PQM+ Quarterly Report – Program Year 1, Quarter 3

April 1, 2020 – June 30, 2020

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Promoting the QUALITY OF MEDICINES Plus

USAID
FROM THE AMERICAN PEOPLE

usp®
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About PQM+
The Promoting the Quality of Medicines Plus (PQM+) Program is a five-year cooperative agreement (No. AID-7200AA19CA00025) between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP) to sustainably strengthen medical product quality assurance systems in low- and middle-income countries (LMICs). PQM+ works to improve medical product quality through cross-sectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system. By sharing scientific expertise and providing technical support and leadership, PQM+ helps to create resilient and sustainable local health systems that ensure access to quality-assured essential medicines for HIV/AIDS tuberculosis, malaria, and neglected tropical diseases as well as for reproductive, maternal, newborn, and child health.

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Acronyms

API  active pharmaceutical ingredient
AWaRE  Access, Watch, Reserve
CAPA  corrective and preventive action
COVID-19  novel coronavirus
CRO  contract research organization
CRP  collaborative registration procedure
CTD  common technical document
DDA  Department of Drug Administration
DFDA  Department of Food and Drug Administration
DFH  Department of Family Health
DGDA  Directorate General of Drug Administration
DNMP  Division of National Malaria Program
DPM  Directorate for Pharmacy and Medicines
DRAP  Drug Regulatory Authority of Pakistan
DT  dispersible tablets (amoxicillin)
EFDA  Ethiopian Food and Drug Authority
FBPDI  Food Beverage and Pharmaceutical Development Institute
FP  family planning
FPP  finished pharmaceutical product
FY  fiscal year
GBT  Global Benchmarking Tool
GMP  Good Manufacturing Practices
HPT  Division of Health Products and Technologies
ICH  International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IDP  Institutional Development Plan
INS  Inspection National de la Santé
ISO  International Organization for Standardization
ISO/IEC  International Organization for Standardization/International Electrotechnical Commission
LMHRA  Liberia Medicines and Health Products Regulatory Authority
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>LIMS</td>
<td>laboratory information management system</td>
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<td>LMIC</td>
<td>low- and middle-income countries</td>
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<td>LNCM</td>
<td>National Medicines Control Laboratory</td>
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<td>LNS</td>
<td>Laboratoire National de Santé</td>
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<td>MCH</td>
<td>maternal and child health</td>
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<td>MedRS</td>
<td>Medicines Risk-based Surveillance</td>
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<td>MEL</td>
<td>monitoring, evaluation, and learning</td>
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<td>MNCH</td>
<td>maternal, newborn, and child health</td>
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<td>MOH</td>
<td>ministry of health</td>
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<td>MQCL</td>
<td>medicines quality control laboratory</td>
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<td>MRA</td>
<td>medicines regulatory authority</td>
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<td>MTaPs</td>
<td>Medicines, Technologies, and Pharmaceutical Systems program</td>
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<td>NAFDAC</td>
<td>National Agency for Food and Drug Administration and Control</td>
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<td>NCEM</td>
<td>National Centre for Medicines, Medical Devices, and Medical Equipment Expertise</td>
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<td>NCL</td>
<td>National Control Laboratory</td>
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<td>NCLB</td>
<td>National Control Laboratory for Biologicals</td>
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<td>NIPRD</td>
<td>National Institute for Pharmaceutical Research and Development</td>
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<td>NML</td>
<td>National Medicines Laboratory</td>
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<td>NMRA</td>
<td>National Medicines Regulatory Authority</td>
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<td>NQCL</td>
<td>National Quality Control Laboratory</td>
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<td>NTDs</td>
<td>neglected tropical diseases</td>
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<td>PCN</td>
<td>Pharmacists Council of Nigeria</td>
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<td>PIC/S</td>
<td>Pharmaceutical Inspection Co-operation Scheme</td>
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<td>PMS</td>
<td>post-marketing surveillance</td>
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<td>PQM+</td>
<td>Promoting the Quality of Medicines Plus program</td>
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<td>PY1, etc.</td>
<td>Program Year 1, etc.</td>
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<td>Quarter 1, etc.</td>
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<tr>
<td>QA/QC</td>
<td>quality assurance/quality control</td>
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<td>QMS</td>
<td>quality management system</td>
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<td>RMNCAH</td>
<td>maternal, newborn, child, and adolescent health</td>
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<td>SATTA</td>
<td>Stepwise Assessment Tool Towards Accreditation</td>
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<tr>
<td>SF</td>
<td>substandard or falsified</td>
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<td>SOP</td>
<td>standard operating procedure</td>
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<td>Abbreviation</td>
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<tr>
<td>SP</td>
<td>Sulfadoxine/pyrimethamine</td>
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<td>TB</td>
<td>tuberculosis</td>
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<td>TWG</td>
<td>technical working group</td>
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<td>USAID</td>
<td>U.S. Agency for International Development</td>
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<td>USP</td>
<td>U.S. Pharmacopeial Convention</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO-PQ</td>
<td>World Health Organization Prequalification</td>
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Overview

The Promoting the Quality of Medicines Plus (PQM+) program sustainably strengthens medical product quality assurance (QA) systems in low- and middle-income countries (LMICs). PQM+ works to improve medical product quality through cross-sectoral and systems strengthening approaches and the application of international QA standards across the pharmaceutical system. By sharing scientific expertise and providing technical support and leadership, PQM+ helps to create resilient and sustainable local health systems that ensure access to quality-assured essential medicines for HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases (NTDs), and other infectious diseases, as well as for reproductive, maternal, newborn, and child health (MCH).

The PQM+ program is pleased to present its performance report for fiscal year (FY) 2020 quarter three (April–June 2020). This report summarizes the activities undertaken during this period, presenting progress by objective and source of funding (country Missions and health elements).

The nature of PQM+’s activities reflects the priorities of a country’s medical product QA system and USAID’s commitment to support development objectives in medicines QA systems strengthening. All activities roll up to support at least one of PQM+’s five program objectives:

1. Improve governance for medical product QA systems.
2. Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors.
3. Optimize and increase financial resources for medical product QA.
4. Increase supply of quality-assured essential medical products of public health importance.
5. Advance a global medical products QA learning and operational agenda.

The PQM+ program is working in 16 countries in Africa, Asia, and Central Asia. PQM+ has offices in six countries: Bangladesh, Ethiopia, Kenya, Nepal, Nigeria, and Pakistan. In addition, the program is working in Burma, Ethiopia, Kazakhstan, Liberia, Mali, Senegal, and Uzbekistan. PQM+ is in discussions to begin work in Benin, Burkina Faso, and Ghana. In addition, PQM+ received core funding for NTDs, MCH, and TB.
Highlights from the Third Quarter

Between April and June, the program started broad-scale implementation as USAID approved work plans for country buy-ins and PQM+ brought more staff on board. Program staff in headquarters and the field adapted to the different challenges posed by the novel coronavirus (COVID-19) pandemic to ensure PQM+ work and activities continued as smoothly as possible. Highlights from this quarter’s program activities, achievements, and innovations are summarized below.

Governance

PQM+’s work related to governance ranged from helping establish institutional frameworks to proposing improvements to public policies related to medical product QA. Its diverse public policy work included the following:

- Supported the Government of Kenya to establish a QA framework for malaria commodities. The framework was developed by the newly established post-marketing surveillance (PMS) technical working group (TWG) that receives technical assistance from the PQM+ program.

- Provided technical assistance to the Drug Regulatory Authority of Pakistan (DRAP) to revise its licensing rules. Consistent with best practices for regulatory reform, DRAP posted the revised document on its website for stakeholder comments. With PQM+ support, it conducted virtual consultative meetings with stakeholders on the proposed amendments, which include revising the licensing regimen.

- Reviewed and edited the draft National Quality Assurance Guideline in Bangladesh.

- Helped to expand the number of laboratories that are progressing toward adoption of international standards for medical product testing and started developing guidelines for a landscape assessment of third-party, private laboratories in Bangladesh.

- Participated in a meeting led by USAID’s Medicines, Technologies, and Pharmaceutical Services program (MTaPs) to provided support to Nepal’s Department of Drug Administration for the review of Drugs Act, 2035 (1978). The program team also helped the MTaPS program and its consortium partners to develop a draft outline for a new drug law for Nepal’s regulatory authority.

Regulatory Systems Strengthening

PQM+ supports countries to improve their regulatory systems as assessed by the World Health Organization’s (WHO) Global Benchmarking Tool (GBT). The institutional development plans (IDPs) developed subsequent to GBT assessments spell out gaps in the country’s regulatory system and identify roles and responsibilities for addressing them.

This quarter, the regulatory authority of Kazakhstan coordinated with PQM+ to clarify how to help address gaps identified by their IDP. PQM+ also supported DRAP’s response to the GBT gap assessment in Pakistan. PQM+ also supported 11 countries to address gaps across a range of regulatory function areas, including market authorization/registration, inspection, post-marketing surveillance, laboratory testing, and bioequivalence studies - as part of clinical trials.
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Registration

PQM+ is helping the medicines regulatory authorities (MRAs) of both Kazakhstan and Uzbekistan to utilize the collaborative registration procedure (CRP), which means regulatory authorities use the outcomes of WHO Prequalification (WHO-PQ) program medicines evaluations and manufacturer inspections when reviewing requests for market authorization. PQM+ completed an assessment to understand why there has been minimal uptake of CRP in these countries, despite having policies that allow for CRP and is now raising awareness of the benefits of CRP and developing standard operating procedures (SOPs) to support its use.

Good Manufacturing Practices Inspection

In Kazakhstan, PQM+ helped to form a working group to guide efforts to accede to the demanding, globally recognized Pharmaceutical Inspection Co-operation Scheme (PIC/S). Similarly, in Uzbekistan, PQM+ helped convene the first online meeting of a PIC/S working group and continued to guide the regulatory agency in establishing a GMP inspectorate compliant with PIC/S requirements.

