Promoting the Quality of Medicines

Promoting the Quality of Medicines (PQM) Program

FY 2017 First Quarter Report
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About the Promoting the Quality of Medicines (PQM) Program

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Agreement Officer's Representative Team	Mr. Bob Emrey, Lead Health Systems Specialist Ms. Elisabeth Ludeman, Senior Pharmaceutical Management Advisor Ms. Tobey Busch, Senior Pharmaceutical Management Advisor
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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 with USAID to address critical pharmaceutical management challenges in developing countries. 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 December 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 to strengthen medicines regulatory capacity and quality assurance systems in developing countries. PQM also supports the manufacture of quality-assured priority 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. PQM's work is measured in three result areas; this report summarizes results achieved during the first quarter of FY17, from October 1 to December 31, 2016.

The first 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 medicines regulatory authority (MRA) to execute policy. Major accomplishments under the first result area include achievement of two internationally recognized accreditations: ISO 17025 accreditation for Agulu laboratory in Nigeria and Nay Pyi Taw Pharmaceutical Chemistry Laboratory in Burma. PQM has also supported the Medicine Inspection Directorate in Ethiopia towards ISO 17020. The adoption of the international standard verifies EFMHACA produces credible inspection reports and therefore creates opportunities for membership in PIC/S in the future.
Also in Ethiopia, inspectors previously trained by PQM, conducted 42 inspections of foreign manufacturers, paving the way for those manufacturers to register products in the country. In a two-day consultative workshop, PQM assisted the Pakistani MRA to draft a roadmap for a reformed registration system from manual based to semi-manual-based. Once this exercise is completed, a searchable database will be available to the public which will include all of the registered products in the market. Following up on a workshop held at USP, PQM made significant progress on finalizing the Guidance for Implementing Risk-based Post Marketing Quality Surveillance in Low and Middle Income Countries (LMIS). With the aim to sustain the post marketing surveillance programs in Mali and Angola, PQM supported the countries' MRAs in the development of sampling guideline which provides direction on sampling strategy, sample collection, testing and reporting. Field staff were also trained in sampling and testing methods, while national laboratories handled samples requiring advanced confirmatory testing. Throughout the quarter, PQM continued its support to post marketing surveillance programs in Angola, Ethiopia, Kenya, Liberia, Mali, and Philippines; samples were collected and tested and results were communicated with the respective MRAs for informed decision making.

Increasing the supply of quality medicines, the second result area, encompasses PQM's broad technical assistance for the manufacturing of quality-assured priority essential medicines. PQM provides support to manufacturers to attain stringent international good manufacturing practice (GMP) standards necessary for the supply of quality medicines. Technical assistance to the Chinese manufacturer, Shangyu Jingxin Pharma, resulted in the WHO prequalification of the active pharmaceutical ingredient for the anti-tuberculosis drug Levofloxacin. The same manufacturer also received the Certificate of Suitability (CEP) for the active pharmaceutical ingredient for the neglected tropical disease medicine Praziquantel. In Nigeria, PQM supported a local manufacturer to reformulate amoxicillin dispersible tablet; trials indicate positive outcomes for critical quality attributes. The new formulation reduces manufacturing time, cost, and energy consumption compared to the previous formulation. In Kenya, PQM supported a local manufacturer in submitting its dossier for chlorhexidine gel to the East African Community, for joint MRA review. Successful approval will result in access to the product across the 6 EAC member state economies and potentially used by hundreds of thousands of newborns. Three Pakistani manufacturers' dossiers for Chlorohexidine gel have received pre- conditional approval. The condition for approval is subject to site visits by the Pakistan regulatory authority's inspectorate, and verification of stability study data. In total, PQM provided support to 25 manufacturers in pursuit of WHO prequalification or stringent regulatory authority, and 20 manufacturers for local MRA approval.

PQM's third result area is the utilization of information on medical products 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 tuberculosis eradication, sharing information on detection tools, developing competency for pharmacists, and supporting regional medicines surveillance.

PQM is proud to share results achieved during the first quarter of FY17, progress which furthers PQM's mission of ensuring the quality, safety, and efficacy of medicines essential to USAID priority diseases.

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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)
DFDA	Department of Food and Drug Administration (Burma)
DGDA	Directorate General of Drug Administration (Bangladesh)
DNME	Divisão Nacional de Medicamentos e Equipamentos (Angola)
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
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
ISO	International Standardization Organization
LMHRA	Liberian Medicines and Health Products Regulatory Authority
LNCQM	National Quality Control Laboratory (Mozambique)
LNS	Laboratoire National de la Santé (Mali)
MNCH	Maternal, newborn, and child health
MOH	Ministry of Health
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)
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMI	President's Malaria Initiative
PMS	Post-marketing surveillance
PQM	Promoting the Quality of Medicines
PTBB	Produk Terapetik 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
SSFFC	Substandard/spurious/falsely-labelled/falsified/counterfeit
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

Since 1992, the U.S. Pharmacopeial Convention (USP), a scientific nonprofit organization, has worked with the United States Agency for International Development (USAID) to assist developing countries address critical issues related to pharmaceuticals. The Promoting the Quality of Medicines (PQM) program was established in 2009 with a mission to 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, undermining decades of health investments, including those made by USAID.

The PQM program has field offices in four countries (Ethiopia, Indonesia, Nigeria, and Philippines) and works in in 30 other countries.

Figure 1: PQM Program Reach Worldwide

Results Framework

PQM's Results Framework is organized according to three result areas. These complementary areas contribute to PQM's approach of affecting a country's health system as a whole. The globally designed systems-based approach is tailored to fit the needs of individual countries or regions and includes key stakeholders throughout the health system.

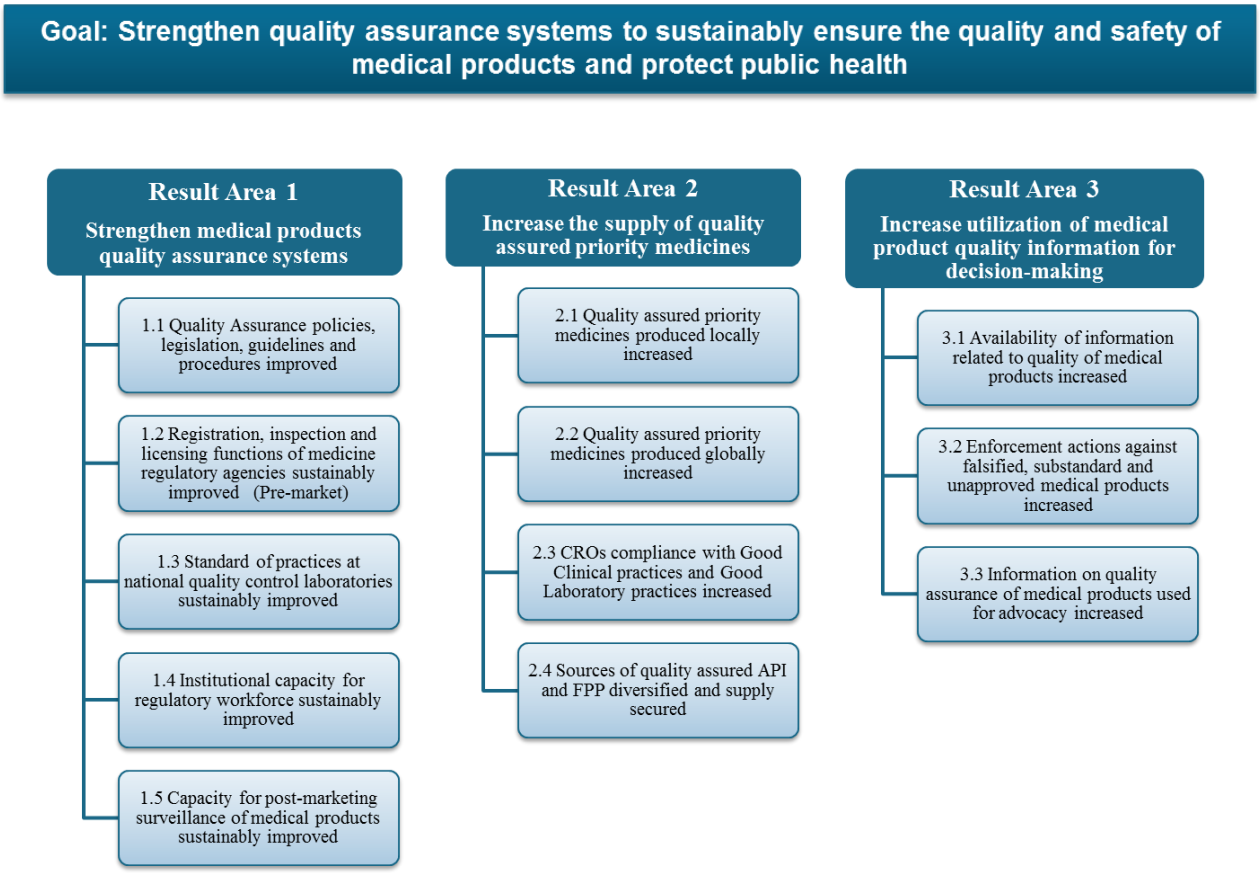


Figure 2: PQM Results Framework

This report presents highlights the results achieved by PQM organized by result area, representing multiple countries where the program works, as well as by global, regional, and country portfolios for the October–December 2016 period.

Quarterly Progress by Result Area

Result Area 1
Strengthen medical products quality assurance systems

Result Area 2
Increase the supply of quality assured priority medicines

Result Area 3
Increase utilization of medical product quality information for decision-making

The first result area encompasses activities which strengthen the capacity of medicines regulatory authorities (MRAs) to review and approve quality-assured essential medicines. Strong MRAs are better able to protect their populations from poor-quality medicines. PQM works with national and regional regulatory authorities to build sustained capacity for medicines evaluation, inspection, and surveillance.

Quality Assurance policies, legislation, guidelines and procedures improved

Appropriate policy frameworks are fundamental for ensuring the quality of medicines and improving health systems; without effective policies, the illegal trade of poor-quality medicines would be uncontrolled. PQM provides 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.

Philippines PQM supported the Food and Drug Administration (FDA) in the development of the Terms of Reference (TOR) for its 5-year Strategic Plan (2017-2022). The TOR was finalized by the FDA's new director general after its review by both Philippines FDA and PQM. .

Ethiopia In this quarter, Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) conducted an assessment on food supplement registration and, based on the gaps identified, 14 EFMHACA staff were trained. PQM provided the technical support while EFMHACA funded the training. The marketing authorization strategy, developed with PQM assistance, underwent additional reviews this quarter by high level officials at EFMHACA. Completion of this strategy is a priority activity for the ministry of health (MOH). Biological registration guidelines were revised and various standard operating procedures (SOPs), such as fast track medicine registration, were developed.

