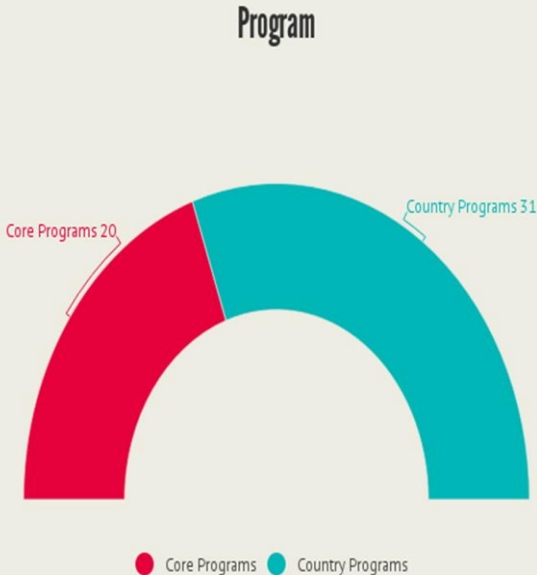


Figure 8: Twenty manufacturers were supported by Core Programs and 31 manufacturers were supported by Country Programs.

Number of Manufacturers Received TA

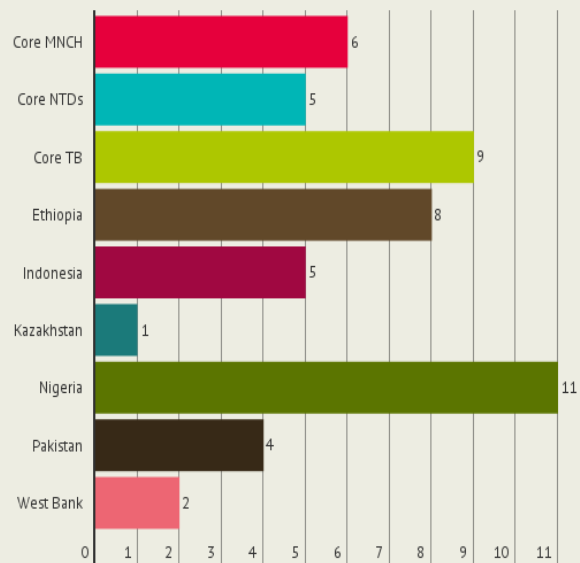


Figure 9: PQM provided technical assistance to 51 manufacturers of priority medicines (\*ARVs, antimalarial, anti-TB, MNCH, and \* NTD products) in 11 countries: \*ARV- Antiretroviral. NTD- Neglected tropical diseases

**Core TB** In the fourth quarter, PQM continued working on providing high-quality technical assistance to manufacturers in support of WHO Prequalification or other stringent regulatory authority approval for six priority tuberculosis medicines: rifampicin, clofazimine, kanamycin, gatifloxacin, moxifloxacin, and rifapentine.

The PQM team provided technical assistance to a rifampicin active pharmaceutical ingredient (API) manufacturer that resulted in WHO Prequalification of rifampicin API in July 2016. PQM staff conducted a GMP assessment of a clofazimine API manufacturer's facility to advance its compliance to ensure that they are meeting WHO's manufacturing requirements. Implementation of corrective actions identified by PQM will increase the company's GMP compliance. The PQM team also met with the WHO Prequalification team (assessment and inspection) to discuss various topics regarding the submission of clofazimine API and finished pharmaceutical product (FPP) dossier for approval. PQM and the company's staff both received informative feedback to allow decision making for next steps. This was yet another success in confirming an effective collaboration among the WHO PQ team, the manufacturer, and PQM.



API manufacturer's facility. A separate confidential audit report was sent to the company to review and implement corrective actions. The FPP manufacturer was identified and is in the process of developing the formulation.

**Core NTDs** During the fourth quarter, PQM continued providing technical assistance to manufacturers of priority neglected tropical disease (NTD) medicines. PQM provided technical assistance to a manufacturer of praziquantel FPP in order to assess a new API source for use in their product. PQM helped in assessing the API's physical characteristics to ensure that they meet the requirements of Bioequivalence.

PQM received revised CAPA rectification on a praziquantel API manufacturer's Active Pharmaceutical Ingredient Master File for two critical observations that were clarified to the manufacturer during the third quarter. Currently, the CAPA is under review and will be addressed in the next visit scheduled for October 2016.

PQM also assisted another manufacturer of praziquantel FPP in product development studies through technical assistance on quantification of needed comparative products for Bioequivalence study. Additionally, PQM assisted in providing comparative products. PQM provided guidance to the company in relation to the process validation of their albendazole API for WHO PQ. PQM reviewed the process validation protocol and provided recommendations. PQM also conducted a mock inspection of the pharmaceutical company relative to its praziquantel API and provided feedback on the CAPA plan that it is currently implementing. The mock inspection report and some SOP templates were provided to the manufacturer.

**Core MNCH** PQM continued to provide technical assistance to manufacturers of essential maternal, newborn and child health products (magnesium sulfate injection, amoxicillin dispersible tablets, chlorhexidine gel, and oxytocin injection) in support of WHO Prequalification or as a source of local production.

PQM provided support to a manufacturer currently developing magnesium sulfate injection. TA was focused on product development to ensure proper formulation. Remote TA was provided to a manufacturer of amoxicillin dispersible tablets in preparation of a PQM gap analysis audit in the first quarter of FY17. In addition, a local manufacturer of amoxicillin dispersible tablets was identified in one of the USAID priority countries. Subsequent completion of the questionnaire by the manufacturer has led to planning a gap assessment of the manufacturing facility. PQM provided remote assistance to an oxytocin manufacturer (API and FPP) in preparation for the upcoming audit of the API facility.

In collaboration with the East African Community (EAC) harmonization efforts, PQM has been supporting the preparation of the joint dossier review of essential medicines planned for December 2016 in Uganda. PQM has also been facilitating the submission of dossiers by Universal (chlorhexidine gel) and CHI pharmaceuticals (zinc

PQM has also provided assistance to a manufacturer in support of kanamycin API in process development. The manufacturer is currently in the process of development to reduce the impurity by ceramic membrane separation.

Additionally, a gatifloxacin API manufacturer is currently implementing corrective actions as a result of the GMP assessment conducted by the PQM team in the third quarter. PQM was successful in identifying a manufacturer for gatifloxacin FPP. This company is currently developing the finished product.

With PQM's technical assistance, a moxifloxacin API manufacturer was successful in its Certificate of Suitability inspection. The PQM team also conducted an initial GMP assessment of a rifapentine

sulfate tablets and oral rehydration salts) to the EAC for approval and subsequent availability in the EAC region. Both manufacturers are recipients of PQM technical assistance.

**Ethiopia** PQM participated in the Ethiopia Health System Transformation Plan GMP road map revitalization process by providing technical support in the second-round assessment of local pharmaceutical industries in collaboration with EFMHACA; United Nations Industrial Development Organization; WHO; and the Food, Beverage, Pharmaceutical Development Institute. The GMP road map is designed to allow GMP experts to assess GMP compliance of select manufacturers and provide recommendations for improvements. At the end of each assessment, on-the-job training on CAPA preparation was provided by PQM in collaboration with the partners. A report is being prepared and PQM will provide TA based on the findings of the report.

