Promoting the Quality of Medicines Plus

# PQM+ Program Year 1, Annual Report

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## Contact Information

Promoting the Quality of Medicines Plus Program
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: +1-301-816-8166
Fax: +1-301-816-8374
Email: PQMplus@USP.org

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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, neglected tropical diseases, and other infectious diseases as well as for reproductive, maternal, newborn, and child health.

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# Contents

## Acronyms

| | |
|---|---|
| **ANAB** | American National Standards Institute National Accreditation Board |
| **CAPA** | corrective and preventive action |
| **COVID-19** | novel coronavirus-2019 |
| **CRP** | collaborative registration procedure |
| **CTD** | common technical document |
| **DDA** | Department of Drug Administration |
| **DFDA** | Department of Food and Drug Administration |
| **DGDA** | Directorate General of Drug Administration |
| **DNF** | National Directorate of Pharmacy |
| **DPM** | Directorate for Pharmacy and Medicines |
| **DRAP** | Drug Regulatory Authority of Pakistan |
| **DRC** | Democratic Republic of Congo |
| **EFDA** | Ethiopian Food and Drug Authority |
| **ELISA** | enzyme-linked immunosorbent assay |
| **FBPIDI** | Food, Beverage, and Pharmaceutical Industry Development Institute |
| **FDC** | fixed-dose combination |
| **FP** | family planning |
| **FY** | fiscal year |
| **GBT** | Global Benchmarking Tool |
| **GHIG** | Global Health Impact Group |
| **GMP** | Good Manufacturing Practices |
| **HPT** | Division of Health Products and Technologies |
| **INEP** | Institute for the Application of Nuclear Energy |
| **ISO** | International Organization for Standardization |

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|---|---|
| **LSHTM IDC** | The London School of Hygiene and Tropical Medicine's International Diagnostics Centre |
| **LMHRA** | Liberia Medicines and Health Products Regulatory Authority |
| **LMIC** | low- and middle-income countries |
| **LNCM** | National Medicines Control Laboratory |
| **LNS** | Laboratoire National de Santé (National Health Laboratory) |
| **MCH** | maternal and child health |
| **MedRS** | Medicines Risk-based Surveillance |
| **MNCH** | maternal, newborn, and child health |
| **MOH** | ministry of health |
| **MQCL** | medicines quality control laboratory |
| **MTaPS** | Medicines, Technologies, and Pharmaceutical Systems program |
| **NAFDAC** | National Agency for Food and Drug Administration and Control |
| **NCEM** | National Centre for Medicines, Medical Devices, and Medical Equipment Expertise |
| **NCL** | National Control Laboratory |
| **NCLB** | National Control Laboratory for Biologicals |
| **NMRA** | National Medicines Regulatory Authority |
| **NQCL** | National Quality Control Laboratory |
| **NTD** | neglected tropical disease |
| **OHS** | Office of Health Systems |
| **PCL** | pharmaceutical chemistry laboratory |
| **PIR** | product information report |
| **PMI** | U.S. President's Malaria Initiative |
| **PMS** | post-marketing surveillance |
| **PPB** | Pharmacy and Poisons Board |
| **PPE** | personal protective equipment |
| **PQM+** | Promoting the Quality of Medicines Plus program |

| | |
|---|---|
| **PY1, etc.** | Program Year 1, etc. |
| **Q1, etc.** | Quarter 1, etc. |
| **QA** | quality assurance |
| **QC** | quality control |
| **QMS** | quality management system |
| **RH** | reproductive health |
| **SATTA** | Stepwise Assessment Tool Toward Accreditation |
| **SOP** | standard operating procedure |
| **TB** | tuberculosis |
| **TWG** | technical working group |
| **UNICEF** | United Nations Children's Fund |
| **USAID** | U.S. Agency for International Development |
| **USP** | U.S. Pharmacopeial Convention |
| **WHO** | World Health Organization |
| **WHO-PQ** | World Health Organization Prequalification |

# 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). By sharing scientific expertise and providing technical support and leadership, PQM+ helps to create resilient local health systems that ensure access to quality-assured essential medicines for HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases (NTDs), other infectious diseases, and reproductive and maternal, newborn, and child health (MNCH).

The PQM+ program is pleased to present its annual performance report for fiscal year (FY) 2020, which serves as the program's annual report. This report summarizes the activities undertaken during this period and presents cumulative progress by objective and source of funding (USAID country Missions and USAID/Washington). 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 align with at least one of PQM+s five program objectives, which are detailed in the Results Framework (see Table 1):

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

Table 1. PQM+ Results Framework

| GOAL: SUSTAINABLY STRENGTHEN MEDICAL PRODUCT QUALITY ASSURANCE SYSTEMS IN LMICs | | | | |
|---|---|---|---|---|
| **Objective 1: Governance for medical product quality assurance systems improved** | **Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved** | **Objective 3: Financial resources for medical product quality assurance optimized and increased** | **Objective 4: Supply of quality assured essential medical products of public health importance increased** | **Objective 5: Global medical product quality assurance learning and operational agenda advanced** |
| 1.1 – Evidence-based medical product quality assurance legislation, policies, and regulations developed/ updated and/or implemented<br>1.2 – Systems that facilitate transparency and accountability promoted<br>1.3 – Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted<br>1.4 – Links among the medical product quality assurance systems and other sectors developed and fortified | 2.1 – Sustainable systems for market authorization/ registration, inspection, and licensing functions of medical product regulatory agencies improved<br>2.2 – Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened<br>2.3 – Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported<br>2.4 – Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported<br>2.5 – Competence, efficiency, and expansion of the medical product quality assurance workforce improved | 3.1 – Allocation and use of investments for medical product quality assurance systems strengthening optimized<br>3.2 – Sustainable resources mobilized | 4.1 – Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/ dossiers supported<br>4.2 – Capacity to conduct bioequivalence studies for dossier submissions strengthened<br>4.3 – Capacity for market intelligence and analytics of public health pharmaceutical markets increased<br>4.4 – Health coverage schemes that incorporate medical product quality requirements supported<br>4.5 – Monograph development and use supported | 5.1 – Evidence-based approaches and tools developed and/or applied<br>5.2 – Research and analysis to support medical product quality assurance systems strengthening conducted<br>5.3 – Advocacy on the importance of medical product quality assurance for public health, including the link between medical product quality and antimicrobial resistance, supported |

PQM+ builds on the legacy of USAID's PQM program (2009-2020), which worked to strengthen medical product quality assurance systems and support manufacturing of quality-assured essential medicines for malaria, HIV/AIDS, TB, NTDs, and MNCH.

PQM+ is helping countries improve their regulatory systems as assessed by the World Health Organization's (WHO's) Global Benchmarking Tool (GBT). Institutional development plans (IDPs) are developed subsequent to WHO GBT assessments to spell out roles and responsibilities for addressing gaps in the country's regulatory system. WHO Maturity Level 3 (on a scale of 1-4) is the minimum acceptable level for a stable, well-functioning, and integrated regulatory system that meets international standards for ensuring the quality of medical products and safeguarding patients from substandard and falsified medicines.

By the end of program year (PY)1, the PQM+ program was working with 14 countries: Bangladesh, Burma, Kazakhstan, Ethiopia, Kenya, Liberia, Mali, Mozambique, Nepal, Nigeria, Pakistan, Senegal, Serbia, and Uzbekistan, as well as with the Asia Regional Bureau. PQM+ also received funding to support COVID-19 response activities in Bangladesh, Pakistan, and Serbia and is in discussions to begin work in an additional 10 countries (Benin, Burkina Faso, Cameroon, the Democratic Republic of Congo (DRC), Ghana, Guinea, Madagascar, Rwanda, Tajikistan, as well as the East Africa Intergovernmental Authority on Development [IGAD]) during PY2. PQM+ also received core funding for Office of Health Systems Cross Bureau, maternal and child health (MCH), TB, and NTD activities. There are six field offices in Bangladesh, Ethiopia, Kenya, Nepal, Nigeria, and Pakistan.

The COVID-19 pandemic significantly impacted the program in its start-up year, as well as its ability to implement work at the country level. All international travel was suspended beginning in March and in many countries, domestic travel and in-person workshops and meetings were curtailed or suspended. Despite this global challenge, the PQM+ program team adjusted its operations by creatively transitioning activities to provide virtual technical assistance, including for lab reaccreditation assessments and technical staff training, and ongoing support remotely. In doing so, the program continued to implement its activities at the global and country levels to make progress toward the overarching goal of sustainably strengthening medical products QA systems in LMICs.

## Highlights

During its first year, the program started broad-scale implementation of USAID-approved work plans for country and core buy-ins, and PQM+ brought more staff on board. Program staff in headquarters and the field adapted to the different challenges posed by the COVID-19 pandemic to ensure that PQM+ work and activities continued as smoothly as possible. Highlights from the 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:

- **Bangladesh:** PQM+ finalized the National Quality Assurance Guideline to strengthen the Directorate General of Drug Administration's (DGDA's) overall QA measures for

pharmaceutical products throughout the supply chain. This document encompasses the QA of medical products from the point of design through manufacture and production, procurement, distribution, quality control (QC), and dispensing to the patient. It will provide the foundational QA principles for stakeholders and partners (governmental and nongovernmental) engaged in providing medical products in Bangladesh.

- **Ethiopia:** The Ethiopian Food and Drug Authority (EFDA) approved the updated registration guidelines, which are expected to increase the speed of registration of essential medicines, thereby contributing toward improved availability of those products.
- **Kenya:** The Government of Kenya established a QA framework for malaria commodities. The framework was developed by the newly established post-marketing surveillance (PMS) technical working group (TWG).
- **Mali:** A national PMS-TWG, comprising representatives from the National Medicines Regulatory Authority (NMRA), the National Quality Control Laboratory (NQCL), and disease programs, was established to coordinate all key elements on PMS and ensure they are all 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 critical medical products.
- **Senegal:** The Directorate for Pharmacy and Medicines (DPM) and National Medicines Control Laboratory (LNCM) established a PMS unit to improve governance and oversight for the QA of medical products and improve the country's regulatory systems to assure the quality of medical products in the public and private sectors. PQM+ drafted the terms of reference for the PMS Unit, which were then reviewed and validated.

## Regulatory Systems

PQM+ supports countries to improve their regulatory systems as assessed by the WHO GBT. The IDPs established subsequent to GBT assessments spell out gaps in the country's regulatory system and identify roles and responsibilities for addressing them.

- **Bangladesh:** In July, PQM+ supported a renewal audit of the National Control Laboratory's (NCL's) physicochemical laboratory. It was conducted virtually by the American National Standards Institute National Accreditation Board (ANAB) assessor (ANAB – International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025/2017 certification). The certification of renewal was obtained on October 18, 2020.
- **Burma:** PQM+ conducted a three-day "Measurement Uncertainty" training in August 2020 to train lab staff to calculate uncertainty values of their measurements, which allows them to interpret the test results more accurately. Due to the ongoing COVID-19 pandemic, the training was delivered virtually. Six key staff from the pharmaceutical chemistry laboratory (PCL) QA team participated. As a result of the training, the lab can calculate uncertainty values of their measurements.
- **Ethiopia:** EFDA has prioritized addressing the gaps identified by WHO's GBT to achieve their goal of Maturity Level 3, which represents a well-functioning regulatory system based on international standards and good regulatory practices. PQM+ is providing support by developing and revising relevant quality management system (QMS) documentation in compliance with the GBT requirements.

- **Central Asia (Kazakhstan):** This year, WHO officially included the Karaganda medicines quality control laboratory (MQCL) in the list of WHO-prequalified (WHO-PQ) laboratories. Building on the support provided to the lab by the predecessor PQM program, PQM+ continues to provide technical assistance to the Karaganda MQCL. This is an important achievement because it is the first laboratory in Central Asia that can reliably test the quality of medicines according to international standards. Karaganda MQCL's experience is valuable because it can also be shared with other laboratories and their staff in the region. In May, PQM+ held a regional online forum, titled "The WHO Prequalification Process: Lessons from Kazakhstan's National Centre for Medicines, Medical Devices, and Medical Equipment Expertise (NCEM) and its Karaganda Medicines Quality Control Laboratory," for more than 100 staff of the NMRAs and their MQCLs from Kazakhstan and Uzbekistan.
- **Mali:** In preparation for PMS sampling and testing in Mali in preparation for ISO/IEC 17025 accreditation, PQM+ trained *Laboratoire National de Santé* (LNS) on key QC testing techniques. To introduce a practical element to this remote training, PQM+ developed seven videos that demonstrate the techniques in LNS's proposed ISO/IEC 17025 accreditation scope from sample preparation to data analysis.
- **Nigeria:** PQM+ supported the Nigerian Institute for Pharmaceutical Research and Development in preparing for a 17025:2017 reaccreditation assessment. Following a successful assessment by the ANAB, the laboratory achieved reaccreditation in April 2020. This lays the groundwork for the National Institute for Pharmaceutical Research and Development's pursuit of WHO-PQ.
- **Pakistan:** WHO conducted a mock gap assessment of Drug Regulatory Authority of Pakistan's (DRAP's) GBT Level 3 compliance and identified areas for improvement in all nine regulatory areas. PQM+ supported DRAP in preparing their draft response and documents for WHO. As a result, DRAP should raise their GBT scores in all nine regulatory areas.
- **Uzbekistan:** The president of Republic of Uzbekistan, Shavkat Mirziyoyev, launched construction of the Tashkent Pharma Park, an innovative scientific and production pharmaceutical cluster in the Zangiata District of Tashkent Province. PQM+ provided technical assistance in developing technical specifications for the layout and design of the MQCLs to ensure that they meet the international standards.

## Financial Resources

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.

- **Ethiopia:** PQM+ and EFDA developed a generic risk-based guideline for PMS (RB-PMS), which was approved and printed. Ethiopia's risk-based PMS guideline is based on the RB-PMS guidance developed under USAID's PQM program. This guidance is generic and meant to provide general guidance to all countries. As a result, the RB-PMS guideline must be customized for country-specific PMS use. Accordingly, the team in Ethiopia used the PQM's guidance as a basis and customized it to be applicable to the local situation. EFDA will now disseminate the guideline, which will serve as a tool to

optimize resources by channeling limited resources toward areas that present the highest risks to patients.

- **Bangladesh:** To support the sustainability of Bangladesh's NCL, PQM+ worked with its management to develop a cost structure that took into consideration the demand for testing, existing fees, and operating costs. The program drafted an assessment report that focuses on the future cost structure and determined analytical costs of test parameters per product performed by NCL.
- **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. PQM+ supported all participating laboratories in harmonizing their quality manuals and other QMS documents as a key first step.
- **Pakistan:** Pakistan's share of the global pharmaceutical market has the potential to increase significantly. Developing a well-conceived national pharmaceutical strategy and private sector engagement plan is the first step. PQM+ developed a concept note for this strategy that includes a multisectoral stakeholder kickoff meeting to define key objectives to achieve over the next decade. It identified potential stakeholders that should be involved and highlighted the need to identify and remove obstacles to achieving the strategy's goals.

## Supply

PQM+ is unique among USAID-funded global health programs in that it provides specific technical assistance to help manufacturers achieve international quality standards by adopting current good manufacturing practices (GMP) in the production of quality-assured essential medicines. In its first year, PQM+ actively engaged with manufacturers of MNCH, malaria, and TB medicines, as well as other medical products, including antimicrobials.

- **Bangladesh:** PQM+ provided technical guidance to Bangladesh's ACI Pharmaceuticals to progress in their objective to manufacture quality-assured, first-line, fixed-dose combination anti-TB medicines. Currently, ACI Pharmaceuticals is in the product development stage of three fixed-dose combination (FDC) products (i.e., 2 FDC, 3 FDC, and 4 FDC) and its dossier preparation toward attaining WHO-PQ.
- **Nigeria:** PQM+ supported seven manufacturers to produce quality-assured medical products for MCH and malaria, including:
    - Working with a local manufacturer in pursuing WHO-PQ of magnesium sulfate 50 percent injection. PQM+ monitored the effectiveness of closed corrective and preventive action (CAPA) plans and supported responses to the WHO-PQ dossier evaluation team's request for further product information.
    - Continuing to support manufacturers of sulfadoxine/pyrimethamine in Nigeria to address key steps toward dossier submission to WHO-PQ for a sulfadoxine/pyrimethamine (500+25 mg) tablet. This includes the review of real-time stability results.
    - Providing support to Juhel Nigeria Ltd. in pursuing WHO-PQ of magnesium sulfate 50 percent injection, a medicine used to treat severe pre-eclampsia, eclampsia, and toxemia during pregnancy.

- **Central Asia (Kazakhstan):** PQM+ supported the Nobel Almaty Pharmaceutical Factory to improve its GMP compliance, namely addressing the first milestone on the manufacturer compliance of the active pharmaceutical ingredient of levofloxacin with WHO-PQ requirements.
- **Pakistan:** 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); and regulated medicinal product information (ISO 11615).
- **Uzbekistan:** PQM+ facilitated discussions 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.

## Learning

Nearly 10,000 people from 65 countries across all regions have registered for the Foundations of GMP eLearning courses developed under the PQM program. To date, more than 4,000 people have completed a GMP course/ module.

The PQM+ program finalized plans to launch a webinar series aimed at USAID staff that is appropriate for a nonspecialist audience and speak to USAID interests and priorities. The webinars will explain PQM+'s work in lay terms and link its importance to health and country programs. They will include a variety of voices from the countries and regions where PQM+ works.