Registration, inspection and licensing functions of medicine regulatory agencies sustainably improved (Pre-market)

After assessing existing quality assurance systems, PQM builds the capacity of the regulatory agencies to strengthen regulations, registration, and inspections processes through hands-on training and technical assistance.

Ethiopia In support of EFMHACA's objectives to achieve international standards (ISO/IEC 17020) for their Medicine Inspection Directorate, PQM provided technical assistance to develop the following procedures:

- compliance and appeal procedure;
- corrective and prevention action (CAPA) procedure;
- procedure for control of records;
- procedure for using facilities and equipment of the medicine inspection directorate;
- document control procedure;
- SOP for inspection process;
- quality manual for medicine inspection directorate;
- SOP for internal audit procedure;
- management review procedure; and
- subcontracting procedure

The medicine inspection directorate staff received training on the new procedures to ensure successful implementation. The ISO/IEC 17020 accreditation places emphasis on organizational ability to manage impartiality, conflicts of interest, accountability, traceability as well as staff technical competence, inspection processes, and equipment. An accredited inspection directorate provides assurance of technically competence and consistently reliable results which will ultimately reduce costs and lower risks. The adoption of the international standard verifies EFMHACA produces credible inspection reports and therefore creates opportunities for membership in Pharmaceutical Inspection Co-operation Scheme (PIC/S) in the future.

PQM led training to 50 EFMHACA administration staff based in Addis Ababa on regulatory packages; EFMHACA provided financing for the training. Training topics included:

- fundamentals of regulation;
- inspection principles and methodologies;
- pharmaceuticals laws and regulations;
- food safety and quality regulation;
- health care quality; and
- professional licensing and regulation

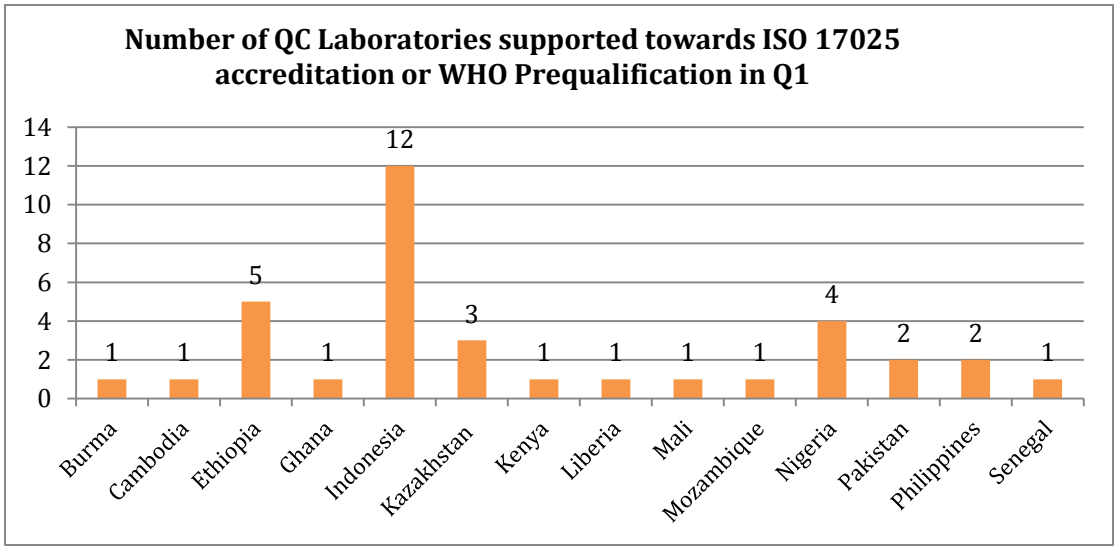
PQM supported the review of the GMP inspection process directives, the qualification training directives, as well as experience requirements of GMP inspectors. The guidelines for the submission of the Site Master File were finalized and approved by the management and staff received on-the-job training on the guidelines. EFMHACA sponsored the training on basic GMP for 25 of its staff with technical support from PQM to prepare the training materials and deliver the training. EFMHACA inspectors, previously trained by PQM, inspected 42 foreign manufacturers during the quarter as compared with 56 in FY16 and zero in FY15 due to EFMHACA's prior lack of capacity and other priorities. As the GMP inspection precedes dossier application in Ethiopia, increasing the coverage of foreign GMP inspections increases the availability of medicines as inspected manufacturers may submit their dossiers and register their products in the country. PQM's observations concur that report writing

and depth of inspection of EFMHACA's staff have improved in line with the accreditation's requirements. Areas of improvement include: technical deficiencies in addressing validation, sterile products manufacturing, Heating Ventilation and Air-Conditioning (HVAC) Systems, and water supply systems during inspection.

Pakistan In this quarter, PQM's Integrated Regulatory Information Management System (IRIMS) Technical Working Group and Drug Regulatory Authority of Pakistan (DRAP) Regulatory Registration team undertook a joint review of DRAP's registration systems and practices with the goal of establishing an IRIMS. The review was accomplished through a two-day onsite workshop at DRAP and a two-day expert consultation meeting at USP Headquarters in October 2016. A major outcome of the workshop was a draft roadmap for reform of DRAP's registration system from manual base to semi-manual and, eventually, to an online system. Another outcome of the two-day expert consultation meeting at USP Headquarters was the provision of technical assistance to strengthen DRAP's registration system in the context of an IRIMS package. The adoption of data standards and establishment of information management systems will facilitate electronic transmission of regulatory information and provide credible and evidence-based data for regulatory decision making. The PQM team placed emphasis on the systematic implementation of IRIMS to strengthen the registration system. DRAP has initiated implementation of the roadmap by digitizing data of registered drugs dating back to 1976. Initial data prepared by the DRAP Product Evaluation and Registration Department will be verified with the help of Industry. The data prepared by the Division is displayed on DRAP's website and the provincial offices of DRAP have been instructed to verify the data. Once this exercise is completed, a searchable database will be available to the public and all of the products in the market that have been registered with DRAP will be known thereby empowering the public to verify that products they use are approved by DRAP.

Standards of Practice at National Quality Control Laboratories Improved

PQM builds the capacity of the National Quality Control Laboratories (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; regulatory agencies and medicines manufacturers typically accept test results only from accredited or WHO-prequalified (WHO PQ) 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 United Nation (UN) agencies and other entities involved in procuring bulk medicine.



Angola In the fourth quarter in FY 16, a proposal was accepted to establish a temporary QC laboratory that will equip the Direcção Nacional de Medicamentos e Equipamentos (DNME) with basic QC equipment. Building on the proposal this quarter, PQM procured quotes for an analytical balance, pH meter, UV-Vis, and some laboratory consumables. Procurement and shipment is slated to begin in February 2017 once a clearing agent has been selected and contracted for clearing shipments to Divisão Nacional de Medicamentos e Equipamentos/Inspector General (DNME/IG). During the February 2017 trip, PQM will identify and finalize staff

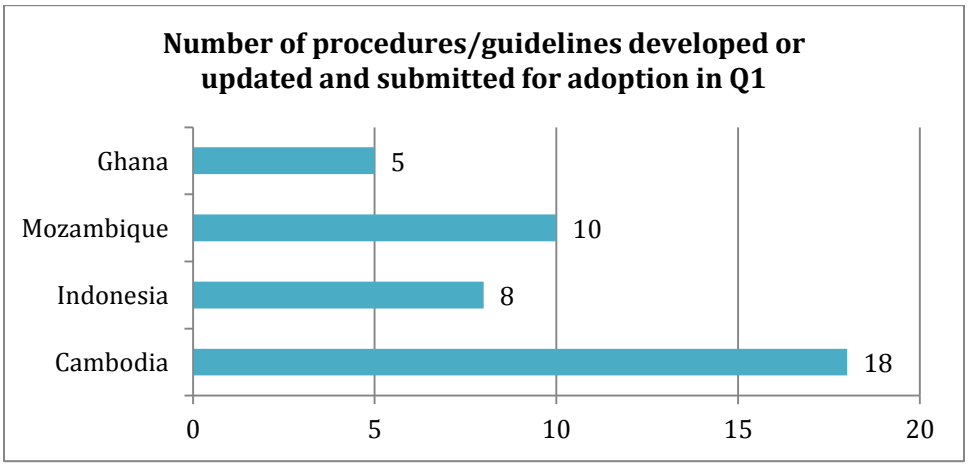
that will be trained to conduct the basic testing on medicines and complete recruitment for an in-country consultant.

Burma The Department of Food and Drug Administration (DFDA) Laboratory in Nay Pyi Taw received their official ISO 17025:2005 assessment visit from ANSI-ASQ National Accreditation Board (ANAB) in December 2016, resulting in an official accreditation status for ten pharmaceutical testing methods. PQM facilitated and coordinated ANAB to conduct the ISO 17025 pre-assessment audit at the Nay Pyi Taw laboratory in October 2016. During the visit, PQM assisted the Nay Pyi Taw Laboratory to address the pre-assessment audit findings before the actual audit in December 2016. Given the adequate preparedness of the laboratory's Quality Management System (QMS) and high level of technical expertise demonstrated by the laboratory analysts, the lead assessor officially re-evaluated the visit, changed the pre-assessment into an accreditation assessment and audit of the QMS system, and closed the visit with a discussion on the findings.

As DFDA is undergoing expansion, the need to modernize its infrastructure to meet the increased demands from the Ministry of Health and Sports, to ensure the safety of medicines and food in the country, has become eminent. Given the fact that there is no local expertise in designing and configuring the analytical laboratories, PQM included an activity on the FY 17 work plan to provide technical assistance on laboratory design for both DFDA's construction projects.

Cambodia During the first quarter of FY 17, PQM reviewed 18 new Standard Operating Procedures (SOP) created by the National Health Products Quality Control Centre (NHQC). As of December 31, 2016, NHQC has approved 60 SOPs, including its Quality Manual.

Ghana Building on the expanded scope of accreditation, in the first quarter, PQM evaluated the accredited scope by verifying compliance with the standard requirement. PQM provided key technical assistance by installing, qualifying, and calibrating key equipment for one of the accredited tests, dissolution. Additionally, PQM verified proficiency test scores on all accredited scopes as well as calibration of key equipment. A proposed training for the relevant accredited tests for medical devices, the physicochemical unit, and microbiology was finalized and the training is due to take place in the second quarter. A trip has also been planned in January 2017 to evaluate relevant SOPs and conduct quality management systems training and set a date for the third quarter ISO 17025 surveillance audits.