**Indonesia** PQM is providing technical assistance to three manufacturers. Zenith Pharmaceuticals, Kalbe Farma, and Sanbe Farma/Caprifarmindo are being supported to attain WHO PQ for levofloxacin 500 mg tablets, a second-line TB drug. GMP assessments on the facility and documentation were conducted, as well as basic training on GLPs and other relevant topics for the staff from the newly renovated quality control laboratory. Progress on the WHO Prequalification project for levofloxacin 500 mg has been slow and, following the facility and documentation assessment, it became evident that many gaps remain in their overall GMP compliance. PQM plans to engage these manufacturers to increase their commitment and actively address the CAPA plan in a timely manner. A follow-up assessment visit was conducted at Kalbe Farma, including follow-up on its CAPA (verification of progress) and assessments of its production facility and laboratory. While making progress on its WHO PQ project for levofloxacin 500 mg, there are still a large number of gaps to be addressed in its overall GMP compliance, which PQM will help them to address over the coming fiscal year. GLP training for the quality control staff is planned for first quarter of FY17. The Indonesian National Agency of Drug and Food Control NADFC or BPOM staff will also participate in the GLP training. Two visits were conducted to Sanbe Farma to follow up on the progress of its WHO PQ project on levofloxacin 500 mg, for which it plans to submit its product dossier to WHO in February 2017. Training conducted included technology transfer documentation, laboratory safety, a hands-on training on gas chromatography to help with residual solvent issues, and an extensive weeklong GLP training for some 25 (19 female and six male) quality control laboratory analysts and other staff. PQM is hopeful that Sanbe Farma will successfully submit its PD by Q2 FY17.

PQM is also supporting Phapros for two fixed dose combinations (FDC) for its TB program. A meeting was held with the president director of Phapros, together with production managers, to discuss progress on the 2FDC for TB as well as other potential products in the pipeline. There is ongoing discussion with Phapros about initiating a WHO PQ project for its pediatric FDCs as global need for these products increases. In addition, discussion revolved around the impending changes in the National TB Program's treatment guidelines to align with new WHO recommendations for inclusion of a short-course regimen for treating multidrug-resistant TB using moxifloxacin. Phapros expressed interest in potentially developing moxifloxacin as a viable product to support the needs of the NTP, and this will need further discussion with NTP, Farmalkes, and other stakeholders to ensure that adequate local supplies are available. This comes at a time when the NTP is shifting from a reliance on the Global Fund for financing its multidrug-resistant TB programs via the Programmatic Management of Drug-Resistant Tuberculosis sites in order to scale up using the State of Indonesia Fiscal Year (Anggaran Pendapatan dan Belanja Negara) budgets and to roll out the services at more hospitals and puskesmas (community health clinics). Further discussion and meetings on this topic are planned for FY17.

PQM supported four BPOM staff (two from the Directorate of Production Control of Therapeutic Products and two from the Directorate of Evaluation of Drug and Product Biology) to participate in a global workshop convened by PQM in Dubai titled "Ensuring the Quality of Anti-TB Medicines—Contributing Towards Ending the TB Epidemic." The goal was to bring manufacturers and regulators together to discuss the current approaches in TB treatment and global needs for medicines procurement and quality. The workshop discussed how to access PQM technical assistance, the WHO Prequalification process, current GMPs, dossier requirements, and data integrity, among other topics. The BPOM officers are expected to organize a transfer of knowledge dissemination workshop for their colleagues, and PQM is also planning a larger dissemination workshop with Farmalkes and NTP staff to ensure harmonization of information during FY17.

**Kazakhstan** PQM continued working with Nobel Almaty Pharmaceutical Factory on its CAPA plan, per results of the latest PQM assessment of its facility. Nobel Almaty Pharmaceutical Factory had teleconferences with PQM consultants and received remote technical assistance on implementation of corrective actions. PQM will continue rendering remote assistance to this manufacturer on implementation of its CAPA plan in support of WHO PQ.

**Nigeria** PQM supports Emzor on the production of zinc/oral rehydration solution (ORS) and chlorhexidine gel. A PQM-identified expert in water qualification and validation assisted the company in completing the first and second phases of water qualification, which has improved processes used at the manufacturing site. During the fourth quarter, NAFDAC inspected the facility and was satisfied with the level of GMP compliance. PQM is planning a follow-up visit to support activities toward the manufacturing of zinc sulfate dispersible and chlorhexidine gel.

PQM provided varying technical assistance to numerous local manufacturers during the quarter. Local manufacturers May & Baker and Daily Needs, which are engaged in the production of antimalarials and amoxicillin dispersal tablets (DT), respectively, reviewed progress made to close the identified CAPAs. A CAPA report for chlorhexidine was sent to UNICEF by another local manufacturer (Drugfield) after various review sessions with the PQM technical team. Primary packaging for oxytocin by a PQM-supported manufacturer (Juhel) was analyzed for safety, and the results showed positive compatibility with low-density polyethylene packaging material. Plans are underway for the initiation of six-month stability of oxytocin by the next quarter. Juhel also commenced dossier preparation for magnesium sulfate as the stability studies of magnesium sulfate are ongoing and expected to be completed by the second quarter of FY17. The quality management system of another PQM-supported local manufacturer (Tuyil) engaged in chlorhexidine gel was strengthened through the commencement of documentation. Six-month stability studies of the product are ongoing.

To help decrease the number of diarrhea-related deaths, 22 technical visits were made to seven supported local manufacturers to provide technical assistance and continuous mentorship for compliance with GMP in line with current national and international guidelines. Bringing these manufacturers to adopt GMP will lead to improved supply of quality-assured antidiarrheal medicines. In addition to the procurement reported in the third quarter, the PQM-supported local manufacturer (CHI) was engaged again during this quarter by UNICEF to procure zinc/ORS (co-pack) worth 1.52 million USD. The supply of chlorhexidine was increased with total sales of 3,844,508 tubes in Nigeria by Drugfield. Additionally, one public health organization has indicated interest to supply quality chlorhexidine gel with a wider reach in the country through its franchise network of over 300 private health facilities and about 90 pharmacy outlets and its presence in the 36 states of the country.

USAID/Nigeria Mission's visit to four PQM-supported local manufacturers of MNCH priority products (CHI, Drugfield, May&Baker, and Emzor Pharmaceuticals) provided the USAID Mission the opportunity to receive feedback on the technical assistance provided by PQM. The outcome of the visit was an impressive commendation for the PQM team on its continuous technical support and the evident positive changes within the supported pharmaceutical manufacturing facilities. Nigeria CHI Pharmaceuticals continues to make progress toward the WHO Prequalification for zinc/ORS with a potential target date in November. The WHO Prequalification questionnaire sent to CHI was completed and sent back to WHO during this quarter. Technical assistance was provided on the equilibrium dialysis of zinc dispersible tablets. The technical capacity of CHI was enhanced through the development of an implementation action plan on the identified CAPAs for Arthemeter Lumenfantrine. The PQM team will continue to follow up on the implementation plan to ensure closed CAPAs for Arthemeter Lumenfantrine are executed within a realistic time frame.

**Pakistan** During this quarter, PQM conducted assessments of two local manufacturers of Chlorhexidine 7.1% Gel—Akhai Pharmaceuticals manufacturing facility and Zafa Pharmaceuticals, both located in Karachi. The assessments were used for developing a road map for the manufacturers to work toward obtaining international accreditation. The audits revealed that each firm had similar observations that are not in compliance with the WHO cGMP for finished pharmaceutical products. The assessment indicated that there was a lack of capacity to understand the important aspects and requirements of cGMP as a primary reason for GMP noncompliance. PQM proposed the two companies submit a CAPA plan to address the findings through the assessment. An additional local manufacturer is scheduled for GMP assessment in the next round.