Post-marketing surveillance

PQM+ helped the MRAs of Mali and Senegal start to create new national PMS units to oversee all PMS activities in their countries. Support for PMS in Bangladesh included procuring two Minilabs™ for field-based screening of medicines in several states. Now the Directorate General of Drug Administration (DGDA) will be able to provide field-based screening of medicines as part of risk-based PMS in all eight divisions of Bangladesh. In Ethiopia, PQM+ worked with relevant directorates at the Ethiopian Food and Drug Authority (EFDA) in the development of a detailed implementation plan for PMS for the current year. A protocol was developed for conducting PMS of selected priority medical products.

Laboratory testing

PQM+ is working with quality control (QC) laboratories in Bangladesh, Burma, Kazakhstan, Kenya, Liberia, Mali, Nigeria, Pakistan, Senegal, and Uzbekistan. Notably, following support from PQM+ for the reaccreditation assessment of the Nigerian Institute for Pharmaceutical Research and Development, the laboratory achieved re-accreditation for ISO/IEC 17025:2017. PQM+ supported the laboratory in preparing for a re-accreditation assessment. This work was done virtually as a result of travel restrictions due to COVID-19. Following a successful assessment by the American National Standard Institute (ANSI) National Accreditation Board, the laboratory achieved re-accreditation in April 2020.

As another illustration of PQM+’s work despite travel limitations due to the COVID-19, this quarter PQM+ held two widely attended virtual events for participants from Kazakhstan and Uzbekistan. In May, PQM+ held a regional online forum: “The WHO Prequalification Process: Lessons from Kazakhstan’s National Centre for Expertise of Medicines, Medical Devices, and Medical Equipment (NCEM) and its Karaganda Medicines Quality Control Laboratory” for 100 senior managers and other staff from MRAs and QC laboratories of Kazakhstan and Uzbekistan. Similarly, more than 100 participants from Kazakhstan and Uzbekistan attended online training on WHO good practices for pharmaceutical QC laboratories.

Financial Resources

In Nigeria, four accredited laboratories will become satellites to one major laboratory, which will reduce the annual cost of accreditation for all laboratories by approximately 50 percent. This quarter, PQM+ virtually supported all participating laboratories in harmonizing their quality
manuals and other quality management systems (QMS) documents as a key first step. PQM+ will continue to provide virtual support of harmonization efforts, including covering laboratory staff’s internet access costs so that they can participate in a series of Zoom meetings to harmonize documents.

PQM+ enhances the financial sustainability of regulatory functions to promote risk-based approaches that allow regulatory agencies to focus their resources on the highest risk challenges. This quarter, PQM+ supported work related to risk-based PMS in Bangladesh, Burma, and Nepal. The program also helped the regulatory authority in Pakistan lay the groundwork for risk-based inspection and licensing.

**Supply**

PQM+ is unique among USAID-funded implementing partners in helping manufacturers achieve recognition by national and global authorities for the quality of their medical products. This quarter, PQM+ was actively engaged with manufacturers of maternal, newborn, and child health (MNCH), malaria, TB, and other medical, including antimicrobial, products in Bangladesh, Kazakhstan, Nigeria, Pakistan, and Uzbekistan. PQM+ developed a concept note for a pharmaceutical sector development strategy for Pakistan. In Pakistan, the program also conducted a four-day virtual training course on risk-based GMP for antimicrobial manufacturers, which attracted more than 400 participants.

In Ethiopia, PQM+ is conducting an assessment of local manufacturers and their capacity to produce essential medicines identified by the ministry of health (MOH) as priorities to support the government’s response to current priority public health needs.

In Uzbekistan, PQM+ facilitated discussion between the Association of Manufacturers and the regulatory agency to organize a webinar on the common technical document (CTD), which is the format in which medicine dossiers must be submitted to both the local regulatory authority and to the WHO-PQ program.

**Partners**

As a follow-on to the technical workshop conducted in Q2, PQM+ began its quarterly conversations with its various partners through the director’s partner email updates. These updates provide a key mechanism to inform partners about what’s going on globally in PQM+. Highlights of the communication included work plan submission status, operational updates such as new field offices, and staffing. Partner engagement will be expanded over the next quarter by inviting partners to present at upcoming PQM+ technical meetings.
Activities and Progress for Cross-Bureau Activities

Risk-based Post-marketing Surveillance Tool: Medicines Risk-based Surveillance

Market surveillance and control, one of the nine functions of a regulatory authority, plays a vital role in ensuring the public is protected from substandard and falsified (SF) medical products. The PQM program developed the Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries. As a companion to the guide, the MedRS tool helps countries objectively identify the most susceptible medicines, determine the number of samples required to achieve statistical significance, and prioritize sampling at the most vulnerable locations to support sample planning.

Under PQM+, the program completed the development of a web-based version of the MedRS tool and the handover to a new generation of technical managers. PQM+ completed a final quality review and has plans to further enhance the user experience and to bring increased value. A draft user manual has been developed and will be shared with PQM+ staff for internal review.

GMP Assessment Tool

In Q3, PQM+ developed a GMP assessment tool to improve manufacturer assessments and product QA. The tool is designed to assess all aspects of pharmaceutical manufacturer GMP status. It is used by PQM+ staff who are providing technical assistance to manufacturers to uniformly assesses compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q7 guidelines. The GMP guideline is the seventh in the quality series. Manufacturers’ GMP assessments are non-subjective and standardized, providing a clear roadmap of when interventions are necessary to improve medical product quality. Technical areas assessed with the current version includes manufacturers’ processes for managing QA, laboratories, facilities, production, warehousing, and active pharmaceutical ingredients.
By the end of Q3, the PQM+ program was working in 13 countries in Africa, Asia, and Central Asia. PQM+ has offices in six country countries: Bangladesh, Ethiopia, Kenya, Nepal, Nigeria, and Pakistan. In addition, the program is working in Burma, Ethiopia, Kazakhstan, Liberia, Mali, Senegal, and Uzbekistan. Country activities support at least one of PQM+’s five objectives and progress is reported by the relevant objective(s).

**Africa Region**

**Ethiopia**

In Ethiopia, medicines are regulated through authorized bodies at federal and regional levels. At the federal level, EFDA does the following: sets standards for medical products; licenses and regulates transregional medical product production, import, export, distribution, and promotion of medical products; and regulates QC laboratories. All other regulatory activities that are not mandated to EFDA fall under the jurisdiction of regulatory bodies of regional or state governments and city administrations.

But the lack of clarity in mandates between EFDA and regional regulatory bodies, the absence of a formal reporting relationship between EFDA and regional regulators, and the poor capacity of regional regulators are compromising proper regulatory oversight of medical products circulating in Ethiopia.

PQM+ has been working with EFDA and the Regional Food Medicine and Health Care Administration and Control Authorities to build their capacity for monitoring medical product quality across the supply chain and to strengthen their collaborative working relationship to create synergy in executing their respective regulatory mandates more efficiently. PQM+ also contributes to building the capacity of local manufacturers to meet international standards to ensure that locally produced medical products are of good quality and not harmful to end users.

In Q3, PQM+ Ethiopia has focused on work plan development and meeting with relevant stakeholders to facilitate the start-up of key activities. After final approval of its work plan in May, PQM+ actively engaged with its main government counterparts to accomplish the following.

- Priority medicines for local production were identified in consultation with the Ministry of Health (MOH). These included essential medicines such as antibiotics, analgesics, anti-asthmatics, and antihypertensive products. In consultation with the Food Beverage and Pharmaceutical Development Institute (FBPDI) and EFDA, a questionnaire was developed to assess the capacity of local manufacturers and the challenges they face. The goal of this assessment is to identify local manufacturers with the capacity to produce the priority medicines. The assessment will also identify challenges that hinder manufacturers’ capability in producing these essential quality-assured medicines. PQM+, in collaboration with government counterparts, will help to address them. Eight out of ten manufacturers have completed and submitted the questionnaire.
• The guideline for PMS was developed, reviewed, and approved and is being printed. The guideline will serve as a resource for the EFDA to identify products for PMS activities based on medical products that were identified using the PMS guidelines. Sampling of these medical products is in progress.

• Addressing the gaps identified by WHO’s GBT is a key priority of EFDA in helping them achieve their goal of becoming a WHO-listed authority (maturity level 3 or higher). PQM+ is providing technical assistance by developing and revising relevant QMS documentations in compliance with the GBT requirements. Technical assistance has been provided for the development of three SOPs and one guideline/directive.

Progress by PQM+ Objective

Objective 4: Supply of quality-assured essential medical products of health importance increased

With the current disruption in the global medicines supply chain due to the ongoing pandemic, Ethiopia continues to face challenges with importing essential medicines. As part of addressing this challenge, PQM+ explored opportunities to help boost local production of medicines. In May, priority medicines for local production were identified in consultation with the MOH. PQM+ also held meetings with the leadership of EFDA and FBPI to discuss the importance of gathering data on the current status of manufacturers and the challenges they are facing. In those meetings, consensus was established to conduct a gap assessment. Accordingly, a questionnaire for assessing the current status and challenges of local pharmaceutical manufacturers was developed, reviewed, and approved in consultation with FBPI and EFDA.

The questionnaire was distributed to all 11 manufacturers for self-assessment. Eight manufacturers have already completed the questionnaire and submitted their responses to FBPI. Once all questionnaires have been completed and the data analyzed, a report will be generated and shared with all relevant stakeholders and partners. This will also help to inform PQM+ on the next steps for technical assistance.

PQM+ also worked with the relevant directorates at EFDA in the development of a detailed implementation plan for PMS for the current year. This quarter, a protocol was developed for conducting PMS of selected priority medical products. After approval of the protocol, staff were briefed and deployed for sample collection.

PQM+ also worked to revise and update the EFDA’s PMS guideline, which was last approved in 2014 but was missing key aspects, such as a risk-based approach to PMS and clearly delineated roles of stakeholders in the adoption and implementation of the national PMS program. PQM+ and EFDA collaborated on the revision of the guideline, which was approved this quarter. The guideline will be available and disseminated soon to stakeholders and partners. The guideline will help EFDA to strategize the planning and implementation of the national PMS program with consideration of the risk associated with products and sampling location to ensure cost effectiveness.