Indonesia Throughout the first quarter, PQM Indonesia continued to implement the delayed FY 16 work plan activities with the aim of above 90% completion by year's end. During this quarter, a number of key trainings and meetings were held with the MOH, the Provincial QC Laboratory (BBPOM) and other government stakeholders. PQM provided training and technical assistance to manufacturers and worked towards ratifying the government-to-government agreements between the U.S and Indonesian Governments. Additionally, USP signed a second procurement and activity contract with the Global Fund in support of 12 Indonesian National Agency of Drug and Food Control (BPOM) provincial laboratories as a follow on to last year's initial project to provide equipment to BPOM's national Therapeutic Product and Hazardous Substances (PTBB), Reference Standard, and Jayapura laboratories.

PQM supported the PTBB laboratory towards WHO PQ and also towards increasing capacity of the laboratory to test essential and priority disease medicines (TB, ARVs, etc.) through cooperation between the Global Fund, PQM Indonesia/USAID, MOH, and BPOM, as established by PQM Indonesia. Efforts are underway to provide both equipment (Global Fund) and technical assistance (PQM Indonesia) to the national and priority provincial BPOM QC laboratories that will expand the capacity for testing medicines in the public and private sectors. This prioritization was brought about through the ongoing advocacy by PQM Indonesia at the laboratory (technical level) in cooperation with requests from the MOH disease control programs, as well as resulting from the revised national policy (Menkes 33/2016) initiated by PQM Indonesia and WHO to ensure adequate coverage, sampling, testing, and reporting of public sector medicines quality.

In line with the above cooperation scheme, PQM Indonesia facilitated the import, delivery, and installation of Dionex Ion Chromatography machines for use by the PTBB (National), Reference Standards (National) and the Jayapura, Papua (Provincial) BBPOM/BPOM laboratories for use in testing kanamycin, streptomycin and amikacin (and other medicines, such as vaccine testing). While the equipment was provided through a Global Fund-USP joint contract that was initiated by PQM Indonesia, PQM Indonesia will provide the ongoing technical assistance on the use of the equipment, including initiating a training program during second quarter in FY 17 and incorporating this testing capacity into BPOM's national PMS program and for reporting to the MOH's TB disease control program.

Nigeria The National Agency for Food and Drug Administration and Control (NAFDAC) Zonal Laboratory of Agulu has received official notification of accreditation from ANAB as of December 2016. The laboratory is now able to conduct multiple pharmaceutical tests. Looking ahead, The QA Team organized a roundtable with the Head of NAFDAC, Central Drug Control Laboratory in Yaba, and other key laboratory staff to discuss preparatory activities towards ISO/IEC 17025:2005 reaccreditation and expansion of scope of the laboratory from seven to ten tests. The outcome of the meeting was a well-defined roadmap on the planned scope expansion and the equipment needed for the reaccreditation. As part of the implementation of the roadmap, PQM conducted a mock audit of the Yaba laboratory with the aim of identifying deficiencies and opportunities for improvement in preparation for the ISO/IEC 17025:2005 reaccreditation by the ANSI-ASQ. Findings from the mock audit include four major non-conformances, nine minor non-conformances and four opportunities for improvement. The team also witnessed ten compendial testing methods demonstrated by the laboratory staff. The PQM team provided technical assistance to the laboratory to address the audit findings. As further support to CDCL Yaba towards the ISO 17025 reaccreditation, PQM procured and delivered some reagents and consumables required for the laboratory demonstrations of the various test scopes to be assessed.

Also during this quarter, NAFDAC labs participated in the Network of Official Medicines Control Laboratories (NOMCOL) inter-laboratory testing and the results are expected to be confirmed in quarter two. Equally important is the participation of, Kaduna, Yaba, NIPRD, IPAN and NAFDAC Agulu laboratories in the Proficiency Testing, and results were shared with the respective participating labs. In an effort to expand the ISO scope for NAFDAC Yaba lab, additional test scope was also obtained. PQM continues to build technical capacity at NAFDAC QC Laboratory in Kaduna in preparation towards ISO 17025 accreditation by reviewing QMS documents and technical SOPs. The procurement process for relevant equipment to support the laboratory accreditation and calibration schedule for existing equipment commenced this quarter.

Pakistan The International Centre for Chemical and Biological Sciences (ICCB) Hussain Ebrahim Jamal Research Institute of Chemistry laboratory in Karachi University and Pakistan Drug Testing and Research Centre (PDTRC) laboratory in Lahore have applied for WHO PQ, and have submitted an Expression of Interest (EOI) in June 2016, along with the Laboratory Information File. A QMS assessment followed and the confidential and non-confidential pre-assessment reports with specific CAPA recommendations were shared with the respective laboratories that were assessed in October 2016. The WHO team also visited Punjab Drug Testing Laboratory (PDTL) for a baseline assessment of their newly refurbished laboratory and their QMS.. In this quarter, PQM also monitored the progress on CAPA by CDL, along with the provision of technical support for QMS and Quality Manual Development (QMD). The PQM team also conveyed confidential and non-confidential assessment reports to the Appellate Laboratory of the National Institute of Health (NIH) in Islamabad, as well as conducted follow-up visits to monitor the progress on CAPA implementation. The PQM team met with the Secretary of Health at the Ministry of National Health Services, Regulations & Coordination in November 2016, together with the USAID Country Mission, to enhance the government's commitment to provide support to the Appellate Laboratory of NIH and to ensure strong engagement with PQM.

Philippines The FDA Alabang Testing and Quality Assurance Laboratory participated in proficiency testing for Camosunate plus Tablets, 300mg/100mg. The report was submitted to USP for verification. Meanwhile, Davao and Cebu Laboratories are scheduled to participate in proficiency testing schemes in 2017 to strengthen the regional FDA office and QC laboratories.

Liberia As part of the PQM staff visit to Liberia in October 2016, the ISO 17025 roadmap was reviewed with the Liberian Medicines and Health Products Regulatory Authority (LMHRA) Quality Control Manager. Additionally, analysts in the QC laboratory were interviewed to determine how much progress LMHRA QCL had made toward ISO 17025 accreditation. Noticeable improvements have been made in sample testing and analysis, proper use of laboratory protective gear, preparation of an analysis plan to test medicines with compendial monograph, and installation of the Empower software to ensure data integrity.

Mozambique PQM continues to build the technical capacity of the national quality control laboratory (LNCQM) by providing pertinent equipment, reagents and supplies needed to operate as a fully functional QC lab. During the first quarter, a second UV-Vis, reagents, supplies and laboratory consumables were procured and shipped to the lab. The LNCQM's sole water purification system has been deteriorating since last year which has led to technical difficulty. During the quarter, PQM ordered a replacement water purification system (to arrive in quarter two) as well as parts required to troubleshoot the original system. Also during the first quarter, the laboratory was contacted and sent an investigation ARV sample to urgently test and provide results for legal action. PQM provided the reference standards for the laboratory to complete the testing and report results.

Mali Laboratoire National de la Santé (LNS) participated in the latest inter-laboratory testing (ILT) provided to members of the Network of Official Medicine Control Laboratories (NOMCOL) – Sub-Saharan Africa. The ILT report from LNS showed improvement in Good Laboratory Practices (GLP) compared to the previous ILT. PQM discussed the challenges that LNS faced in completing the testing and the gaps identified in the report. Forthcoming laboratory training to address these gaps and challenges will be provided. PQM was prompted to focus on an additional gap analysis as a result of an assessment of LNS capacity and inventory of its activities implemented during the period of 2011 through 2015. PQM addressed the gap analysis for the Medicine Quality Control Services of LNS and examined all the quality control tests conducted, examined the types of medicines tested in 2016, and collected information on the staff able to carry out each test. Information was also collected on the source of samples tested in the laboratory, the cost of each test, and equipment available and their service status. Additionally, PQM procured calibration kits for spectrophotometers and a dissolution tester. Preparation for training on calibration/verification of the equipment is underway.

Kazakhstan PQM performed an initial assessment of three NQCLs in Karaganda, Pavlodar, and Kostanay for their compliance with WHO and ISO 17025 requirements and their capability to participate in the WHO PQ program. During this quarter, PQM finalized two remaining confidential assessment reports for Kostanay and Pavlodar quality control laboratories which provided individual observation details, objective evidence of the observations, suggested corrective actions and a suggested timeline for implementation. PQM also translated all three confidential reports into Russian. The assessment reports and their translations were delivered to the Kazakhstan FDA and three NQCLs.

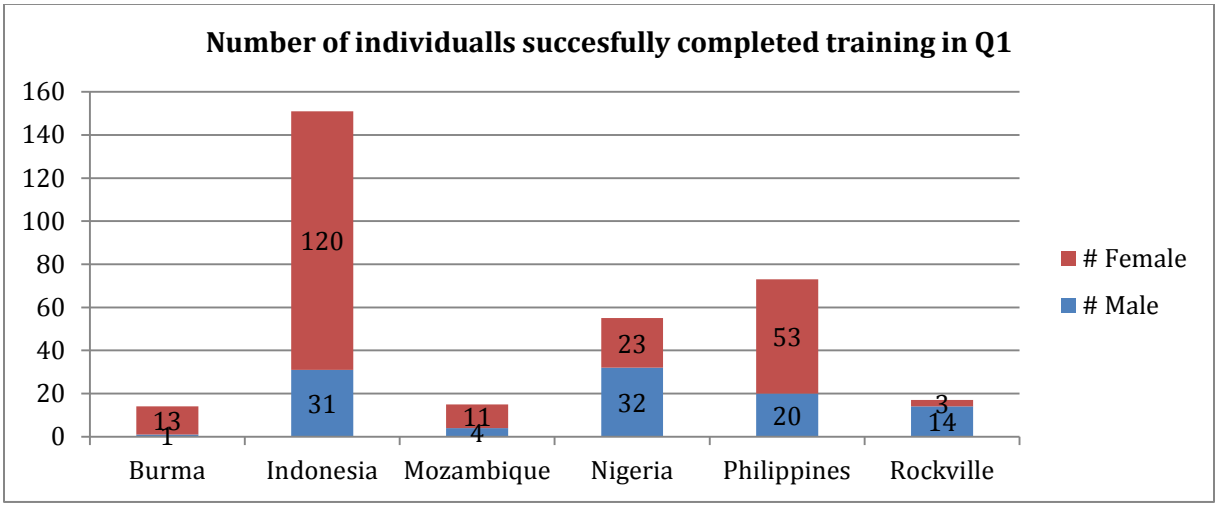
Based on PQM's recommendations, Karaganda and Kostanay laboratories developed corrective action plans (CAPAs); PQM reviewed them and provided comments on the CAPAs for improvement. Through a series of conference calls, PQM provided further clarifications and recommendations to the staff of the laboratories. PQM, the Kazakhstan FDA, and the laboratories agreed on the action plan for implementation of the corrective actions with remote assistance from PQM. According to the plan, these two laboratories should be ready for follow up assessment by PQM in May 2017. Also, it was agreed that as relocation of Pavlodar Laboratory from the apartment building in short- or mid-term is not feasible, this laboratory would not be eligible for WHO prequalification. Based on Kazakhstan FDA's suggestion, support will be provided to Astana Laboratory instead of the Pavlodar Laboratory.