**Uzbekistan** In September 2016, in collaboration with Uzpharmsanoat (Uzbek State Joint-Stock Concern of Pharmaceutical Industry), an association of pharmaceutical manufacturers, PQM conducted an initial assessment of three manufacturers of anti-TB medicines. The goal of the assessment was the identification of manufacturers that have potential and are committed to improvement of their quality standards with the technical assistance of PQM. PQM also assessed the potential of Uzbekistan manufacturers to participate in the WHO PQ program for anti-TB medicines, which will allow local manufactures to increase the quality of their products and expand export opportunities. As a result of the assessment, two manufacturers were identified for PQM's technical assistance: Nika Pharm and Nobel Pharmsanoat. Nobel Pharmsanoat currently produces the



important anti-TB medicine Levofloxacin. It was agreed that PQM will provide technical assistance to the manufacturer to comply with international GMP standards and also to compile and submit a dossier for WHO PQ program approval. Nika Pharm plans to develop an anti-TB medicine and start its production. PQM will provide technical assistance in development of the product, as well as in improvement of GMP standards toward WHO PQ. Next steps for PQM will be to provide a thorough GMP assessment of the selected manufacturers to develop comprehensive audit reports and corrective action plans, as well as to provide on-site and remote technical assistance to manufacturers on corrective actions.

**West Bank/Gaza** A three-member PQM team traveled to the West Bank to conduct a full GMP assessment of two Palestinian drug manufacturers—Pharmacare PLC and Jerusalem Pharmaceuticals Co.—and identified several major deficiencies. Both manufacturers should address the deficiencies in order to be in good position to pass GMP inspection from the Pharmaceutical Inspection Cooperation Scheme member inspectorate. The PQM team determined that the manufacturers should prepare a detailed CAPA plan based on the assessment findings. PQM will evaluate the proposed CAPA, provide feedback, and follow up on the implementation of the CAPA. During the aforementioned visit, the PQM team also conducted a one-day GMP workshop with staff from the Palestinian Authority. The workshop was focused on presenting the Pharmaceutical Inspection Cooperation Scheme GMP guidelines and benefits. The workshop was attended by 19 staff (17 females and 2 males) from various departments, including the inspectorate and registration. The workshop served as a venue to discuss the requirements needed by the Palestinian Authority to become a member and how this membership can facilitate local manufacturers accessing new markets outside Palestine.

### **IR 3: Capacity to Detect Poor Medical Products Increased**

PQM helps combat falsified and substandard medicines by collaborating with country medicines regulatory authorities and national health programs by establishing or strengthening PMS systems that regularly examine the quality of medicines circulating in markets. PQM supports the national regulatory authorities to assess existing medical products by selecting sites to monitor based on criteria such as epidemiology, geography, border region, and history of trafficking fake medicines. This also includes training field staff in sampling, testing with Minilab™ methods, and data reporting, as well as training Official Medicines Control Laboratory staff in advanced test methods. Minilab™ is a mobile and inexpensive field test kit with rapid drug quality verification and counterfeit medicines detection.

#### **Reporting the Incidence of Poor Quality Medical Products Increased**

PQM assists countries to implement PMS programs where little capacity exists, and works to enhance existing PMS systems through a wide range of activities, including providing supplies, conducting trainings on use of PMS technologies and inspection processes, strategic planning, strengthening implementation, and conducting studies to inform overall PMS approaches.

**Angola** In August 2016, a draft sampling protocol for surveillance of quality of medicines was developed and discussed with DNME, the National Malaria Control Program, and Inspector General Staff. Three (one male, two female) DNME staff were trained on proper sampling procedures. PQM worked closely with DNME to identify 18 initial sentinel sites with medicines samples to be collected. In September 2016, four additional Minilabs™ and eight replenishment kits for reagents and reference tablets were procured to cover the sentinel sites selected for the medicines quality monitoring. A Minilab™ training was provided to 27 (nine male, 18 female) DNME and Inspector General staff to further strengthen their capacity to conduct medicines quality screening of antimalarials. All sentinel sites with PQM trained staff will be mapped out and one final training/sample collection will be conducted in the first quarter of FY17 to address some of the sampling challenges encountered during the August 2016 training. Consequently, DNME will officially start post-marketing surveillance after the last training, planned for November/December 2016. The map of all areas where staff have been trained will serve as a tool to evaluate the first round of results and determine if additional corrections or retrainings are required.

**Benin** PQM collaborated with LNCQ, the National Malaria Control Program, and the Direction de la Pharmacie, du Médicament et des Explorations Diagnostiques to conduct surveys for antimalarial medicines. The aim of these surveys is to gather preliminary information related to the quality of antimalarial medicines, institute good practices in conducting quality monitoring activities, and ultimately help establish a strong post-marketing

surveillance program. PQM facilitated the survey in six regions, known as Departments: Atlantique, Coffou, Littoral, Mono, Ouémé, and Plateau. A total of 174 antimalarial samples were collected from the public sector, private pharmacies, and informal sector (54 percent public sector, 24 percent private pharmacies, 22 percent informal market). All the samples underwent careful visual inspection. Following the visual inspection, 52 samples were selected for further screening using Minilab™ kits. A total of 10 samples did not comply with the quality specifications, of which six samples lacked the active pharmaceutical ingredient. The LNCQ submitted an official letter to the regulatory authority requesting regulatory actions on the noncompliant products.

**Burkina Faso** PQM provided technical assistance to LNSP to conduct a survey in the Bogodogo, Baskuy, Saaba, Nongre-Massom, Boulmiougou, and Komsilga communes of Ouagadougou. A total of 124 antimalarial samples were collected, visually inspected, and screened using Minilab™ testing kits. With PQM's technical assistance, LNSP compiled the sampling and screening data, reviewed and analyzed the data, and drafted a report. Of the samples, 51 percent were collected from the public sector, 39 percent from private pharmacies, and 10 percent from the informal market. Using Minilab™ screening tests, 11 samples were determined to be doubtful and needed further laboratory testing. LNSP conducted confirmatory testing; the report is still under review and will be communicated to PQM in a timely manner.

**Core Malaria** Preparation for the study assessing a diversion of antimalarial medicines from public to private sectors was completed in quarter four. The antimalarials included in the study were Coartem and Sanofi's Winthrop Artesunate/Amodiaquine. Each study was designed to provide evidence of diversion, if it is occurring, and data on variations between market price set by vendors, batch numbers, date of expiry, the name of manufacturer, the country of manufacture, the type of outlets where the medicines were purchased, and the outlets' locations. Secondary objectives, which provide additional context on local public health status and help the President's Malaria Initiative (PMI) make informed decisions about future programming, included getting additional data on availability of antimalarials and diagnostics in the market. The information can also be used for public awareness and to empower the public about proper use of antimalarial medicines and the fight against poor-quality antimalarials.

Leading up to the study preparation, an updated protocol was finalized to carry out the diversion study in three African countries (Benin, Malawi, and Nigeria), and PMI Washington confirmed the medicines to sample. PQM sampled Novartis' Coartem, Artemether/Lumefantrine in all countries where the study was performed in this round. The samples of Coartem and Artesunate/Amodiaquine were collected from informal and formal drug stores using convenience sampling. Both urban and rural areas were covered. The regions/locations for sampling were identical, where possible, to the regions/locations where sampling occurred in previous studies in each country

In all three countries, USAID Coartem, as specified by its packaging, was not as readily available in the private-sector market as seen in previous studies. As a result the batch numbers of the samples of interest were collected and sent to PMI Washington when possible. Samples of Coartem and Sanofi's Winthrop Artesunate/Amodiaquine collected in the study within the three countries will be confirmed as diverted (or not) and provided in the final report. A detailed report on findings will be submitted to PMI Washington.