EFDA plans to achieve WHO’s GBT maturity level 3 and is working toward attaining this goal. PQM+ is providing technical assistance to the Authority in terms of developing/revising relevant QMS documentation in compliance with the GBT requirements. To date, technical assistance has been provided to develop three SOPs and one guideline/directive, all relevant to the inspection function of EFDA. Development and review of other QMS documents that span
across the major regulatory functions including market authorization, inspection, QC testing, and PMS is in progress.

**Priority Activities for Next Quarter**

PQM+ plans to:

- Support the generation of evidence on barriers to import active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs) for emergency response to help policymakers make informed and timely decisions. This activity will leverage knowledge from USP’s new Pharmaceutical Supply Chain Center.
- Identify a list of SOPs, directives, or guidelines to be drafted and reviewed; develop a plan of action to support EFDA in addressing WHO’s GBT assessment findings; and update regulations/directives and guidelines related to market authorization and importation.
- Work with EFDA to complete the sample collection and then begin testing.
- Produce the PMS report for EFDA.
- Develop/update four SOPs as part of preparation for fulfilment of requirements to GBT and/or ISO 17020.

**Kenya**

In Kenya, PQM+ is building on the PQM program’s achievements. With support from The U.S. President’s Malaria Initiative (PMI) and the Office of Maternal and Child Health and Nutrition, PQM+ continues to strengthen the quality of medical products in Kenya by improving governance structures and regulatory systems. The program provides technical assistance to the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL), the Division of National Malaria Program (DNMP), Department of Family Health (DFH), MOH’s Division of Health Products and Technologies (HPT), and the counties to strengthen the medical product QA system in Kenya.

This past May, PQM+ welcomed a new Chief of Party for Kenya and a new senior finance and operations manager. Both staff were introduced to the Agreement Officer’s Representative Team, the USAID Mission, and other country stakeholders, including the PPB, the NQCL, the DNMP and the HPT. Recruitment for a senior technical advisor for regulatory systems strengthening/QA was initiated during Q3 and is ongoing. Though PQM+ is registered in Kenya, plans for opening the local PQM+ office were delayed, given COVID-19 restrictions in Kenya. The country’s PY1 work plan was approved in May.

**Progress by PQM+ Objective**

**Objective 1: Governance for medical product quality assurance systems improved**

During Q3, PQM+ continued to follow up with PPB on the inauguration of a TWG for PMS and pharmacovigilance. This activity was originally scheduled for March 30 but was postponed due to COVID-19 restrictions. With the uncertainty of COVID-19, PQM+ recommended that PPB
plan for an online inauguration of the TWG to prevent any further delays. The TWG inauguration is anticipated to happen in Q4 and will be followed by two technical working sessions with members to develop a strategy and guidelines for a unified PMS approach. In addition, PPB received nominees this quarter from the MOH DFH to join the TWG to ensure reproductive, maternal, newborn, child, and adolescent health (RMNCAH) representation, based on recommendations from PQM+.

PQM+ also continued to provide support to the DNMP on developing a QA framework for all malaria commodities (bed nets, rapid diagnostic tests medicines, and indoor residual spray products). PQM+ developed a draft framework and shared it with the Mission. The framework will provide a harmonized approach to QA of all commodities used in malaria prevention, chemoprophylaxis treatment, and vector control. In addition, PQM+ initiated discussions with DNMP to develop a plan to share and gather input on the draft framework from key stakeholders who were not represented during the consultative workshop in December 2019. PQM+ is following up with DNMP on the establishment of a QA TWG under DNMP's Procurement and Supply Management Committee of Experts. This was identified by the malaria program as the appropriate structure to house the QA TWG.

Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved

PQM+ is supporting the NQCL to procure a Karl Fischer Titrator for use in analysis of select malaria and RMNCAH products. PQM+ worked with the NQCL to define technical specifications and develop plans for the procurement of the titrator. Potential suppliers for this equipment in Kenya have been identified, and the procurement process will be completed in Q4.

PQM+ also provided support to PPB on creating an organizational capacity development platform for self-directed learning. The vision includes a PPB e-resource center and an e-learning strategy. PQM+ and PPB technical teams held several online meetings to plan for the implementation of this activity. These discussions were centered around four themes: 1) PPB organizational capacity development, including alignment with internal staff development plans and career pathways; 2) content development, including learning outcomes, curriculum design, and the WHO Competency Framework for Regulatory Agencies; 3) platforms: technological options for delivering and monitoring trainings; and 4) assessment of learning, including monitoring and evaluation.

Priority Activities for Next Quarter

In Q4, PQM+ plans to:

- Provide support to the PPB PMS TWG to increase its functionality and sustainability. Expected deliverables are: 1) strategy and guidelines for integrated, risk-based PMS developed using the MedRS tool; and 2) universal protocol for PMS, which can be domesticated for RMNCAH medical products.

- Support NQCL to conduct a human resources assessment to promote organizational capacity improvements. The expected deliverable is the NQCL HR assessment report.

- Provide support to the MOH’s HPT department to develop guidance on QA requirements for procurement of medical products at the county level. Expected deliverables are: 1) report on current gaps in QA requirements and practices for
procurement at the county level; and 2) draft guidance on QA requirements for procurement of QA of medical products.

- Support NQCL to procure a Karl Fischer Titrator for use in analysis of select malaria and MCH products.
- Contribute to the development of the PPB organizational capacity development platform for self-directed learning. Expected deliverable: training needs for PPB mapped.

Liberia

The USAID Mission requested support from the PQM+ program to provide technical assistance to strengthen the country’s regulatory system, specifically focused on supporting the Liberia Medicines and Health Products Regulatory Authority and its QC laboratory. PQM+ visited Liberia in December 2019 for a scoping visit and based on the observations made during that visit, proposed the following activities:

- Perform a rapid assessment of the pharmaceutical market to identify threats to quality-assured medicines in Liberia.
- Conduct an analysis of select Liberia Medicines and Health Products Regulatory Authority (LMHRA) functions and fees.
- Perform an in-depth assessment of laboratory needs to allow basic functionality.
- Develop a strategic plan for the life of the program and specific activities to be implemented through the end of September 2020.

Progress by PQM+ Objective

**Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved**

This quarter, the first three activities mentioned above (i.e., the rapid assessment, analysis of LMHRA functions, and the lab needs assessment) were finalized. All three activities took into account the findings of the last WHO GBT from 2017 and built on those recommendations. It was noted that limited progress had been made in addressing findings from that assessment.

Draft reports on both the rapid assessment of the pharmaceutical market and the analysis of select LMHRA functions and fees were submitted this quarter and reviewed by the PQM+ technical team. Based on that review, the report was revised. The final draft was completed at the end of June and will be finalized in mid-July. Findings indicate that the LMHRA is severely restricted in performing key regulatory functions due to limited capacity of staff and funding constraints. Furthermore, fundamental policies, regulations, and guidelines that would provide an adequate enabling environment for LMHRA to perform its duties still need to be drafted or enacted.

Finally, the assessment of lab functions was conducted virtually this quarter with lab staff in collaboration with a local consultant and PQM+ quality assurance/quality control (QA/QC) expert based in Ethiopia. The report was reviewed by the PQM+ technical team and will be finalized by mid-July.
Priority Activities for Next Quarter

PQM+ plans to:

- Discuss findings from the implemented activities during Q3 and next steps with the USAID Mission and national stakeholders.
- Submit a full work plan through September 2021.
- Initiate agreed-upon activities to support LMHRA and the lab.

Mali

The medicine regulatory system in Mali is fragmented. There is a lack of clarity around the roles and responsibilities of the different institutions involved in the system. Important regulatory functions, such as PMS and pharmaceutical inspection, are lacking in the regulatory framework. At present, Laboratoire National de Santé (LNS) is mandated to collect and test medical products from the market, and the National Inspectorate of Health (Inspection National de la Santé or INS) inspects pharmaceutical outlets. However, the INS does not have a comprehensive mandate for inspecting pharmaceutical establishments. The INS and LNS mandates need to be revised and coordinated between the two institutions clearly defined.

To address the lack of coordination around sample collection between the INS and LNS and other gaps, PQM+ will work closely with NPRA to strengthen the risk-based medicine PMS system. PQM+ will help NPRA adopt a risk-based approach to PMS to optimize resources by channeling limited resources toward areas that present the highest risks to patients. A risk-based approach will also be applied to testing the collected samples. PQM+ will provide select technical assistance to LNS to help it comply with International Organization for Standardization (ISO) 17025:2017 requirements and progress toward achieving WHO-PQ and sustainability.

In PY1, PQM+ is working toward the achievement of two country-specific goals:

- Improve LNS’ PMS system to assure the quality of malaria and MCH medical products in the country.
- Strengthen the capacity of LNS’ physicochemical laboratory to perform QC testing or priority essential medical products.

A program manager based in Ghana was recruited and onboarded in early May. A consultant based in Mali was identified to support implementation of activities and will be onboarded in Q4. The Mali work plan was approved in May.

Progress by PQM+ Objective

| Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved |

The PQM+ program in Mali aims to improve the country’s regulatory systems to assure the quality of medical products in the public and private sectors by ensuring the National Medicines Regulatory Authority (NMRA) and NQCLs have a robust system in place to detect substandard or falsified (SF) malaria and MCH medical products. A national PMS unit, comprised of
representatives from the NMRA, NQCL, and disease programs, will enable a coordinated effort to ensure all key elements on PMS are taken into consideration during the design of national guidance, protocols, plans, and regulatory actions, thereby improving the country’s ability to ensure the quality of these critical medical products.

This quarter, DPM and LNS completed the nomination forms for candidates for the national PMS-TWG that will oversee and manage all PMS activities in the country. An introductory email was sent to new members introducing them to the program, PMS objectives, and planned activities in the PQM+ work plan. The invitation was also extended to the HIV/AIDS, tuberculosis, malaria, and MCH disease program leads to ensure representation on this TWG. They are: Cellule Sectorielle de Lutte contre le Sida, la Tuberculose et les Hépatites virales (Sectoral Unit for the Fight Against AIDS, TB, and Hepatitis), Programme National de Lutte contre la Paludisme (National Program to Fight Malaria), and Division Santé de la reproduction à la Direction Générale de la Santé (Ministry of Health and Social Action), respectively.