Institutional capacity for regulatory workforce sustainably improved

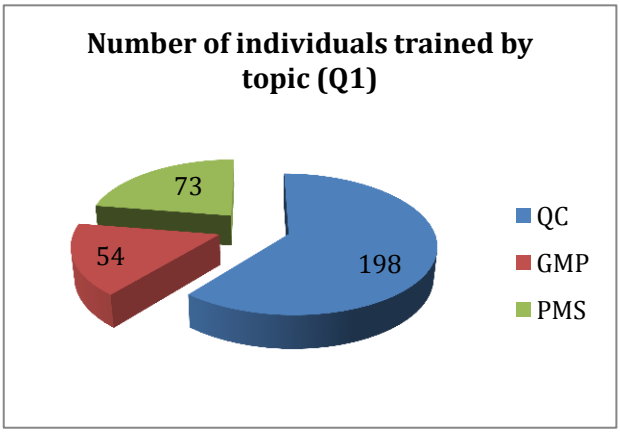
PQM collaborates with the World Health Organization (WHO), its regional and country offices, and national health authorities to conduct training courses on a broad spectrum of quality control test procedures and Good Manufacturing Practices (GMP). The courses, held onsite at national drug quality laboratories 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.

Burma PQM partnered with a lead assessor from ANAB and traveled to DFDA Nay Pyi Taw to conduct Measurement Uncertainty training to ten laboratory analysts from DFDA Nay Pyi Taw, two laboratory analysts from DFDA Mandalay, and two laboratory analysts from DFDA Yangon. The analysts from DFDA Pharmaceutical Chemistry laboratories of Nay Pyi Taw, Yangon, and Mandalay performed pre-assessment for ISO 17025:2005 accreditation at DFDA Nay Pyi Taw PC laboratory.

Ghana PQM sponsored two FDA staff to attend GMP and PIC/S training at USP headquarters to strengthen facility inspection capability. Ghana FDA provided a report to PQM on the benefits of this training, stating how they plan to apply lessons learned at their agency. For example, knowledge from the training will be used to guide Ghanaian local manufacturers to work towards filling the gaps identified in the audit of their plants with regards to the FDA's roadmap program of the local industry to WHO GMP compliance by the year 2020. Additionally, the trainees provided new areas for PQM to support the agency based on GMP practices learned during the training.



Indonesia During this quarter, PQM Indonesia continued its support to strengthen the technical capacity of BPOM GMP inspectors. Two GMP inspectors from BPOM participated in PQM's global training on GMP Inspections and PIC/S that was held during the first quarter at USP headquarters. The results and information gained from this training will be disseminated to other BPOM inspectors during the second quarter, as well as disseminated to key pharmaceutical manufacturers. PQM Indonesia has identified the need to intensify its support to the BPOM GMP inspectorate in order to increase the practical compliance of local pharmaceutical manufacturers with GMP standards, to ensure proper expertise of the BPOM inspectors, proper follow up, and adequate regulatory responses to noncompliance.



During the first quarter, as part of the FY 16 approved activities, PQM Indonesia conducted an "Analytical Method on Dissolution for Testing HIV Medicines and PVT Dissolution Apparatus Training" in BBPOM Jayapura (Papua). This training also included participants from Jayapura as well as the regional dissolution reference laboratory in Makassar (South Sulawesi), Bandung (West Java), and Benjarmasin (South Kalimantan) to increase impact of the trainings and utilize resources for multiple laboratories. PQM trainers provided support and guidance on the proper techniques for dissolution testing of ARVs according to USP dissolution general chapters and monographs (international standards), as well as providing tools, standards, and techniques for proper conduct of full parameter testing and mechanical calibration, and Performance Verification Test (PVT) for

dissolution apparatus using USP reference materials. PQM trainers also provided additional guidance not found in the USP General Chapters which will enhance the laboratories' ability to produce valid, precise, and accurate results on dissolution testing of priority medicines and to minimize the need for frequent troubleshooting and error. While not under the geographic focus area, PQM Indonesia will continue to support the Makassar regional reference laboratory on dissolution, since it is responsible for receiving samples from pilot provinces, including Papua and West Papua for screening and reporting to the national PTBB laboratory for dissolution results.

The QMS team also had the opportunity to provide an extensive follow-up on site with the Medan (North Sumatra) BBPOM laboratory to support training on implementing: CAPA, Root Cause Analysis, Document and Record Control for Good Documentation Practice and other follow-up. These trainings have resulted in better capacity for Medan to implement CAPA following assessments, and to incorporate the use of a standardized laboratory notebook system as part of implementing GDP in compliance with both ISO 17025 and general good laboratory practices. The analysts also have new skills to conduct Root Cause Analysis for deviations or non-conformity in routine test results, which is an important component of the overall functions required of a quality control laboratory.

Nigeria In this quarter, the GMP team organized a training course on Advanced GMP for 37 participants. This was a follow up from the March 2016 advanced GMP training course conducted in Lagos, Nigeria in which representatives of NAFDAC Drug Evaluation & Research and market authorization holders were in attendance. Fourteen modules were covered. The QA/QC team organized a refresher training workshop for the Kaduna zonal laboratory staff as a part of preparation towards accreditation of the lab. Eighteen participants were trained on QMS topics such as:

- Internal Audit;
- Root Cause Analysis;
- Corrective and Preventive Action;
- Handling "Out of Specification" and
- Measurement of Uncertainty

One of the participants conducted two sessions of step-down training for 14 staff of the laboratory based on knowledge gained from the training.

Philippines In October 2016, a seminar was conducted for Local Government Units at the regional level to strengthen FDA's national advocacy program and PQM program activities in ensuring the quality, safety, and efficacy of TB drug products and other pharmaceuticals through regulation and promotion of rational use. In addition, a concept note for advanced training for FDA inspectorate group on GMP and Good Dispensing Storage Practices inspections was developed and shared with the FDA for consideration to advocate the improvement of regulatory capacity of Philippines FDA.

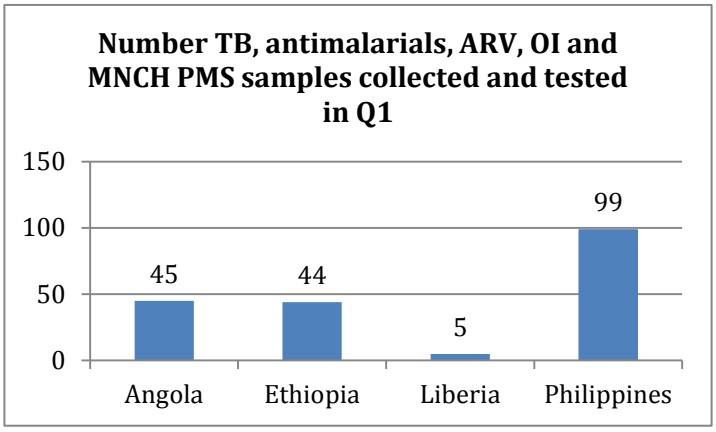
Capacity for post-marketing surveillance (PMS) of medical products sustainably improved

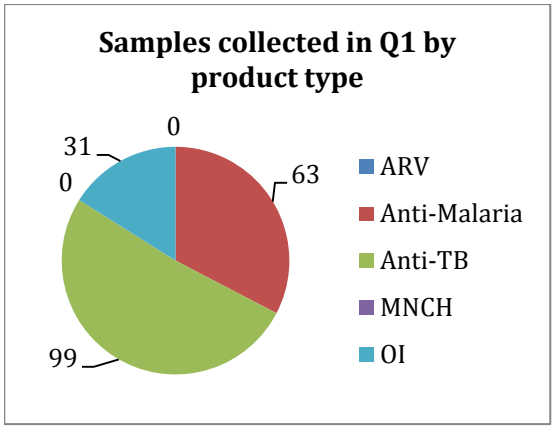
PQM combats falsified and substandard medicines by collaborating with country medicines regulatory authorities and national health programs by establishing or strengthening PMS systems that regularly examine the quality of medicines circulating in markets. PQM supports the national regulatory authorities 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 NQCL staff in advanced test methods. Minilab™ is a mobile and inexpensive field test kit with rapid drug quality verification and counterfeit medicines detection. 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 this quarter, a PMS sampling protocol was drafted and translated into Portuguese. Subsequent to the February Minilab™ training, a finalized PMS guideline that details the sample size, antimalarial, and sentinel sites will be launched in the third quarter. During the August 2016 Minilab™ training, 45 antimalarial samples were collected from over eight provinces as a training tool and shipped to Ghana FDA ISO 17025 accredited QC laboratory for compendial testing. The results were provided to PQM in December 2016 with 16 samples (36%)

failing to meet the quality requirements. As a training tool, these results and failures will be discussed with DNME during the February 2017 trip with an intention to advocate and promote regulatory actions and also emphasize the importance of building in- country quality control testing capacity. Additionally, to better support DNME/IG's understanding of proper screening methods for antimalarial, 22 antimalarial and antibiotic Minilab™ monographs have been translated into Portuguese. Additional Minilab™ and supplies have been shipped to Angola that will subsequently be transported to the selected sentinel sites to prepare for the third quarter launch of the medicine quality monitoring program.

Cross Bureau Following up on the workshop held at USP at the end of the fourth quarter in FY 16, PQM made significant progress on finalizing the Guidance for Implementing Risk-based Post-Marketing Quality Surveillance in Low and Middle Income Countries (LMIS). PQM also continued to engage with the University of Washington, Global Medicines Program on the development of a framework to encourage medicine regulatory agencies in LMICs to proportionately allocate and sustain resources to key regulatory functions for pharmaceutical quality assurance to maximize public health impact in their countries.





Ethiopia PQM continued its support to EFMHACA branch labs through the procurement of laboratory supplies such as a PVT kit and provision of reference standards to be used for verification of dissolution test apparatus at each branch laboratory. The branch laboratories continued screening of priority medicine samples using Minilab™ and compendial techniques. In the first quarter, they collected 44 samples for screening of which 13 were antimalarial and 31 opportunistic infection (OI) medicines. All samples passed the quality testing.

FY16 PMS data has been compiled, data cleaning completed, and the report is currently being written. Preliminary results showed that the quinine sulfate tablet failed the identity test and has been reported to WHO. The finding of PMS regarding quinine is being further investigated to identify the source of the product.

Ghana PQM's mission is to ensure a sustainable institutionalization of the MQM program into Ghana's PMS program. With funding from USAID and PQM's interventions, the failure rate of antimalarial has steadily decreased over time. This has gone hand in hand with swift regulatory action taken by Ghana FDA once substandard medicines are identified. However to ensure sustainability and continued improvement in Ghana FDA's regulatory function, PQM evaluated the availability of a PMS protocol and sampling guideline in this quarter. A written protocol or guideline was not available, thus PQM initiated a draft guideline that will be shared with the Ghanaians FDA during a PQM January 2017 trip. Additionally, a sampling of Zinc formulation will start in January 2017 with subsequent sampling and testing of uterotonics, RDTs and antimalarial in the second to fourth quarters.