- PQM+ presented at the 40th Annual Scientific Conference of the Ethiopian Pharmaceutical Association in August 2020 on "The COVID-19 Pandemic and National Logistics Preparedness for Ensuring Access to Quality Assured Medical Products: Role of Pharmacists and the Way Forward." The event was an important platform to disseminate information about medicines quality and to raise awareness about the need to prevent the circulation of poor-quality medical products.
- PQM+ submitted a proposal and received USAID funding to develop a model that countries can use to estimate the health and economic costs of substandard or falsified medicines to patients and to different parts of the health system. With this support, in PY2 PQM+ will develop a user-friendly, open-source model to help senior public health specialists estimate the costs of use of substandard or falsified medicines of a given class for specific priority health programs in their country.

## Health Elements

### Core Maternal and Child Health

The PQM+ program administered a survey in eight countries (Bangladesh, Ethiopia, Ghana, Kenya, Mali, Mozambique, Nepal, and Nigeria) to understand the regulatory authority's PMS system organization and processes, including how decisions are made for MNCH product PMS. PQM+ also developed the first draft of the risk-based categorization guidance document for

PMS of MNCH medical products and continued the quarterly collaboration meetings with the United Nations Children's Fund's (UNICEF's) supply division.

### Neglected Tropical Diseases

Building on the progress achieved under the PQM program, PQM+ worked with two manufacturers for the albendazole and praziquantel finished pharmaceutical products toward achieving WHO-PQ. In particular, PQM+ continued to support the manufacturer Mepro Pharmaceutical Private Limited to manufacture quality-assured albendazole 400 mg chewable tablets for WHO-PQ approval. PQM+ also supported the manufacturer Medopharm Pharmaceutical Private Limited to manufacture quality-assured praziquantel 600 mg film-coated tablets toward WHO-PQ.

### Partners

As a follow-on to the technical workshop conducted in Q2, PQM+ began quarterly conversations with its various partners through the director's partner email updates. These updates provide a key mechanism to inform partners about what PQM+ is doing globally. Highlights of the communications included work plan submission status, operational updates such as new field offices, and staffing. Partner engagement will expand over the next quarter with invitations to partners to present at upcoming PQM+ technical meetings.

PQM+ is also in the process of providing partners with access to key U.S. Pharmacopeial Convention (USP) resources (e.g., USP/National Formulary, USP Dictionary, and Pharmacopeial Forum) to assist in their capacity building and further prepare them to provide technical assistance to countries. With assistance from IntraHealth, organizational development resources from the Accelerating Support to Advanced Local Partners (ASAP) project were shared with the partners. ASAP is a USAID-funded project through which IntraHealth International and partners work with sub-Saharan countries in Africa to rapidly prepare local organizations and government entities to serve as prime partners for USAID and U.S. President's Emergency Plan for AIDS Relief (PEPFAR) programming. CORE-FLEX partners now have access to ASAP's resources and will be able to receive alerts on free webinars and new resources on organizational development.

## Activities and Progress for Office of Health Systems Cross-Bureau

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

Market surveillance and control, one of the nine functions of a regulatory authority as defined by the WHO GBT, plays a vital role in ensuring protection of the public from substandard and falsified 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 Medicines Risk-based Surveillance (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. PQM+ completed a final quality review and plans to further enhance the user experience and to bring increased value. A draft user manual has been developed pending further

enhancements of the tool. In addition, training materials have been developed and used with the MRAs in Mali and Senegal. After a pause-and-reflect session undertaken by PQM+'s technical team and workforce development advisor, further changes were made to the PQM+ MedRS tool (e.g., more terms were defined, the tool was edited, resources were added, the look and feel was improved) and the training program was modified. PQM+ plans to release the final web-based tool in April 2021.

## Human Resources Assessment Tool

PQM+ recognizes that many LMICs have an insufficient number of adequately trained staff to ensure medical product QA. The existing regulatory and QA staff in these countries face significant gaps in technical capacity and knowledge, often due to lack of experience and formal training. Also, many regulatory and QA organizations have weak human resources planning and policy environments to underpin the regulatory workforce. The human resources assessment helps PQM+ counterparts (e.g., MRAs, QC laboratories) to develop and institutionalize systems that support full human resources and institutional capacity for effective and efficient delivery of medical products. This assessment is based on the PQM+ theory of workforce development change across four pathways: staffing, skills, working conditions, and motivation.

In addition, the assessment complements and is linked to the WHO GBT. This tool is implemented with the full cooperation and engagement of partners. The tool has been adapted from the USAID and UNICEF's People that Deliver HR Assessment and Theory of Change for Supply Chain Management tool to suit medicines quality assurance and quality control systems. A theory of change graphic and presentations on this approach to workforce development were also developed in conjunction with the HR Assessment Excel tool.

Since the tool and methodology have been applied in country contexts with Mission buy-ins, PQM+ assessments were or are being implemented in Mali, Kenya, and Nepal. Mali was the first implementation of the Medical Product QA's human resources assessment and it was the first remote implementation. All interviews were conducted via WebEx, and the methodology was modified to include an all-of-workforce survey. This work was coordinated and implemented remotely with support from one Mali-based consultant. Products customized and applied in country buy-ins include: Human Resources Assessment Introductory PowerPoint (English, French), Human Resources Assessment Excel tool (English, French), and the theory of change graphic (English, French).

## GMP Assessment Tool

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 assess compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Q7 guidelines. The GMP guideline is the seventh of the council's 14 quality guidelines. Manufacturers' GMP assessments are nonsubjective and standardized, providing a clear roadmap of when interventions are necessary to improve medical product quality. Technical areas assessed with the current version include manufacturers' processes for managing QA, laboratories, facilities, production, warehousing, and active pharmaceutical ingredients.

## Activities and Progress by Country and Regional Buy-Ins

By the end of Y1, the PQM+ program was working with 14 countries and Bureaus: Bangladesh, Burma, Kazakhstan, Ethiopia, Kenya, Liberia, Mali, Mozambique, Nepal, Nigeria, Pakistan, Senegal, Serbia, and Uzbekistan, as well as with the Asia Regional Bureau. PQM+ also received funding to support COVID-19 response activities from the Bangladesh, Pakistan, and Serbia Missions and is in discussions to begin work in an additional 10 countries during PY2. PQM+ also received core funding for Cross Bureau, MCH, TB, and NTDs activities.

### Africa Region

### Ethiopia

In Ethiopia, PQM+ is building the capacity of the EFDA and the Regional Food Medicine and Health Care Administration and Control Authorities to monitor medical product quality across the supply chain and to strengthen their collaborative working relationship and create synergy in executing their respective regulatory mandates. PQM+ also contributes to building the capacity of local manufacturers to meet international standards to ensure that locally produced medical products are safe and of good quality.

**Key accomplishments in PY1**

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. An assessment was conducted on the current status and challenges of local pharmaceutical manufacturers in collaboration with Ethiopia's Food, Beverage, and Pharmaceutical Industry Development Institute (FBPIDI) and EFDA to identify local manufacturers with the capacity to produce the priority medicines.

PQM+ and EFDA developed a generic risk-based guideline for PMS that was approved and printed. EFDA will disseminate the guideline, which will serve as a tool for EFDA to optimize resources by channeling limited resources toward areas that present the highest risks to patients.

EFDA has prioritized addressing the gaps identified by WHO's GBT to 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.

#### Progress by PQM+ Objective

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

EFDA approved the revised registration guideline in May 2020, which should help to increase the speed of registration of essential medicines, thereby contributing toward improved availability of those products. Under the new guidelines, key changes include: an abbreviated procedure for products approved by stringent regulatory authorities; a risk-based assessment strategy and an expedited assessment that includes conditional approval; a collaborative approach for products prequalified by WHO; and fast-track

designation of priority products such as those for HIV/AIDs, Malaria, TB, vaccines, and MNCH products.

Addressing the gaps identified by WHO's GBT is a key priority of EFDA to achieve their goal of becoming a WHO-listed authority (Maturity Level 3 or higher). PQM+ developed and revised relevant QMS documentation in compliance with the GBT requirements. To date, seven standard operating procedures (SOPs) and one guideline have been developed. Four of the SOPs were completed during Q4. Achieving compliance with GBT requirements and becoming a WHO-listed authority would signal that EFDA has the essential competencies needed to properly regulate medicines from product development and manufacture to use by the patient.

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

PQM+ worked with relevant EFDA directorates to develop a detailed implementation plan for PMS. During Q3, the protocol was developed for conducting PMS of selected priority medical products, and samples were collected. In Q4, laboratory testing of these samples was completed, and test results are available for further analysis and compilation. Preliminary results indicate more than 20 percent of alcohol-based sanitizers failed to meet the specifications. To further strengthen EFDA's laboratory to monitor the quality of alcohol-based sanitizers, a digital alcoholometer is being procured. This device will help to determine the alcohol content of products marketed during the COVID-19 pandemic.

EFDA's regulation of medical products is supported by five branch laboratories situated in strategic geographic locations. PQM+ is supporting EFDA's efforts toward their accreditation for ISO 17025:2017. PQM+ trained 41 staff from branch laboratories and EFDA headquarters to use the Stepwise Assessment Tool Toward Accreditation (SATTA). The training also covered the basics of internal quality auditing. The goal was to build staff capacity to conduct self-assessments of their laboratories. After verification/validation of the self-assessment findings through supportive supervision, the results will be used to develop branch-specific roadmaps. Accredited laboratories at the branches will substantially improve EFDA's capacity to detect substandard or falsified medical products circulating in the Ethiopian market by conducting regular PMS with a broader geographic and product coverage.

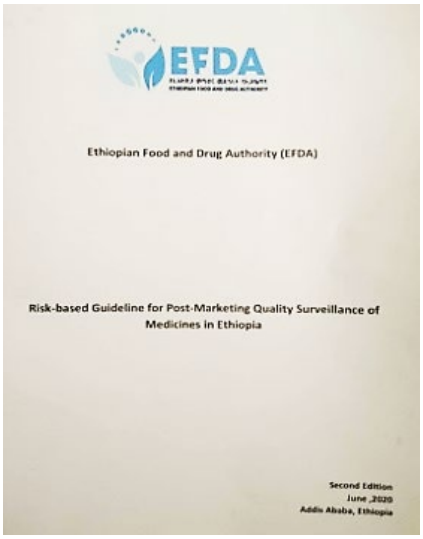


*Figure 1: EFDA's updated PMS guideline.*

PQM+ also revised and updated EFDA's 2014 PMS guideline, which was missing key aspects, such as a risk-based approach to PMS and clearly delineated roles of stakeholders. PQM+ and EFDA collaborated on the revision. This quarter, the guideline was printed and made available 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. Consequently, it will serve as a resource for EFDA to optimize its resources by channeling limited resources toward areas with the highest risks to patients.

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

With the current disruption in the global medicine supply chain, PQM+ is exploring opportunities to boost the local production of medicines. PQM+ helped to conduct an assessment on the current status and challenges of local manufacturers. The FBPIDI and EFDA are reviewing a draft report of the assessment findings. Once completed, the report will be disseminated to all relevant stakeholders and partners.

The assessment identifies needs and/or gaps for technical assistance. PQM+ will work with EFDA and the FBPIDI to address these gaps. More importantly, PQM+ will help relevant government counterparts to use the evidence generated by the assessment to support policy action to resolve major bottlenecks hindering local manufacturers from producing at full capacity. At present, most of the manufacturers are working below 50 percent of their capacity.

## Objective 5 – Advance national medical product QA learning and operational agenda

As part of this effort, PQM+ presented at the 40th annual scientific conference of the Ethiopian Pharmaceutical Association on August 29, 2020. The Chief of Party's presentation was "The COVID-19 Pandemic and National Logistics Preparedness for Ensuring Access to Quality Assured Medical Products: Role of Pharmacists and the Way Forward." He also participated in a panel discussion on the topic. Pharmacists across the health and pharmaceutical systems attended this event. It was an important platform to disseminate information about medicines quality and to raise awareness about the need to prevent the circulation of poor-quality medicines and medical products.

### Kenya

With support from The U.S. President's Malaria Initiative (PMI) and the Office of Maternal and Child Health and Nutrition, the PQM+ program aims to strengthen the quality of medical products in Kenya by improving governance structures and regulatory systems. PQM+ delivers technical assistance to the Pharmacy and Poisons Board (PPB), the NQCL, the Division of National Malaria Program, Department of Family Health, the Ministry of Health's Division of Health Products and Technologies (HPT), and the counties to further strengthen in-country stakeholders' capacity in ensuring access to quality-assured medical products for the population. In May, PQM+ welcomed a new Chief of Party for Kenya and a new senior finance and operations manager.

**Key accomplishments in PY1**

PQM+ supported the establishment of a TWG on pharmacovigilance and PMS to provide strategic technical assistance and coordination on these two regulatory functions. Due to COVID-19 restrictions, the program facilitated a virtual inauguration of the TWG that the MOH's chief administrative secretary presided over. It included 41 participants from local government agencies, WHO Kenya, and PPB.

PQM+ also facilitated the development of a draft QA framework for malaria commodities. This framework covers all the necessary aspects of ensuring and maintaining quality throughout the commodity lifecycle from manufacturing to patient use. It is a critical first step in providing a more robust governance structure for stakeholders involved in ensuring the quality and safety of these commodities.

## Progress by PQM+ Objective

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

*1.1 Provide support to the PPB PMS technical working group to increase its functionality and sustainability*

PQM+ provided technical assistance, recommendations, and logistical support to the PPB that culminated in the inauguration of the PPB's joint pharmacovigilance and PMS TWG on August 19, 2020. This high-profile virtual event was presided over by the MOH's chief administrative secretary with 41 participants attending, including the USAID/Kenya activity managers for PQM+, the WHO Kenya representative, the chief executive officer of PPB, and PPB. Shortly afterward, PQM+ helped PPB to organize and convene the first meeting of the pharmacovigilance-PMS TWG on August 25, 2020. This well-attended virtual meeting included 16 of the 21 TWG members. The TWG is the first of its kind for PPB and will help to provide more efficient technical support and coordination for the pharmacovigilance and market surveillance of medical products in Kenya.

*1.2 Support NQCL to conduct a human resources assessment to support organizational capacity improvements*

In Q4, PQM+ started to assist the NQCL to sustainably strengthen its workforce capacity in QA systems. PQM+ developed a scope of work for a local consultant to conduct a human resources capacity assessment and, by the close of Q4, identified a local consultant who is being onboarded. The assessment will take place in Q1 of PY2. Developing a productive and sustainable medical QA workforce will contribute to strengthening and ensuring quality-assured medicines that can be used by national public health programs in Kenya, including those on malaria and maternal, newborn, child, and adolescent health.

*1.3 Provide support to NMCP to develop a framework for QA of malaria commodities*

During Q4, PQM+ assisted the Division of the National Malaria Program to conduct a further technical review of the draft QA framework for malaria commodities by incorporating technical inputs from stakeholders that focused on products used for the control of both the malaria parasite and the mosquito vector. This draft QA framework was submitted to the National Malaria Program for their review and clearance. It will be finalized, printed, and disseminated in Q1 of FY21.

In tandem, PQM+ initiated discussions with the Division of National Malaria Program to establish a malaria commodity QA TWG under the Procurement and Supplies Management Committee of Experts of the Division of National Malaria Program. This TWG is important because it brings together the key stakeholders involved in the QA of commodities for the malaria program. As such, the TWG will help with the coordination, communication, and strengthening capacity of those involved in QA of malaria commodities. The Division of National Malaria Program management will convene a meeting in Q1 of PY2 to guide the establishment of the proposed QA TWG. The TWG will:

- Provide technical input on the QA of malaria commodities
- Monitor and recommend actions related to the quality of malaria commodities
- Review and advise on malaria commodities QA policies
- Report regularly and advise the Procurement and Supplies Management Committee of Experts on the quality of malaria commodities

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

*2.1 Provide support to Health Products and Technologies department of MOH to develop guidance on QA requirements for procurement of medical products at the county level*

PQM+ held technical discussions with the MOH's HPT department to review existing policy provisions and mechanisms for the QA of pharmaceuticals and other health products used in Kenya's malaria and maternal, newborn, child, and adolescent health programs at both the national and county levels. It was noted that almost all commodities used by county-level health facilities are sourced from the Kenya Medical Supplies Authority and therefore are subjected to stringent Kenya Medical Supplies Authority QA protocols. PQM+ will work collaboratively with HPT and Kenya Medical Supplies Authority to derive, adapt, and disseminate simplified county-level guidelines based on the national QA guidelines from HPT and Kenya Medical Supplies Authority.

During Q4, at the request of the HPT department, PQM+ provided technical input on the draft of the national HPT supply chain strategy. The strategy provides a framework for incorporating QA guidance into the national pharmaceutical sector governance and health product policies. It documents the foundation for strengthening QA systems and tools for national, county, and health facility-level product QA mechanisms for malaria and maternal, newborn, child, and adolescent health commodities and other health products. The guidance document will be disseminated to national- and county-level governments, which will be required to adopt the QA guidance and use it in their procurements.

*2.2 Support NQCL to procure a Karl Fischer titrator for use in analysis of select malaria and MCH products*

The NQCL is the official regulatory QC laboratory for testing of medical products in Kenya. Only certificates of analysis issued by NQCL are deemed legal for a regulatory action to be taken against any poor-quality product. It is, therefore, critical that the laboratory has the capacity and resources to perform and administer accurate and efficient results. During Q4, PQM+ began processing the procurement of a Karl Fischer titrator for the NQCL, based on the technical specifications that were jointly defined by the PQM+ and NQCL technical teams in Q3. Karl

Fischer titration is a standard method for the determination of water content that gives accurate and precise results within minutes during characterization of Pharmaceutical Reference Standards and active pharmaceutical ingredients. The equipment will shorten the turnaround time for QC analysis and help NQCL maintain its ISO 17025.

The procurement for this equipment is near completion. PQM+ and NQCL technical teams jointly reviewed vendor bids and clarified a few remaining questions before awarding the contract in Q1 of FY21.

*2.3 Contribute to the development of the PPB organizational capacity development platform for self-directed learning*

During PY1, PQM+ provided technical assistance to PPB in developing scopes of work for local consultants to perform a rapid training needs assessment, develop content, and facilitate the configuration for an e-learning platform for the agency. The assessment of training needs and review of existing content for conversion to a self-directed format will occur in Q1 of PY2 and will inform the content of the e-learning course.

The e-learning course will help to increase technical capacity and provide a sustainable solution that is less reliant on in-person technical assistance/training. The course will contain training materials that new and existing staff can access for self-directed learning and will provide a way to monitor which staff have undergone training. PQM+ intends to work with PPB to review the results from the training needs assessment to identify content that should be included in this course.

## 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 (LMHRA) and its QC laboratory. PQM+ visited Liberia in December 2019 for a scoping visit; based on the observations made during that visit, the program 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 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

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

In PY1, the first three activities—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 and reviewed by the PQM+ technical team. The final draft was completed during the quarter and shared with the Mission. 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 needs to be drafted or enacted.

Finally, the assessment of lab functions occurred virtually with lab staff in collaboration with a local consultant and PQM+ QA/QC expert based in Ethiopia. The report was finalized during the quarter and shared with the Mission.

During Q4, PQM+ shared the results of the assessment and plans for moving forward with the Mission. At the end of September, the LMHRA invited PQM+ to a meeting with other stakeholders to discuss the LMHRA's plans to relocate the lab to a new temporary space located outside Monrovia and initiate plans to build a new structure that will hold the lab and the LMHRA offices. Following this meeting, PQM+ met with the LMHRA to discuss proposed activities.

### Mali

The medicine regulatory system in Mali is fragmented. Important regulatory functions, such as PMS and pharmaceutical inspection, are lacking in the regulatory framework. At present, LNS is mandated to collect and test medical products from the market, and the National Inspectorate of Health (*Inspection National de la Santé*) inspects pharmaceutical outlets. However, the inspectorate does not have a comprehensive mandate for inspecting pharmaceutical establishments. The *Inspection National de la Santé* and LNS mandates should be revised and coordinated.

To address the lack of coordination and other gaps, PQM+ is working closely with LNS and DPM to strengthen the risk-based medicine PMS system. PQM+ is helping the National Pharmaceutical Regulatory Agency 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 support to LNS to strengthen compliance with the ISO 17025:2017 requirements, implement progress toward achieving WHO-PQ, and improve its capacity to ensure a sustainable functioning QC laboratory.

**Key Accomplishments in PY1**

Established a national PMS-TWG, comprising representatives from the NMRA, NQCL, and disease programs in the country.

Developed a national risk-based PMS protocol for antimalaria and MCH medicines.

Facilitated the institutionalization of the SATTA at LNCM.

Conducted virtual training of accreditation scope techniques to improve the competency of LNS's LCQM staff in preparation for ISO/IEC 17025 accreditation. Seven practical videos were filmed in an accredited laboratory setting with real analysts and experts demonstrating the techniques learned in the theoretical presentations to enhance participants' learning of key techniques.

Conducted a human resource assessment of LNS.

## Progress by PQM+ Objective

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

PQM+ aims to improve Mali's regulatory systems to assure the quality of medical products in the public and private sectors by ensuring that DPM and LNS have a robust system in place to detect substandard or falsified malaria and MCH medical products. PQM+ coordinated the establishment of a national PMS-TWG in Mali. The TWG will coordinate efforts to ensure all key elements on PMS are taken into consideration during the design of national guidance, protocols, plans, and regulatory actions. It will improve the country's ability to ensure the quality of critical medical products. In addition, implementing a risk-based PMS protocol will help Mali to optimize the use of resources and support them in transitioning from donor-supported surveys to locally funded and sustainable PMS programs that are integrated and implemented as a core regulatory function.

The PMS-TWG includes representatives from the LNS, DPM, *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), *Division Santé de la reproduction à la Direction Générale de la Santé* (Ministry of Health and Social Action), *Pharmacie Populaire de Mali* (procurement agency and medical stores), *Conseil National de l'ordre des pharmaciens* (the Pharmacy Council), *l'Institut National de Santé Publique* (Public Health Institute), *l'inspection National de la santé* (National Health Inspectorate), *and Association des Grossistes Privées (*private wholesalers' association). A chair, vice-chair, and secretariat for the group were elected by consensus.

During Q4, the program supported the official inauguration of the PMS-TWG that introduced members to the DPM, LNS, and the National Health Inspectorate—the three institutions with oversight on medicines quality in Mali. Sixteen participants attended the virtual event. The institutions thanked the members for their commitment and reassured them of their full support for the critical journey the group was about to embark on to help the country's fight against substandard and falsified medicines.

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

In Q4, PQM+ trained the PMS-TWG on the principles of risk-based PMS and how to use the MedRS tool. PQM+ also began working with the TWG to develop the risk-based PMS protocol that will be deployed for sampling and testing of anti-malarial and MCH medicines in PY2.

PQM+ also worked to increase LNS's capacity to assess its progress toward accreditation by training LNS staff on the SATTA. The tool is designed to support the assessment of different aspects of QMS of the NQCL and assist in identifying areas for improvement. LNS was trained on internal auditing and the use of SATTA through presentations, a user's manual, and a practical session to demonstrate how this Excel tool is used.

In Q4, the LNS's LCQM QA team developed an internal SOP for the use of SATTA to conduct internal audits. Top management approved it. The MQCL, under the supervision of PQM+, conducted one internal audit using SATTA, per selected chapters in the ISO/IEC 17025 standard. PQM+ reviewed the internal audit report and worked with the QA team to develop a corrective action plan. PQM+ will work with LNS to monitor progress on the corrective action plan through PY2.

In preparation for PMS sampling and testing, while also building technical personnel competency in preparation for ISO/IEC 17025 accreditation, PQM+ trained LNS on key QC testing techniques. PQM+ developed seven training videos that demonstrate the techniques in LNS's proposed ISO/IEC 17025 accreditation scope from sample preparation to data analysis. A videographer was recruited to film and produce the training videos that were conducted in an accredited laboratory setting.

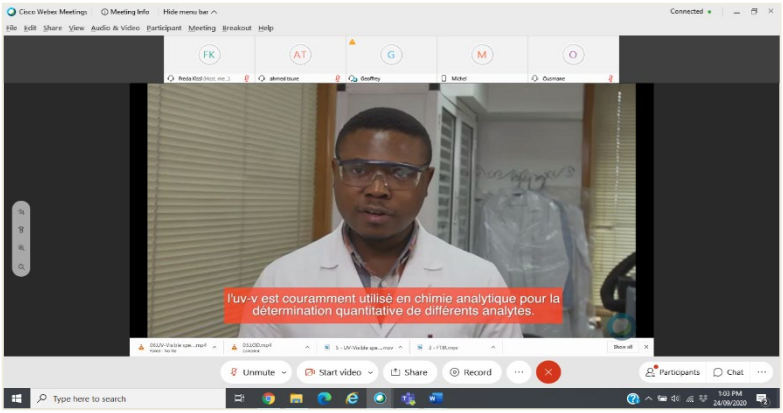


*Figure 2: Clip from one of the QC training videos.*

The training design included presentations followed by the viewing of these practical QC videos and practical exercises in the laboratory, which PQM+ supervised virtually. The results from tests administered during the training showed an increase of 20 percent in participants' knowledge and skills, which demonstrated the effectiveness of this training methodology. Participants were extremely appreciative of the opportunity to benefit from the remote practical sessions built into the training approach.

Due to high staff turnover at LNS, the program also worked with its leadership to assess organizational capacity, including staffing levels, staff competency, and human resource needs. PQM+ conducted a human resources assessment via several interviews with LNS personnel, a survey administered to personnel and a focus group discussion. During Q4, the findings of this assessment and proposed interventions were presented to LNS management at a validation workshop. The major findings included an inadequate performance support system linked to technical competencies; a lack of implementable training plans across LNS; and a lack of a systematic annual professional development plan and processes for staff. LNS reminded PQM+

that it is a state establishment, making it difficult for them to implement some recommendations. However, they agreed to study the results and conduct a prioritization exercise to develop an action plan to address the findings. PQM+ will monitor this through PY2.

## Mozambique

Mozambique's health system is highly dependent on foreign aid; approximately half of its funding comes from donor sources.[1] Mozambique's inability to finance and strengthen the NMRA specifically jeopardizes the health and safety of the population by preventing the regulation of quality medical products.

Mozambique's National Directorate of Pharmacy (DNF) was established in 2017 as a transitional organization, working toward becoming an autonomous NMRA. It was created from the MOH Pharmacy Department after the promulgation of the revised pharmaceutical law supported by the predecessor PQM program. As a result of this transitional phase, DNF is establishing and strengthening its core regulatory functions, processes, and systems to ensure they meet international standards for pharmaceutical and other medical products regulatory agencies. PQM+ is providing technical assistance to improve DNF's regulatory capacity for assuring the quality of medical products and to work toward improving its financial sustainability. The Mozambique work plan was approved in July 2020, and a local consultant was recruited to manage and assist with implementation.

### Key Accomplishments in PY1

Despite travel restrictions due to COVID-19, activity implementation successfully commenced during Q4. The program held virtual discussions with DNF and the NQCL, Department of Drug Quality Check, to align on program goals and objectives, discuss current gaps and challenges, and agree on next steps of implementation.

### Progress by PQM+ Objective

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

As a first step, PQM+ is engaging with DNF to discuss and agree on a program framework for collaboration between the program and DNF. The framework would lay out the roles and responsibilities of DNF and PQM+ and ensure alignment on program goals and objectives, as well as establish a stepwise approach to self-reliance. PQM+ is holding collaborative meetings with DNF to develop this framework, which is expected to be completed in Q1 of PY2. During the presentation of the work plan with DNF, it was agreed that PQM+ would start with updating the laboratory regulation. In Q4, the program worked with the DCQ (formerly known as *Laboratório Nacional de Controle de Qualidade dos Medicamentos*) to update the content in the regulation to reflect the laboratory's current status as a department under the new DNF and to incorporate clauses that will aid good laboratory practices.

[1] https://www.who.int/countries/moz/areas/health_system/en/index1.html

## Objective 2: Regulatory systems to assure the quality of medical products in the public and private sectors strengthened

As a step toward building an effective workforce, PQM+ will assess the capacity of personnel in the two DNF departments responsible for medical products evaluation and pharmaceutical inspection and licensing of establishments: the Department of Evaluation of Medicines, Vaccines, and Biological Health Products and the Department of Pharmaceutical Licensing and Inspection. In collaboration with partner IntraHealth, PQM+ started working on a training needs assessment tool that will capture the information needed to inform a robust training plan and ensure that staff have the technical capacity to carry out these critical regulatory functions.

### Nigeria

Nigeria has a significant local manufacturing industry, but nearly 70 percent of medical products in the market are imported, complicating medicines regulation and increasing the prevalence of substandard and falsified medical products in the national market.[2] A 2018 study by Anyakora et al.[3] on quality medicines for maternal health in Nigeria found that 74 percent of oxytocin injection samples failed the assay test, thus failing to meet required standards. Despite efforts by the National Agency for Food and Drug Administration and Control (NAFDAC) and other government agencies, ensuring the availability of quality-assured medical products, including those for malaria, remains a critical issue.

**Key Accomplishments in PY1**

Supported local manufacturers toward WHO-PQ of quality assured essential MNCH and malaria medical products:

Drugfield's chlorhexidine 7.1 percent w/w digluconate 3g gel obtained approval by the West African Medicines Regulatory Harmonization Project for use across the Economic Community of West African States region with validity up to March 1, 2025.

Swipha became the first pharmaceutical company in Nigeria to conduct a bioequivalence study with a WHO-PQ contract research organization for SP tablets.

Juhel's Magnesium sulfate 50 percent w/v injection dossier was received by WHO-PQ for evaluation.

The National Institute for Pharmaceutical Research and Development central laboratory successfully attained reaccreditation to ISO 17025:2017 through remote assessment.

Initiated working with NAFDAC's laboratory on multisite ISO accreditation to reduce the annual cost of accreditation for all laboratories.

Completed a desk review of the current situation of QA and regulatory systems at the state level, focused on community pharmacies and proprietary and patent medicine vendors.

In PY1, the PQM+ program collaborated closely with government agencies to implement activities aimed at improving the governance for medical product QA systems, strengthening

[2] Imperatives for Drug Security. NAFDAC. https://www.nafdac.gov.ng/imperatives-for-national-drug-security/
[3] Quality medicines in maternal health: results of oxytocin, misoprostol, magnesium sulfate, and calcium gluconate quality audits. https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-018-1671-y

regulatory systems, optimizing and increasing resources for QA systems, and increasing the supply of quality-assured MNCH and malaria medical products. ‘

## Progress by PQM+ Objective

### Objective 2: Regulatory systems to assure the quality of medical products in the public and private sectors strengthened

In Nigeria, the population can access medical products through community pharmacies and proprietary patent medicine vendors. However, many of these retail outlets are unregistered and have unlicensed premises; in some cases, nonpharmacists operate them, increasing the risk of inadequate medical product quality.[4] To assess the regulatory and QA system for medical product retail outlets, the PQM+ program conducted a desk review earlier this year to understand the challenges, gaps, and opportunities that exist in ensuring the quality of medical products in three USAID priority states (Bauchi, Sokoto, and Ebonyi). PQM+ worked with the Pharmacists Council of Nigeria and other stakeholders to review data and reports on state-level regulatory functions that exist, particularly licensing establishments and regulatory inspection. The review also looked at the regulatory framework and modality to ensure sustainable sourcing of quality-assured medical products.

During Q4, PQM+ designed the state-level assessment process based on findings from the desk review, 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. The questionnaires/data collection tools have been designed and reviewed with the Pharmacists Council of Nigeria. The next step will be to disseminate the findings of the Bauchi, Ebonyi, and Sokoto state-level assessments and implement priority activities that will improve the quality of medical products and the number of registered outlets in these states.

The Nigerian Institute for Pharmaceutical Research and Development was established to aid novel research in pharmacognosy, medicinal chemistry, and the promotion of indigenous and local content in the pharmaceutical sector. This year, PQM+ supported the laboratory in preparing for an ISO/IEC 17025:2017 reaccreditation assessment. This work occurred virtually as a result of travel restrictions due to COVID-19. Following a successful assessment by the ANAB, the laboratory achieved reaccreditation in April 2020. This lays the groundwork for the National Institute for Pharmaceutical Research and Development’s pursuit of WHO-PQ.

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

Addressing the challenge of mobilizing sustainable domestic resources and optimizing the allocation and use of such resources is critical to strengthening medical product QA systems. ISO accreditation recognizes the quality of a laboratory’s performance and instills trust in laboratory results. The cost of annual accreditation or reaccreditation, however, is high for many laboratories. To reduce these costs, PQM+, with support from NAFDAC,

[4] UNIDO 2011. PHARMACEUTICAL SECTOR PROFILE Nigeria. https://www.unido.org/sites/default/files/2011-04/Nigeria_Pharma%20Sector%20Profile_032011_Ebook_0.pdf

initiated a plan to harmonize the accreditation status of its four laboratories, called multisite accreditation.

Under this initiative, the four accredited laboratories will become satellites to one major laboratory. The entire agency will now have one group accreditation certificate, rather than multiple certificates. Prior to this arrangement, each laboratory would have paid $10,000 per year for reaccreditation. With the new group accreditation certificate model, the cost will be reduced by approximately 50 percent ($5,000 per site). A virtual assessment will precede the multisite accreditation and has been scheduled with ANAB for November 2020. PQM+ is supporting NAFDAC with the preparation for this virtual assessment.

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

PQM+ is helping to strengthen the capacity of Nigeria's pharmaceutical manufacturers to produce quality-assured priority medical products by addressing GMP and other quality-related challenges. PQM+ provided technical assistance to seven manufacturers during the program's first year.

- PQM+ continues to provide support to Juhel Nigeria Ltd. in pursuing WHO-PQ of magnesium sulfate 50 percent injection, a medicine used to treat severe pre-eclampsia, eclampsia, and toxemia during pregnancy. PQM+ monitored the effectiveness of closed CAPAs through the review of updated key QMS documents. PQM+ also provided support in response to the WHO-PQ dossier evaluation team's request for further product information making. The WHO-PQ team is reviewing the updated information.
- PQM+ continues to support manufacturers of sulfadoxine/pyrimethamine (500+25) mg tablet to address key steps towards dossier submission for WHO-PQ. This includes the review of real-time stability results. WHO recommends sulfadoxine/pyrimethamine for the intermittent preventive treatment of malaria during pregnancy.
    - PQM+ provided technical assistance to Emzor Pharmaceutical Industries to produce a test batch (bio-batch) to demonstrate bioequivalence following excellent laboratory tests results of samples from the batches of the optimized formulation.
    - The PQM+ program is supporting the dossier compilation for a second sulfadoxine/pyrimethamine manufacturer, Swiss Pharma Nigeria Ltd (Swipha). With the easing of the COVID-19 lockdown in Jordan, the bioequivalence study of their brand of sulfadoxine/pyrimethamine has commenced. PQM+ will continue to monitor progress of the study. Positive results from the Jordan bioequivalence study will need to be included in the manufacturer's dossier submission to WHO-PQ.
- The pandemic has had a major impact on the progress of the palatability study due to a low turnout of patients at the test centers. PQM+ will continue to monitor progress made while reviewing other product data, such as real-time stability data for zinc sulfate 20 mg dispersible tablets.
- Based on recommendations from the GMP Roadmap, PQM+ commenced a pilot to support five selected manufacturers of antimalaria and MNCH medicines to prepare CAPA plans to address audit findings that were identified during the development of the

roadmap project. The CAPA plans will serve as a basis for their recategorization based on risk to GMP compliance by the NAFDAC.

- Support the implementation of GMP roadmap recommendations in collaboration with NAFDAC and the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria.

## Senegal

The Government of Senegal recently developed a five-year (2019–2023) Integrated Strategic Plan for DPM and the LNCM. The plan outlines a vision of building "an efficient system of regulation and control which ensures the development and application of quality standards and guarantees access to medicines and other quality health products that are effective and safe for the entire population.[5]" While progress has been made over the past decade, the plan recognizes that work remains.

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. To address these areas and realize the vision described above, the strategic plan outlines 17 subobjectives under seven general objectives.

In PY1, PQM+ Senegal contributed to the strategic plan's first and third objectives, "Establish an appropriate institutional framework for the optimal implementation of pharmaceutical regulatory and control functions" and "Evaluate and control the quality of drugs." The program worked closely with DPM and LNCM to establish a PMS Unit that will oversee all PMS activities in the country to help improve coordination and communication among the different stakeholders involved. National guidance for risk-based PMS and a risk-based PMS protocol for antimalaria medicines were developed during Q4.

PQM+ Senegal also facilitated the institutionalization of the SATTA at LNCM through training on the use of SATTA, supportive assistance to the QA team to develop an SOP to use SATTA for internal audits, and to conduct an internal audit using SATTA. Through this internal audit that LNCM conducted, areas for improvement in the laboratory's pursuit for ISO accreditation and WHO-PQ were identified and a corrective action plan was developed by LNCM to address the identified gaps. These activities contribute directly to the two subobjectives from the strategic plan's first and third objectives, bringing DPM and LNCM closer to building a more robust and efficient regulatory system.

**Key Accomplishments in PY1**

Worked closely with DPM and LNCM to establish a PMS Unit that will oversee all PMS activities in the country to improve coordination and communication among stakeholders.

Facilitated the institutionalization of the SATTA at LNCM through training and supportive assistance to develop an SOP to conduct an internal audit.

Developed national guidance for risk-based PMS and a risked-based PMS protocol for antimalaria medicines.

[5] *Plan Stratégique Intégré de la Direction de la Pharmacie et du Médicament et du laboratoire National de Contrôle des Médicaments : 2019–2023.* December 2018

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

PQM+ provided support to DPM and LNCM with the establishment of a PMS Unit to improve governance and oversight for the QA of medical products and improve the country's regulatory systems to assure the quality of medical products in the public and private sectors. PQM+ drafted the terms of reference for the PMS Unit, which each member reviewed and validated.


L'UNITÉ NATIONALE POUR LA SURVEILLANCE POST-MARKETING SÉNÉGAL

*Figure 3: Senegal PMS Unit*

The PMS Unit includes representation from the DPM, LNCM, *Programme National de Lutte Contre le Sida* (AIDS control program), *Programme National de Lutte Contre la Tuberculose* (TB control program), *Programme National de Lutte Contre le Paludisme* (malaria control program), *Direction de la Santé de la Mère et de l'Enfant* (Department of Maternal Child Health), *Syndicat des Pharmaciens Privés du Sénégal* (private pharmacists' syndicate), *Association des Producteurs de médicaments du Sénégal* (Pharmaceutical manufacturers' association), *Grossistes-Répartiteurs privés* (private wholesalers' association), *l'Association des pharmaciens hospitaliers du Sénégal* (clinical pharmacists' association), and *Pharmacie National de l'Approvisionnement* (PNA – procurement agency). A chair, vice-chair, and joint secretariat for the unit were elected by consensus.

The official inauguration of the PMS Unit occurred during Q4. It included 22 participants, and members were officially introduced to the DPM and LNCM. Both organizations thanked the members for their commitment and reassured them of their full support for the critical journey the group was about to embark on to help the country's fight against substandard or falsified medicines.

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

In PY1, the national PMS Unit worked with PQM+ to develop national guidance for risk-based PMS. In addition to this, PQM+ trained the PMS Unit on the principles of risk-based PMS and operating the MedRS tool, which they will use to develop their risk-based PMS protocol for sampling and testing of malaria medicines in PY2. Implementing a risk-based PMS protocol will help Senegal to optimize the use of resources and support them in transitioning from donor-supported surveys to locally funded and sustainable PMS programs that are integrated and implemented as a core regulatory function.

The program focused on introducing the SATTA for conducting laboratory audits to enhance the laboratory's ability to continuously improve its QMS. This will ensure that the laboratory has the capacity and competencies required to accurately ascertain the quality of medicines being registered and circulating in the Senegalese market. In Q4, PQM+ trained LNCM to use SATTA by sharing presentations and a user's manual, as well as holding virtual sessions to demonstrate how the Excel tool works. The QA team then developed an SOP for the use of SATTA to conduct internal audits. Top management approved the SOP, after which the medicines QC lab within LNS, under the supervision of PQM+, conducted one internal audit using SATTA as per the ISO/IEC 17025 standard. PQM+ reviewed the internal audit report, conducted a training on corrective action management, then worked with the QA team to develop a corrective action plan to address the nonconformances identified. PQM+ will work with LNCM to monitor progress through PY2.

## Asia Region

### Bangladesh

The medicine market in Bangladesh is enormous, comprising more than 280 licensed allopathic medicines manufacturers, more than 30,000 registered brands, and 127,000 registered medicines outlets. Due to the lack of properly trained personnel 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 (FP/RH) medical products that are procured through Ministry of Health and Family Welfare programs is siloed. Support is needed to implement comprehensive, evidence-based regulatory standards and processes for medical product PMS.

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 FP medicines.

**Key Accomplishments in PY1**

PQM+ completed the technical review and editing of the draft National Quality Assurance Guideline, which should strengthen overall QA measures for pharmaceutical products throughout the supply chain.

Assisted the NCL in building its technical capacity in terms of compendial testing of priority medical products.

To support the NCL's sustainability, PQM+ began working with its management to develop a cost structure that took into consideration the demand for testing, existing fees, and operating costs.

Provided technical guidance and recommendations to ACI Pharmaceuticals to manufacture quality-assured, first-line, fixed-dose combination anti-TB medicines.

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

PQM+ completed the technical review and editing of the draft National Quality Assurance Guideline, which should strengthen the DGDA overall QA measures for pharmaceutical products throughout the supply chain. This guideline will provide the foundational QA principles for stakeholders and partners (governmental and nongovernmental) engaged in providing medical products in Bangladesh. PQM+ shared the guideline with the DGDA, the Directorate General of Health Services, and the Directorate General of Family Planning for any last comments and will next finalize it.

## 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 the use of its regulatory resources to protect the public's health. 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 the DGDA to scale up PMS of priority products in two new geographic divisions, Sylhet and Mymensingh. To this end, the program helped the NCL 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 DGDA's surveillance department. The Minilab™ is a portable device that allows rapid quality verification of priority medicines, such as anti-infective medicines, and the detection of substandard or falsified pharmaceuticals. 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 the country.

This quarter, PQM+ assisted the NCL in building technical capacity in terms of compendial testing of priority medical products. PQM+ also helped to improve resource planning to allow for timely procurements of laboratory supplies during analysis (such as reference standards, columns, reagents, and chemicals) and generating a requirements list to help with a purchase requisition before analysis. PQM+ conducted a training on impurity analysis for NCL analysts to increase their capacity for advanced testing.

To support the NCL's sustainability, PQM+ began working with its management to develop a cost structure that took into consideration the demand for testing, existing fees, and operating costs. A draft assessment report was prepared focusing on the future cost structure and determining analytical costs of test parameters per product performed by NCL.

In July, PQM+ supported a renewal audit of the NCL's physicochemical laboratory. It was conducted virtually by the ANAB assessor (ANAB-ISO/IEC 17025:2017 certification). The certification of renewal was obtained October 18, 2022.

*Figure 4: Virtual ANAB Assessment*

To improve data integrity, ensure data backup, and shift from the existing paper-based system to an electronic system, PQM+ supported the NCL to draft preliminary user requirements specifications for a laboratory information management system.

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

PQM+ continued to support ACI Pharmaceuticals Ltd. by addressing the CAPAs identified during PQM's 2019 inspection. In the fourth quarter, PQM+ provided technical guidance and recommendations to ACI Pharmaceuticals to manufacture quality-assured, first-line, FDC anti-TB medicines. ACI Pharmaceuticals is in the process of the product development stage of three FDC products (2 FDC, 3 FDC, and 4 FDC) and its dossier preparation toward attaining WHO-PQ.

Key prerequisites for WHO-PQ include bioequivalence studies to demonstrate that a generic product will achieve the same blood concentration and hence be as effective as the innovator product. This quarter, PQM+ started working toward selecting a competent contract research organization in Bangladesh to support bioequivalence studies. In August, PQM+ supported a mapping survey of contract research organizations.

### Burma

PQM+ 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 substandard or falsified 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.

**Key Accomplishments PY1**

During its first year in Burma, PQM+ supported the DFDA Nay Pyi Taw PCL to strengthen its QMS systems and prepare for ISO 17025:2017 reaccreditation.

At the same time, PQM+ worked closely with DFDA senior management on the reconfiguration of its Mandalay PCL to achieve accreditation in PY2. PQM+ also reviewed the current PMS system at DFDA's field offices and will roll out the MedRS tool in PY2.

## Progress by PQM+ Objective

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

At the beginning of Quarter 4, PQM+ organized a virtual quarterly coordination and review meeting among DFDA, PMI staff from the Mission, and PQM+. The aim of this meeting is to promote transparency and accountability in implementation of the PQM+ program and collaboration among the key stakeholders. During the meeting, the stakeholders discussed the implementation of activities under the PY1 work plan, the challenges encountered, and planned activities for Q4. PQM+ also presented the activities planned for PY2.

This is the first of the coordination and review meetings PQM+ planned to conduct quarterly. Another meeting was held at the end of Q4.

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

This quarter, PQM+ and DFDA senior management reviewed the issue of high workload at DFDA Nay Pyi Taw PCL during the annual management review meeting. PQM+ proposed implementing a risk-based approach so that the laboratory can identify high-risk samples and prioritize them while maintaining the optimum testing output of 70 samples per month. After a thorough discussion, DFDA senior management decided to implement risk-based testing and asked PQM+ to provide technical assistance in developing a risk model and implementing it in the laboratory.

In addition, PQM+ conducted a three-day "Measurement Uncertainty" training in August 2020. Due to the COVID-19 pandemic, it was delivered virtually. Six key staff from the PCL QA team participated. As a result of the training, the lab can calculate uncertainty values of their measurements, which allows them to interpret the test results more accurately. Additionally, PQM+ conducted a site visit to DFDA Mandalay PCL at the request of the director general of the DFDA. PQM+ assessed the current configuration of the Mandalay PCL and shared technical recommendations for further renovation of the laboratory with DFDA's senior management. They agreed to implement PQM+'s recommendations and the Mandalay PCL can start to prepare for ISO 17025:2017 accreditation with support from PQM+ in 2021. PQM+ also conducted an assessment of the current PMS and medical product QC system at DFDA. The assessment is ongoing at the Bago and Kayin DFDA field offices.

In PY1, PQM+ supported DFDA's Nay Pyi Taw PCL for the relocation to the new facility. DFDA initially planned the relocation in Q3, but COVID-19-related travel restrictions delayed the

process by one year. Hence, at DFDA's request, PQM+ supported the PCL as it prepares for ISO 17025:2017 reaccreditation at the current facility.

PQM+ held a series of meetings with DFDA senior management and provided orientation on the implementation of the risk-based approach in DFDA's PMS activities and the introduction of the MedRS tool. At the request of DFDA senior management, PQM+ also reviewed the inspector module of the Integrated Regulatory Information Management System at DFDA. PQM+ assessed the application, conducted several interviews with inspectors, and provided recommendations to address the technical and systematic issues. DFDA senior management decided to rebuild the inspector module with its own resources and asked PQM+ to provide support to determine technical specifications and data standards.

## Nepal

USAID/Nepal engaged PQM+ to provide technical assistance to strengthen medical product QA and QC systems of the Department of Drug Administration at the federal and peripheral levels. PQM+ will also strengthen the National Medicines Laboratory and its corresponding entities at the peripheral 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 substandard or falsified medical products.

In PY1, the program focused on key startup activities, including opening an office, establishing and building working relationships with key stakeholders, finalizing the PY1 work plan, and kickstarting technical implementation. The program facilitated introductory virtual meetings with critical stakeholders, including the Department of Drug Administration (DDA), National Medicines Laboratory, and leadership from the Medicines, Technologies and Pharmaceutical Services (MTaPS) program, to help inform and align PQM+ goals, objectives, and technical assistance.

PQM+ implementation then focused on conducting a rapid assessment of DDA's regulatory systems: PMS, inspection, and QC testing. Preparations began to carry out an assessment of systems in place that would support a productive workforce for both the DDA and the National Medicines Laboratory. This assessment complements the GBT and is a deep dive into workforce development. This lays the foundation for advising the DDA on how to build sustainable systems and practices to support the workforce moving forward. The assessment will carry over into PY2. The rapid assessment also looked at workforce capacity to assess human resource needs for these critical regulatory functions. The program shared the initial findings and recommendations on PMS and the inspection system with DDA for their review and feedback. The related assessments for QC testing and workforce development are in progress.

PQM+ also worked closely with the MTaPS program to provide technical inputs related to PMS, QA/QC, and inspection for a new drug law and QMS activities. The program will continue its close collaboration with the MTaPS program, given the complementarity in the statements of work for both programs.

**Key Accomplishments in PY1**

Conducted a rapid assessment of DDA's PMS, inspection, and QC testing systems. The assessment also looked at workforce capacity to assess human resource needs for these critical regulatory functions. Shared the initial findings and recommendations on PMS with DDA for their feedback.

Worked closely with the MTaPS program to provide technical inputs related to PMS, QA/QC, and inspection for a new drug law and QMS 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

To enhance regulatory and QA capacity, the PQM+ program initiated an in-depth assessment of the human resource needs for the following regulatory functions: inspections, laboratory testing, and PMS. The program coordinated with DDA to collect the preliminary information for a desk review and to finalize the tools, methodology, and list of key informants for the rapid assessment. The program team shared the draft methodology and tool with DDA leadership for their review and consensus. The assessment will inform the creation of a health product QA workforce development plan, which is a recommendation in the IDP of DDA Nepal and will help to build a productive and sustainable workforce.

PQM+ also collaborated with DDA to design a training needs assessment form to identify training requirements and develop needed training materials, job aides, learning assessments, and training evaluation questionnaires. The program will support the DDA with the collection of information.

The Government of Nepal seeks to strengthen its PMS program to effectively monitor the quality and safety of medical products on the local market. PQM+ oriented DDA leadership and its PMS management division on the PQM+ risk-based approach. Relevant information about the existing PMS and medical product system was collected through a questionnaire and reviewed together with the PMS management division. A draft report of the findings was shared with DDA leadership and the PMS management division for their review and inputs. Key findings included the need to establish a PMS-TWG, finalize the terms of reference, and integrate regulatory information management tools. The program will assist DDA to develop a risk-based PMS approach and plan a stakeholder meeting with the Ministry of Health and Population next quarter to disseminate the findings from the assessment, introduce the RB-PMS approach, and draft the RB-PMS plan.

The role of Nepal's National Medicines Laboratory in assuring medical product quality has been limited due to financial, human, and technical resource constraints. During Q4, the PQM+ program conducted an inventory of the laboratory's capacity as part of a preliminary step before implementing the SATTA. Results collected from this exercise will help to inform the National Medicines Laboratory's design of a strategic plan to achieve PQ or accreditation status by identifying areas for improvement. The program team also assisted the National Medicines Laboratory to access the U.S. Pharmacopeia Convention (USP)-National Formulary online version, which features monographs for drug substances, dosage forms, and compounded preparations. This will help the National Medicines Laboratory improve its testing methods by adopting standard processes for testing.

PQM+ also began to coordinate closely with the DDA and the MTaPS program. Initial collaboration included a review of the existing drug law and the DDA's QMS. The program provided technical inputs and recommendations related to PMS, inspection, and QA/AC components in the initial draft of the new drug law for DDA.

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

During Q4, PQM+ reviewed the DDA GMP code for inspection of manufacturers, importers, and distributors to determine if there are any gaps and inconsistencies with international standards and WHO guidelines. PQM+ translated the code from Nepali to English.

PQM+ is also working to strengthen DDA's inspection capabilities. This year, PQM+ collaborated with DDA leadership and its Inspection Division to discuss the current GMP inspection system and identify areas for improvement. The team used the information gleaned from these discussions and designed a detailed questionnaire to collect additional information as supporting evidence for proposed activities. The program team analyzed the information and drafted a report. PQM+ shared the report with DDA leadership and the Inspection Division for their feedback on the recommendations.

The recommendations will be used to develop a rigorous but sustainable plan to strengthen Nepal's risk-based inspection system. This will 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 follow national legislation and regulations.

## Pakistan

In PY1, the PQM+ program provided technical support to DRAP in preparing their response to the findings from a WHO GBT gap assessment conducted in November 2019. This support will help DRAP achieve WHO Maturity Level 3, the minimum acceptable level for regulatory agencies to ensure a stable, well-functioning, and integrated system. Based on the WHO recommendations, DRAP revised and updated 10 guidelines and SOPs to improve their GBT score in nine regulatory areas during Q4.

**Key Accomplishments PY1**

Facilitated a virtual training for DRAP and manufacturers on the principles of risk management and their application to GMP. A total of 400 participants from industry and the regulatory authority attended this four-day virtual event.

Focused on strengthening medicines QC laboratories to improve Pakistan's ability to reliably test the quality of products on the market. The program supported DRAP's National Control Laboratory for Biologicals (NCLB) to address gaps with compliance to ISO 17025 standards and WHO GBT lot release indicators, which were identified by PQM in 2019.

Organized a virtual training on the development and implementation of a CAPA plan to address identified gaps from an assessment. Following the training, the program facilitated a mock exercise in which NCLB completed a root cause analysis and developed their own CAPA plan to address the gaps from the 2019 PQM assessment.

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

DRAP works to ensure that all establishments comply with risk-based GMP requirements and 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 active pharmaceutical ingredients). Pakistan's existing licensing system has no uniformity, consistency, transparency, or accountability of regulatory requirements. GMP inspection 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 PY1, PQM+ assisted DRAP to revise the licensing rules, uploaded the revised document on the DRAP website for stakeholder comments, and conducted virtual consultative meetings with stakeholders on proposed amendments. A virtual consultative meeting was held in June in coordination with DRAP, Pharma Bureau (multinational pharmaceutical manufacturers), and the Pakistan Pharmaceutical Manufacturer Association. More than 600 technical and higher management representatives participated. In Q4, the program supported DRAP in incorporating feedback from key stakeholders. A finalized draft will be presented to the policy board in the first quarter of PY2.

DRAP is struggling to achieve WHO Maturity Level 3 based on the GBT. Level 3 is the minimum acceptable level for a stable, well-functioning, and integrated regulatory system. By achieving Maturity Level 3, DRAP would attain WHO Listed Authority status, enabling it to meet international standards for ensuring quality of medical products and safeguarding patients from substandard and falsified medicines.

In November 2019, WHO conducted a mock gap assessment of DRAP's GBT Level 3 compliance and identified further areas for improvement in all nine regulatory areas. In Q4, the PQM+ program supported DRAP in preparing their draft response to the WHO. This included developing the DRAP competency framework and reviewing updated guidelines and SOPs, as recommended by WHO. This technical support resulted in DRAP raising its GBT scores in all nine regulatory areas during the mock gap assessment. With support from PQM+, the following documents were developed:

- Adaptation of good clinical practices
- Assessment of therapeutic goods
- DRAP strategic vision
- Establishment licensing system
- Good review practices guidelines
- Guideline on conflict of interest
- Inspection guidelines
- Policy document on shifting from QC to quality assurance
- Registration procedure guidelines
- Competency framework

These documents should help DRAP improve its GBT maturity level during the official audit. Having a well-conceived National Pharmaceutical Strategy and Private Sector Engagement Plan is the first step in developing the potential of Pakistan's pharmaceutical industry. PQM+ developed a concept note for creating a strategy. The concept note includes the organization of a multisectoral stakeholder kickoff meeting planned for PY2 to define the key objectives to be achieved in the next 10 years. It identified potential stakeholders that should be involved and highlighted the need to identify and remove obstacles to achieving the strategy's goals.

PQM+ conducted a four-day virtual training on risk-based GMP for antimicrobial manufacturers (June 29–July 2, 2020). There was keen interest in this training, with more than 400 participants from the industry (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 the 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 International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Q9). PQM+ added sessions for those who are actively involved in performing, overseeing, auditing, or managing training of their organizations.

## 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 the development and implementation of a CAPA plan for DRAP's National Control Laboratory for Biologicals (NCLB) technical staff. Last year, PQM conducted a detailed gap assessment of NCLB regarding its compliance with ISO 17025-2017 standards and WHO GBT indicators. PQM+ held a virtual training session that 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. Based on this training and exercise, NCLB revised their CAPA SOP and started developing their own CAPA plans. Once completed, the PQM+ team will review the NCLB CAPA plan and arrange further trainings if required.

PQM+ continued technical support to the Central Drug Laboratory Karachi to address the ISO 17025:2017 pre-assessment audit observations related to the QMS. This includes the development of a competency program, the procedure for analyst qualification before performing any test, SOP for preventive maintenance, SOP for handling out-of-order equipment, and laboratory information management system validation. Moreover, with PQM+ advocacy to DRAP's management, the lab shifted to a new building, which was one of the preassessment audit recommendations. The Central Drug Laboratory submitted the preassessment audit observation responses to the Pakistan National Accreditation Council and are awaiting its confirmation of dates for a final assessment. The program also supported the Central Drug Laboratory in preparing and submitting its laboratory file, which the WHO PQ program accepted during Q4.

## Objective 4: Increase supply of quality-assured essential medical products of public health importance.

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. 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)

PQM+ experts shared the presentation and roadmap with DRAP's registration division. DRAP officials are reviewing the standards and proposed roadmap in the local context.

# Europe and Eurasia Region

## Kazakhstan

PQM+ is helping the NCEM to ensure quality by strengthening its regulatory systems and MQCLs to reliably and accurately test the quality of medicines produced locally as well as those imported from other countries. PQM+ is also tackling the issue of quality from the source by working with local manufacturers to increase the supply of locally manufactured, quality-assured TB medicines in the local markets.

In PY1, due to COVID-19 restrictions, PQM+ shifted to virtual program implementation. This required developing consensus within the NCEM and MQCLs to assign working groups for each activity and collaborating with these working groups to implement the planned activities, such as virtual trainings and virtual assessments.

**Key Accomplishments PY1**

WHO prequalified the Karaganda MQCL in February 2020.

The Almaty laboratory applied for WHO peer audit and started preparation.

NCEM started developing the procedures and manufacturers' guideline for registration of medicines through the WHO collaborative registration procedure (CRP).

The GMP inspectorate's QMS has been approved and the PMS guideline has been drafted and is being finalized.

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

In February 2020, WHO officially added the Karaganda MQCL to the list of WHO-PQ laboratories. This is an important achievement because it is the first laboratory in Central Asia that can reliably test the quality of medicines according to international standards. Karaganda MQCL's experience is valuable because it can also be shared with other laboratories and their staff in the region. In May, PQM+ held a regional online forum: "The WHO Prequalification Process: Lessons from Kazakhstan's NCEM and its Karaganda Medicines Quality Control Laboratory" for more than 100 staff of the MNRAs and their MQCLs of Kazakhstan and Uzbekistan. The speakers presented on the WHO PQ process and the benefits of achieving international recognition. The forum encouraged the laboratories of the region to collaborate on strengthening their quality management systems.

The program continued to support the Nur-Sultan, Almaty, and Karaganda MQCLs. In particular, PQM+ worked with the Almaty and Nur-Sultan laboratories in improving their QMS, including reviewing the current quality manual and several related SOPs. PQM+ also provided continued support to the Almaty laboratory in preparation for the WHO PQ peer audit. It was agreed that in the next quarter (PY2 Q1), PQM+ will conduct a virtual internal audit of the Almaty laboratory to prepare the lab for a WHO peer audit.

PQM+ began technical assistance to NCEM for strengthening the medicines registration system. PQM+ engaged with the working group that was established at the NCEP on the assessment of the current medicines registration system. PQM+ started reviewing documents related to medicines registration, including templates for the summary of product characteristics, packaging and labeling information, and the SOP on review of registration dossiers. PQM+ will work with NCEP to identify areas where PQM+ assistance is needed for improving the system to ensure that it meets the GBT Maturity Level 3 requirements.

PQM+ also worked with NCEP to ensure the operationalization of the WHO Collaborative Procedure for Accelerated Registration, which will help with the timely registration of WHO-PQ medicines in Kazakhstan. PQM+ assessed the current status using the WHO collaborative procedure for review and registration of WHO prequalified medicines in Kazakhstan to identify any gaps. Then PQM+ organized virtual training sessions on the procedure and the steps needed for approval of the WHO-PQ products. PQM+ guided the NCEM staff on the development of the procedures for the review and registration of medicines. PQM+ also presented the guideline for manufacturers. NCEM is working to finalize these documents.

PQM+ engaged with NCEM to strengthen the PMS system, provided an overview of the risk-based PMS concept, and introduced the Medicines Risk Based Surveillance tool, MedRS, which the PQM program developed. PQM+ assessed the current status of PMS and found that PMS in Kazakhstan is not efficient, and improvements can be made to address the key risk factors. PQM+ assisted in developing a draft customized risk-based PMS guideline, which is being finalized.

Kazakhstan aspires to comply with the Pharmaceutical Inspection Co-operation Scheme membership standards and become a member. PQM+ proposed establishing a working group composed of staff from the NCEM and the MOH's Committee for Quality Control and Safety of

Goods and Services. The working group will provide extensive support in addressing the gaps identified during PQM+'s initial assessment of the current GMP inspectorate. PQM+ supported the revision of the current organizational structure, improving QMS of the GMP inspectorate, and improving inspection procedures, identified capacity-building needs, and developed a training plan for the inspectorate's staff.

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

In PY1, PQM+ continued to work with the Nobel Almaty Pharmaceutical Factory to improve its GMP compliance as it prepares for WHO PQ of its product levofloxacin. Work included starting to prepare the dossier. In collaboration with Nobel, PQM+ prepared a timeline with milestones on the anticipated time for dossier development and improvement of GMP compliance. In Q4, PQM+ began work with Nobel on the first milestone toward manufacturer compliance of the active pharmaceutical ingredient of levofloxacin with WHO-PQ requirements and provided corresponding guidance. PQM+ also started preparation for an online risk management training for Nobel to be provided by a PQM+ technical expert. Nobel needs to demonstrate that they are managing a cross-contamination risk for levofloxacin production effectively.

## Uzbekistan

Uzbekistan is graduating from GF-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.

PQM+ continues to strengthen systems to improve access to quality-assured medicines for TB and other essential medicines. In PY1, due to COVID-19 restrictions, PQM+ shifted to virtual program implementation. This required developing consensus within the Agency for Development of the Pharmaceutical Industry (the Agency) and MQCLs to assign working groups for each activity and collaborate with these working groups to implement the planned activities, such as virtual trainings and virtual assessment.

Also in the first year, the procedure for registration of medicines through WHO collaborative registration procedure (CRP) and guidelines for the manufacturers was finalized. These documents are in the approval process. Once they are approved, the manufacturers of WHO-PQ medicines will have an opportunity to apply for registration of their medicines through WHO CRP in Uzbekistan. This would be an important step toward ensuring access to quality-assured medicines.

With PQM+ technical assistance, the Tashkent and Adijan laboratories strengthened staff capacity in many areas of the MQCL operations. PQM+ began technical assistance in designing the new building for the laboratory to ensure that it complies with the international standards. PQM+ assistance to the laboratories is essential to ensure that they operate according to Good Laboratory Practices standards. PQM+ assistance helped the Agency to progress in terms of implementation of the Pharmaceutical Inspection Co-operation Scheme accession roadmap, particularly in strengthening the inspectorate's QMS.

**Key Accomplishments PY1**

Procedure for registration of medicines through WHO CRP and guidelines for the manufacturers finalized. Documents are in the approval process.

Tashkent and Andijan laboratories strengthened staff capacity in many areas of MQCL operations.

Began supporting the design of the new building for the laboratory to ensure that it complies with international standards.

## 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

In Q4, PQM+ continued its technical assistance to the Agency to operationalize the WHO CRP for registration of WHO-PQ medicines. Based on the analysis of gaps identified during the initial assessment, PQM+ worked with the staff of the Agency to better understand the process. In addition, PQM+ provided assistance in developing the SOP for review and registration of WHO-PQ medicines through the WHO CRP process and provided guidelines for the manufacturers. These documents were submitted for internal approval.

In collaboration with the Agency's working group, PQM+ began the assessment of the medicines review and registration system. After completing the assessment, a detailed action plan will be developed, which will include streamlining the medicines registration procedures, making them more transparent, and strengthening staff capacity at the Agency. PQM+ continued to support the Agency in implementing the Pharmaceutical Inspection Co-operation Scheme accession roadmap. The Agency has progressed in terms of establishing GMP inspectorate's QMS, including developing a quality manual and corresponding SOPs. In addition, PQM+ provided recommendations on the GMP inspectorate's organizational structure. Those recommendations are being considered for adoption by the Agency.

The president of the Republic of Uzbekistan, Shavkat Mirziyoyev, launched the construction of the Tashkent Pharma Park, an innovative scientific and production pharmaceutical cluster in the Zangiata District of Tashkent Province. The Pharma Park will include a number of facilities, including MQCLs, research laboratories, a pharmaceutical university, and pharmaceutical production sites. PQM+ responded to the request of the Agency and started providing technical assistance in developing technical specifications for the layout and design of the MQCLs to ensure that they meet the international standards.

PQM+ worked closely with the corresponding working groups to coordinate PQM+ technical assistance to Tashkent and Andijan MQCLs. Based on the initial assessment results, PQM+ provided assistance in strengthening the QMS and building the capacity of the staff of the laboratories. Particularly, PQM+ provided a series of targeted online trainings, including WHO good practices for pharmaceutical QC laboratories, good documentation practices, internal audits, and handling of laboratory reagents.

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

Following PQM+'s recommendations, Nobel is working on mitigating the risk of cross-contamination between penicillin and other products. PQM+ began supporting Nobel to prepare the product dossier for WHO-PQ. PQM+ developed a list of documents on product development for dossier preparation and GMP for Nobel. They will prepare these documents and send them to PQM+ for review. Finally, PQM+ facilitated discussions between the Association of Manufacturers and the Agency to organize a training 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, making it important for regulators and manufacturers to have the same level of knowledge and understanding of requirements regarding the CTD.

## COVID-19 Response Activities

### Bangladesh

In June 2020, PQM+ received COVID-19 supplemental funds to help the Government of Bangladesh and the in-country manufacturing sector respond to the COVID-19 pandemic. As in other countries, availability of personal protective equipment (PPE) to protect health care providers has been a serious concern. The PQM+ program created visual inspection checklists to inform quality assessments for five COVID-19-related PPE items: gowns, coveralls, fabric masks, surgical masks, and KN95/N95/FFP2 respirators. PQM+ works with local manufacturers to adopt elements from this checklist into existing QA systems. The program also developed a PPE database that lists manufacturers of PPE and hand sanitizers with the DGDA's No Objection Certificate. This database is hosted on DGDA's website and will provide uniform information and tracking of these manufacturers to all relevant authorities.

To ensure efficient registration of critical COVID-19 medical products, the program assisted the DGDA to develop a comprehensive guideline for implementing a risk-based approach to registration. The guideline includes job aids for reviewers and inspectors to help with understanding of the regulatory requirements for the emergency use authorization or a No Objection Certificate. In Q4, this guideline was shared with DGDA for comments, and the program expects to finalize and disseminate the guideline during the first quarter of P2.

The program also worked closely with the NCL to strengthen testing capabilities for COVID-19 medical products and prepared a final report that mapped out the laboratory needs for COVID-19-related testing and associated costs for seven pre-registered products (favipiravir tablets, hydroxychloroquine sulfate tablets, ivermectin tablets, lopinavir and ritonavir tablets, oseltamivir phosphate capsules, remdesivir injection, and dexamethasone tablets). PQM+ analyzed these costs and observed that the average cost of testing one product is 18,996 BDT ($220 USD), but NCL charges only about 41 percent of this cost: 7,857 BDT ($91 USD). PQM+ recommended in the final report that NCL immediately revise its fee structure to help with the cost of resources needed to ensure the timely testing of medical products used in the treatment of COVID-19.

During Q4, PQM+ supported NCL to develop risk-based testing protocols for favipiravir tablets and dexamethasone tablets, which are widely used for the treatment of COVID-19 in

Bangladesh. This activity will assist DGDA with conducting PMS of these products to ensure they are of quality and safe for patient use.

## Pakistan

*Technical Area 1. Regulatory system strengthening support to respond to COVID-19 and future public health emergencies*

PQM+ is working to improve access to new treatments, medical products, and technologies through risk-based emergency use authorization regulatory approvals from DRAP reference countries. This quarter, the PQM+ team completed a desk review of the best international practices and guidelines related to medical devices and medical products and shared the report with DRAP. The DRAP medical board has reviewed the emergency use authorization guidelines and has been customizing them for local needs, including issuing temporary registration for potassium iodide (nuclear medicines for local production) tablets following the remdesivir emergency use authorization temporary registration. PQM+ and DRAP also discussed the implementation and monitoring mechanism of all items approved under emergency use authorization by stringent regulatory authorities. The decision was made to track and keep a record of all emergency use authorization medical products issued. PQM+ suggested that DRAP devise a mechanism to collect data on emergency use authorization-granted products, including reports on clinical settings. Moreover, mechanisms should be in place to recall and reconcile the stock in case of severe adverse events and/or after the expiration of emergency use authorization validity.

*Technical Area 2. Uninterrupted access to quality-assured medical products during the COVID-19 pandemic and future public health emergencies*

Under this technical area, PQM+ Pakistan is looking to support DRAP in conducting fast-track QC testing of priority medical products for COVID-19. During Q4, the PQM+ team completed mapping the equipment required for PPE testing and shared the list of needed equipment with the Central Drug Testing Laboratory. PQM+ also met with the executive director of the National Institute of Health regarding the adoption of WHO/EU/FDA/ISO PPE standards as national PPE standards. The team is also looking to provide regulatory support to DRAP and contract research organizations on COVID-19-related bioequivalence studies. This quarter, PQM+ shared the WHO draft terms of reference for the National Bioethics & Review Committee (Institutional Review Board/Central Review Board) with DRAP and expects to receive DRAP's response after their internal consultation.

*Technical Area 3. Private Sector Engagement (PSE) to address COVID-19 emergency*

To address the COVID-19 emergency, PQM+ Pakistan needs to engage private sector laboratories to test PPE and local private sector manufacturers to manufacture quality-assured PPE and remdesivir. In Q4, PQM+ worked with the Prime Lab in Islamabad to conduct a gap analysis of their staffing, equipment, and standards. The team consulted with the Prime Lab on their draft PPE standards. In addition, PQM+ received an expression of interest from one of the private sector laboratories to start PPE testing. Furthermore, this is Pakistan's first WHO-PQ lab in the private sector.

PQM+ also completed a mapping of PPE manufacturers in Pakistan to prepare a request for an expression of interest from these manufacturers. From this mapping, the team identified two major PPE manufacturers, Greys and Anwer Khawaja Composite, based in Sialkot. They have shown keen interest in PQM+ assistance in obtaining certification for the manufacturing of N-95 masks, special surgical masks, face shields, and protection suits, per international standards.

They have also shared details of all the equipment they recently imported and invited the PQM+ team to visit for a needs assessment/gap assessment next week. Anwer Khawaja Composite leadership has requested PQM+ technical assistance to register their products with DRAP as the first PPE registered manufacturer. Moreover, they have shown interest in PQM+ technical assistance for market access of their PPE products outside Pakistan, especially for the United States, by securing USFDA approval.

PQM+ is working with Ferozsons Laboratories to support remdesivir local production and WHO-PQ. In Q4, the team discussed the stability requirements and the expectation of stability data submission to DRAP and WHO-PQT with Ferozsons' leadership team. PQM+ is also supporting the lab in establishing an uninterrupted supply of active pharmaceutical ingredients to manufacture remdesivir as a finished pharmaceutical product. PQM+ advised Ferozsons to use two approved sources of active pharmaceutical ingredients, one from India and the other from China. Ferozsons is conducting stability studies on the product manufactured from both sources, as advised by PQM+ in line with DRAP/WHO stability data requirements.

In addition, PQM+ provided guidance to technical staff on how to compile a quality overall summary from the beginning steps, such as product development, stability data, and method validation. On September 18, the PQM+ team visited the Ferozsons remdesivir production facility for document verification and discussion about its progress. Moreover, the PQM+ team has developed and shared the WHO-PQ project milestone template, which encompasses a list of key documents, timelines for product development, completion of dossier, and submission. The PQM+ team visited the Ferozsons Manufacturing Facility at Lahore to assess its compliance with GMP principles. The assessment included a survey of the premises, equipment, documentation, materials, validation, sanitation and hygiene, production, and QC, utilities, water system, and air handling unit.

*Technical Area 4. Strengthening of public sector diagnostic laboratories' testing quality*

To strengthen public sector testing, PQM+ will introduce and implement a QMS in the Pakistan Institute of Medical Science public diagnostic laboratory. This quarter, the PQM+ team drafted an internal monitoring checklist based on WHO Guidelines for the Stepwise Laboratory Improvement Process Towards Accreditation, which will help both the lab and PQM+ monitor the implementation of a QMS. To support the lab in its ISO 15189 accreditation, PQM+ requested an expression of interest from the ISO 15189 consulting firms, selected the firm, and is in the process of contracting.

*Technical Area 5. Risk-based post-marketing surveillance of COVID-19 medical products*

PQM+ plans to conduct a consultative meeting to develop a risk-based PMS plan for COVID-19 products based on the existing risk-based PMS framework with DRAP and regulatory systems in the provinces. In Q4, the PQM+ team shared the list of proposed COVID-19-related medical products for risk-based PMS with DRAP. DRAP appointed a focal person for the project, who will coordinate with PQM+ and the provinces to conduct a consultative workshop for the risk-based PMS of selected COVID-19 response products. PQM+ also needs to build the capacity of public sector tertiary care hospitals for in-house manufacturing of alcohol-based hand rub. During this quarter, the initial assessment of the Pakistan Institute of Medical Sciences facility for alcohol-based hand rub was conducted. This included the production area layout planning and equipment requirements. PQM+ finalized the equipment list required to start the production of alcohol-based hand rub at PIMS. The plan has been shared with WHO Pakistan, which will procure the equipment for the Pakistan Institute of Medical Science. Once the equipment is installed, PQM+ will train staff on production.

### Serbia

In August 2020, PQM+ began to work with the Government of Serbia to respond to the COVID-19 pandemic by exploring options for external evaluation and market entry of their enzyme-linked immunosorbent assay (ELISA) test kit. This is produced by the Institute for the Application of Nuclear Energy (INEP) at the University of Belgrade, Serbia, for regional and/or international markets. The INEP hopes to increase investment in and expand manufacturing should sufficient market opportunities exist. Specifically, PQM+ was tasked with:

- Providing assistance to the INEP for third-party performance validation/evaluation of the ELISA COVID-19 test
- Implementing a market demand/competitiveness assessment of the ELISA kit

In Q4, PQM+ held several planning meetings between USAID and the INEP to discuss activities for the program. PQM+ drafted and submitted a work plan to the USAID agreement officer's representative team. Then PQM+ hosted introductory calls between the INEP and The London School of Hygiene and Tropical Medicine's International Diagnostics Centre (LSHTM IDC), a technical resource partner on the PQM+ program, and the Global Health Impact Group (GHIG). Both the LSHTM IDC and the GHIG will work with PQM+ to provide technical assistance to the INEP for third-party independent validation/evaluation of its ELISA test kit as well to conduct a market demand and competitiveness assessment to identify potential markets/countries for registration.

To initiate activities, PQM+ drafted a nondisclosure agreement between USP and the INEP. The nondisclosure agreement has been reviewed legally by both parties and is in the process of being signed. PQM+ is also working on awarding a contract to the GHIG, which will manage the operational and financial side of LSHTM IDC's work. Finally, on September 30, PQM+ hosted a technical call with the INEP, the GHIG and the LSHTM IDC to discuss next steps. During the meeting, the team discussed the INEP's vision of how the ELISA test will be commercialized, its capacity to increase manufacturing, the operations of sending test kits to laboratories, and information that the INEP needed to share so that the assessments could start.

## New Buy-Ins

Table 2 provides a summary of discussions with USAID and national stakeholders and work planning for funding received over the course of the year, as well as initial discussions on new buy-ins projected for FY21. These include Benin, Burkina Faso, Cameroon, DRC, Ghana, Guinea, Madagascar, Rwanda, Tajikistan, and the IGAD in East Africa. PQM+ will discuss priority activities and draft work plans for these portfolios in FY21.

Table 2. Summary Discussions with USAID for Priority Activities for Future Funding

| USAID Team | Summary and Next Steps |
|---|---|
| **Asia Regional Bureau** | PQM+ submitted the full Asia Regional Bureau work plan, received feedback from USAID, and submitted a revised work plan. PQM+ also received concurrence from USAID/India for the development of an online current GMP course for manufacturers in India and the Southeast Asia region in collaboration with MTaPS, WHO, USAID India, and JSS University. Over the course of Q4, PQM+ technical staff met on several occasions with MTaPS, WHO, and JSS University to discuss course content and development. |
| **Benin** | PQM+ met with the USAID Mission and discussed priority activities for the country, including strengthening the NQCL to conduct routine PMS testing of antimalarials. Based on this discussion, PQM+ submitted a work plan to USAID and received feedback. A revised work plan was submitted at the end of Q4. PQM+ has also initiated recruitment of an in-country consultant. |
| **Burkina Faso** | PQM+ submitted a work plan to USAID, received feedback, and submitted a revised version in Q4. At the end of the quarter, PQM+ hired an in-country consultant who has been collecting information to lay the groundwork for smooth implementation once the work plan is fully approved. |
| **Cameroon** | PQM+ held discussions with USAID regarding priority activities that will be initiated once funds are obligated. |
| **DRC** | PQM+ held discussions with USAID regarding priority activities that will be initiated once funds are obligated. |
| **Ghana** | PQM+ submitted a work plan to USAID, received feedback, and submitted a revised version in Q4. |
| **Guinea** | PQM+ met with USAID Guinea to discuss forthcoming funding and areas of needed support. PQM+ shared the final report and transition plan developed under PQM with the Mission. The Mission offered to have an initial meeting with the national regulatory authority to discuss its priorities. PQM+ hopes to submit a work plan in the first quarter of PY2. |

| USAID Team | Summary and Next Steps |
|---|---|
| **Madagascar** | PQM+ held discussions with USAID regarding priority activities that will be initiated once funds are obligated. |
| **Rwanda** | At the end of Q4, PQM+ met with USAID/Rwanda to discuss forthcoming funding and priority activities. PQM+ was asked to review the scope of work prepared during the previous quarter and submit any additional comments. PQM+ will review the scope of work and send any updates early in Q1 of PY2. |
| **Tajikistan** | At the end of Q4, PQM+ met with USAID to discuss forthcoming funding for Tajikistan and priority activities. PQM+ plans to submit a work plan during Q1 of PY2. |

## Progress by Health Elements

### Core Maternal and Child Health


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 MCH work plan was approved April 20, 2020. PQM+'s activities for core MNCH fall under PQM+ objectives 2 and 4. During its first six months, the program:

- Administered a survey in eight countries (Bangladesh, Ethiopia, Ghana, Kenya, Mali, Mozambique, Nepal, and Nigeria) to understand the regulatory authority's PMS system organization and processes, including how decisions are made for MNCH product PMS.
- Developed the first draft of the risk-based categorization guidance document for PMS of MNCH medical products.
- Continued quarterly collaboration meetings with the UNICEF supply division to exchange information to advance MNCH medical products supply.

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

Medicines regulatory authorities are responsible for conducting PMS of essential medicines to detect and remove substandard or falsified medicines from circulation in the local markets. Because the PMS process is resource intensive, the PQM program 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 fiscal year, PQM+ developed and administered an assessment in eight countries where the PQM+ program is present (Bangladesh, Ethiopia, Ghana, Kenya, Mali, Mozambique, Nepal, and Nigeria) to determine the PMS status of MNCH products. The focus of the assessment included probing about existing procedures and practices for PMS and about the decision-making process to include MNCH products in annual PMS activities. During this quarter, the collected country data were reviewed and analyzed. A draft summary report was prepared. The next steps for this activity are to finalize and disseminate the summary report.

PQM+ was also asked to develop a risk-based categorization guidance document for MNCH products. This guidance document will explain how to define probability and impact risks for priority MNCH products and will make it easier for countries to develop sampling plans using the MedRS tool. This quarter, based on the preliminary information collected from countries on PMS, PQM+ finalized the draft of the PMS risk-based categorization guidance document.

PQM+ is developing user-friendly job aids for three product information reports (PIRs) that were developed under the PQM program for chlorhexidine digluconate (7.1 percent) gel, oxytocin injection, and amoxicillin. PIRs documents provide critical technical information and guidance related to the manufacture of medicines that are of global public health importance. Each PIR synthesizes available physicochemical, pharmacokinetic, toxicological, and other information for a product and analyzes key manufacturing challenges. PIRs are intended to support informed decision-making regarding product development, scale-up, and manufacturing by proactively identifying and addressing potential manufacturing issues.

PQM+ is working on developing user-friendly job aids to support decision-making for regulatory activities, such as registration (i.e., synthesizing information required for dossier review in CTD format) and inspections (i.e., prioritized areas to assess during manufacturer audits). The first two draft job aids are expected next quarter.

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

UNICEF is one of the main suppliers of 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 increasing local sources of MNCH products through information-sharing sessions. These sessions facilitate collaboration and PQM+ technical assistance efforts to local manufacturers.

This quarter, PQM+ conducted a desktop research using pharmaceutical databases such as Cortelis Regulatory Intelligence to identify manufacturers in the Africa region working on amoxicillin. PQM+ developed a scope of work and commenced the procurement and

contracting process to engage a PQM+ core flex partner, Muhimbili University in Tanzania, that will support the landscape analysis for amoxicillin dispersible tablets in the Africa region.

Earlier this year, PQM+ met with the UNICEF supply division team to discuss key challenges and supply implications for MNCH medicines in LMICs during COVID-19. They also discussed modalities for information sharing and exchanged information in areas of shared interest. 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 that want to achieve WHO-PQ. Historically, the uptake of amoxicillin dispersible tablets in countries has been slow, and the local "proximate" supply of quality-assured amoxicillin dispersible tablets has been inadequate; that is, the supply is not as close to the user/clients as needed. To increase local supply of quality-assured amoxicillin dispersible tablets, PQM+ is conducting a landscape analysis of amoxicillin dispersible tablet manufacturers throughout Africa to identify potential and existing manufacturers for these tablets. PQM+ developed the purpose statement and research questions for this landscape analysis. A technical meeting was held virtually with the UNICEF team to inform the research questions. The purpose statement and research questions were then discussed with the USAID MNCH team to ensure that all priority areas were captured.

## Core Neglected Tropical Diseases


The 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.

The NTD work plan was approved September 8, 2020. PQM+'s activities fall under 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+ uses a systems strengthening approach to build local organizational and individual capacity of pharmaceutical manufacturers to achieve this goal. During the first year, PQM+ continued to work with two manufacturers for albendazole and praziquantel finished pharmaceutical product toward achieving WHO-PQ.

### Progress by PQM+ Objective

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

This quarter, PQM+ finalized key priority activities for inclusion in the PY1/2 work plan with input from USAID's NTD team. PQM+ also continued to support the India-based manufacturer Mepro Pharmaceutical Private Limited to manufacture quality-assured albendazole 400 mg chewable tablets for WHO-PQ approval. The predecessor PQM program provided support to the manufacturer for this product to achieve WHO-PQ. The manufacturer successfully completed bioequivalence studies for albendazole tablet, and a pre-submission meeting was held with WHO on July 24, 2020. The WHO-PQ team accepted all of the requirements submitted, including the bioequivalence study and stability study outcome. WHO asked the manufacturer to provide additional information before proceeding to full dossier submission. PQM+ is supporting

the manufacturer to address the requirements from the WHO-PQ team. PQM+ is also helping the company compile the full product dossier for submission for WHO-PQ.

PQM+ also supported the manufacturer Medopharm Pharmaceutical Private Limited to manufacture quality-assured praziquantel 600 mg film-coated tablets toward WHO-PQ. Under the PQM program, the praziquantel medical product dossier was finalized and submitted to the WHO-PQ team in September of 2019. WHO prescreened the dossier and accepted it for evaluation in November 2019. WHO asked for additional data from the manufacturer and the contract research organization facility that conducted the bioequivalence study. After review, the WHO-PQ team approved the bioequivalence study. WHO continued reviewing the quality part of the dossier. The PQ team sent a request for information letter to the manufacturer in late July 2020. PQM+ has worked with the manufacturer to understand and respond to the questions. Medopharm submitted responses to WHO-PQ in September 2020 and is awaiting feedback.

PQM+ began detailed activity planning for the PY2 work plan and allocated resources to begin implementation of PY2 activities.

# Program Support

## Monitoring, Evaluation, and Learning

PQM+ has an approved program-wide MEL plan designed to capture performance under all objectives and subobjectives in the PQM+ Results Framework. The MEL plan includes indicators (and their corresponding Performance Indicator Reference Sheets) that are used by PQM+ buy-ins and the program globally. Individual buy-ins/projects have buy-in-specific MEL plans that include a subset of the program indicators to reflect the planned work per their approved work plans.

The table in Annex A shows results for PY1 for PQM+ globally and for countries that had approved work plans in PY1. Results are organized by objective and subobjective and reported by country. Where baseline data have been collected, baseline values are included in the table.

Following the table is a discussion of each indicator that provides additional detail on or interpretation of the reported results.

COVD-19-related travel limitations inhibited many teams' ability to visit supported sites to capture data needed for some indicators. Travel limitations also inhibited some teams' ability to establish the working relations that facilitate counterparts' willingness to share sensitive regulatory information with PQM+ teams. These factors limited PQM+'s ability to collect and report data for some indicators.

## Communications

During the fourth quarter, PQM+'s communications activities continued to expand as the program activities ramped up. Highlights include:

- PQM+ launched and disseminated the first issue of its newsletter, which will provide a concise, quarterly round-up of activities and progress. It will be an efficient vehicle for sharing new tools, resources, and information with key audiences.

- PQM+ developed a webinar series aimed at USAID staff and designed for a lay audience to help them better understand medical products QA systems and their connection to USAID global health programs. The first webinar will cover “How do medical product QA systems affect your health program?” It will be November 17, 2020.
- PQM+ revised the Malaria Health Element fact sheet. The text was finalized and approved by USAID. It is with USP’s design team and will be disseminated in PY2 Q1.
- PQM+ is developing program social media handles on Twitter, Facebook, and LinkedIn. These will be separate from the USP handles that the program has been using. The new PQM+ handles will be rolled out early in PY2.
- The senior communications manager attended the Central Asia Republic Mission’s social media and communications virtual training. She then met with PQM+’s Central Asia Republic’s team to discuss content ideas for the Mission. She also worked with the Burma Chief of Party to develop social media content in response to a Mission request.
- PQM+ developed several social media posts to highlight the successful global uptake of the foundations of the GMP e-learning course.
- The senior communications manager also gave an orientation to Pakistan’s new monitoring and evaluation and communications specialist and is working to familiarize him with PQM+ communications activities and needs.

## Annex A – MEL Reporting

The table that follows shows results for PY1 for PQM+ globally and for countries that had approved work plans in PY1. Results are organized by objective and subobjective and reported by country buy-in. Note that country or core buy-ins select indicators that reflect the focus of their programs, so that no country reports on all of the indicators included in PQM+'s overall MEL plan. Also, only indicators for which there were results in PY1 are included in the table. Where baseline data have been collected, baseline values are included. If a cell in the baseline column is blank, that means no baseline values exist for that indicator yet. If a cell in another column is blank, that means there were no results to report for that indicator that quarter.

Table 3. PQM+ FY 2020 M&E Indicator Results

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| **Objective 1: Governance for medical product quality assurance systems strengthened** | | | | | | | |
| **1.1 Evidence-based medical product quality assurance legislation, policies, and regulations developed/updated and/or implemented** | | | | | | | |
| **1.1a. # of policies, laws, regulations, and guidelines on medical product quality assurance that were developed or revised with PQM+ support and submitted for adoption** | | | | | | | |
| Bangladesh<br>• National Quality Assurance Guidelines<br>• Guidelines on a Risk-Based Approach to Registration of COVID-19 Medical Products | | 0 | | | | 2 | 2 |
| Ethiopia<br>• Guidelines for Registration of Medicines<br>• Risk-Based Guideline for PMS | | 0 | | | 2 | | 2 |
| Kenya<br>• QA Framework for Malaria Commodities | | 0 | | | | 1 | 1 |
| Mali<br>• National Guidance for RB-PMS | | 0 | | | | 1 | 1 |
| Pakistan<br>• BioPharma Strategy Concept<br>• Roadmap for Adopting ISO Identification of Medicinal Products (IDMP)<br>• Establishment Licensing Regulations & Inspection System (Product Lifecycle)<br>• Guidelines on Emergency Use Authorization of Medical Devices<br>• Updated Good Review Practice Guidelines<br>• Updated Conflict of Interest Guidelines | | 0 | 1 | | 3 | 2 | 6 |
| Senegal<br>• National Guidance for RB-PMS | | 0 | | | | 1 | 1 |
| | *Total: 1.1a # of new regulatory policies* | | 1 | | 5 | 7 | 13 |
| Regulatory guidelines were the most common type of regulatory policy submitted, with four of those focused on guidelines for risk-based regulatory approaches. | | | | | | | |
| **1.4 Links among the medical product quality assurance systems and other sectors developed and fortified** | | | | | | | |
| **1.4a. % of core functional components in place for a multisectoral group supported by PQM+ to advance medical product quality assurance** | | | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| Kenya | | 0% | | | | 70% | |
| Mali | | 0% | | | | 100% | |
| Nigeria | | 0% | | | | 10% | |
| Senegal | | 0% | | | | 100% | |
| Four countries worked to establish functioning multisectoral groups to advance medical product quality assurance (e.g., Technical Working Groups on risk-based post-marketing surveillance). All started from a baseline of zero. By the end of the year, multisectoral groups in two countries (Mali and Senegal) were fully functional with all five components in place: (1) a coordination framework, (2) a chairperson in place, (3) regular meetings per the planned schedule, (4) meeting minutes distributed, and (5) the majority of participating agencies in attendance at the majority of meetings. | | | | | | | |
| **Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved** | | | | | | | |
| **2a. % of medical products assessed by a PQM+-supported MRA through post-marketing surveillance that failed to pass a QC test (scores averaged across product types)** | | | | | | | |
| Burma - % of products assessed (n = 989) that failed QC tests<br>• Malaria: 1%<br>• Other: 7% | | 0 | | | 6% | | |
| Ethiopia - % of products assessed (n = 40) that failed QC tests<br>• COVID-19/hand sanitizer: 23% | | 0 | | | | 23% | |
| Nepal - % of products assessed (n = 51) that failed QC tests<br>• FP/RH: 9%<br>• MNCH: 25% | | 0 | | | | 12% | |
| There were post-marketing surveillance results from three countries. While PQM+ did not support post-marketing surveillance activities in Burma and Nepal in FY2020, those results are shown here. Additionally, the MRA of Ethiopia conducted PMS of a limited number of samples (40) of hand sanitizer used for COVID-19 in a limited number of locations. | | | | | | | |
| **2b. WHO GBT maturity level of PQM+-supported MRA** | | | | | | | |
| Bangladesh<br>• In market surveillance and control<br>• In laboratory testing | | 1<br>1 | | | | | |
| Kazakhstan<br>• In registration and marketing authorization<br>• In market surveillance and control<br>• In regulatory inspection | | 2<br>2<br>1 | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| • | In laboratory testing | 2 | | | | | |
| **2.1 Sustainable systems for market authorization/ registration, inspection, and licensing functions of medical product regulatory agencies improved** | | | | | | | |
| **2.1b.1. Score on institutionalization of quality checklist for dossier review at PQM+-supported MRA** | | | | | | | |
| Kazakhstan | | 50% | | | | 50% | |
| Uzbekistan | | 12.5% | | | | 12.5% | |
| PQM+ has numerous indicators that track the extent to which our counterparts have institutionalized use of new approaches or tools that PQM+ has introduced to improve their performance. "Institutionalization" for this and other institutionalization indicators means the counterpart has the following in place to ensure its ongoing implementation of the new approach or tool:<br>(1) SOPs that reference use of the approach or tool;<br>(2) a training program that the counterpart uses to train its staff to use the approach or tool;<br>(3) supportive supervision of staff use of the approach or tool; and<br>(4) performance indicator(s) to track use of or results from use of the approach/tool.<br>In two countries (Kazakhstan and Uzbekistan), PQM+ started working to help the MRA institutionalize use of a dossier quality checklist when reviewing registration applications. The baseline and year-end scores for institutionalization of this tool were 50% (4 of 8 possible points) and 12.5% (1 of 8 possible points), respectively. | | | | | | | |
| **2.1b.P-3. Score on institutionalization of Emergency Use Authorization (Pakistan)** | | | | | | | |
| Pakistan | | 0% | | | | 25% | |
| PQM+ in Pakistan started working to institutionalize Emergency Use Authorization to support the government's response to the coronavirus pandemic. PQM+ helped the regulatory agency develop SOPs and a system to capture performance information from procurers, to achieve a score of 25% (2 of 8 possible points) for institutionalizing this important regulatory approach. | | | | | | | |
| **2.1c. # of recommendations for the facility inspection regulatory function in the country's Institutional Development Plan (IDP) that were completed with PQM+ support** | | | | | | | |
| Pakistan | | 0 | | | | 11 | 11 |
| PQM+ is working to help the MRA of Pakistan address recommendations in the WHO GBT IDP for the facility inspection regulatory function. This year, PQM+ helped the MRA address 11 of these recommendations. | | | | | | | |
| **2.1g. Average duration of the scientific assessment phase of medical product registration for the PQM+-supported MRA (annual average)** | | | | | | | |
| Kazakhstan | | 110 | | | | | |
| Uzbekistan | | 65 | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| The average duration of the registration scientific assessment phase was reported as 110 days by the MRA in Kazakhstan and 65 days by the MRA in Uzbekistan. These are considered baseline values. | | | | | | | |
| **2.1i. % of milestones to prepare for PIC/S accession achieved by the MRA with PQM+ support** | | | | | | | |
| Bangladesh | | 0% | | | | 20% | |
| Kazakhstan | | 10% | | | | 22% | |
| Uzbekistan | | 0% | | | | 10% | |
| PQM+ is helping the regulatory authorities of Bangladesh, Kazakhstan, and Uzbekistan pursue accession to PIC/S. PQM+ technical specialists develop plans with milestones toward this end. All three countries made progress in completing milestones in FY2020 toward the long-term goal of PIC/S accession. While each was able to report progress in achieving the milestones in its individual plan, the milestones and method of calculating this indicator was not necessarily consistent across all three countries. | | | | | | | |
| **2.2 Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity** | | | | | | | |
| **2.2b. # of methods for which the laboratory received accreditation, WHO pre-qualification, or re-accreditation with PQM+ support (total # of methods across all PQM+-supported laboratories in the country)** | | | | | | | |
| WHO PQ | | | | | | | |
| | Bangladesh | 0 | | 19 | | | 19 |
| | Kazakhstan | 0 | | 8 | | | 8 |
| | Pakistan | 0 | | 7 | | | 7 |
| ISO 17025 | | | | | | | |
| | Bangladesh | 0 | | | | 10 | 10 |
| | Burma | 0 | 10 | | | | 10 |
| | Kazakhstan | 0 | 25 | | | | 25 |
| | Nigeria | 0 | | 65 | 6 | | 71 |
| National accreditation | | | | | | | |
| | Kazakhstan (dosage forms) | 0 | | | 30 | | 30 |
| | Uzbekistan (dosage forms) | 0 | 56 | | 105 | | 161 |
| An important PQM+ intervention is strengthening MRA's QC laboratories to test the quality of medical products in their countries. ISO accreditation (or periodic reaccreditation) or WHO prequalification (PQ) are evidence that respected international bodies have assessed the laboratory's performance and attested to the quality of the laboratory's work. Laboratories get accredited or pre-qualified for specific laboratory methods. The table above shows the ISO accreditations, reaccreditations, WHO PQ, and in the case of Kazakhstan and Uzbekistan, national | | | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| recognition of the laboratories' performance for countries that occurred this year. Note that accreditations and prequalifications do not happen annually, so there are other PQM+-supported laboratories that have achieved this recognition but did not need recertification this year. Other laboratories that are newly supported by PQM+ have not yet attained this important milestone. | | | | | | | |
| **2.2c.1. Score on institutionalization of training program at PQM+-supported QC laboratories (scores averaged across supported laboratories in the country)** | | | | | | | |
| Burma | | 16.7% | | | | 20.8% | |
| Kazakhstan | | 75% | | | | 75% | |
| Uzbekistan | | 18.8% | | | | 18.8% | |
| In three countries (Burma, Kazakhstan, and Uzbekistan), PQM+ started working to help QC laboratories institutionalize training programs for their staff. The baseline scores for institutionalization of training programs averaged across all supported QC laboratories in those countries were 16.7%, 75%, and 18.8%, respectively. By the end of the year, there was a modest improvement in the score for QC laboratories in Burma. Note that, in many cases, these scores are self-reports given the inability of PQM+ QC laboratory experts to visit laboratories due to travel restrictions. | | | | | | | |
| **2.2c.2. Score on institutionalization of preventive maintenance program at PQM+-supported QC laboratories (scores averaged across supported laboratories in the country)** | | | | | | | |
| Bangladesh | | 25% | | | | 25% | |
| Kazakhstan | | 75% | | | | 75% | |
| Uzbekistan | | 18.8% | | | | 18.8% | |
| In three countries (Bangladesh, Kazakhstan, and Uzbekistan), PQM+ started working to help QC laboratories institutionalize preventive maintenance programs for their equipment. The baseline scores for institutionalization of these programs averaged across all supported QC laboratories in those countries were 25%, 75%, and 18.8%, respectively. These scores did not change over the course of the year. Note that, in many cases, these scores are self-reports given the inability of PQM+ QC laboratory experts to visit laboratories due to travel restrictions. | | | | | | | |
| **2.2c.3. Score on institutionalization of calibration program at PQM+-supported QC laboratories (scores averaged across supported laboratories in the country)** | | | | | | | |
| Bangladesh | | 50% | | | | 50% | |
| Burma | | 25% | | | | 25% | |
| Kazakhstan | | 75% | | | | 75% | |
| Uzbekistan | | 31.3% | | | | 31.3% | |
| In four countries (Bangladesh, Burma, Kazakhstan, and Uzbekistan), PQM+ started working to help QC laboratories institutionalize calibration programs for their equipment. The baseline scores for institutionalization of these programs averaged across all supported QC laboratories in | | | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| those countries were 50%, 25%, 75% and 31.3%, respectively. These scores did not change over the course of the year. Note that, in many cases, these scores are self-reports given the inability of PQM+ QC laboratory experts to visit laboratories due to travel restrictions. | | | | | | | |
| **2.2c.4. Score on institutionalization of competency assessment program at PQM+-supported QC laboratories (scores averaged across supported laboratories in the country)** | | | | | | | |
| Bangladesh | | 25% | | | | 25% | |
| Burma | | 16.7% | | | | 20.8% | |
| Kazakhstan | | 75.% | | | | 75.% | |
| Uzbekistan | | 37.5% | | | | 37.5% | |
| In four countries (Bangladesh, Burma, Kazakhstan, and Uzbekistan), PQM+ started working to help QC laboratories institutionalize competency assessment programs for their staff. The baseline scores for institutionalization of these programs averaged across all supported QC laboratories in those countries were 25%, 16.7%, 75% and 37.5%, respectively. By the end of the year, the score for QC laboratories in Burma improved. Note that, in many cases, these scores are self-reports given the inability of PQM+ QC laboratory experts to visit laboratories due to travel restrictions. | | | | | | | |
| **2.2c.5. Score on institutionalization of internal performance review at PQM+-supported QC laboratories (scores averaged across supported laboratories in the country)** | | | | | | | |
| Bangladesh | | 50% | | | | 50% | |
| Burma | | 20.8% | | | | 25% | |
| Kazakhstan | | 75% | | | | 75% | |
| Mali | | 0% | | | | 75% | |
| Senegal | | 0% | | | | 75% | |
| Uzbekistan | | 25% | | | | 25% | |
| In six countries (Bangladesh, Burma, Kazakhstan, Mali, Senegal, and Uzbekistan), PQM+ started working to help QC laboratories institutionalize internal performance review programs. The baseline scores for institutionalization of internal performance review programs averaged across all supported QC laboratories in those countries were 50%, 20.8%, 75%, 0%, 0%, and 25%, respectively. By the end of the year, there was some improvement in the score for QC laboratories in most countries, most notably in Mali and Senegal, which each increased from 0 to 75% (6 of 8). Note that, in many cases, these scores are self-reports given the inability of PQM+ QC laboratory experts to visit laboratories due to travel restrictions. | | | | | | | |
| **2.2c.6. Score on institutionalization of QMS at PQM+-supported QC laboratories (scores averaged across supported laboratories in the country)** | | | | | | | |
| Bangladesh | | 50% | | | | 50% | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| Burma | | 20.8% | | | | 20.8% | |
| Kazakhstan | | 75% | | | | 75% | |
| Uzbekistan | | 25% | | | | 25% | |
| In four countries (Bangladesh, Burma, Kazakhstan, and Uzbekistan), PQM+ started working to help QC laboratories institutionalize QMS. The baseline scores for institutionalization of QMS averaged across all supported QC laboratories in those countries were 50%, 20.8%, 75%, and 25%, respectively. These scores did not change over the course of the year. Note that, in many cases, these scores are self-reports given the inability of PQM+ QC laboratory experts to visit laboratories due to travel restrictions. | | | | | | | |
| **2.2g. # of proficiency tests or inter-laboratory tests passed by the PQM+-supported QC laboratory** | | | | | | | |
| Bangladesh | | | | | | 7 | 7 |
| Burma | | | | | | 2 | 2 |
| Kazakhstan | | | | | 6 | 2 | 8 |
| Mali | | | 7 | | | | 7 |
| Nigeria | | | | | | 6 | 6 |
| | *Total # of methods for which laboratories reported passing PT or ILT* | | | | | | 30 |
| QC laboratories participate in proficiency testing (PT) or inter-laboratory testing (ILT) schemes, which are external assessments of a QC laboratory's testing or measurement capabilities for specific laboratory methods. QC laboratories in Bangladesh, Burma, Kazakhstan, Mali, and Nigeria shared their PT/ILT results for the last year. The number of methods for which the laboratories passed a PT or ILT are shown in the table. | | | | | | | |
| **2.3 Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported** | | | | | | | |
| **2.3c. Score on institutionalization of use of a reliance method/mechanism at PQM+-supported MRA** | | | | | | | |
| Kazakhstan | | 0% | | | 12.5% | 25% | |
| Uzbekistan | | 0% | | | | 25% | |
| PQM+ started helping the MRAs of two countries (Kazakhstan and Uzbekistan) to institutionalize use of the Collaborative Registration Procedure (CRP). The baseline scores for institutionalization of this approach were 0% in both countries. By the end of the year, scores had increased to 25% in both countries. Note that while PQM+ is not reporting institutionalization of CRP by the MRA of Pakistan (DRAP), DRAP registered its first medicine (Oxytocin injection from Indonesia) using the CRP this year. This is an important step to increase efficiency and speed of some medical product registrations. | | | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| **2.5 Competence, efficiency, and expansion of the medical product quality assurance workforce improved** | | | | | | | |
| **2.5a. # of in-service training programs that address quality assurance/quality control topics delivered with PQM+ support** | | | | | | | |
| Bangladesh | | 0 | 4 | | | 1 | 5 |
| Burma | | 0 | | 1 | | 1 | 2 |
| Ethiopia | | 0 | | | | 1 | 1 |
| Kazakhstan | | 0 | | | 3 | 2 | 5 |
| Mali | | 0 | | | | 3 | 3 |
| Senegal | | 0 | | | | 3 | 3 |
| Uzbekistan | | 0 | | | 3 | 2 | 5 |
| | *Total: 2.5a # of training events delivered* | | 4 | 1 | 6 | 13 | 24 |
| PQM+ conducted training events in most supported countries in FY2020. As shown in the table, 24 training programs were delivered, some of which comprised multiple days or modules. Due to travel and meeting restrictions arising from the coronavirus pandemic, many of these trainings, especially in the last two quarters, were virtual. The most common training topics were analytical laboratory services and QMS. | | | | | | | |
| **2.5b. # of individuals who successfully completed PQM+-supported in-service training (total #/# who were female)** | | | | | | | |
| Bangladesh | | 0 | 73 / 18f | | | 8 / 2f | 81 / 20f |
| Burma | | 0 | | 35 / 33f | | 6 / 6f | 41 / 39f |
| Ethiopia | | 0 | | | | 33 / 6f | 33 / 6f |
| Kazakhstan | | 0 | | | 96 / 54f | 37 / 28f | 133/82f |
| Mali | | 0 | | | | 49 / 22f | 49 / 22f |
| Pakistan | | 0 | | | 25 / 1f | 650/18f | 675/19f |
| Senegal | | 0 | | | | 42 / 19f | 42 / 19f |
| Uzbekistan | | 0 | | | 74 / 44f | 16 / 4f | 90 / 48f |
| | *Total: 2.5b # of people who completed training event* | | 73 | 35 | 195 | 841 | 1,144 / 255f |
| More than 1,100 host country staff completed training events conducted by PQM+ in FY 2020. The numbers in the table show how many people completed training in total and how many of the trainees were female (f). As the year progressed, there was a large increase in the number of people who completed training, which was heavily influenced by some very large-scale training events in Pakistan. The percentage | | | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| of trainees who were female was higher than or comparable to the percentage of trainees who were male in Burma, Kazakhstan, Mali, Senegal, and Uzbekistan. | | | | | | | |
| **2.5c. # of training programs developed by PQM+** | | | | | | | |
| Pakistan | | 0 | | | | 1 | 1 |
| PQM+ Pakistan has a custom indicator to track the number of training programs It developed in the year. In FY2020, PQM+ Pakistan developed a training program on the Pakistan Integrated Regulatory Information Management System (PIRIMS), one of the first online integrated regulatory information management systems in the region. The regulatory agency will use PIRIMS to manage licensing, registration, and inspection data. PQM+ developed the training modules on PIRIMS and imparted trainings to officials of DRAP and the pharmaceutical industry. | | | | | | | |
| **2.5f. # of membership organizations that were strengthened in advancing members' understanding of medical product quality assurance by PQM+** | | | | | | | |
| Nigeria<br>• Pharmaceuticals Manufacturers Group of the Manufacturers Association of Nigeria | | 0 | | | | 1 | 1 |
| Uzbekistan<br>• The Pharm Association | | 0 | | | | 1 | 1 |
| | *Total: 2.5c # of membership organizations strengthened* | | | | | 2 | 2 |
| PQM+ works with an array of organizations in addition to our main host country counterparts. This serves to build constituencies for medical product quality assurance and to expand the supply of relevant services. In FY2020, PQM+ worked with two pharmaceutical manufacturers groups, working through them to reach their members efficiently and helping them build programs that will help their members improve the quality of their medical products. | | | | | | | |
| **Objective 3: Financial resources for medical product quality assurance optimized and increased** | | | | | | | |
| **3.1a.1. Score on institutionalization of risk-based approach to post-marketing surveillance at PQM+-supported MRA** | | | | | | | |
| Bangladesh | | 25% | | | | 25% | |
| Burma | | 0% | | | | 0% | |
| Ethiopia | | 0% | | | | 62.5% | |
| Kazakhstan | | 50% | | | | 50% | |
| Kenya | | 0% | | | | 0% | |
| Mali | | 0% | | | | 12.5% | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| Nepal | | 0% | | | | 0% | |
| Senegal | | 0% | | | | 25% | |
| | *Average: 3.1a.1. score on institutionalization of RB-PMS* | 9.4% | | | | 21.9% | |
| PQM+ emphasizes adoption of RB-PMS to enhance the value and efficiency of post-marketing surveillance. In addition to directly supporting RB-PMS in many countries, PQM+ started working to institutionalize this approach in many countries. As shown in the table, there was a significant increase in the number of institutionalization components that were in place by the end of the year in three of those countries (Ethiopia, Mali, and Senegal). | | | | | | | |
| **3.2.N-c. Cost savings from use of new approaches or tools supported by PQM+ at MRA** | | | | | | | |
| Nigeria | | 0 | | | | $20,000 | $20,000 |
| In FY2020, PQM+ Nigeria introduced a multi-site accreditation approach for NAFDAC laboratories. By integrating the QMS of multiple, related laboratories, NAFDAC will pursue one multi-site accreditation, rather than each member laboratory pursuing its own accreditations and paying for the accreditor's travel to each laboratory. It is estimated that this will save approximately 50% of the individual accreditation expenses, or approximately $20,000 per year. Cost reductions such as these improve the financial sustainability of the laboratories. | | | | | | | |
| **3.2b.5. PQM+-supported MRA analyzed its costs for laboratory testing to support review of the fee structure or to improve budgeting and planning** | | | | | | | |
| Bangladesh | | | | | | Yes | Yes |
| MRAs must mobilize resources, in the form of budget allocations or user fees, to fund their operations. Adequate resources allow them to pay for the staffing, infrastructure, equipment, and other inputs required to provide high quality service at the necessary scale. PQM+ helps MRAs calculate the costs of their services to inform decisions about user fee schedules or budget allocations. In FY2020, the MRA of Bangladesh analyzed the costs of its laboratory testing services. | | | | | | | |
| **Objective 4: Supply of quality-assured essential medical products of public health importance increased** | | | | | | | |
| **4c. # of new sources/market authorizations** | | | | | | | |
| Nigeria | | 0 | | 1 | | 1 | 2 |
| Building on work with manufacturers that started under PQM, several PQM+-supported manufacturers of MNCH finished pharmaceutical products (FPPs) in Nigeria achieved market authorization for their products in FY2020. Notably, WAHO approved Chlorhexidine digluconate 7.1% from a Nigerian manufacturer. This allows expedited registration of that product in all 15 member countries of ECOWAS, pending the manufacturer's payment of registration fees in those countries. Also, the Government of Nigeria authorized marketing of zinc sulphate manufactured locally. | | | | | | | |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| **4.1c. # of medical product sources supported by PQM+ (by country)** | | | | | | | |
| Bangladesh | | | | | | | 3 |
| India (under NTD buy-in) | | | | | | | 2 |
| Kazakhstan | | | | | | | 1 |
| Nigeria | | | | | | | 21 |
| Pakistan | | | | | | | 3 |
| Uzbekistan | | | | | | | 1 |
| | *Total # of new sources supported* | | | | | | 31 |
| PQM+ helps manufacturers in numerous countries improve the quality of their medical products and obtain market authorization for those products. In many cases, PQM+ helps manufacturers develop and seek authorization for multiple medical products, each of which would count as a "new source." In FY2020, PQM+ worked to develop 21 new sources of priority medical products in the countries listed above. | | | | | | | |
| **# of medical product sources supported by PQM+ (by health area)** | | | | | | | |
| COVID-19<br>• Remdesivir<br>• PPE | | | | | | | 3 |
| Malaria<br>• ALu 20/120<br>• ALu 40/240<br>• Sulfadoxine pyrimethamine 500/25 | | | | | | | 8 |
| MNCH<br>• Amoxicillin 125<br>• Amoxicillin 250<br>• Chlorhexidine digluconate 7.1%<br>• Magnesium sulfate<br>• Oxytocin<br>• Zinc sulfate | | | | | | | 13 |
| NTD<br>• Albendazole<br>• Praziquantel | | | | | | | 2 |
| TB | | | | | | | 5 |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| | • Levofloxacin<br>• Various fixed-dose combinations | | | | | | |
| | *Total # of new sources supported* | | | | | | 31 |
| In FY2020, PQM+ actively supported the development of 16 medicines of global public health priority plus personal protective equipment. PQM+ strengthened multiple suppliers of most of these medicines (with each combination of a manufacturer and a medicine counting as one "new source"), as shown in the table. | | | | | | | |
| **4.4a. # of medicines policies, laws, regulations, guidelines, or procedures developed or revised to incorporate quality assurance requirements with PQM+ support** | | | | | | | |
| Kenya<br>• Health Products & Technologies Supply Chain Strategy | | 0 | | | | 1 | 1 |
| **Objective 5: Global medical product quality assurance learning and operational agenda advanced** | | | | | | | |
| **5.1a. # of new medical product quality assurance or regulatory tools with tested efficacy supported by PQM+** | | | | | | | |
| Video-recorded trainings on laboratory methods (developed and shared in order to continue to support laboratory training when in-person training was not possible due to COVID-19 travel restrictions) (Developed by USP-Ghana; first used by PQM+ Mali) | | 0 | | | | 1 | 1 |
| A Human Resources Assessment Tool for regulatory authorities/QC laboratories (tested in Mali) | | 0 | | | | 1 | 1 |
| PPE supplier database (developed by and being tested in Bangladesh) | | 0 | | | 1 | | 1 |
| Visual inspection checklists for fabric masks, surgical masks, N95/KN95 masks (developed by and being tested in Bangladesh) | | 0 | | | | 3 | 3 |
| Guidance on quality requirements for procurement of gowns, coveralls, fabric masks (developed by and being tested in Bangladesh) | | 0 | | | | 3 | 3 |
| Job aides for PPE market authorization reviewers and inspectors (developed by and being tested in Bangladesh) | | 0 | | | | 1 | 1 |
| Risk-based testing protocol for COVID-19 products (Favipiravir and Dexamethasone) (developed by and being tested in Bangladesh) | | 0 | | | | 2 | 2 |
| Guidance for EUA of ventilators (developed by and being tested in Bangladesh) | | 0 | | | | 1 | 1 |
| Guidance on risk-based approach to COVID-19 product registration (developed by and being tested in Bangladesh) | | 0 | | | | 1 | 1 |
| Report on QC lab costs to test priority COVID-19 medicines (hydroxychloroquine tablet, dexamethasone tablet, ivermectin tablet, oseltamivir | | 0 | | | | 1 | 1 |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| | capsule, lopinavir/ritonavir tablet, favipiravir tablet, remdesivir injection) (developed by and being tested in Bangladesh) | | | | | | |
| | PQM+ works to develop new approaches and tools that can improve medical product quality, enhance efficiency, or improve sustainability. Two innovative new tools developed and tested this year are listed above. As well, PQM+ worked to develop and roll out numerous new tools to support the manufacture, authorization, and inspection of COVID-19 medical products (personal protective equipment and medicines). | | | | | | |
| | **5.2a and c. # of technical publications/presentations that were authored by PQM+ or to which PQM+ contributed** | | | | | | |
| | Ethiopia<br>• Presentation: COVID-19 Pandemic & National Logistics Preparedness for Ensuring Access to Quality Assured Medical Products: Role of Pharmacists & the Way Forward | 0 | | | | 1 | 1 |
| | Kazakhstan<br>• Presentation: Prequalification Program of Quality Control Laboratories<br>• Presentation: Overview of Risk-Based Post-Marketing Surveillance<br>• Presentation: WHO Prequalification Process | 0 | | 1 | 1 | 1 | 3 |
| | Kenya<br>• Publication: QA Framework for the National Malaria Program | 0 | 1 | | | | 1 |
| | Pakistan<br>• Presentation: Roadmap for Implementation of Identification of Medicinal Products (IDMP) Standards in Pakistan<br>• Presentation: Deployment and training of PIRIMS<br>• Consultative Meeting on Establishment Licensing Regulations & Inspection System (Product Lifecycle) (contributing author) | 0 | | | 1 | 2 | 3 |
| | Uzbekistan<br>• Presentation: WHO Prequalification Process | 0 | | | 1 | | 1 |
| | Global<br>• Presentation: Pharmaceutical Quality at the Global Level<br>• Presentation: The Role of Local Production as a Response to COVID-19<br>• Presentation: Overview of GBT for USAID (contributing author)<br>• Publication: National Academies of Sciences 2020 Consensus Report on Stronger Food & Regulatory Systems Abroad (contributor/reviewer) | 0 | 1 | | 2 | 1 | 4 |
| | *Total: # of technical publications/presentations authored by PQM+ or to which PQM+ contributed* | | 2 | 1 | 5 | 5 | 13 |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| **5.2d. # of pageviews of PQM website or PQM+ webpage content** | | | 10,816 | | 10,601 | | 21,147 |
| There were 10,816 page views of content accessible via the PQM website or PQM+ webpage in the first six months of FY2020, and 10,601 such page views in the second six months, totaling 21,417 page views for the year. Page views of contents accessed through the PQM+ webpage accounted for approximately 26 percent of the total. Additionally, PQM and now PQM+ supported development and use of the Foundations of GMP eLearning courses. More than 10,000 people from 65 countries have registered for courses, and more than 4,000 people have completed courses/modules. | | | | | | | |
| **5.3a. # awareness raising or advocacy events around medical product quality that were supported by PQM+** | | | | | | | |
| Ethiopia<br>• Annual Scientific Conference of the Ethiopian Pharmaceutical Association | | 0 | | | | 1 | 1 |
| Kazakhstan<br>• WHO Prequalification Process: Lessons from Kazakhstan's National Centre for Expertise of Medicines and Medical Devices (NCEM) and its Karaganda Medicines Quality Control Laboratory. Online Forum | | 0 | | | 1 | | 1 |
| Uzbekistan<br>• PQM+ Uzbekistan Launch Event<br>• WHO PQ Forum | | 0 | | 1 | 1 | | 2 |
| *Total: 5.3a # awareness raising/advocacy events* | | | | 1 | 2 | 1 | 4 |
| **5.3b. # of instances of media coverage of PQM+-supported medical product quality assurance-related events or topics** | | | | | | | |
| Bangladesh – multiple instances of print and digital coverage of the National Control Laboratory achieving WHO prequalification | | 0 | | 2 | 2 | | 4 |
| Uzbekistan – social media coverage of USAID launching new TB control projects, the regional WHO PQ Forum, and regional Good Laboratory Practice training | | 0 | | 1 | 3 | | 4 |
| *Total: 5.3b Media coverage* | | | | 3 | 5 | | 8 |
| **Cross-Cutting** | | | | | | | |
| **CC.PPP.a and b. # public-private partnerships (PPP) that PQM+ helped establish and outcomes of interest (where relevant)** | | | | | | | |
| Ethiopia<br>• Partner: Pharmaceutical Manufacturers Association<br>  ○ Outcome: Understand local manufacturing capacity and challenges | | 0 | | | 1 | | 1 |

| Code | Indicator | Base-line | 2020 Q1 | 2020 Q2 | 2020 Q3 | 2020 Q4 | Total |
|---|---|---|---|---|---|---|---|
| Kazakhstan<br>• Partner: Pharmaceutical manufacturer | | 0 | | | | 1 | 1 |
| Nigeria<br>• Partner: Pharmacists Council of Nigeria<br>o Outcome: Understand members' needs and challenges<br>• Partner: Pharmaceuticals Manufacturers Group of Manufacturing Association of Nigeria<br>• Partner: Pharmacy Schools Nigeria Universities | | 0 | | | | 3 | 3 |
| Pakistan<br>• Partner: Private sector laboratory that will test PPE<br>o Outcome: Obtain access to specialized/expanded resources<br>• Partners: 2 manufacturers of PPE<br>• Partner: Pharmaceutical manufacturer of COVID-19 medicine | | 0 | | | | 4 | 4 |
| Uzbekistan<br>• Partner: Association of manufacturers | | 0 | | | | 1 | 1 |
| Global<br>• Partner: UNICEF<br>o Outcome: Initiate regular collaboration re procurement of quality-assured medical products<br>• Partner: Global Steering Committee for Quality Assurance of Health Products & Services and the Private Sector Advisory Council<br>o Outcome: Ongoing coordination and collaboration | | 0 | | 1 | | 1 | 2 |
| | *Total: CC.PPP.a # public-private partnerships supported by project* | | | 1 | 1 | 10 | 12 |
| PQM+ seeks to engage a wide array of non-governmental actors to support public efforts to improve medical product quality and quality assurance. Examples of such partners with which PQM+ initiated engagement in FY2020, as well as outcomes achieved to date from those engagements, are listed in the table. | | | | | | | |