**Ethiopia** With PQM's support, EFMHACA continued safeguarding the public by conducting reliable testing of condoms. During this quarter, the laboratory tested 60 batches of condoms, out of which 39 failed. This finding was confirmed through repeated testing at the EFMHACA laboratory in the presence of both the manufacturer and importer. The manufacturer accepted the results and all of the 141 total imported batches, worth approximately \$2 million, have been banned from distribution. This is compelling evidence of the critical role that the laboratory can play in protecting the public.

EFMHACA branch laboratories, as part of a routine regional PMS, collected and screened a total of 44 medicines samples: 24 antimalarial, 17 opportunistic infection, and 3 antiretroviral medicines. All samples passed the screening. EFMHACA also collected a total of 501 PMS samples (antimalarials, MNCH, and opportunistic infection medicines) from private and public medicines outlets. The samples were tested using compendial methods. Three antimalarial samples failed. Writing of the final report is in progress.

**Guinea** Following Minilab™ refresher training provided by PQM staff, the LNCQM staff performed basic tests (visual inspection and Minilab™) on 14 out of 52 samples collected from the private, public, and informal sectors of Conakry's five communes during an initial survey of antiretrovirals, antibiotics, antimalarials, and antituberculosis medicines. Five of the 14 samples tested by Minilab™ showed doubtful results. After test



completion of the remaining 38 samples, PQM is planning to send all doubtful and failed samples, plus 20 percent of passed samples, to an accredited laboratory for confirmatory testing and then share outcomes with key stakeholders.

**Indonesia** During the third quarter, PQM conducted two semi-national, regional workshops convening officials from MOH and BPOM, including law and planning bureaus, for extensive discussion, dissemination, and action planning on a regulation (Menkes 33/2016) for quality assurance and PMS signed by the Minister of Health to include additional provisions. Based on discussions between MOH and BPOM during these two workshops, during the fourth quarter, there was a revision in Menkes 2/2016 to become Menkes 33/2016 signed by the Minister of Health to include additional provisions, most important that (1) the BPOM national PMS sampling strategy must be revised to include recommendations from MOH based on priority public program medicines; and (2) data from BPOM's PMS, the testing results on the medicines quality, must be shared with MOH within 10 days for the relevant programs (for failed or Out-of-Specification products), and routinely every three months.

The importance of these revisions by MOH cannot be understated. This regulation provides the regulatory framework going forward to ensure that MOH and BPOM are collaborating on matters of importance for quality control of medicines in Indonesia—something that did not happen prior to PQM's intervention to initiate this regulation. This also is a milestone in sustainability for the PQM program that this regulation and the positive effects toward building quality control systems in Indonesia will far outlive the PQM program itself. MOH and BPOM cooperation is vital for the long-term monitoring and control of quality of public medicines, which will in turn support data generation for MOH to use for considering the procurements, can aid the national disease control programs in complying with Global Fund Quality Assurance policy requirements, and can provide them with information on the quality of locally manufactured medicines by the state-owned manufacturers, especially for TB and HIV. This will also usher in more discussions and collaboration among manufacturers, MOH, and BPOM and establish reporting algorithms that should decrease the lead time between discovery of poor-quality products and the regulatory enforcement measures needed to remove them from the markets, thereby protecting patients and ostensibly increasing positive health outcomes.

**Kenya** The sixth round of the MQM program, which covered 11 sites, was led by the Pharmacy and Poisons Board in collaboration with staff from Kenya Medical Supplies Agency and the National Malaria Control Program. A total of 673 antimalarial medicines from the public, private, and informal sectors were collected and screened using on-site Minilabs™. The results of the screening revealed that 35 samples were doubtful and two failed. Final results are still pending as the next step will involve confirmatory testing, using compendial methods, for all failed and doubtful samples as well as on 10 to 20 percent of passed antimalarial samples.

The second major activity conducted during this quarter was the monitoring and evaluation of MQM activities at four selected sites. The monitoring and evaluation visit revealed that the MQM teams at eight of the 11 sites applied the sampling and testing according to MQM protocol and guidelines. Main challenges identified were due to high turnover of personnel and absence of experienced personnel to join the team. This visit also showed the high commitment of the Minister of Health of Kisii and Kisumu in sustaining Minilab™ activities by sponsoring more staff to be part of MQM program and by dedicating facility for Minilab™ activities within their hospitals.

**Latin America and the Caribbean** During this quarter PQM continued strengthening the capabilities for sustainable PMS of medicines quality. Beta testing activities continued for the online and mobile-device applications developed to support Physical and Visual Inspection in the field (Level 1 of the Three-level Approach).

**Liberia** As part of PMS activities in Liberia, 11 antimalarial samples were collected from two sentinel sites (Gbanga and Ganta) and subsequently tested using Minilab™. None of the medicines sampled were registered. Six of the 11 samples failed. One of the failed samples has been subjected to compendial testing at USP's Rockville laboratory with the result still pending. LMHRA continues to take regulatory action when poor-quality medicines are identified through its routine PMS. PQM is preparing to participate in an MQM dissemination meeting in Liberia scheduled for October 24–28, 2016. The main goal of the meeting is to share the results of the MQM program and other activities funded by USAID PMI in Liberia to a broader audience, including in-country donors, partners, and decision makers.

**Mali** PQM reviewed and analyzed the data from previous rounds of sampling and testing of antimalarial medicines. The results will be included in a report to be presented to the National Commission against Illicit

Marketing of Medicines and Counterfeiting. The analysis will also inform the planning of the next round of sampling and testing of testing of antimalarials.

**Mozambique** During the fourth quarter, it was discovered that some of the provinces had not completed the MQM samples that were not previously screened or sent to LNCQM for confirmatory testing. Due to the lack of results for FY16, an email was sent to the Mission requesting the samples to be shipped to an ISO 17025 accredited laboratory for confirmatory testing to provide results. The delays in testing the MQM samples from various provinces were discussed with the director of LNCQM, and a written request will be submitted to the head of the Drug Regulatory Authority regarding the screening delays, as well as LNCQM's ability to complete the testing in a timely manner. In FY17, PQM will support the Drug Regulatory Authority to address these issues and provide targeted interventions to ensure all samples are screened and tested in a timely manner.

**Nigeria** During the second and third quarters, PQM provided technical support to the NAFDAC PMS unit to conduct MQM sampling exercises in six sentinel sites in the six geopolitical zones of the country. During the fourth quarter, a final report on the survey was shared with NAFDAC for review and concurrence, and detailed reports will be shared once available. Confirmatory tests showed 41 samples (4.6%) failed out of 892 samples of antimalarials collected. The antimalarial samples collected all passed Level 1 visual inspections, 788 samples underwent Minilab™ screening, and confirmatory testing was performed on 104 samples that did not pass Minilab™ screening, along with 20% of passing samples. Similarly, 682 samples of MNCH medicines were analyzed in the ISO 17025 accredited NAFDAC laboratory Yaba, and the following failure rates were recorded: 33 percent of 166 samples of Misoprostol, 2 percent of 164 samples of magnesium sulfate, and 7 percent of 148 samples of calcium gluconate. Results for oxytocin are currently pending. Of the 204 collected samples of oxytocin, 15 percent were analyzed in the USP-India laboratory, with a 79 percent failure rate, and the remaining oxytocin samples are still pending testing and will be reported once testing is complete. Notable reasons for failure included impurities, no active pharmaceutical ingredients, and high disintegration time for the antimalarial. With PQM's technical advice, the NAFDAC PMS directorate plans to put hold on any further distribution of the affected drugs, conduct a medicines mop-up exercise at the various locations, and commence possible prosecution.