PQM+ provides technical assistance to increase LNS’ capacity to self-assess its progress toward accreditation. This includes training LNS staff on the Stepwise Assessment Tool Towards Accreditation (SATTA). The tool is designed to support the assessment of different aspects of QMS of NQCL and assist them in identifying areas for improvement in their pursuit of accreditation. To facilitate the introduction and use of the SATTA tool at LNS, a user guide was developed this quarter and is undergoing review for finalization. Training slides were also developed in preparation for a virtual training on how this tool can be used by LNS lab units to conduct internal audits.

The program will work with LNS leadership to assess organizational capacity, including staffing levels, staff competency, and human resource needs. Background information on LNS’s organogram, job descriptions, training plans, national policy on development for human resources for health, the human resource management tool, and salary scales were collected from LNS and are being reviewed. An HR assessment interview is planned for July and will help the laboratory to optimize resources and increase operational efficiencies.

Priority Activities for Next Quarter

PQM+ plans to:

- Conduct trainings for LNS staff on how to use SATTA, conduct an internal audit, and complete a CAPA.
- Supervise the SATTA assessment at LNS.
- Hold the inauguration meeting for the PMS-TWG.
- Focus attention on the development of the RB-PMS protocol and sampling plan.
- Conduct a human resources assessment of LNS.
Nigeria

An important challenge affecting Nigeria’s health system is the lack of availability of quality-assured essential medical products. Nigeria has the highest burden of malaria globally, accounting for 11 percent of maternal mortality, 60 percent of out-patient visits, and 42 percent of hospitalizations among children under the age of five. Seventy percent of medicines in Nigeria are imported. Seventy percent of medicines in Nigeria are imported. A 2018 study by Anyakora et al. on quality medicines for maternal health in Nigeria found that 74 percent of oxytocin injection samples failed the assay test. Many imports pass through open medical products markets, introducing SF medical products into the legitimate supply chain. PQM+ is helping address these challenges by working to improve medical product QA system governance, strengthen regulatory systems, optimize and increase resources for QA systems, and increase the supply of quality-assured MNCH and malaria medical products.

Progress by PQM+ Objective

Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved

To understand the challenges in addressing medical product quality issues at the state level, PQM+ is working with the Pharmacists Council of Nigeria (PCN) to conduct a desk review of state-level regulatory functions, particularly related to licensing establishments and regulatory inspection. PQM+ has completed the collection and review of documentation and data and is drafting the report. The review is informing plans for state-level assessments to be conducted in Bauchi, Sokoto, and Ebonyi states. These assessments will identify state-specific gaps that relate to medical product sale, QA, and regulatory systems. PQM+ has designed the state-level assessment process, including identifying the institutions that will be represented on the data collection team and determining the types of institutions that will be interviewed in the states. PQM+ also has started developing the questionnaires/data collection tools that will be used.

The Nigerian Institute for Pharmaceutical Research and Development (NIPRD) was established to aid novel research in pharmacognosy, medicinal chemistry, and the promotion of indigenous and local content in the pharmaceutical sector. The PQM program helped the NIPRD laboratory achieve ISO/IEC 17025:2017 accreditation. This quarter, PQM+ supported the laboratory in preparing for a re-accreditation assessment. This work was done virtually as a result of travel restrictions due to COVID-19. Following a successful assessment by the ANSI National Accreditation Board, the laboratory achieved re-accreditation in April 2020. This lays the groundwork for NIPRD’s pursuit of WHO-PQ. PQM+ is helping NIPRD develop a road map toward WHO-PQ that includes estimates of the required investment and the time frame.

Objective 3: Financial resources for medical product quality assurance optimized and increased

ISO accreditation recognizes the quality of a laboratory’s performance and instills trust in laboratory results. The cost of annual accreditation or re-accreditation, however, is high for many laboratories. To reduce these costs, PQM+ is supporting the National Agency for Food and Drug Administration and Control (NAFDAC) in harmonizing the accreditation status of its
laboratories. Four accredited laboratories will become satellites to one major laboratory, which will reduce the annual cost of accreditation for all laboratories by approximately 50 percent. This quarter, PQM+ virtually supported all participating laboratories in harmonizing their quality manuals and other QMS documents as a key first step. PQM+ will continue to provide virtual support of harmonization efforts, including covering laboratory staff’s internet access costs so that they can participate in a series of Zoom meetings to harmonize documents.

**Objective 4: Supply of quality assured essential medical products of health importance increased**

Building on the PQM legacy, PQM+ continues to provide technical assistance to Nigerian manufacturers of priority medicines to improve their compliance with GMP and to resolve manufacturing-related quality issues. Progress this quarter included the following:

- **Magnesium sulfate 50 percent injection:** PQM+ is helping Juhel Nigeria Ltd. pursue WHO-PQ of magnesium sulfate, which is used to treat severe pre-eclampsia, eclampsia, or toxemia in pregnancy. PQM+ helped Juhel close out the corrective and prevention action (CAPA) plan developed after a mock GMP audit that was conducted in March 2020 to prepare the company for the upcoming WHO audit. PQM+ also supported Juhel in reviewing product data and responding to requests from the WHO-PQ dossier evaluation team. The real time stability test for magnesium sulfate injection, in which the product is stored at recommended conditions and monitored until it fails the specification, is ongoing and currently in its 32nd month. The WHO-PQ GMP inspection visit has been delayed due to COVID-19 travel restrictions.

- **Sulfadoxine/pyrimethamine (SP) (500+25) mg tablet:** SP is used to treat acute, uncomplicated *P. falciparum* malaria for those patients in whom chloroquine resistance is suspected or as intermittent preventive treatment of malaria in pregnant women. PQM+’s support for SP manufacture in Nigeria addressed numerous steps in the long process of achieving prequalification. This support included:
  - Providing technical assistance to Emzor Pharmaceutical Industries in formulation optimization or developing formulations that consistently deliver uniform tablets from its new oral solid dosage facility. This support is being provided prior to Emzor’s production of the test batch to be used to demonstrate bioequivalence (i.e., the bio-batch) as part of the prequalification process.
  - Reviewing the protocol for the bioequivalence study and the contract between Emzor and the contract research organization (CRO) that will conduct the bioequivalence study. The CRO currently is sourcing the comparator product for the BE study.
  - Providing ongoing support for dossier compilation for a second SP manufacturer, Swiss Pharma Nigeria Ltd (Swipha). COVID-19 impacted some key activities required to generate data for product dossier compilation for this manufacturer.

- **Zinc sulfate 20mg dispersible tablet.** PQM+ advised Swipha on the modality for conducting a palatability study for these tablets, which are used to reduce severity and duration of diarrhea in children. PQM+ continues to monitor the progress of the palatability study, although the study has experienced some delays due to COVID-19.

**Priority Activities for Next Quarter**

PQM+ plans to:
• Continue to work with PCN to complete the state-level gap assessments and then develop state-specific action plans to improve access to quality-assured medical products at the privately owned retail outlets.

• Conduct a gap assessment of NAFDAC Zonal Laboratory Agulu; a technical report and costed action plan will be generated as deliverables.

• Develop and finalize a costed action plan for WHO-PQ for NIPRD and NAFDACs’ laboratories.

• Continue to work on financial sustainability for the four NAFDAC accredited laboratories.

• Continue to provide support to Juhel in providing additional product data for the magnesium sulfate injection submission to the WHO-PQ dossier evaluation team. Follow up on implementation of the CAPAs closed.

• Provide support to Emzor in the production of the test batch for bioequivalence study; monitor and review accelerated stability study data of SP and compilation of product dossier in the CTD format.

• Provide support to Swipha in the review of the dossier for SP and follow up with on BE study of SP.

• Provide support to five companies of antimalaria and MNCH medicines to prepare CAPA plans to address audit findings that were conducted during the PQM-supported NAFDAC GMP roadmap inspections of all pharmaceutical manufacturing companies. This took place between November 2018 and May in 2019. The CAPA report is a requirement in the process of being re-assessed by the MRA and re-categorization of the risk level regarding GMP compliance.

• Provide support in developing the QMS documentation for the Emzor Ready to Use therapeutic plan.

**Senegal**

The Government of Senegal recently developed a five-year (2019–2023) Integrated Strategic Plan for the Directorate for Pharmacy and Medicines (DPM) and the National Medicines Control Laboratory (LNCM) with the vision of building “an efficient system of regulation and control which ensures the development and application of quality standards and which guarantee access to medicines and other quality health products that are effective and safe for the entire population.” The plan recognizes that while progress has been made over the past decade, in part due to the support provided through USAID’s PQM program, there is still much work to be done.

The plan cites areas of weakness for both the DPM and the LNCM that include scarce financial resources, insufficient human resources, poor information systems, and lack of coordination and communication among relevant stakeholders engaged in the medical product QA system. In order to address these areas, and realize the vision described above, the strategic plan outlines 17 sub-objectives under seven general objectives. PQM+ will contribute to the plan’s first and third general objectives: “Establish an appropriate institutional framework for the optimal implementation of pharmaceutical regulatory and control functions” and “Evaluate and control
the quality of drugs.” PQM+ will work on addressing the following sub-objectives under those two general objectives:

- Meet the conditions for [WHO] certification and [ISO 17025] accreditation of LNCM.
- Ensure PMS of medical products.

A program manager based in Ghana was recruited and onboarded in early May. The program also started the recruitment process for a local consultant to support implementation in Senegal. The consultant will be onboarded during Q4. The work plan was also approved in May.

**Progress by PQM+ Objective**

| Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved |

The PQM+ program in Senegal is working to improve the country’s regulatory systems to assure the quality of medical products in the public and private sectors by ensuring the NMRA and NQCL have a robust system in place to detect SF medicines. To improve governance and oversight for the QA of medical products, a national PMS unit, comprised of representatives from the NMRA, NQCL, and disease programs, is being established to manage all PMS activities in the country.