Kenya During this quarter, the Pharmacy and Poison Board (PPB) completed the implementation of Round 6 of Medicine Quality Monitoring (MQM) activities in 11 sites. After sample collection (637 samples) and testing with Minilab™ basic tests at the sites, all the passed, doubtful, and failed samples were sent to PPB. The National Malaria Control Program (NMCP) focal point representative validated the samples to be tested at an accredited lab. After comparing the cost of the compendial testing by different labs, PPB and NMCP opted to send 10% of the passed samples and all failed samples to the Mission for Essential Drugs and Supplies for quality control (QC) testing.

To ensure that the MQM activities have been conducted according to MQM protocol and guidelines, PQM staff, along with officers from NMCP and PPB, conducted a monitoring and evaluation (M&E) visit at selected sites. The M&E visit revealed that the MQM team carrying out the activity has shown tremendous improvement compared to the previous rounds. The procurement, sample preparation, spotting, and conclusions were completed according to the protocol and Minilab™ training. Level one of the sample testing via Minilab™ was successfully completed at the 11 sites. Also, occurring during this visit was a meeting with the County Executive Minister for Health for Kisii County and Kisumu County Executive Minister for Health. Both ministers promised to allocate a larger room at Kisii Level V hospital for the future use of Minilab™ testing and to allocate funding for MQM activities in their respective counties. Last year, four staff members were sponsored by these counties.

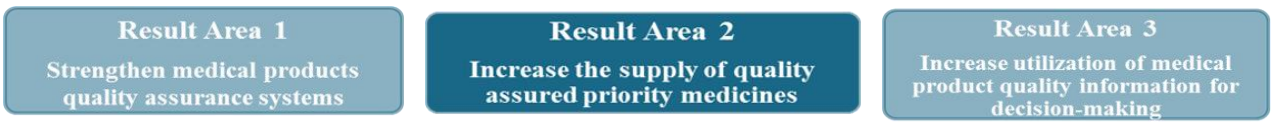
Liberia PQM's consultant participated in a two-day PMS exercise in Monrovia with the LMHRA. One poor quality quinine sample was identified at Rescue Pharmacy in Monrovia; NMCP was notified. The product appears to be a counterfeit of a Mission Pharma product. In Liberia, Mission Pharma products can only be found in the public sector. The investigation is ongoing and an administrative hearing has yet to take place because LMHRA is currently in court with Rescue Pharmacy for operating without a pharmacist and importation permit.

Mali PQM held discussions with LNS on ways to improve PMS activities to lessen the burden on the laboratory staff and avoid delays in completing the sampling, screening and laboratory testing. A preliminary sampling plan was developed which strategizes sampling collection and type of antimalarial medicines based on the previous round of sampling and testing and recent information available to LNS. PQM introduced a risk-based approach in the sampling and testing plans which will make these PMS activities more manageable and sustainable. During these discussions, the laboratory manager showed PQM staff falsified medicines that were found during a round of sampling and testing conducted in November 2016. The certificates of analysis of these samples were immediately provided to the Mali's Directorate of Pharmacies and Medicines (DPM). The laboratory manager also showed several falsified medicines available in the informal market.

The Laboratory of Applied Molecular Biology (LBMA) completed the study on the efficacy of artemisinin-based combination therapy (ACT). PQM reviewed the report that LBMA submitted for the closeout of the current Fixed Amount Award (FAA). The study showed an alarming rate of treatment failure that may compromise the use of ACT for the treatment of uncomplicated malaria in Mali. PQM discussed with LBMA the scope of work for the new FAA on the studies of ACT efficacy and resistance to the combination of Sulfadoxine-Pyrimethamine plus Amodiaquine.

Mozambique PQM procured and shipped Minilab™ replenishment in preparation for PMS activities planned for FY 17. In August 2016, 95 samples of anti-retroviral, anti-malarial, antibiotics, analgesics, and anti-tuberculosis medicines were discovered in the LNCQM laboratory due to late shipment from the sentinel sites. These samples were supposed to be tested but due to the late shipment to the lab, LNCQM was unable to complete compendial testing. PQM shipped the samples to an ISO 17025 accredited laboratory and the testing completed in December 2016 and will be reported in the second quarter.

Philippines PQM continued supporting FDA's PMS system through random sampling of TB products circulating in the country and screened the quality through Minilab™ kits. During this quarter, PQM staff and analysts from FDA travelled to the Island of Mindoro for four days to provide an assessment of the quality of TB medicines available to patients. Facilities with known presence of TB medicines were visited and inspected. TB medicines in TB directly observed treatment short-course Directly Observed Treatment, Short-course (DOTS) facilities and local pharmacies were collected and tested. Among the 35 TB medicines collected, two medicines were found to be substandard. A total of 99 TB samples were collected and tested from October to December 2016 with the Minilab™ kit. More data is expected to be added from the Cebu sentinel site. The final confirmed Minilab™ report will be released in the second quarter.



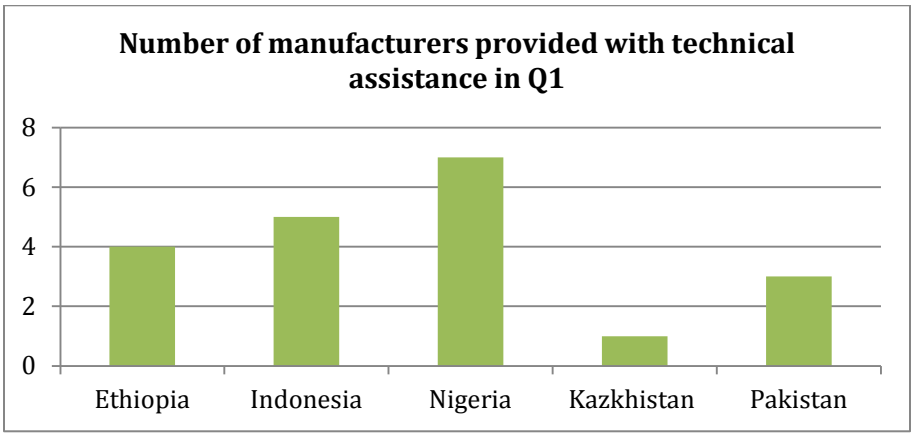
The second result area PQM Good Manufacturing Practice specialists travel to manufacturing sites in order to support companies improve their compliance with WHO standards and develop dossiers to submit to the WHO

Prequalification of Medicines Program for certification. WHO Prequalification, and other stringent regulatory authority approval, 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.

Quality assured priority medicines produced locally increased

PQM delivers broad technical assistance to local manufacturers to address GMP and other quality-related issues. By doing so, PQM increases 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.

Ethiopia The assessment report on the level of GMP compliance for four local manufacturers was developed during this quarter. A key next step will be for all manufacturers assessed to submit CAPAs for review. PQM and United Nations Industrial Development Organization (UNIDO) will review the CAPAs and provide the necessary technical support. PQM visited another manufacturer to follow up on the WHO PQ status of the Ethambutol 400mg tablet. A WHO team is expected to conduct a site approval visit in March 2017.



Indonesia As part of its ongoing program of technical assistance towards WHO PQ, during this quarter, PQM Indonesia provided on-site support at Kalbe Farma and Sanbe Farma/Caprifarmindo as they work towards compiling their product dossier, both for a levofloxacin 500mg tablet. Stemming from new initiatives to provide both GMP and QC support to manufacturers (in response to shifts in focus by the WHO inspectors assessing production sites for product Prequalification purposes), PQM Indonesia held a seven day didactic and practical training at the quality control laboratories of both Kalbe Farma and Sanbe Farma/Caprifarmindo. During previous assessments, PQM identified a crucial need to support development of appropriate Good Laboratory and Good Documentation Practices at both sites as an integral component of the WHO PQ assessment as well as for compliance with GMP. PQM also conducted a special training on Data Integrity for Kalbe Farma as it continued to develop its product dossier. Kalbe Farma, through PQM Indonesia support, identified weaknesses in its acceptance criteria for their assay for content of the levofloxacin tablet. Kalbe Farma, at PQM Indonesia's behest, conducted investigations into the cause of consistently low assay for content results in their finished product during pilot batch studies, creating the need to change their product formulation. As a result, under the new reformulation, their assay for content is within acceptable limits and they are proceeding accordingly. For both Sanbe Farma/Caprifarmindo and Kalbe Farma, PQM Indonesia will intensify its technical assistance during FY17, as both manufacturers intend to submit their compiled product dossier to WHO for Prequalification during this fiscal year.

Nigeria This quarter marked significant progress towards supporting local manufacturers in building their capacity to produce priority quality-assured essential medicines. The three months accelerated stability report for Magnesium Sulfate injection was reviewed and the report indicated that the medicine stability was within specification. Progressive measures were made for the requalification of the HVAC system and supplier for the API master file for magnesium sulfate was identified. Next steps for the local manufacturer include:

1) Continuing with the real-time stability studies;
2) Commencing leachable, extractable test and stability study for oxytocin, which is scheduled on arrival of the cold chain chambers and;
3) Commencing the scheduled equipment calibration

To ensure compliance with quality standards, PQM supported the local manufacturer to reformulate the amoxicillin dispersible tablet. Compared to the previous formulation, trials using the new formulation indicated positive outcomes for critical quality attributes. This new formulation will be cost effective for local production and will yield quality products following the positive outcome. The new formulation reduces manufacturing time, consumption of the energy and saves about $80,000 as compared to the previous formulation. The next step is to make a bulk order for the API to facilitate the scale-up of production of batches for stability studies. Another local manufacturer, CHI Pharmaceuticals, responded to WHO's request for the interpretation of differential scanning colorimeter result of the zinc sulfate dispersible tablet. Results of twenty-four months real time stability study of Zinc Sulfate dispersible were submitted. WHO has requested for the repeat of the palatability study.

WHO conducted a GMP inspection of PQM supported manufacturer Juhel Pharmaceuticals. The inspection report was received this quarter and it cited the existence of an effective quality assurance system that captures necessary documentation to support the batch release of products. However, there were some deficiencies indicated in the report such as management of reference standard. The PQM team commenced discussions with the management of Juhel Pharmaceuticals on measures to improve on the cited deficiencies. As a result, the management team reviewed existing SOPs and made critical additions for improvement. The PQM team will continue to follow up on other identified CAPAs to ensure GMP standards are improved. In FY 16, UNICEF conducted a facility audit of a PQM supported local manufacturer with a strong interest in the local production of Chlorhexidine. During this quarter, the identified CAPAs were resolved and a response was sent to UNICEF. PQM was requested by UNICEF to carry out another inspection to ascertain the effectiveness of the CAPAs and status of GMP compliance of the local manufacturer. The PQM team scheduled the facility inspection in the second quarter. As a result of PQM's continued technical assistance to the local manufacturer the Partnership for Supply Chain Management indicated interest to purchase Chlorhexidine for implementation of their public health interventions in Nigeria. The organization conducted an audit of the local manufacturer and the feedback is expected by the next quarter.