This quarter the system strengthening of the NAFDAC PMS unit in monitoring the quality of medicines underwent a significant expansion at various levels of the supply chain for pharmaceuticals and their ingredients. This was achieved through the conclusion of the PQM-facilitated in-country review process. The framework was developed in conjunction with relevant stakeholders, including regulatory agencies (NAFDAC), Pharmacist Council of Nigeria, Federal Ministry of Health (FMOH), Pharmaceutical Society of Nigeria, Nigeria Medical Association, Association of Community Pharmacists, the academic community, and the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria.

**Philippines** In collaboration with the Product Research and Standards Development Division and Regional Inspectors of the FDA, PQM is continuously providing technical support to strengthen medicines regulatory systems. To continue improving the country's PMS system, desk review continued identifying essential information (e.g., number of licensed establishments nationwide). A technical report is being finalized and will serve as reference material in guiding the revision of the current PMS strategy.

PQM has been in collaboration with the Philippines FDA to prepare a one-day seminar, titled "Ensuring the Quality, Safety, and Efficacy of TB Drug Products and Other Pharmaceuticals through Regulation and Promotion of Rational Use," for local government unit staff, pharmacists, supply officers, provincial health office staff, and city health office staff. The objective of the seminar is to communicate the roles and responsibilities of the FDA and PQM in ensuring the quality, safety, and efficacy of TB drug products and other pharmaceuticals, and establish closer collaboration with the local government units. Administrative Order No. 2016-0003 was issued to streamline regulatory approaches in licensing of drug establishments, thereby providing faster access of drug products to the public. At the end of the seminar, the participants will instruct compliance to the standards of GDP and good storage practices (GSP), and promote accountability and public health in the government sector.

PQM is currently redesigning the PMS strategy of FDA to move toward sustainability and ownership of quality monitoring activities. This activity will entail collaboration with Department of Health and the NTP in partnership with FDA regional offices and local government units. The FDA will develop a department order for PMS on quality activities in the Philippines to be signed by the secretary of health.

As of September 2016, there were 176 anti-TB samples collected and screened using the GPHF-Minilab™ kit. One out of 176 samples failed after confirmatory testing. The product did not comply with the dissolution specifications and the sample is under investigation by the FDA. In this quarter, a total number of 129 anti-TB medicines samples were collected and are being screened using the Minilab™ kit. Results are expected to be reported in October 2016.

### **Innovative Tools and Approaches to Strengthen Medicines Quality Assurance Introduced**

PQM strives to develop innovative tools and novel approaches to medicines quality evaluation and assurance by interfacing with academia.

**Cross Bureau** PQM convened a consultative workshop with academic experts from the University of Washington; Johns Hopkins University; and the WHO Collaborating Center for Advocacy and Training in Pharmacovigilance, Ghana, to address the need for developing risk-based PMS guidelines for low- and middle-income countries. Presentations, case studies, and plenary discussions were used to collect views, share experiences, and identify best practices that will serve as references for the development of the aforementioned guidelines. Based on the discussions and recommendations, PQM drafted an outline of the framework for implementing a risk-based PMS as well as the first draft of the framework.

**Ghana** In late FY15, PQM initiated a pilot study of the Sproxil technology in Ghana as a tool to detect unregistered medicines. Sproxil is a mobile product authentication technology that uses text messages to ensure that consumers don't buy counterfeit medicines. The proposed Sproxil technology will be used by field inspectors using mobile devices with internet connectivity to access drug registration information. Inspectors can determine in a short period of time whether a given medicine found in a facility is registered. The technology is easily scalable to the other regional facilities where FDA operates. FDA Ghana has been able to provide all the pertinent documentation necessary to gather data for field launch of Sproxil. Thus far, Ghana FDA has been able to provide pertinent registration information to PQM for forwarding to Sproxil to be used in generating the ideal and practical field tool before it is ready to be launched and tested in Ghana.

## **IR 4: Use of Information for Decision Making Increased**

PQM serves as a global technical leader in medicines quality assurance and an advocate for medicines quality in collaboration with a number of partners. Technical leadership entails contributing to an expanding body of knowledge on pharmaceutical quality-related health systems research, as well as developing and disseminating innovative and efficient quality testing techniques and approaches. Advocacy efforts involve the promotion of quality medicines and eradication of falsified and substandard products, forged through collaboration with diverse partners at local, national, and international levels, as well as visibility in external information outlets.

### **Availability of Information Related to Quality of Medicines Increased**



Poor-quality medicines pose a grave threat to patients in developing countries, but their presence remains a largely unknown problem—something that USAID, PQM, and national authorities are working diligently to combat. PQM uses a variety of methods to raise awareness about the potential

Workshop “Ensuring the Quality of Anti-Tuberculosis (TB) Medicines—Contributing Towards Ending the TB Epidemic,” Dubai, September 2016

dangers of using substandard or counterfeit medicines, each tailored to best reach the individual audiences including MRAs, ministries of health, public health partners, and the general public. PQM uses communication channels to increase public awareness about the importance of medicines quality assurance and stimulate the interest of stakeholders in the issues surrounding medicines quality.

**Core TB** PQM held a workshop, “Ensuring the Quality of Anti-Tuberculosis (TB) Medicines—Contributing Towards Ending the TB Epidemic,” in Dubai in September 2016. Regulators and manufacturers from various countries were invited to attend and interact with PQM and other invited guest speakers. Speakers included individuals from the WHO TB program, the Global Drug Facility, and South Africa, as well as various technical subject matter experts. Twenty-three participants representing regulators, as well as new and existing manufacturers from seven countries (Pakistan, Jordan, Morocco, Indonesia, Korea, Tanzania, and Kazakhstan) participated in the workshop. The objective of the workshop was to raise awareness about pharmaceutical quality and to provide information to manufacturers of anti-TB medicines about opportunities for using PQM technical assistance to strengthen their quality systems. The topics discussed in the workshop included the trends of TB control and treatment, the WHO Prequalification process, current GMPs, dossier requirements, and data integrity. Participants of the workshop also learned about the Global Drug Facility procurement process and quality standards, as well as WHO’s Collaborative Registration Procedure. Upon completion of the workshop, PQM staff held one-on-one meetings with manufacturers interested in discussing their status and interest in receiving PQM’s TA. New manufacturers were eager to engage with PQM, and next steps for possible TA were outlined during each meeting.

**Cross Bureau** In this quarter, PQM documented new reports on incidents of poor-quality medicines and updated the compilation of media reports on medicines quality. The compilation was posted on the PQM webpage. In close collaboration with USP, PQM produced a video on the importance of ensuring the quality of medicines, featuring the PQM program. The video will be available for viewing on the PQM website and disseminated to collaborating countries.

To play its advocacy and technical leadership role in medicines quality assurance, PQM attended and presented at the Scientific Exchange ‘SCIX’ 2016 Meeting held in Minneapolis, MN. PQM presented on the assessment of the effectiveness of the CD3+ tool to detect falsified and substandard antimalarials. The presentation was made at the session on counterfeit challenges in biopharmaceuticals. Speakers in this session were from the pharmaceutical industry and regulatory authorities. The participation in the SCIX Meeting was also an opportunity to gather information on new developments in spectroscopy technology with potential use in the detection of substandard and falsified medicines.