During Q3, PQM+ provided support to both DPM and LNS with the establishment of a PMS unit to help improve the country’s regulatory systems to assure the quality of medical products in the public and private sectors. Both DPM and LNS completed nomination forms for candidates—representatives from the NMRA, NQCL, and disease programs—to be part of the new national PMS unit and oversee all PMS activities in country. An introductory email was sent to selected candidates for the unit introducing them to the program, PMS objectives, and planned activities in the PQM+ work plan for Senegal. The invitation was also extended to the HIV/AIDS, Tuberculosis, Malaria, and MCH disease programs (Programme National de Lutte Contre le Sida, Programme National de Lutte Contre la Tuberculose, Programme National de Lutte Contre le Paludisme, and Direction de la Santé de la Mère et de l’Enfant) to ensure representation on this PMS unit.

The program is also focusing on introducing a new, efficient tool for conducting laboratory audits to LNCM that will enhance the laboratory’s ability to continuously improve its QMS, thereby ensuring the laboratory has the capacity and competencies required to accurately ascertain the quality of medicines being registered and circulating in the Senegalese market. To facilitate the implementation and uptake of the new SATTA tool at LNCM, a user guide was developed during this quarter and is undergoing review for finalization. Training slides were also developed in preparation for a virtual training on how this tool can be used by LNCM to conduct internal audits and track improvements in their QMS for next quarter.

**Priority Activities for Next Quarter**

PQM+ plans to:
- Conduct SATTA training for LNCM staff.
- Supervise SATTA assessment at LNCM.
- Conduct the PMS unit inauguration meeting.
- Develop the national PMS guidance document and PMS plan for FY 21.
Asia Region

Bangladesh

The size of the medicine market is enormous in Bangladesh. There are more than 200 licensed allopathic medicines manufacturers, 29,000 registered brands, and 13,000 registered medicines outlets in the country. Due to the lack of properly trained personnel, limited capacity, and the staggering volume of medicines to be tested, the government’s current PMS program is limited to sporadic inspections with irregular and unrepresentative sample collection. Moreover, PMS of TB, MCH, and family planning/reproductive health medical products that are procured through different programs of the Ministry of Health and Family Welfare is siloed. Support is needed to implement comprehensive, evidence-based regulatory standards and processes for PMS of medical products.

The PQM program supported the drug QC laboratory responsible for rigorous, confirmatory product quality testing according to international standards. With PQM’s support, the National Control Laboratory (NCL) achieved International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2017 accreditation for its physicochemical laboratory in 2018. PQM+ will support the NCL in achieving World Health WHO-PQ as further evidence of its ability to meet all international standards.

Bangladeshi pharmaceutical manufacturers (both public and private) and professional pharmaceutical associations also require support to comply with national and WHO GMP standards and to obtain WHO-PQ status for selected medical products. Targets for WHO medicines prequalification in Bangladesh are for select TB, MCH, and family planning (FP) medicines, in particular, first-line TB medicines.

PQM+ Bangladesh Health Priorities

- TB: 53% of funding
- MNCH: 29% of funding
- FP/RH: 18% of funding

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

PQM+ is reviewing and editing the draft National Quality Assurance Guideline that was initially drafted under the PQM program to strengthen DGDA’s overall QA measures for pharmaceutical products throughout the supply chain. This guideline will provide the foundational QA principles for stakeholders and partners (governmental and non-governmental) engaged in providing medical products in Bangladesh. After internal review and editing, PQM+ will share the guideline with the DGDA, the Directorate General of Health Services, and the Directorate General of Family for its review, finalization, and dissemination.

To help expand the number of laboratories that can be used to support medical product testing, PQM+ is developing guidelines for a landscape assessment of third-party, private laboratories that might be able to play such a role.

Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved
Given the size of the pharmaceutical marketplace in Bangladesh, it is critical that the government optimize use of its regulatory resources to protect the public. This includes optimization of PMS or monitoring the safety of a pharmaceutical drug or medical device after release on the market. PQM+ promotes risk-based approaches to PMS that consider and assess multiple types of risk factors and prioritize activities to maximize the utility of the surveillance. PQM+ is helping DGDA to scale up PMS of priority products in two new geographic divisions, Sylhet and Mymensingh. To this end, the program helped the NCL for medical products develop a list of priority medical products (i.e., TB, MNCH, FP, malaria, HIV, and COVID-19) that are to be sampled for PMS.

PQM+ also is procuring two Minilab™ screening tools for the surveillance department of DGDA. The Minilab™ is a portable device that allows for rapid quality verification of priority medicines, such as anti-infective medicines, and the detection of SF pharmaceuticals in the field. With these additional Minilabs™, DGDA will be able to provide field-based screening of medicines as part of risk-based PMS in all eight divisions of Bangladesh.

To improve adoption of electronic information systems and data standards at NCL, on June 16, 2020, PQM+ convened a consultative meeting with the NCL and the WHO to assess the requirements and steps to implement laboratory information management system (LIMS) software at NCL. Two companies, one being the software supplier for NCL and another that provides technical assistance in LIMS, jointly organized a virtual conference call on June 17, 2020, which was requested by NCL, to provide details on the software being considered for the information system. PQM+, WHO, and a representative of the MTaPs attended. The NCL then drafted preliminary user requirements specifications for the system. Based on the specifications, WHO is assessing the financial support required for licensing and the operational costs of the LIMS. PQM+ is helping NCL to define the data standards required for the LIMS to ensure use of structured format and standardized terminology for electronic information exchange and to improve data integrity. PQM+ also advises NCL on data back-up and how to transition from the existing paper-based system to an electronic system.

PQM+ Bangladesh’s work plan included supporting DGDA participation in a PIC/S committee meeting in April in Geneva, Switzerland. Due to the inability to travel internationally, this meeting was cancelled.

**Objective 4: Supply of quality assured essential medical products of public health importance increased**

Building on PQM’s work with manufacturers, PQM+ continued to support ACI Pharmaceuticals in developing a CAPA plan to address gaps identified during PQM’s inspection of the company in April 2019. PQM+ provided technical guidance and recommendations for ACI Pharmaceutical’s CAPA plan in early June. ACI is working to address the CAPAs, which are required to prepare it to manufacture quality-assured, first-line, fixed-dose combination anti-TB medicines.

ACI Pharmaceuticals is also in the process of procuring APIs for product development batches of these first-line anti-TB medicines. This is an early step in preparing to seek WHO-PQ for this medicine.

PQM+ also developed a work plan, which was approved June 10, to support the government’s response to COVID-19. With this new funding, PQM+ will:
• Support DGDA in mitigating medical product shortages, facilitate expedited regulatory pathways/exemptions and registration decisions for COVID-19-related medical products as appropriate, and complete other related regulatory functions, including participating in regional harmonization efforts.

• Provide technical assistance to manufacturers for the local production of personal protective equipment and other medical devices and supplies used to respond to COVID-19.

• Protect patients from SF medical products, including by implementing risk-based quality surveillance and inspection, supporting testing of priority medical products for COVID-19, and sharing product quality surveillance information.

Priority Activities for Next Quarter

PQM+ plans to:

• Finalize the National Quality Assurance Guideline.
• Review the PIC/S pre-accession applicant questionnaire and pre-accession applicant audit checklist and share it with DGDA for onward submission.
• Procure two new Minilabs™ to facilitate RB-PMS in the two remaining divisions.
• Train NCL staff to conduct impurity analysis of first-line anti-TB medicines.
• Assist TB medicine manufacturer ACI to address CAPA from PQM inspection.

Burma

The PQM+ Program in Burma is working to improve the regulatory systems of Burma’s Department of Food and Drug Administration (DFDA) to assure the quality of medicines in the country and thereby contribute toward malaria elimination. Discussions are in place for the introduction of a risk-based approach in PMS activities to improve the detection of SF antimalarials in the country. PQM+ is also supporting the ISO 17025:2017 reaccreditation of the Pharmaceutical Chemistry Laboratory, Nay Pyi Taw, to ensure the accuracy and reliability of its quality testing results, which will in turn support the PMS activities.

Progress by PQM+ Objective

Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved

PQM+ assisted the Pharmaceutical Chemistry Laboratory’s quality assurance team on the QMS document review as part of the preparations toward re-accreditation. PQM+ is coordinating between DFDA and ANSI National Accreditation Board for the assessment, which is planned for October 2020.

PQM+ and DFDA management discussed the introduction of the MedRS tool and implementing a risk-based approach when conducting PMS activities on anti-malarials in Burma. The MedRS tool will be piloted in Kayin State, which has a high malaria burden, and Bago Region, which has a low and stable malaria burden. DFDA also asked PQM+ to review their IRIMS, which is
not functional due to technical and user experience issues and identify the underlying causes – institutional and technical.

PQM+ is reviewing the IRIMS with a focus on the data standards and specifications for each scope or feature of the tool. As part of the review, PQM+ will work with DFDA to define user specifications while advocating for a local developer/help desk funded by DFDA to provide ongoing support and regular updates in order to adapt to changing demands. Due to the in-country travel restrictions in Burma, the roll-out of the MedRS tool and the training for the inspectors have been delayed. In-country travel resumed in June and the roll-out of the tool has been shifted to Q4.

Priority Activities for Next Quarter

PQM+ plans to:

• Conduct a stakeholder coordination meeting among DFDA, PQM+, and USAID/PMI to review the completion of programmatic activities, assess the challenges, and map the critical needs to be addressed in PY2.

• Provide further coordination between the Pharmaceutical Chemistry Laboratory and the ANSI National Accreditation Board to plan for the remote ISO 17025:2017 re-accreditation assessment. The Measurement Uncertainty training will be provided to the analyst prior to the assessment.

• Introduce the MedRS tool to two DFDA State/Region Field offices and train the staff on the tool and the data collection in the next quarter.

Nepal

To date, the government has struggled to ensure the quality of medicines used by the people of Nepal. As evidence, a surveillance study implemented by the Nepal Health Resource Council in 2015 found that 32.5 percent of tested medicine samples from Kathmandu Valley were of substandard quality.