Local manufacturers such as DANADAMS-BAKAI with an interest in Ready-to-Use Therapeutic Foods (RUTF) reached out to PQM for technical support. This is a critical development as it extends the PQM support to the northern region of the country. PQM provided technical assistance for the design of the new RUTF facility and modification of the existing pharmaceutical facility to meet GMP standard. The team received the facility drawings for evaluation. Additional support was extended to DABA Nutritional Foods that also has interest in the local production of RUTF. The manufacturer had undergone a facility audit in FY 16 and deficiencies in the Hazard Analytical Critical Control Point were identified. PQM contributed to the development of a roadmap to address the deficiencies and will follow up closely in the implementation of the roadmap.

Pakistan PQM conducted an assessment of another potential local manufacturer, Atco Laboratories, of Chlorhexidine 7.1% Gel in Karachi during this quarter. The assessment aimed to determine its GMP compliance level and proposed corrective and preventive actions. Atco completed the bio-batch stability studies for six months, and the data was successfully submitted to DRAP. Atco has also completed the manufacturing of a pilot-batch of Chlorhexidine 7.1% Gel and process validation is currently in progress. PQM also performed follow up assessments of Zafa and Akhai Pharmaceuticals to gauge CAPA implementation. These manufacturers have completed the six month stability studies, and their data has been submitted to DRAP for assessment. Zafa's and Akhai's follow up assessment revealed that the manufacturers have successfully implemented most of the recommendations outlined in the confidential trip reports that were sent to the respective manufacturers.

At the level of DRAP, three manufacturers' dossiers have been pre-conditionally approved:

- Atco during DRAP's Drug Registration Board (DRB) 259th meeting in September, 2016
- Akhai during DRB's 263rd meeting in November, 2016
- Zafa during DRB's 264th meeting in December, 2016

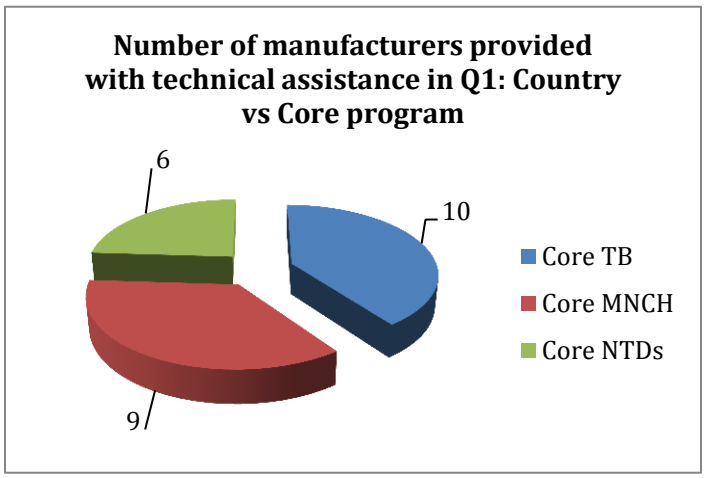
Approval is subject to site visits by the DRAP Inspectorate, and verification of stability study data, as per The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ICH Guidelines, Climatic Zone IVB. The DRAP and provincial inspectors will visit Atco for data verification in January 2017.

The PQM team also conducted a mapping exercise of other potential manufacturers of maternal, newborn, and child health (MNCH) and family planning (FP) products using a pre-defined screening questionnaire. The five identified manufacturers - Indus Pharma Karachi, Pharm Eveo Karachi, Wilshire Pharmaceutical Lahore, Mactor Pharma Karachi and Ferozsons laboratories, and Nosherah KPK - are good candidates to receive PQM technical assistance in order to achieve the quality assured/WHO prequalified MNCH and FP product manufacturing status.

Quality assured priority medicines produced globally increased

PQM delivers broad technical assistance to global manufacturers to address GMP and other quality-related issues. By doing so, PQM ensures a steady supply of essential medicines of assured quality, safety, and efficacy, to meet the global demand and compensate for medicines unable to be sourced locally.

Core TB During the first quarter of FY 17, PQM GMP team continued to provide technical assistance at various stages to manufacturers of priority TB medicines as agreed upon by USAID and PQM. These key medicines are clofazimine, gatifloxacin, rifapentine, kanamycin, linezolid, and first line FDC for selected manufacturers for local procurement. As a result of the continued technical assistance provided, Shangyu Jingxin Pharma, located in the Shangyu Zhejiang Province of China, received full WHO Prequalification for levofloxacin API. Shangyu Jingxin Pharma is only the second manufacturer to receive full prequalification approval and will be an invaluable source for FPP manufacturers in search of quality-assured levofloxacin API.



As many countries transition from donor funding for TB medicines to local procurement, availability of quality of medicines has become even more essential. For donor funded procurement, there are mechanisms in place to assure that the medicines delivered to the country are tested for quality and efficacy. As a pilot activity, USAID TB team and PQM have identified Pakistani manufacturers to provide assistance to ensure quality of locally manufactured and procured TB medicines. In September 2016, PQM GMP team established contact with two Pakistani manufacturers at the workshop “Ensuring Quality of Anti-TB Medicines – Contributing towards Ending the TB Epidemic” organized by PQM in Dubai. These manufacturers are focused on first line TB medicines (FDCs) for the local market. During this quarter, PQM sent and received the questionnaires along with supplemental documents from the manufacturers and was able to review them in detail. The GMP team is planning to schedule on-site visits to conduct GMP assessments in the second quarter.

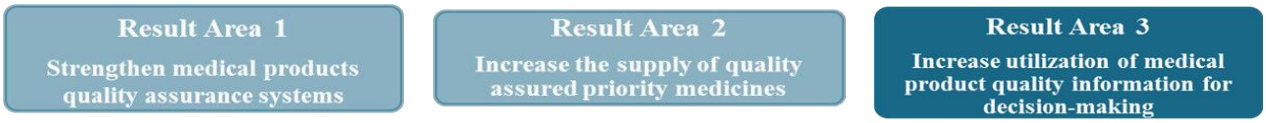
In the first quarter, the PQM GMP team provided technical assistance to a manufacturer in support of Clofazimine API and FPP by conducting a risk assessment visit to the Contract Manufacturing Organization (CMO) and contributed to the drafting of the risk assessment documents for the facility. The PQM team also joined the WHO Inspection team’s visit to the CMO as an observer and provided any needed translation. The PQM team ensured that the risk assessments are completed and available for WHO’s visit. Further assistance was provided to manufacturers in support of Kanamycin FPP and PAS Sodium whereby PQM staff responded to the dossier queries from WHO. The manufacturers for Rifapentine API and FPP and Gatifloxacin API and FPP participated in GMP assessment at their facilities and these manufacturers are currently implementing CAPAs.

Another source for Kanamaycin API was identified and PQM is currently providing assistance on risk assessment and designing of cross-contamination monitoring protocol. GMP assessments are planned for the second quarter for the manufacturers of FDC (for local procurement) after receipt of their questionnaires and supplemental documents. Furthermore during this quarter, the PQM team also conducted a GMP assessment for the manufacturer of Pyrazinamide API and a confidential report for the manufacturer is currently being written.

Core Neglected Tropical diseases (NTD) During the first quarter, the PQM GMP team continued to provide technical assistance at various stages to manufacturers of priority NTD medicines. As a result of the continued technical assistance provided, Shanghai Jiayi Pharma located in Shanghai, China, received Certificate of Suitability (CEP) approval for praziquantel API. CEP approved API suppliers may be used by FPP manufacturers interested in WHO Prequalification or other SRA approval for praziquantel. So, this potentially would increase supply of such needed quality assured praziquantel on the global market. PQM will continue to provide assistance to the manufacturers to ensure availability of essential NTD medicines globally. Support to other manufacturers of praziquantel API included a GMP assessment for one manufacturer, implementation of CAPA plan based on PQM and WHO audits for another manufacturer, and technical assistance to a third manufacturer in clarification of the GMP observations by WHO and planning for their corrections. Currently, PQM is supporting three manufacturers of praziquantel FPP. One manufacturer is receiving technical assistance for BE study design, the second is receiving assistance for the preparation for Expert Review Panel (ERP) submission and with planning for development of new validation batches for BE study as API source has changed. Similar support was provided to the third manufacturer as manufacturing site has been relocated.

Core Maternal and Newborn Child Health (MNCH) The PQM GMP team continued to provide technical assistance to manufacturers of priority MNCH medicines (chlorhexidine, magnesium sulfate, oxytocin, and amoxicillin dispersible tablet) in pursuit of local approval, WHO prequalification, or stringent regulatory authority approval. As a result of the continued technical assistance provided, Universal Corporation, located in Kenya, submitted their chlorhexidine (CHX) gel dossier to the East African Community (EAC), for joint MRA review. This comes after successfully registering their CHX gel in Kenya in 2016. Universal Corporation has also submitted the dossier to FHI 360 to be considered for procurement by the Global Health Supply Chain Program; the dossier is still under evaluation. PQM will continue to provide dossier support to Universal Corporation for queries received from EAC and FHI 360. , Two manufacturers were identified by PQM for the production of Oxytocin API and FPP, and PQM is currently working to engage the manufacturers for technical assistance towards WHO prequalification.

Kazakhstan Remote technical assistance from PQM on the implementation of a CAPA plan was provided to Nobel Almaty Pharmaceutical Factory. During this year, Nobel Almaty Pharmaceutical Factory will transfer production of anti-TB medicines to a new facility. PQM will continue rendering remote assistance to this manufacturer on implementation of their CAPA plan with the focus on the new manufacturing site.



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 medical products increased

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Core Tuberculosis (TB) PQM participated in the 47th Union World Conference on Lung Health and presented a poster presentation on “Strengthening Quality Assurance Systems of Pharmaceutical Manufacturers to Ensure Availability of Affordable TB Medicines on the Global Market.” The presentation discussed PQM’s approaches towards ensuring availability of quality assured anti-TB medicines on the global market and the achievements in

this regard. PQM will submit a proposal for organizing a symposium on the 48th UNION conference in 2017 addressing the issue of quality of anti-TB medicines.

Core MNCH The PQM team participated in two meetings: the 17th General Membership Meeting of the Reproductive Health Suppliers Coalition (October 2016) and the MCH Commodities Sourcing Strategy Partners Meeting (November 2016). At the former meeting, PQM participated and contributed to the work of the System Strengthening Working Group, Generic Manufacturers Caucus and Maternal Health Supplies Caucus meetings. During this week-long meeting, PQM was able to initiate collaboration with Monash University. The Institute of Pharmaceutical Sciences at Monash University has an Oxytocin team that is engaged in an ongoing program investigating the quality of oxytocin injection ampoules supplied to resource poor settings. This program currently comprises of collaboration with the UNFPA to understand the robustness of oxytocin supplies to repeat exposure to elevated temperatures, and audits of oxytocin quality in the Democratic Republic of Congo (ongoing) and Ethiopia (proposed). PQM was requested to provide assistance to understand the compliance of collected samples with the USP monograph methods for assay and related substances. PQM received the samples (ampoules) of oxytocin collected by Monash team in the DRC and is currently testing for content and related substances using approved USP monograph testing methods. The main aim of the testing is to identify whether an unknown impurity is detected in all DRC ampoules tested by Monash using an alternate non-USP method. The main topic of discussion during the MCH Commodities Sourcing Strategy Partners Meeting was the landscape of manufacturing and supply of Maternal, Child, and Newborn commodities. PQM provided a presentation discussing challenges and successes of the local manufacturing of the MCH products in Sub-Saharan Africa and Southeast Asia and participated in all of the technical discussion at the different session.

Core Malaria PQM continues the development of country profiles on national Quality Assurance (QA) systems as they relate to ensuring the quality of antimalarials. A profile for Ghana had been delivered previously, and during this quarter a second profile, for Ethiopia, was developed and submitted to the AOR team for review. Based on the AOR team's comments, an outline was proposed and accepted for the profiles, following which the Ethiopia and additional country profiles will be developed and submitted.

Cross Bureau PQM continue to use communication channels to increase public awareness about the importance of medicine quality assurance and stimulate the interest of stakeholders in the issues surrounding medicines quality. In this quarter, PQM identified new incidents of poor quality medicines in the media, which were compiled in media reports on medicines quality. The updated compilation is in the process of being posted on PQM webpage. PQM also initiated thorough analysis of data on antimalarial medicines included in Medicines Quality Database.

To play its advocacy and technical leadership role in medicines quality assurance arena, PQM participated and presented at the American Society of Tropical Medicine and Hygiene (ASTMH) 2016 Annual Meeting in Atlanta, Georgia, USA. PQM's presentation on "Surveillance of Medicines Quality in Select African Countries: Challenges and Opportunities," was made at the session on Poor Quality Medicines, in addition to PQM's six other speakers. The attendance to ASTMH Annual Meeting was also an opportunity to participate in the Medicine Quality side meeting organized by USP PQM and Infectious Diseases Data Observatory (IDDO), formally known as WWARN. Twenty nine participants from 18 institutions/programs attended this meeting. The participants discussed ways to formalize this group and agreed on the following action points:

1) Create a platform to keep the group connected;
2) Map points of interest, relationships and projects in progress within the group to facilitate synergies and opportunities for collaboration;
3) Define a collaborative research agenda and
4) Define subgroups and assign leaders (Advocacy, Devices/technologies, Epidemiology of medicines quality, and Impact [modeling and Economics]).

A summary report of the meeting will be disseminated during second quarter.

Asia Regional PQM Indonesia, together with the Asian Development Bank and WHO, convened a Southeast Asian regional workshop in Jakarta during this quarter entitled: "Joint Regional Training Workshop on Surveillance and Reporting of SSFFCs." This workshop was a follow up from a previous regional workshop held in Singapore during the third quarter in FY 16 in cooperation with USP, WHO, ADB, and CoRE Duke-NUS Medical School. The training was attended by 56 participants from 11 SEAR countries, including Bangladesh, Burma, Indonesia and Thailand who participated in classroom, practical exercises, and case studies on how to investigate and report to the WHO SSFFC Rapid Alert System. PQM trainers have presented the following

topics: Good Documentation and Recording of Samples, Sampling of Pharmaceutical Products, Testing Protocols, and New Field Detection Technologies for Counterfeit Medicines (SSFFCs). Following the regional training, an Indonesian national training workshop on “Management and Investigation of Events Involving SSFFC Medical Products” was conducted for participants from BPOM national and provincial institutions, police, customs, the judiciary, the Ministry of Health, and the Ministry of Information and Communication. Training also focused on investigating illegal websites and online commerce of medicines. Key recommendations and actions plans produced during this workshop will be follow-up by the government, and PQM Indonesia will continue to work with ABD and WHO to ensure use of the information and skills gained during the workshop.

Mali To promote action-taking on poor quality medicines, in collaboration with Direction de la Pharmacie et du Médicament (DPM), PQM facilitated a workshop to share the results of antimalarial quality surveillance with members of The National Commission on Illicit Sale of Medicines and Counterfeit (NCISM). Twenty-seven participants including nine members of the NCISM attended the workshop. PQM reviewed all the results of antimalarial quality surveillance obtained from 2010 to 2015 with Laboratoire National de la Santé (LNS) and LNS analyzed and presented the results. Three local newspapers covered this event which was also relayed by local radios. The participants also discussed the NCISM draft implementation plan and made the following recommendations:

1) revision of the regulatory provision for the creation of the NCISM;
2) collect feedback and proposition from the members of the NCISM on the draft action plan and its improvement;
3) involve DPM in the sampling of medicines for quality control; and
4) LNS to notify DPM immediately of any finding of non-compliant products for action taking

Nigeria PQM paid advocacy visits to four organizations namely United Nations Industrial Development Organization (UNIDO), United Nations Children's Fund (UNICEF), World Bank and Institute of Public Analysts of Nigeria (IPAN) to discuss possibilities of collaboration and partnership towards the assistance for NAFDAC and the pharmaceutical sector in Nigeria. One of the organizations, UNIDO is currently proposing a number of projects such as supporting the National Meteorological Institute towards being a national calibration body as well as planning to make NAFDAC a Proficiency Tests provider for external laboratories in Nigeria. They are also working on setting up a Nigerian Accreditation Service which will be a national accreditation body.

Kenya This quarter was marked by the publication of a PPB newsletter with PQM’s technical support that included MQM activities. The newsletter was posted on the PPB website and shared with healthcare professionals and the general public. The next step is to complete the QC testing and share data with PPB for any necessary regulatory actions.

Kazakhstan PQM completed editing of the Russian translation of WHO PQ documents for manufacturers. WHO PQ documents are ready for dissemination among the interested parties. The translated documents were submitted to WHO and will become an official Russian translation by WHO. The availability of this crucial document would support the pharmaceutical manufacturers in Russian speaking countries to improve their quality assurance standards and benefit with WHO PQ.

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 In the previous quarters, Malawi, Nigeria and Benin were confirmed by PMI as priority countries to assess the diversion of antimalarial medicines (namely, Coartem and Sanofi’s Winthorp Artesunate/Amodiaquine donated by US Government) from public sector facilities to those in the private sector. For the purpose of the diversion this studies, Coartem donated by USAID was designated as Coartem A and was identified by the package information and design. The diversion studies in Benin, Malawi, and Nigeria began on July 25, 2016 and concluded in October 10, 2016. Each study was designed to provide evidence of diversion in sites visited, if occurring, and data on prices set by vendors in the private sector, batch numbers,

date of expiry, name and country of manufacturers, type of outlets where the medicines were identified and their location.

The following is the summary of findings based on data collected:

Country	Number of Provinces Assessed	Private facilities visited/ facilities with Coartem A		Number of presumptive diverted Coartem A batches	Number of batches confirmed to be diverted by USAID[1],[2]
		Formal	Informal		
Benin	6	210/8	93/5	5	3
Malawi	10	166/1	50/0	1	0
Nigeria	6	337/9	127/1	4	4

Additional data agreed upon with PMI was also gathered in the sites visited, among them availability of Coartem A in the public sector facilities, availability of other antimalarials in private sector facilities, requirements for prescription for sale of antimalarials, and distance of private facilities to the closest public sector facility. The premise was that this information might unveil gaps in the system that the National Malaria Control Program, the MRA, or the Presidential Malaria Initiative (PMI) could address in the future. During this quarter, PQM prepared a detailed report on findings from the diversion study in Benin. A draft of the report was submitted to the AOR in November 2016. Final submission of the three studies' reports to PMI Washington is expected in the next quarter.

Liberia In October 2016, PQM staff participated in one-day Minilab™ training. PQM participation provided support to LMHRA by demonstrating the use of physical inspection to determine substandard medicines. The training was conducted by staff from the LMHRA office and QC lab and NMCP and the training content was prepared jointly by PQM, LMHRA, and NCMP. Thirty participants from customs, police, immigration, and other security branches of the government, also known as the Joint Security Task Forces (JSTF), working around the border in Guinea attended the training. Participants acknowledged the benefits of recognizing falsified antimalarials, inappropriate labeling, expiration dates, and suspicious colors.

PQM also participated in a three-day joint NMCP-LMHRA PMS in Nimba and Gbanga counties where four different falsified artemether injections were identified. These products are imitation of an artemether imported by Sonia Pharmacy, Bushroad Island. To date, over 200 packs have been confiscated. Details of failed medicines were sent to NMCP. Documented details are currently being used by the LMHRA, including for the purposes of informing the public via electronic and print media about the danger of using falsified products.

Information on quality assurance of medical products used for advocacy increased

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.

Cambodia PQM advocated for additional funding to support NHQC activities towards ISO/IEC-17025 accreditation. As a result of this advocacy, the NHQC is a Primary Recipient of Global Fund award to fund the laboratory equipment calibration which is essential to laboratory functions. NHQC is currently evaluating the prices and service providers to perform the calibration of the laboratory equipment.

Indonesia USP signed a new contract with Global Fund for a second round of procurement of laboratory equipment to be provided to selected provincial BPOM QC laboratories under the PQM-initiated program with the MOH to increase capacity for sampling and testing TB and HIV medicines. This $2 million award includes essential equipment for 12 laboratories as well as building in financial support for joint sampling activities between MOH and BPOM to ensure adequate coverage, testing capacity, and timely reporting (to implement Menkes 33/2016 in addition to establishing basic good practices within the government QA system).

[1] There is no record in USAID of non-confirmed batches

[2] One of the non-confirmed batches in Benin is suspicious of being falsified based on package information

Additionally, funds are allocated for human resource support for both procurement and activity implementation, in which short term consultants will be housed within the PQM Indonesia office for the duration of the contract.

Liberia A PQM staff presented at a one-day dissemination meeting outlining the steps and support needed for the LMHRA QC lab to reach ISO 17025 accreditation. In attendance were representatives from the USAID/Liberia Mission, WHO, the National Legislature, the Ministry of Health, and other implementing partners. In addition to the PQM presentation, the head of LMHRA, and the PMI advisor shared with the audience how USAID funding and PQM TA improved the QA/QC in Liberia, and provided an update on the main activities conducted by LMHRA and NMPC on ensuring good quality of medicines, including antimalarials in the Liberian market. This meeting also served as a venue to share with partners of LMHRA the successes and challenges of the LMHRA in the fight against poor quality medicines. More than 50 people attended the meeting which was held in Monrovia City.