To provide up-to-date data and information on medicines quality, PQM updated the Medicines Quality Database (MQDB) with the addition of 1,023 new entries from Ethiopia, Ghana, and Mozambique. The MQDB Alerts feature was finalized and three incidents of falsified antibiotics found in Cameroon and Congo were added. Based on an analysis of MQDB data, PQM drafted an outline of a manuscript focused on antimalarial monotherapies. In this quarter, 511 viewers visited MQDB, and MQDB alerts were visited 46 times.

To increase knowledge and recognition by key audiences on the importance of medicines quality assurance systems strengthening, PQM is developing an e-learning course that will provide an introduction to the quality assurance of medicines. PQM finalized the draft outline and proposal of the course, which will include eight modules.

**Indonesia** During this quarter, the PQM program team participated in the National TB Program Meeting on Planning TB Logistics, in which PQM presented on “Joint Ministry of Health (MOH)-National Agency for Drug and Food Control (NADFC or BPOM) Medicines Sampling: Implementation of MOH Regulation 33/2016” to inform NTP officers on revision of the Menkes regulation, and to discuss upcoming joint sampling exercises to be sponsored by the government, the Global Fund, and PQM, to implement this regulation and to generate valuable data on program medicines in the public sector warehouses and other facilities. There were also a number of meetings to complete the first-tranche Global Fund procurement contract in support of ion chromatography testing of TB medicines. PQM acted as procurement agent for the Global Fund to support a reprogramming of Global Fund from NTP to three BPOM laboratories. Additionally, final delivery of all the commodities was completed, and PQM will plan for ion chromatography training in support of this equipment procurement during FY17. There is also an anticipated second contract under Global Fund’s new funding model to support \$2 million procurement for 10 BPOM laboratories using a similar contract structure with USP during FY17.

PQM staff sponsored a seminar during the national IAI-Indonesian Pharmacists' Association's annual Scientific Seminar, titled "Developing Pharmacists' Role for Better Quality of Life in the Association of South-East Asian Nations Economic Community (AEC) Era." PQM presenters/topics/discussions included Michael Megargee on "Dossier Compilation and Product Quality" and "International GMP Expectations and Inspections" and Lawrence Evans on "Good Storage Practices—Importance of Storage in Maintaining the Quality of Medicines." This was a unique opportunity to bring PQM's messages and potential technical assistance in Indonesia to a national audience of industry and government pharmacists, and there will be significant follow-up with a number of potential partners from this event. The intended outcome of the participation at the meeting was for pharmacists to realize their individual impact on product quality. PQM Indonesia personnel will be working closely with the meeting organizers to discuss participation for next year's meeting planned for early 2017.

A follow-up workshop for Southeast Asian region countries (11 member states) is currently being planned to take place in Jakarta, Indonesia, in October (first quarter of FY17) and sponsored by BPOM, the Asian Development Bank, WHO, and PQM. Following the regional training, there will be a dedicated, two-day follow-on national workshop for law enforcement, MOH, and regulatory task force members to discuss further action plans on substandard, spurious, falsely labeled, falsified, and counterfeit medical products in Indonesia.

**Mali** Upon request from USAID-Mali Mission, PQM is serving as a mechanism to support a study on the efficacy of artemisinin combination therapy medicines carried out by the Laboratory of Applied Molecular Biology of the University of Science and Technology of Bamako. The Laboratory of Applied Molecular Biology enrolled 121 patients and performed follow-up tests on them. Two cases of treatment failure were tested. PQM reviewed the laboratory's results and processed payment according to the milestone accomplished.

**Nigeria** During this quarter, PQM participated in a stakeholders meeting where pneumonia received some attention. The meeting was held with the FMOH and USAID to discuss the availability of amoxicillin dispersible tablets. Outcomes of the meeting include FMOH revising the Essential Drug List used in all health facilities in Nigeria to include amoxicillin dispersible tablet, and revising treatment manuals to include amoxicillin dispersible tablet for treatment of pneumonia in children and making it a drug that can be readily purchased over the counter. Pneumonia is the leading cause of death in children under 5 around the world. In Nigeria, pneumonia is the second-leading cause of death for children under 5. Accelerating uptake of proven interventions for pneumonia control is urgently needed to propel the country's march toward the United Nation's Sustainable Development Goal 3 targets. The meeting was part of the PQM advocacy strategy in which PQM provided technical input.

**Benin** PQM analyzed a survey on the quality of medicines data and drafted a presentation that LNCQ adapted and presented at a close-out workshop by Population Services International/Association Béninoise pour le Marketing Social et la communication pour la santé, a communication campaign against falsified artemisinin-based combination therapies in Cotonou. Fifty-one participants attended this workshop held on September 29, 2016.

### **Enforcement Actions Against Falsified, Substandard, and Unapproved Medical Products Increased**

PQM works to detect cases of falsified and substandard medicines. When poor-quality medicines are detected, PQM engages in timely information sharing and cooperative action to facilitate local MRA enforcement actions to remove poor-quality medicines from the market and warn stakeholders and the public of specific cases.

**Core Malaria** The PQM Core Malaria team continued analysis of antimalarial medicines quality control data from the medicines quality database. Data analysis is organized by region (Africa, Asia, and Latin American Countries) between 2005 and 2015. PQM continued its work to develop country profiles, which include information on available tools and systems to support quality assurance of malaria medicines. Previously, a country profile for Ghana was submitted to PMI Washington. In this quarter, the profile for Ethiopia was submitted for internal review after its content was verified with PQM and other stakeholders in Ethiopia. In addition, the profiles for Nigeria, Cambodia, Liberia, Benin, and Malawi are being developed. As part of this activity, interviews with in-country staff of the medicines regulatory authority and other related stakeholders in Benin, Malawi, and Nigeria were conducted to gain a comprehensive insight into many aspects of the health system that affect the regulation, availability, proper use, and quality of antimalarials. Documents to help understand country policy and health facilities operations were obtained. These will be used as reference

materials for other activities within the Core Malaria portfolio. They will also provide a basis to inform PMI priorities, future activity planning, and implementation.

**Indonesia** This quarter, PQM conducted two trainings, “Dissolution Analytical Method for Testing TB Medicines” and “Dissolution Performance Verification Test (PVT),” held on August 1–5 and August 8–12, 2016, in Manokwari and Denpasar, respectively, for regional BPOM laboratories. A total number of 25 analysts (seven males and 18 females) were trained. Dissolution is an important analytical method to determine the overall bioavailability of a medicine by looking at its ability to properly dissolve in the stomach and to reach target tissues to exert its therapeutic effects. During this training, locally manufactured FDC antiretroviral medicines were sampled from a hospital in West Papua. During both trainings, the medicine failed dissolution testing. PQM reported this to the BBPOM authority, and at the time of this report the sample is under official testing at the Manokwari reference laboratory for dissolution testing. PQM is following up very closely on this. Timely follow up and reporting to the Directorate of Pharmaceuticals and Medical Devices of Ministry of Health and Farmalkes is crucial so that they can recall the medicine and stop consumption at health facilities.

**Philippines** Through PQM’s effort, an FDA advisory notice for a Bacciter/Generic: Isoniazid/Dosage: 400 mg tablet product was released on August 22, 2016, by the FDA to the healthcare professionals and the general public not to purchase or use this illegal product. Upon evaluation, the sample submitted is an unregistered drug product, and the registration number does not belong to any registered drug product. The FDA authorities are also taking legal actions against the manufacturing company of this product for manufacturing without a valid certificate of product registration. PQM has shared the FDA advisory document to inform the TB program and USAID Philippines during the Inter-CA, COP, and Partners Meeting.