USAID/Nepal engaged PQM+ to provide technical assistance to strengthen medical product QA and QC systems at the Department of Drug Administration (DDA) in Nepal at federal and provincial levels. PQM+ also will strengthen the National Medicines Laboratory (NML) and its corresponding entities at the provincial level as well as private medicines testing laboratories and local medicine manufacturers (both public and private allopathic and ayurvedic manufacturers). Finally, the program will build awareness of the threat of SF medical products.

PQM was not active in Nepal, so the PQM+ program is new to the country. The Chief of Party joined the program halfway through the quarter, but due to COVID-related travel restrictions, he can’t relocate to Nepal yet and is working remotely. The Finance & Operations manager joined the program in early May and is establishing operations in the country. Two other specialists, the technical advisor for Regulatory System Strengthening and the procurement officer, will join the team by mid-July.

Progress by PQM+ Objective

PQM+ Nepal Health Priorities

- MNCH: 61% of funding
- FP/RH: 39% of funding
**Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved**

The Government of Nepal seeks to improve its PMS of medicines to help ensure the quality of medicines on the market. PQM+ promotes risk-based approaches to PMS that consider and assess multiple types of risk factors and prioritize activities to maximize the utility of PMS. In Q3, PQM+ oriented DDA leadership, its PMS management division, the NML, and other stakeholders on the PQM+ risk-based approach. The group also reviewed the existing PMS and medical product QC system. PQM+ developed a questionnaire and used it to collect relevant information from the PMS management division and the NML. The program is analyzing the data and will use the information to plan a detailed gap analysis and early activities. PQM+ also began to coordinate closely with the DDA and the MTaPs. Initial collaboration included a review of the existing drug law and DDA QMS. PQM+ supported the drafting of an outline of a new drug law for DDA.

**Objective 4: Supply of quality assured essential medical products of public health importance increased**

PQM+ will review the Nepalese GMP code for inspection of manufacturers, importers, and distributors to determine if there are any gaps and inconsistencies with international standards and WHO guidelines. As a first step, PQM+ is having the code translated from Nepalese to English.

PQM+ met with DDA leadership and its Inspection Division to discuss the GMP inspection system. The inspection system seeks to ensure that operations at medical product manufacturers, distributors, re-packagers, re-labelers, importers, agents, traders, wholesalers, and retailers are carried out in accordance with approved standards, norms, and guidelines and are in compliance with national legislation and regulations. The team is using information gleaned from these discussions to design a detailed questionnaire to be used to identify gaps in the inspection system and to plan early activities.

**Priority Activities for Next Quarter**

PQM+ plans to:

- Develop a regulatory systems/medicines QA workforce development plan and focus on assessing human resources for regulatory inspections, laboratory testing, and market surveillance.
- Lay the groundwork for use of PMS data to inform regulatory actions through collaboration with MTaPs on the revision of the National Medicine Policy and Drug Act.
- Develop a strategy for risk-based PMS and conduct a PMS rapid assessment.
- Collect background information from the NML on QC testing needs and orient NML staff to the SATTA tool.
- Ensure alignment with international standards on GMP regulations by working to translate the current Nepali GMP regulations and then compare them to international standards.
Pakistan

Pakistan’s regulatory system has limited capacity for medicines quality surveillance, contributing to the proliferation of SF medical products. Lack of regulatory enforcement and availability of centers to conduct reliable bioequivalence studies reduces confidence in the efficacy of generic medical products manufactured in the country. Inconsistent government policies for the pharmaceutical sector have undermined the private sector’s potential role in improving health outcomes. The PQM+ Pakistan program is addressing these challenges through four areas: improving governance of medical product QA systems; strengthening medical product regulations; enhancing private sector engagement; and reducing the availability of SF medical products.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

The Drug Regulatory Authority of Pakistan works to ensure that all establishments comply with risk-based GMP requirements and to maintain a balance between the potential health benefits and risks posed by therapeutic products. The existing licensing system is not in line with international standards and its scope is limited to manufacturing facilities (both for finished pharmaceutical products and APIs). In Pakistan’s existing licensing system, there is no uniformity, consistency, transparency, and accountability of regulatory requirements. GMP inspections practices vary significantly.

To comply with international standards and requirements, Pakistan’s licensing rule (1976 Chapters I and II) must be revised to include all activities relevant to the safety, efficacy, and quality of therapeutic goods. In Q3, PQM+ provided technical assistance to DRAP to revise the licensing rules, place the revised document on the DRAP website for stakeholder comments, and conducted virtual consultative meetings with stakeholders on proposed amendments. The virtual consultative meeting was held on June 5 in coordination with DRAP, Pharma Bureau (which oversees pharmaceutical manufacturers), and the Pakistan Pharmaceutical Manufacturer Association. More than 600 technical and higher management representatives participated.

In Q3, PQM+ continued supporting DRAP in preparing its draft response to the WHO GBT gap assessment, which was conducted in November 2019. This included developing the DRAP competency framework and reviewing updated guidelines and SOPs, as recommended by WHO.

Objective 2: Country and regional regulatory systems to assure the quality of medical products in public and private sectors improved

PQM+ organized a virtual training on development and implementation of a CAPA plan for DRAP’s National Control Laboratory for Biological (NCLB) technical staff. Last year, PQM conducted a detailed gap assessment of NCLB regarding its compliance with ISO 17025 standards and WHO GBT indicators. The training outlined CAPA guidelines (USFDA and WHO), root cause analysis reasons for CAPA, steps in the CAPA procedure, and common mistakes in CAPA management. The session was followed by a mock exercise in which NCLB staff completed the root cause analysis and CAPA development for an audit observation. This
CAPA training and mock exercise will help NCLB staff revise their CAPA SOPs and start developing CAPA plans based on the gap assessment report submitted by PQM in 2019.

In Q3, PQM+ continued technical support to the Central Testing Laboratory in Karachi to address the ISO 17025-2017 pre-assessment audit observations related with the QMS. Moreover, through PQM+ advocacy with DRAP management, the lab was shifted to a new building, which was one of the pre-assessment audit recommendations. CDL will be ready for a complete ISO 17025-2017 audit next quarter.

**Objective 3: Private sector engagement in pharmaceutical manufacturing increased**

At present, Pakistan exports an estimated $200 million in pharmaceutical products annually, or approximately 0.02 percent of annual global sales. With careful planning, strategic policy-making, investment, and a strong commitment from the government and the pharmaceutical industry, Pakistan’s share of the global pharmaceutical market can exponentially increase.

In Q3, PQM+ developed a concept note for a pharmaceutical development strategy kick-off meeting for Pakistan. The concept note defines the key objectives of a first meeting of multisectoral stake holders to work to develop a strategy for next 10 years. Potential stakeholders can be involved in a multifaceted, parallel approach to removing roadblocks and obstacles to achieving the established goals.

PQM+ followed up on a training needs assessment of manufacturers conducted by PQM and the pilot of a new risk-based inspection system by DRAP. There was keen interest in the training, with more than 400 participants from industries (including technical staff from QA, validation, manufacturing, management, and training responsibilities) as well as from regulatory authorities. The training was divided into 13 modules that covered all aspects and critical elements of GMP. The course also identified basic principles of GMP for different dosage forms. The modules included alternative approaches to regulatory compliance as well as the use of quality risk management principles (per ICH Q9). PQM+ added sessions for those who are actively involved in performing, overseeing, auditing, or managing training for their organizations.

**Objective 4: Supply of quality assured essential medical products of public health importance increased**

The ISO Identification of Medicinal Products standards specify the use of standardized definitions to identify and describe medicinal products for human use. The purpose of these standards is to facilitate the reliable and consistent exchange of medicinal product information by providing a common product “language” for stakeholders to use in their interactions. In Q3, PQM+ consulted with DRAP on adopting and implementing data standards that will help to identify and exchange information on:

- Substances (ISO 11238)
- Pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO 11239)
- Units of measurement (ISO 11240)
- Regulated pharmaceutical product information (ISO 11616)
- Regulated medicinal product information (ISO 11615)
Priority Activities for Next Quarter

PQM+ plans to:

- Provide technical assistance to DRAP to prepare the final draft of establishment licensing, which is to be presented to the DRAP policy board after incorporation of stakeholder comments/suggestions.
- Review the revised SOPs and support CAPA plan development and implementation.
- Hold a consultative meeting with DRAP on the development of a road map for adoption of data standards and development of antimicrobial dashboard in PIRIMS.
- Support the NCLB to develop a CAPA plan based on the gap assessment report for WHO GBT (lot Release function) and ISO 17025 standards.
- Continue technical assistance to the Central Drug Testing Laboratory in Karachi for final ISO 17025 assessment (expected in September 2020).
- Review the laboratory QMS SOPs of National Appellate Laboratory in Islamabad.
- Under DRAP, review the new proposed inspections procedures and jointly review of progress over the IDPs implementation.
- Hold a consultative meeting with DRAP to develop risk-based regulations for market authorization of high-risk medical devices.
- Hold a consultative meeting with DRAP and WHO to develop draft regulatory actions framework based on the Access, Watch, Reserve (AWaRE) list.

Europe and Eurasia Region

Central Asia/Kazakhstan

Kazakhstan has made significant steps in recent years in its battle against TB, with TB incidence having fallen steadily since 2004 and the government ensuring universal treatment coverage for TB. But the nation still has one of the highest multidrug-resistant TB burdens globally, with multidrug-resistant TB and rifampicin-resistant TB together making up 27 percent of new TB cases and 64 percent of previously treated cases in the country.

With funding from the USAID Mission in Central Asia, the PQM+ program supports strengthening the QMS of the medicines quality control laboratories (MQCLs) to reliably and accurately test the quality of medicines produced locally as well as those imported from other countries. The program will also focus on increasing the supply of locally manufactured quality-assured TB medicines in local markets.

This quarter, PQM+ continued to provide support to the NCEM in Kazakhstan as well as the MQCL and selected pharmaceutical manufacturers. PQM+ also continued the work related to WHO’s assessment of NCEM using the GBT.

Progress by PQM+ Objective
Objective 2: Country regulatory systems to assure the quality of medical products in the public and private sectors improved.