Key Challenges

Challenges relating to bureaucratic constraints continue to stall the implementation of a few activities. For instance in Uzbekistan, the PQM program is not yet approved by the Government, which continues to prevent implementation. At the beginning of the second quarter in FY17, PQM and USAID are organizing meetings with the different Ministries in Uzbekistan to accelerate an approval of the PQM program. In Nigeria, NAFDAC staff embarked on a three-week nationwide industrial strike, which also affected implementation of some activities. Separately, Indonesia continues to face ongoing challenges with regards to the legal agreements between the US Government (USAID) and the Indonesian Government (MOH and BPOM) in the form of requirements for ratified documents (Individual Arrangement, Technical Agreement), which are requisites for PQM's work to proceed unhindered. This process has incurred delays in the overall implementation of the work plan and its review as required by BPOM (in lieu of signed Technical Agreement as of yet), and the processing of the required legal work permits and stay visas for expatriate staff. Immigration issues stemming from a lack of IMTA/KITAS required to be employed full time in Indonesia have affected other organizations working under USAID, not only USP. PQM is hopeful that during the second quarter, the IMTA/KITAS will be finalized, as well as the signing of the TA between USAID and BPOM.

Financial and human resource constraints are also common challenges faced within program implementation. In Kenya, implementation of PQM activities was a challenge after the departure of two points of contact from PPB and NMCP. As a result, PQM hired an in-country consultant this quarter that will ensure all PQM-planned activities are conducted in a timely manner to benefit key stakeholders. In Ethiopia, the main challenge has been funding uncertainties which lead to subsequent revisions to the FY17 work plan and delay in the execution for some activities. Also in Liberia, there is limited funding to adequately prepare the LMHRA lab for ISO accreditation. Lastly in Mali, the DPM was prevented from organizing regular NCISM meetings because of a lack of funding. However, LNS management indicated that the lab was willing to cover the cost of the next meeting.

Sustainability, Partner Contributions, and Ownership

Building a laboratory infrastructure and financing equipment for laboratory testing is a significant expense for many regulatory agencies, and typically there are delays due to lack of funding. However, the regulatory agencies in Kazakhstan, Liberia, and Cambodia are making contributions toward their respective needs. Recently in Liberia, the LMHRA, through EERP of the World Bank, received funding to purchase laboratory supplies, including a new HPLC machine. Additionally, in November 2016, two analysts from the QC lab were trained at USP's CePAT facility in advance compendial testing. This recent training will support the LMHRA move closer toward attaining ISO 17025 accreditation, which will potentially increase LMHRA's income and narrow the funding gap needing to effectively run the authority. In Cambodia, the NHQC will leverage funding support from the Cambodian government in 2017 for equipment calibration purposes. In addition, WHO has confirmed their financial contribution to support jointly with PQM to conduct training on compendial techniques for NHQC analysts in compliance with some newly finalized SOPs.

In Kazakhstan, there is high commitment by the Ministry of Health and the National Center for Expertise of Medicines, Medical Devices, and Medical Equipment (Kazakhstan FDA) to improve the quality of their

laboratories. A dedicated QA manager from Kazakhstan FDA HQ supervises preparation for WHO PQ in the selected laboratories and is in constant communication with the PQM team.

The accreditation of Nigeria's Agula laboratory and Burma's DFDA Nay Pyi Taw laboratory provides each country with a significant step forward for sustainability of its operations. The accreditations will enable the labs to introduce a new revised fee-for-service structure that can generate revenue. In Burma, PQM has initiated a discussion with the DFDA and the lab leadership about bringing a new cost structure to reduce the government subsidy while increasing the ownership in generating revenues toward gradual sustainability.

In Kenya and Mali there is strong financial commitment from government regulators towards PMS activities. In Kenya, the PPB, through PQM technical support and USAID-PMI financial aid, has begun to establish and implement a robust PMS system. It is working to institutionalize PMS activities by incorporating them into its organizational structure, training its personnel, increasing budgetary allocation (from $50,000 USD to $200,000 USD) to the directorate that carries out PMS activities, introducing retention fees to fund PMS activities, and ensuring that PMS activities form part of the Registrar's Performance Contract each year. Likewise in Mali, the LNS management agreed to contribute 5% of the cost to of the upcoming round of sampling and testing of antimalarial medicines. In Ethiopia, EFMHACA and Addis Ababa city administration regulatory authorities financed and organized three training while only leveraging human resources support from PQM.

In Bangladesh, PQM is partnering with the relevant divisions of DGDA and SIAPS (for regulatory functions), with WHO (for GMP and dossier compliance of manufacturers), and with Challenge TB, MoHFW/NTP, and MaMoni HSS Project (for quality assurance systems) to coordinate activities that will be managed through the Task Force Committee that was established in December 2016. The overall mission of the Task Force is to support delivery of outcomes. This, in turn, will build sustainability of DGDA, its supporting laboratories, and the local manufacturers.

As for the Core TB, NTD, and MNCH programs, the technical assistance provided to the manufacturers is a long-term learning process. The PQM GMP team works side-by-side with the manufacturers to ensure that the facility will meet the rigorous GMP requirements of WHO or a stringent regulatory authority. The team will also work with the manufacturers to compile common technical documents for submission. This long process is a hands-on learning experience for the manufacturers, and PQM builds sustainability into the activity for future submissions by the manufacturers.

Lessons Learned

Whether funding cuts are imminent or distant, making sensible collaborations are essential for growth and sustainability. In Mali, collaboration between DPM and LNS is crucial for the success of both institutions since they are interconnected. Previously, misunderstandings and artificial hurdles were preventing close collaboration. PQM was successful in bringing the DPM and LNS to the same table which opened the doors to more collaboration.

A lesson learned as in the case of Indonesia is the ongoing need for continued and sustained advocacy and exposure to all stakeholders to ensure adequate uptake of the regulation, and to make concrete and actionable plans towards its effective implementation. Although a formal policy is in place by the MOH that requires sampling, testing, and reporting of public sector medicines by BPOM, simply having this policy in place is not enough. In order for an effective quality assurance system to develop and ensure that good quality medicines are available to the patients that need them, PQM must continue in our endeavors to work behind the scenes with the key stakeholders and decision makers to bring policy into practice.

In Pakistan, PQM learned the significance of diversify their relationship and communication with government entities which will in turn boost PQM's position in country. Under those circumstances, the PQM team visited the Secretary of Federal Ministry and his team, as well as the Secretary of Health, Department of the Government of Punjab. To ensure sustainability, PQM has come to the conclusion that it must continue to work parallel with all stakeholders (federal government, DRAP, provincial governments, and the pharmaceutical industry).

Management Overview

PQM's major focus during the first quarter surrounded obtaining USAID Mission and Core Health Element team approval for FY17 work plans. Before the end of the quarter, 15 out of 26 work plans (58%) had been fully approved, with an additional two work plans tentatively or partially approved. The strides that PQM has made in committing to timely approval of work plans can be seen in comparison to the previous fiscal year, when at the end of FY16 Q1, only 10 out of 24 work plans (41%) were fully approved. In early January 2017, three additional work plans received full approval; bringing PQM's total to 18 work plans fully approved, with additional approvals expected early in Q2.

After a consultation meeting between PQM and the Drug Regulatory Authority on Pakistan (DRAP) in Islamabad in August 2016 to review the current process, procedures, and practices in medicines registration (MRS) in Pakistan and draft a road map for strengthening the registration system of Pharmaceutical Products and Biologicals for Human Use, PQM organized a two-day expert consultation meeting on October 20-21, 2016 at USP-Rockville with the objective to develop a guidance document for adoption of international standards of regulatory information, the electronic regulatory submissions/filings, and interoperability for efficient management and transmission of regulatory information. The guidance document will be used as a basis for developing an integrated regulatory information management system (IRIMS) covering the key functions of DRAP. PQM is working to finalize the draft report of that consultation meeting and will share with the meeting participants for their inputs to finalize the report document. In FY17 Q2 though Q4, PQM will, in collaboration with other experienced partners and in close consultation with DRAP, develop the guidance document on adoption of the international standards of regulatory information management system in view toward an IRIMS for DRAP with adaptability for any other developing countries interested in similar system.

During the first quarter, PQM also worked in partnership with an existing initiative at USP to create a series of webinars highlighting careers opportunities in Global Pharmacy for students. CAREERS BEYOND the Pharmacy Counter provides pharmacy students information about less traditional careers for pharmacists. Through the Global Pharmacy series, PQM organized filming sessions with two key partners to create three webinars. Negussu Mekonnen, Country Representative with Management Sciences for Health, shared his experiences working in Pharmacy Academia in developing countries and his inspiration for becoming an educator. He also offered insight on the importance of working as a pharmacist in international development and encouraged others to do the same. Steve Onya, CEO of Chi Pharmaceuticals Limited and Fellow of the Pharmaceutical Society of Nigeria, reflected on his career pathway and his current work as a leader in pharmaceutical manufacturing in Nigeria. The webinar series will be shared with schools of pharmacy in countries where PQM works in an effort to showcase opportunities for rising students.

The PQM Director also attended several key events in November 2016. The biennial Health Systems Research Symposium held in Vancouver, Canada from November 14-18 and themed, "Resilient and Responsive Health Systems for a Changing World," built off of the lessons learned and ways forward from the Ebola crisis two years prior, emphasizing the need for strong, effective health systems. The event was attended by more than 1,500 global health professionals and discussed the importance of sustainable health systems strengthening activities geared to supporting universal health coverage, preparedness for health crises, and mitigating the effects of antimicrobial resistance. While the issue of quality medicines was touched upon in certain sessions, it was not a central theme of the symposium and speaks to the need for broader advocacy efforts on the issue. The preliminary sessions leading up to the 17th International Conference for Drug Regulatory Authorities (pre-ICDRA), held in Cape Town, South Africa from 27-28 November was also attended. Themed "Patients are Waiting: How Regulators Collectively Make a Difference," the conference was attended by hundreds of regulators globally, with heavy participation from African regulators. Sessions focused on several key themes, including the importance of and need for increasing harmonization efforts, the linkages between cooperation and sustainability, and methods for tackling key issues such as health crises and drug shortages. PQM was able to connect and deepen engagements with key regulators in priority countries, including from Nigeria, Ghana, and Kenya, as well as strengthen ties with essential stakeholders, such as the Medicines Control Council (MCC) of South Africa, the Bill and Melinda Gates Foundation, the New Partnership for Africa's Development (NEPAD), European Medicines Agency (EMA), and the World Health Organization.