### **Regional and Global Collaboration for Medicines Quality Enhanced**

PQM raises awareness about the dangers of falsified and substandard medicines and provides information to the public and respective governments. PQM supports regional and global initiatives to promote medicines quality via regional partner meetings, development of regional databases and alert systems, and encouraging collaboration among stakeholders.

**Angola and Mozambique** During this quarter, PQM assisted two Mozambique MOH staff to support Minilab™ training in Angola. This training presented an opportunity for the two countries to collaborate and exchange experiences related to quality assurance of medical products. This collaboration proved essential, as PQM has trained and supported Mozambique since 2012 and with their improved technical capacity, the two trainers from Mozambique were able to apply lessons learned from their experience in their country in relaying the proper sampling and screening protocol.

**Regional and International Collaboration on Surveillance and Reporting of Substandard, Spurious, Falsely Labeled, Falsified, and Counterfeit Medical Products** PQM, in collaboration with WHO (Headquarters, South-East Asia Regional Office (SEARO), and country offices in South East-Asia) and the Asian Development Bank, took part in the planning and preparation for convening a regional training workshop for 11 countries’ regulators in Southeast Asia in Jakarta, Indonesia, in October 2016. Multi-country USAID Missions (Indonesia, Regional Development Mission for Asia, Burma, Pakistan, and Bangladesh) were contacted for contribution to support the participation of PQM experts and country regulators.

## **Key Challenges**

Challenges are an inevitable part of program implementation, but also serve as an important source of strategy recalibration and experiential-based growth. During the quarter, challenges were experienced across a wide range of issues.

Implementation challenges related to local funding, capacity, and human resources are common constraints. For example, limited funding to adequately prepare the Liberian LMHRA quality control laboratory has led to delayed technical assistance. The laboratory has limited laboratory space and equipment and requires more advanced training to cover its planned scope of accreditation. Similarly, Mozambique faced the inability to initiate the MQM program for this fiscal year and a lack of space to house key equipment that was shipped to the laboratory. The

increased equipment also brought electrical capacity problems that required PQM's intervention, as the space was not originally built to support a laboratory.

Key challenges were noted during the trainings held in Indonesia this quarter, including the lack of a recommended mechanical calibration apparatus for dissolution, limited laboratory consumable supplies to support the testing activity, limited availability of reference standards for medicines available in the market in Indonesia, and a lack of Indonesian Pharmacopeial validated methods to test medicines that are registered or brought in by the government under the Special Access Scheme. In addition, the line ministry, BPOM, experienced important human resource challenges. The head of the National Drug Quality Control Laboratories retired during the third quarter and has yet to be replaced. Also, there is a new head of BPOM itself, and thus there will be a steep learning curve for the PQM program once the technical assistance is finally signed between USAID and BPOM, enabling work to continue. This represents challenges for PQM in terms of needing to start over to ensure strong buy-in and support for the multi-year projects already in motion, such as the WHO PQ activities. PQM is hopeful that their replacements will be strong leaders who can carry the program forward and collaboratively work together. Inefficient and inadequate communications within and between the government partners has a negative impact on overall project progress. There are significant delays and ineffective implementation from inadequate communication channels and delivery that PQM has seen through the process of the USG-GOI agreement negotiations. Lack of reporting within divisions and a lack of mechanism for bringing MOH-BPOM together has hampered overall progress and created a number of additional challenges for the program.

In Pakistan, challenges in implementation of the program remain unchanged due to logistics and visa processing for travel to the country. The Ministry of Interior of Pakistan has a restriction on multiple entry visas, and the travel requires eight weeks' planning. Another challenge for PQM is the likelihood of change in the regulatory landscape due to political considerations. The 18th amendment of the constitution has transferred the authority of regulation of drugs to the provinces; however, under the constitution, three provinces of Pakistan, namely Punjab, Sindh, and Khyber Pakhtunkhwa, have empowered the federation to establish a Drug Regulatory Authority. The post-marketing surveillance and quality of medicines, along with sale and distribution of medicines, fall under the provincial regulatory functions in DRAP's Act 2012 and Drug Act 1976. To this effect, the regulatory landscape is unclear. For example, the Punjab government is now establishing a state-of-the-art reference laboratory for testing of samples failed by other laboratories and is being challenged by the manufacturers. As the largest province in Pakistan, Punjab will set a precedent for other provinces to follow. The government of Khyber Pakhtun Khwa is now deliberating on increasing the number of quality control laboratories in its province. The Pakistan Drug Testing and Research Center in Lahore (an independent laboratory facility in Punjab) also requested assessment of its laboratory, as it is expecting a facility visit by the WHO PQ program. Given these changes in the regulatory landscape, it is strategically important for PQM to understand the country's political and health-sector strategy changes in order to make objective and appropriate program decisions on where to invest its technical assistance to maximize health outcome benefits.

In Uzbekistan, PQM still experiences significant bureaucratic challenges in terms of approval of the PQM program by the government of Uzbekistan. Currently, PQM is assisting the manufacturers association, Uzpharmsanoat, in preparation of the updated Project Passport, which is required to obtain approval from the Uzbek government for further activities in the country. One of the critical issues is procurement of equipment for the identified manufacturers to strengthen their quality-assurance system. The equipment and the manufacturer are still to be determined during detailed GMP assessment.

PQM Core portfolios are also experiencing challenges. Core TB has limitations in terms of field support funding that does not allow for technical assistance for local manufacturers of important anti-TB medicines. For example, during the workshop held this quarter in Dubai, two key manufacturers from Pakistan expressed their earnest desire to work with PQM to obtain WHO PQ of first-line TB medicines. This work would be very important, as Pakistan will soon be one of the countries that no longer receive Global Fund donations. But PQM does not currently have funding from the USAID Mission in Pakistan to work on the TB medicines. Within Core NTD, challenges relate more to products. The lack of good-quality API for an NTD medicine is the critical challenge. To combat this, PQM is attempting to address the shortage of the API for the finished product manufacturers. The low NTD product global market value for many of the FPP manufacturers is another challenge.

## Lessons Learned

The experiences of the quarter are crucial for the PQM program to continuously improve program delivery, building on the lessons learned, avoiding pitfalls, and seizing opportunities for partnership and improved country ownership.

In Benin, applying a risk-based approach to the testing of antimalarial medicines demonstrated a rapid turnaround time for reporting. The risk-based approach for the medicines survey allowed the laboratory staff to complete the testing, and capture and report all data in a relatively short time. In turn, this allowed the management to write a letter to the regulatory authority on the products that failed to meet the specifications in less than a week after the testing was completed. Successes from the risk-based approach build a strong case for its application in other settings.

In Thailand, partner coordination is essential to achieving activity implementation and obtaining reports on results. This is becoming more complex due, in part, to the level of participation of partners and the new political environment. Additionally, the lack of a local staff or consultants based in Thailand has led to a communication gap between PQM and Thai program partners, including the MOH, Bureau of Vector-Borne Disease Control, Bureau of Drug and Narcotics, and FDA. A major lesson learned from this situation is that it is very important to have a local native country consultant in place for day-to-day communication, coordination, and face-to-face meetings with program partners and PMI-USAID/Regional Development Mission for Asia to ensure the effectiveness and continuity of the program activity implementation on the ground. Similarly, a lesson learned from the Core Malaria program this quarter was that the collection of information for the development of malaria country profiles is much more effective through visiting the countries rather than doing so remotely. Without conducting interviews and visiting the partner organizations and facilities, obtaining necessary information and data is challenging. In-person visits allow for the knowledge transfer to be seamless and produce more accurate country profiles.

The PQM team also learned that involving non-traditional partners in program activities can have positive effects. During this quarter, the PQM Nigeria team decided to include the academic community (lecturers and students of faculty of pharmacy) as participants in the series of training sessions provided to NAFDAC laboratory staff. The intention was to extend the knowledge and skills transfer to various universities, and expose the students and lecturers to recent and practical activities in the pharmaceutical sector. This will support the university system's efforts to produce graduates with skills in both theoretical and practical quality assurance techniques and thus make positive contributions to the pharmaceutical manufacturing sector. Appreciation letters were received from the students and lecturers citing benefits and impacts of the training sessions. Taking this approach to training and multi-level partner inclusion in PQM's future activities will increase local program sustainability and ownership.

## Sustainability, Partner Contributions, and Ownership

PQM strives to embed sustainability in its programming in an effort to create strengthened systems that will one day be capable of assuming responsibility of all relevant processes and operations. Sustainability, in this context, is defined as the set of physical resources, processes, regulations, and partnerships that enables the eventual independent operation and full function of the institution or program in compliance with its mandate.

During the fourth quarter, PQM portfolios increased sustainability by transferring ownership of medicines quality activities, by cascading knowledge through a systems-based approach, and by building partnerships. Transference of activities to local government authorities signals an increased degree of technical and financial competence, and thus a more sustainable health system. Knowledge transfer enables regulatory and manufacturer personnel to utilize the knowledge gained from PQM technical assistance to be applied broadly across the health system. Last, forging partnerships enhances coordination, promotes synergy, and expands access to more diverse funding and resources.



In Ethiopia, Indonesia, Mali, Liberia, and Nigeria, strong commitment from government regulators resulted in incremental ownership of activities. Regulatory agencies assumed greater financial responsibility over training, post-marketing surveillance activities, and equipment calibration, signaling incremental progress toward sustainability.



EFMHACA engineers receiving training on maintenance of laboratory equipment

During the quarter, the Ethiopian Medicines Authority, EFMHACA, began funding specific training activities such as on-the-job training of staff working in product registration, process validation, and analytical method validation. PQM has made a strategic shift in the delivery of trainings by focusing on specialized trainings and allowing EFMHACA to take the lead on the basic trainings. EFMHACA has also signed an agreement with the Global Fund to provide fee-based testing services; this has helped EFMHACA to generate funds for its laboratory and sustain its activities. The Indonesian provincial and district health offices are seeking local government budget support for QC testing of medicines, identifying it as a key component of their overall service delivery. In Mali, PQM negotiated with the medicines regulator (LNS) to contribute toward the cost of the next

round of sampling and testing of antimalarial medicines. LNS agreed to cover 4.7 percent of the cost of the next round; PQM and LNS are currently working on a sustainability plan toward ownership of these activities. The Liberian MQM program is achieving greater sustainability with the increased medicines regulator's contribution of 19 percent of the total fixed amount award budget. Finally, in Nigeria, NAFDAC leadership is in the process of assuming the expenses of equipment calibration by contracting with a PQM-recommended vendor.

The effects of direct technical assistance were amplified during the quarter through knowledge transfer, an essential component of sustainability. Knowledge transfer was achieved through replication of trainings in Nigeria, Ethiopia, and Liberia, as well as the application of principles gained through technical assistance in the areas of site visit findings, GMPs, and PMS activities in Core Malaria and Core TB programs. The leadership of the Nigerian authority, NAFDAC, continued to demonstrate commitment to improve technical capacity of the laboratory staff by sponsoring top managerial staff from the Kaduna regional laboratory to observe various training sessions and the accreditation process in the Agulu Lab in order to transfer knowledge to the Kaduna Regional Laboratory staff as they prepare for ISO 17025 Accreditation. NAFDAC has also organized inter-laboratory training sessions facilitated by NAFDAC staff trained by PQM, as this will increase institutional capacity within NAFDAC's laboratories in the country. Staff from Ethiopia's main QC laboratory are now providing on-the-job training to staff of branch labs and those working at ports of entry to transfer knowledge and skills gained from PQM TA. In Liberia, the national lab's QC manager received training at USP's laboratory in Rockville, MD, to allow the QC manager to provide training to other analysts in the lab.

In the Core programs, manufacturers and regulators are using information and skills gleaned from PQM technical assistance to apply to other aspects of health systems strengthening. Information derived from in-country interviews and site facility visits in the Core Malaria Program will not only be useful to PMI from a PQM medicines quality perspective, but will also be used by USAID missions for planning and supporting the implementation of different activities to fulfil the PMI strategic objectives. For example, PQM's visit to Malawi was welcomed by the Mission, which leveraged PQM's work to provide information, insight, and recommendations to the overall malaria strategy implementation in the country, which has the potential to impact broad sectors of Malawi's health system. The Core TB program provided technical assistance to manufacturers of anti-TB medicines to improve their quality assurance systems, which, in turn, enables them to utilize the knowledge that they have gained through the work of Prequalification or other Stringent Regulatory Authority approval and apply it to other products in their pipeline.

Partner collaboration was demonstrated most significantly in Indonesia through the revision of the Menkes 33/2016 regulation (formerly Menkes 2/2016), which provides the legal framework and requirements for the ministry of health and the government regulatory agency (BPOM) to work together on issues of quality control of medicines for the long term. This regulation is the single most important achievement by the PQM program in Indonesia to date, and will serve as a lasting imprint of the impacts that PQM had in Indonesia post-2019. In Cambodia, PQM initiated discussion with WHO to provide technical assistance to build the capacity of the Department of Drugs and Food on the Drug Registration System and support NHQC in attaining ISO 17025 Accreditation. As a result, WHO is interested in collaboration with PQM to set up the Drug Registration System for the Department of Drugs and Food, and allocated \$10,000 to support training on compendial techniques for NHQC analysts. Finally, through PQM's support, two Mozambique ministry of health staff supported Minilab™ training in Angola which provided an opportunity to collaborate and exchange experiences related to quality assurance of medical products

## Management Overview

A major accomplishment for the PQM team during the fourth quarter was the successful submission of all FY17 work plans by the USAID deadline of August, 31. PQM drafted FY17 work plans for 19 country Missions, one Regional Mission, four directed Core portfolios, and one Cross Bureau. The works plans outlined the background and rationale, PQM's strategic approach, and planned activities for the fiscal year, as well as highlighting the associated program management, monitoring and evaluation, knowledge management and communication, and budgetary information. Each work plan also included a performance monitoring plan, budget, activity monitoring matrix, technical resource allocation, and environmental mitigation and monitoring plan. These comprehensive documents provide USAID with a considerable amount of information that allows USAID activity managers to clearly understand the plan for the upcoming fiscal year. By submitting the work plans at the end of August, PQM anticipates many work plans receiving USAID approval early in the new fiscal year and swift implementation thereafter. Pending strategic planning by USAID for the Regional Malaria Program, one additional work plan will be developed for FY17.

During the fourth quarter, PQM also added two new staff to the Analytical Laboratory Services group within the PQM Technical Support team. The Scientist III and IV positions will enhance the Analytical Laboratory Services' capacity to respond to the growing demand of QC testing of medicines in PQM-supported countries. In addition to QC testing, the team now has competent instrument maintenance specialists to support countries' development of medium- to long-term sustainable instrument maintenance policies and procedures to prevent frequent breakdowns and maximize instrument utilization. With improved instrument utilization, PQM can enhance the capacity of NQCLs to increase the detection of substandard and falsified medicines for improved health worldwide.