PQM+ reviewed the documents related to the WHO GBT assessment, which was conducted in 2018, including the draft IDP. The documents were provided by the NCEM. PQM+ arranged an introductory call with the working group established by NCEM to discuss PQM+ technical assistance in medicines registration system (including WHO CRP), GMP inspections, and medicines quality control. NCEM finalized and submitted the IDP to WHO for their review, also indicating PQM+’s availability for technical assistance in the different functional areas of NCEM.

PQM+ also developed a WHO Collaborative Registration Procedure questionnaire and introduced the questionnaire to the working group responsible for registration of medicines. The working group completed the WHO CRP Assessment Questionnaire on behalf of NCEM. PQM+ reviewed the completed questionnaire. The assessment showed gaps in understanding of the WHO CRP and absence of the corresponding procedures. PQM+ organized a short virtual training on introduction to and benefits of WHO CRP. The training was attended by five NCEM representatives and a Drugs Quality Management specialist from USAID.

PQM+ continued providing technical assistance to the Nur-Sultan, Almaty, and Karaganda MQCLs following the technical assistance visit in January 2020. Specifically:

- PQM+ held a series of calls with Nur-Sultan laboratory to improve their QMS documents in compliance with WHO Good Laboratory Practices and ISO 17025 international standards. PQM+ reviewed the current Quality Manual and several SOPs of the laboratory and provided recommendations for WHO-PQ compliance.
- PQM+ provided the first online training for the staff of Nur-Sultan MQCL. The training focused on Good Documentation Practices for Quality Control Laboratories and was attended by 27 participants from the Nur-Sultan laboratory. PQM+ organized a follow-on call to discuss the participants’ questions.
- PQM+ organized an introductory call with Almaty laboratory and provided an overview of the findings from the January visit. As Almaty is getting ready for the WHO peer audit in November 2020, PQM+ reviewed the laboratory’s plan on preparation for WHO-PQ and provided recommendations. The laboratory will update the WHO-PQ plan and send it to PQM+ for review. PQM+ will identify areas of technical assistance for WHO-PQ.

In addition, on May 14, 2020, PQM+ held a regional online forum: “The WHO Prequalification Process: Lessons from Kazakhstan’s NCEM and its Karaganda Medicines Quality Control Laboratory” for the staff of the MRAs and their MQCLs of Kazakhstan and Uzbekistan. The purpose of the forum was to share Karaganda laboratory’s journey toward WHO PQ. The forum included presentations, case studies, and discussions on the WHO-PQ process and the benefits of achieving international recognition. The forum encouraged the laboratories of the region to collaborate. More than 100 participants attended the online forum, including the senior management of the MRAs of Kazakhstan and Uzbekistan, and staff from the eight laboratories (three from Kazakhstan and five from Uzbekistan).

Between June 16 and 19, PQM+ provided a regional online training on WHO good practices for pharmaceutical quality control laboratories to the staff of Kazakhstan’s NCEM headquarters, three Kazakhstan MQCLs (Nur-Sultan, Karaganda, and Almaty), and two Uzbekistan MQCLs (Tashkent and Andijan). The WHO Good Laboratory Practices training was divided into four sessions and focused on providing participants with an overview of WHO Technical Report Series, No. 957, 2010: WHO Good Practices for Pharmaceutical Quality Control Laboratories.
**and Basic Principles on How to Implement QMS in Quality Control Laboratories.** The training covered WHO requirements for management, infrastructure, materials, equipment, instruments, and other devices, as well as procedures and safety in the Pharmaceutical Quality Control Laboratories. More than 100 participants attended the online training. The participants had several technical questions during the discussions and after the training. PQM+ arranged an additional follow-up session to respond to the participants’ questions. The USAID Central Asia Mission highlighted the successful training in its June 19, 2020 biweekly report.

A PIC/S working group was formed that included representatives from the Committee for Quality Control and Safety of Goods and Services and NCEM. PQM+ organized a series of meetings with the committee and worked on responding to the gaps identified during the technical assistance visit in February 2020. The working group through PQM+’s technical assistance is addressing organizational structure, QMS, training procedure, and legislation for the inspectorate.

**Objective 4: Supply of quality-assured essential medical products of public health importance increased.**

PQM+ had several calls with Nobel Almaty Pharmaceutical Factory to discuss the status of levofloxacin production (intended for WHO-PQ) and PQM+’s technical assistance. One of the challenges with levofloxacin was cross-contamination among levofloxacin, cephalosporins, and other products. Nobel is planning the reconstruction of the facility to minimize cross-contamination. The reconstruction, however, has been postponed due to COVID-19 restrictions. To identify next steps, PQM+ prepared a document with a timeline of milestones, which will help get additional information from Nobel and determine the anticipated time for dossier development and improvement of GMP compliance.

**Priority Activities for Next Quarter**

PQM+ plans to:

- Work with the NCEP to develop a detailed plan for its technical assistance to help comply with the good regulatory practices, including strengthening the medicines registration system after WHO provides comments on the IDP.
- Provide technical assistance on WHO CRP to develop capacity and procedures to ensure use of WHO CRP for registration of WHO-PQ medicines, including TB medicines.
- Continue to provide targeted capacity building on QMS for MQCL to the laboratories, such as training and SOP development, for WHO-PQ.
- Continue to provide support on PIC/S to the working group to respond to the issues arising during preparation for PIC/S application.
- Support the dossier development to Nobel pharmaceutical for WHO-PQ for levofloxacin.
Uzbekistan

According to the WHO, the estimated incidence of TB in Uzbekistan is very high, with 70 cases per 100,000 individuals. There is a network of QC laboratories in the country that includes the laboratories of the State Center as well as four regional laboratories. The central laboratory of the State Center is ISO/IEC 17025 certified, but only by the local certification agency. The regional laboratories are neither internationally ISO/IEC 17025 accredited nor WHO-PQ.

The country is graduating from Global Fund-supported procurement of TB medicines to domestically funded procurement. Uzbekistan also plans to gradually increase the allocation of funding for procurement of second-line medicines. The government’s strategy is to ensure that domestically produced, quality-assured medicines are available for procurement.

Building on achievements of the PQM program, PQM+ has received funding from USAID/Central Asia/Uzbekistan to continue to strengthen systems to improve access to quality-assured medicines for TB and other essential medicines in the country. The program will provide continued support to the MQCL laboratories and pharmaceutical manufacturers and expand the scope to include assistance to the national regulatory agency.

Progress by PQM+ Objective

Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved

PQM+ initiated technical assistance to the national medicines regulatory authority (the Agency) to strengthen the review and registration system for medicines. PQM+ met with the Agency’s director to finalize PQM+ technical assistance, and it was agreed that the program will: assess the medicines review and registration system; optimize the business processes for medicines review; develop corresponding SOPs; introduce key performance indicators into QMS; and recommend structural changes as needed.

PQM+ initiated the assessment of the current system during this quarter and started to collect existing documents related to medicines review and registration for PQM+ review. Additionally, PQM+ has regular meetings with the staff of the Agency to ensure smooth collaboration.

To start to operationalize the WHO CRP for registration of WHO-PQ medicines, PQM+ developed a questionnaire to conduct remote assessments of the current procedures and capacity for working groups established by the Agency. Results from the assessment showed gaps in understanding, capacity, and limited procedures on WHO CRP. In June, PQM+ started a series of trainings to familiarize staff in the WHO CPR process. Internal guidelines and SOPs for using WHO CRP for registration of WHO-PQ medicines will be developed next.

The Agency has established a working group to coordinate PQM+ technical assistance to the National GMP Inspectorate on PIC/S ascension. In April, PQM+ organized the first online meeting with the representatives of the working group and shared the findings from the technical visit in March 2020. In subsequent meetings, PQM+ assigned tasks to the working group to achieve PIC/S compliance. Through teleconferences with the working group on May 22 and June 10, PQM+ provided guidelines on the structure of the quality manual and the SOP for training inspectors and reviewed QMS documents developed by the Inspectorate. PQM+ also
assigned tasks to the working group on the different aspects for achieving PIC/S compliance. The group also discussed an updated list of inspectors.

The Agency established two working groups to coordinate PQM+ technical assistance to Tashkent and Andijan MQCLs. Based on the gaps identified in the technical visit in January 2020, PQM+ organized a series of targeted online trainings for the laboratories to improve their compliance with international standards for quality control laboratories. These online trainings included:

- Multiple trainings for employees/analysts of Andijan laboratory on elements of quality control laboratories, handling of laboratory reagents that enabled analysts to understand the importance of using quality reagents.
- A regional online forum for the staff of the MRAs and their MQCLs of Kazakhstan and Uzbekistan was facilitated in May to share Karaganda (Kazakhstan) laboratory’s journey towards WHO-PQ achieved through PQM and PQM+ technical assistance (see description above).
- PQM+ also provided regional online training for headquarters staff of the Kazakhstan MRA, three Kazakhstan MQCLs (Nur-Sultan, Karaganda and Almaty) and two Uzbekistan MQCLS (Tashkent and Andijan) on WHO good practices for pharmaceutical quality control laboratories (see description above).

PQM+ held a series of meetings with Nobel Pharmasonat. In compliance with PQM+ recommendations, Nobel is working on mitigating the risk of cross-contamination between penicillins and other products. PQM+ will also provide technical assistance to Nobel on preparation of the product dossier for WHO-PQ. PQM+ developed a list of documents on product development for dossier preparation and GMP for Nobel. They will then prepare these documents and send to PQM+ for review.

Finally, PQM+ facilitated discussions between the Association of Manufacturers and the Agency to organize a webinar on the CTD. WHO-PQ requires submission of the dossiers in the CTD format. The Agency also plans to make the CTD format mandatory for the dossier submission in the future. PQM+ is preparing materials for an online CTD training tentatively planned for August 2020. The CTD training will not only increase awareness of the manufacturers, but also develop capacity of the regulators to provide such trainings in the future.

Priority Activities for Next Quarter

PQM+ plans to:

- PQM+ will develop a plan to improve the regulatory practices of the Agency and continue to work the Agency in this effort.
- PQM+ will provide technical assistance to develop internal guidelines and SOPs for using WHO CRP for registration of WHO-PQ medicines.
- PQM+ will continue to guide the Agency in establishing GMP inspectorate compliant with PIC/S requirements and will monitor the progress in implementing the roadmap for PIC/S ascension.
- PQM+ will continue to provide targeted training to the laboratories in preparation for the WHO-PQ.
- PQM+ will continue to provide technical assistance to Nobel on preparation of the product dossier for WHO-PQ.
PQM+ will organize a webinar on the CTD for the Association of Manufacturers and the Agency.

**New Buy-Ins**

In addition, this quarter PQM+ held discussions with four USAID missions in the African and Asian regions about future work and country priorities. Please see Table 1 for a summary of those discussions.

<table>
<thead>
<tr>
<th>USAID Team</th>
<th>Summary and Next Steps</th>
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<tbody>
<tr>
<td>Ghana</td>
<td>PQM+ met with the activity manager and MCH team from the USAID mission and identified priority activities for Ghana including: 1) PMS systems strengthening and conducting PMS for Malaria and MCH medicines; 2) supporting a local manufacturer to attain WHO-PQ for artemether/lumefantrine tablets; and 3) supporting the FDA Ghana laboratory to attain WHO-PQ. PQM+ is drafting the full work plan, which will be submitted in Q4.</td>
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<tr>
<td>Asia Regional Bureau</td>
<td>PQM+ worked in collaboration with MTaPs to develop a concept note for the Association of Southeast Asian Nations (ASEAN) to kick-off discussions on potential areas of technical support. This concept note was modified after several meetings with USAID Asia Bureau and the U.S. Department of Commerce to tailor the activities toward the needs of the ASEAN consultative Committee on Standards and Quality. PQM+ will finalize the full work plan for the Asia Bureau and submit it to USAID for review and approval.</td>
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<tr>
<td>Mozambique</td>
<td>PQM+ consulted with national stakeholders in Mozambique to understand priorities and tailor activities accordingly. A draft work plan was prepared, and recruitment of a local consultant began. The work plan will be submitted in Q4.</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>PQM+ met with the USAID Mission and identified priority activities for Burkina Faso, which include strengthening the NQCL, supporting the MRA to conduct PMS for malaria, and assisting the MRA and NQCL to establish a framework for collaboration. PQM+ also initiated the recruitment of a local consultant and will submit the work plan early in Q4.</td>
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Progress by Health Elements

Core Maternal and Child Health (MCH)

Medicines of good quality are required to ensure efficacy and safety, particularly in vulnerable populations. Therefore, PQM+ support to USAID’s core MNCH work focuses on providing assistance to medicine regulatory authorities and manufacturers and supporting global leadership efforts in collaboration with other MNCH partners to continue to advance USAID, global, and country MNCH agendas and to increase access to quality-assured lifesaving medicines for women and children in LMICs.

The proposed activities for core MNCH fall under PQM+ objectives number two and four.

Progress by PQM+ Objective

Objective 2: Country and regional regulatory systems to assure the quality of medical products in public and private sectors improved

MRAs are responsible for conducting PMS of essential medicines to detect and remove SF medicines from circulation in the local markets. Because the PMS process is resource intensive, PQM developed a risk-based framework and guideline to help regulators streamline the PMS process and focus limited resources on the medical products that present the highest risks to patients.

This quarter, PQM+ collected historical information from several countries where the PQM program supported PMS (Ethiopia, Nigeria, and the Intergovernmental Authority on Development) to determine to what extent MNCH products were included in PMS activities. The list of focus products and a summary of findings were shared with USAID’s MNCH team. Going forward, PQM+ will track countries that implement PMS for MNCH products and share information on what products were sampled, the findings, and any actions taken to safeguard the local population.

Objective 4: Supply of quality-assured essential medical products of health importance increased

UNICEF is one of the main suppliers of donated essential medicines for MNCH in many LMICs. One of UNICEF’s key goals is to increase local sourcing of quality-assured essential medicines for children. PQM+ works collaboratively with UNICEF to support this goal of increasing local sources of MNCH products through information sharing sessions that help facilitate the collaboration and support PQM+ technical assistance efforts to local manufacturers.

This quarter, PQM+ met with the UNICEF supply division team to discuss key challenges and supply implications for MNCH medicines in LMICs during the COVID-19 lockdown period. Both parties discussed next steps to support the collaboration and assigned timelines to meet agreed-upon requirements.

WHO recently issued an expression of interest for manufacturers of amoxicillin dispersible tablets (DT) who want to achieve WHO-PQ. Historically, the uptake of amoxicillin DT in countries has been slow, and the local “proximate” supply of quality-assured amoxicillin DT has
been inadequate. To facilitate the need for a local supply of quality-assured amoxicillin DT, PQM+ is conducting a landscape analysis of amoxicillin DT manufacturers throughout Africa to identify potential and existing manufacturers for amoxicillin DT. This quarter, PQM+ developed the purpose statement and research questions for this landscape analysis. A technical meeting was held with the UNICEF team to brainstorm current challenges and gaps that informed the research questions. The purpose statement and research questions were further discussed with the USAID MNCH teams to ensure all priority areas on gaps and interests were captured in the research questions.

Priority Activities for Next Quarter

PQM+ plans to:
- Continue collecting historical PMS data from other countries with MNCH funding. It will be used in the development of a guidance document to explain how to define probability, and impact risks for priority MNCH products will also commence.
- Further refine research questions and drafting sub-components for each question for USAID’s review and agreement before data collection process can commence.

Core Neglected Tropical Disease (NTD)

Major constraints to the effective scale-up of NTD control and elimination programs are the scarcity of quality-assured medical products suppliers and the limited number of products. The USAID NTD program targets the most prevalent NTDs that also have proven, cost-effective health interventions—Lymphatic Filariasis, Blinding Trachoma, Onchocerciasis, Schistosomiasis, and Soil Transmitted Helminths.

PQM+’s proposed activities fall under PQM+’s program objective 4. The overall goal of the Core NTD program is to ensure the availability of affordable, quality-assured NTD medicines for the patients in need. PQM+ will use a systems strengthening approach to build local organizational and individual capacity of pharmaceutical manufacturers to achieve this goal.

Progress by PQM+ Objective

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<th>Objective 4: Supply of quality-assured essential medical products of health importance increased</th>
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During this quarter, PQM+ continued to deliberate with USAID’s NTD team on key priority activities for inclusion on the PY1/2 work plan. The full work plan was drafted and submitted to USAID for review and approval.

Priority Activities for Next Quarter

PQM+ plans to:
- Receive work plan approval and begin activity implementation.
Program Support

Finance and Operations
This quarter, PQM+ operations moved forward with onboarding field staff to support the establishment of field offices in Nepal and Kenya and staffed up both program and operations staff in Nigeria, Bangladesh, and Pakistan. The Chief of Party joined the Nepal program, and the senior finance and operations managers started in Nigeria and Nepal. Additional finance and procurement and logistics staff were hired for Nepal, Bangladesh, and Pakistan.

In addition, office space was identified in Nepal, Kenya, and Nigeria, but leases have not yet been signed due to COVID-19 restrictions in these countries. Along with hiring key field staff, PQM+ brought on a program manager in the Rockville office and was in the process of finalizing recruitments for additional technical and program support positions toward the end of the quarter.

PQM+ also began the process of engaging some of its core partners to identify areas where they can contribute to program activities in PY2. As a follow-on to the technical workshop conducted in Q 2, PQM+ began its quarterly conversations with its various partners through the director’s partner email updates. These updates provide a key mechanism to inform partners of the what’s going on globally in PQM+. Highlights of the communication included work plan submission status, operational updates such as new field offices, and staffing. Partner engagement will be expanded over the next quarter by inviting partners to present at upcoming PQM+ technical meetings.

The program began preparations for PY2 planning more generally, including refining the budget template to be used. Finally, PQM+ instituted a new quarterly pipeline reporting format that provides actual expenditures as well as projections for the upcoming quarter and includes a system to trigger alerts when spending falls below set thresholds. The finance and operations team will be working with the program teams going forward to refine the process for obtaining projections to better anticipated costs throughout PY2.

Monitoring, Evaluation and Learning (MEL)
USAID approved the PQM+ program-wide monitoring, evaluation, and learning (MEL) plan that includes indicators for each program objective and sub-objective. PQM+ selected indicators for buy-ins with approved work plans, started submitting buy-in specific MEL plans, and started planning baseline data collection for buy-ins. PQM+ completed setting up the majority of indicators in the program’s monitoring and evaluation information system (DevResults) and provided training to staff on how to enter data, upload documentation, review reported results, and develop dashboards to display results.

Communications
This quarter, PQM+’s communications activities continued to grow as the program expanded into more countries and activity implementation ramped up. In early June, all PQM+ staff, including field office staff, received a communications orientation, which covered a wide range of topics, such as USAID marking and branding requirements, PQM+ templates, and communications products like success stories and social media posts.

In addition, the following communications activities took place:
• Finalized and posted the PQM+ program one-pager to the PQM+ landing page on the USP corporate website. Disseminated the one-pager via social media.

• Finalized a concept note and plans to develop a PQM+ program newsletter.

• Discussed with the Agreement Officer’s Representative team how best to communicate PQM’s legacy as it relates to ongoing PQM+ activities.

• Wrote a PQM legacy story on “Stronger Medical Product Quality Assurance Systems Respond During the COVID-19 Pandemic,” which features Pakistan and Indonesia, and submitted to USAID for review and approval.

• Drafted a second success story on laboratory PQ highlighting Bangladesh, Kazakhstan, and Pakistan and shared it with the relevant COPs and the technical team for their review and approval.

• Wrote the Malaria Health Element fact sheet and sent it for review by technical team; it will serve as a prototype for other health element fact sheets.

• Supported PQM+ director’s participation in the WHO/UNCTAD webinar on “The role of investment in quality local production in developing countries to address supply bottlenecks during the pandemic crisis,” which took place in April.

• Collaborated with USP’s communications team on social media dissemination for two peer-reviewed journal articles authored by PQM+ staff:
