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PUBLICATIONS ON SDG-17

PARTNERSHIP FOR THE GOALS

2021-22

Publications Related to SDG-17

1. Bovilla VR, Kuruburu MG, Bettada VG, Krishnamurthy J, Sukocheva OA, Thimmulappa RK, Shivananju NS, Balakrishna JP, Madhunapantula SV. Targeted Inhibition of Anti-Inflammatory Regulator Nrf2 Results in Breast Cancer Retardation In Vitro and In Vivo. Biomedicines. 2021 Aug 30;9(9):1119. doi: 10.3390/biomedicines9091119. PMID: 34572304; PMCID: PMC8471069.
2. lga A. Sukocheva, Rebekah Maksoud, Narasimha M. Beeraka, SabbaRao V. Madhunapantula, Mikhail Sinelnikov, Vladimir N. Nikolenko, Margarita E. Neganova, Sergey G. Klochkov, Mohammad Amjad Kamal, Donald R Staines, Sonya Marshall-Gradisnik,. Analysis of post COVID-19 condition and its overlap with myalgic encephalomyelitis/chronic fatigue syndrome,Journal of Advanced Research,2021,ISSN 2090-1232, https://doi.org/10.1016/j.jare.2021.11.013.
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Promoting the
QUALITY OF MEDICINES Plus

PQM+ Program Year 2 Annual Report

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USAID
FROM THE AMERICAN PEOPLE

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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.

Cover Photo

A risk-based post-marketing surveillance activity in Kenya. (PQM+ photo.)

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Contents

Acronyms

ANAB	American National Standards Society National Accreditation Board
API	active pharmaceutical ingredient
CAPA	corrective and preventive action
COVID-19	novel coronavirus of 2019
CRP	collaborative registration procedure
CTD, eCTD	common technical document / electronic common technical document
DT	dispersible tablets (amoxicillin)
EPI	Expanded Program on Immunization
EUA	emergency use authorization
FP	family planning
FPP	finished pharmaceutical product
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practice
GSDP	Good Sales and Distribution Practices
HR	human resources
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission
LMIC	low- and middle-income countries
MCH	maternal and child health
MedRS	Medicines Risk-based Surveillance
MNCH	maternal, newborn, and child health
MOH	ministry of health
MOU	memorandum of understanding
MQCL	medicines quality control laboratory
MRA	medicines regulatory authority
MTaPS	Medicines, Technologies, and Pharmaceutical Systems program
NCL	National Control Laboratory
NMRA	national medicines regulatory authority
NTD	neglected tropical disease
PIC/S	Pharmaceutical Inspection Co-operation Scheme

PMI	U.S. President's Malaria Initiative
PMS	post-marketing surveillance
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
QRM	quality risk management
RB	risk-based
RBI	risk-based inspection
RIMS	regulatory information management system
RMNCAH	reproductive, maternal, neonatal, child, and adolescent health
SATTA	Stepwise Assessment Tool Towards Accreditation
SF	substandard or falsified
SOP	standard operating procedure
TB	tuberculosis
TOR	terms of reference
TWG	technical working group
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeia
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification

Letter from the PQM+ Director

At the end of its second year, the Promoting the Quality of Medicines Plus (PQM+) program is reflecting on substantial work on its objectives, with highlights such as working with manufacturers toward 52 WHO pre-qualifications, ISO accreditations, or local authorizations, and supporting 16 countries to strengthen 32 medical product quality control labs.

This Program Year 2 annual report demonstrates not only how countries and institutions have used our program's technical support to continue expanding access to quality-assured medicines, but also the importance of planning a sustainable future for medical products quality assurance systems at the national, regional, and international levels. Providing sustainable solutions is the foundation of our approach and we will continue to look for ways to ensure that.

As the PQM+ program enters its third year this FY22, we focus our attention on accelerating the implementation of our interventions and expanding the benefits of our work. PQM+ now implements activities in 21 countries. The new year provides tremendous opportunities to implement activities related to COVID-19 and introduce new technical offerings in pharmaceutical sector strategic planning, regulatory pathways, vaccines quality control, medicaldevices, data standards, and regulatory information management systems.

Ensuring technical and operational excellence is paramount as we continue to expand into new areas. Our technical assistance recipients yearn to learn best practices on implementation and see rapid impact. Given global realities, this is particularly true of our work that focuses on COVID-19. Areas that will support our scaling and implementing are operational in nature, which requires process innovation and continuous improvements to ensure efficiency. In response, we have expanded our team to include innovative roles, specifically in pharmaceutical strategy and data analytics, to steward our technical and operational excellence. This pivotal year will ascertain our readiness to scale resources and ensure solid implementation for our growing portfolio.

Strengthening our engagement with partners is paramount. Our PQM+ partners bring complementary technical competencies that provide tremendous opportunities to leverage expertise and technical offerings to achieve our technical objectives. In PY3, we will have engaged 13 of our 19 partners in various activities. We will seek to continuously integrate core partners into PQM+ management and build the capacity of our Core-FLEX partners in key technical areas.

PQM+ remains dedicated to our goal of strengthening quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health. There is still work ahead, and we are eager to expand on this year's accomplishments. It is a great honor to do the work we do, and to have the opportunity to collaborate with our committed partners at the global, regional, and local levels. Please continue following our progress toward ensuring that quality-assured medicines are available to those who need them most.

Jude I. Nwokike
Director, Promoting the Quality of Medicines Plus

Executive Summary

The Promoting the Quality of Medicines Plus (PQM+) program is working with 21 low- and middle-income countries (LMICs) to sustainably strengthen their medical product quality assurance (QA) systems. PQM+ helps ensure access to quality-assured essential medicines for HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases (NTDs), COVID-19 and other infectious diseases as well as for maternal, newborn, and child health (MNCH).

During the program's second year, the ongoing COVID-19 pandemic continued to impact PQM+ and its ability to implement work at the country level. In response to this global challenge, PQM+ developed innovative solutions and adjusted its operations at the global and country levels. As a result, the program was able to continue making progress toward the overarching goal of sustainably strengthening medical products QA systems in LMICs.

This annual report covers Program Year (PY) 2, spanning October 1, 2020, to September 30, 2021, with a focus on Quarter 4. The report summarizes activities by objective and funding source (USAID country Missions and USAID/Washington). All activities align with at least one of PQM+'s five program objectives detailed in the Results Framework (Figure 1). This report also includes the results for the monitoring, evaluation, and learning (MEL) indicators, included as Annex 1.

Figure 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 1.2 – Systems that facilitate transparency and accountability promoted 1.3 – Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted 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 2.2 – Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened 2.3 – Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported 2.4 – Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported 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 3.2 – Sustainable resources mobilized	4.1 – Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/ dossiers supported 4.2 – Capacity to conduct bioequivalence studies for dossier submissions strengthened 4.3 – Capacity for market intelligence and analytics of public health pharmaceutical markets increased 4.4 – Health coverage schemes that incorporate medical product quality requirements supported 4.5 – Monograph development and use supported	5.1 – Evidence-based approaches and tools developed and/or applied 5.2 – Research and analysis to support medical product quality assurance systems strengthening conducted 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

Governance. The PQM+ program has engaged in governance-strengthening activities in many of the countries where it works. During the year, PQM+ supported 10 countries in **advancing 35new policies, laws, regulations, and guidelines** on medical product quality assurance, including for medical products related to COVID-19. During Quarter 4 alone, the Liberia

Medicines and Health Regulatory Products Authority (LMHRA) reviewed an initial set of **seven regulations drafted in collaboration with PQM+** on processes such as the labeling, recall, and registration of medicines and health products. Formalization of these measures has been pending since Liberia established the regulatory agency in 2010, and the assistance from PQM+ has positioned LMHRA to assume ownership of the process, with the program's future support taking the form of reviewing content rather than generating it. In Mozambique, PQM+ isworking with the Department of Drug Quality Check (DCQ) to develop an updated, robust regulation that will support and facilitate the department's **implementation of good laboratorypractices**.

Regulatory Systems Strengthening. PQM+ supports countries to improve their regulatory systems as assessed by the WHO Global Benchmarking Tool (GBT), which identifies gaps and weaknesses in a country's regulatory system. In Bangladesh, PQM+ helped **address 206 of 274 recommendations from its GBT assessment** to strengthen the country's medicines regulatory authority.

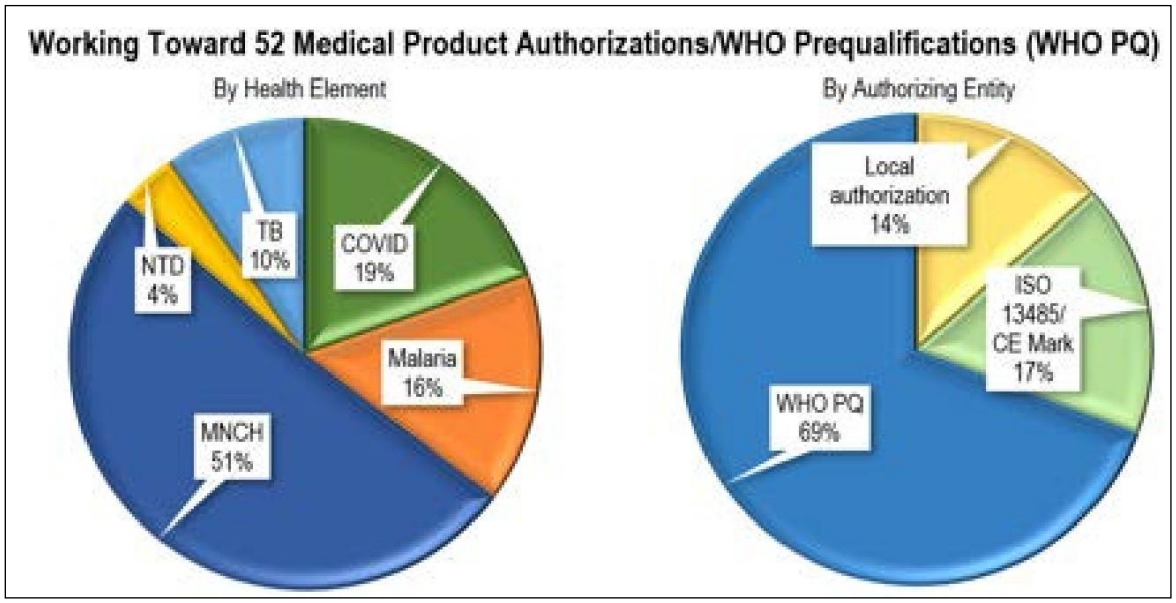
National quality control laboratories play a critical function in the regulatory process. During PY2, the program assisted 16 countries to **strengthen 32 laboratories**, including several labs each in Bangladesh, Ethiopia, Nigeria, and Pakistan. Ten laboratories made substantial progress in institutionalizing improved approaches (e.g., quality management systems, equipment preventive maintenance and calibration programs, and competency assessment programs) that will allow them to improve their performance on a sustainable basis. This fiscal year, 10 PQM+-supported laboratories were reaccredited; seven of these expanded their scopeof accreditation. In addition, 12 countries in Africa and Asia have scaled up **risk-based post- marketing surveillance (RB-PMS)** to detect, prevent, and respond to the presence of substandard and falsified medicines and medical products, including antimalarials and essentialmaternal and child health medicines.

Financial Resources Optimized. PQM+ enhances the financial sustainability of regulatory functions by supporting regulatory agencies to optimize their limited resources. In five countries (Bangladesh, Ethiopia, Kenya, Liberia, and Mali) during Q4, PQM+ supported government agencies to **revamp or establish fee structures** for medicines quality testing services to increase the financial sustainability of laboratories they operate. For example, PQM+ technical and financial experts advised officials in Mali on applying a new costing model to determine **more accurate costs of** quality control tests, taking into consideration expenses related to equipment calibration, requalification, preventive maintenance, reaccreditation fees, continuous professional development for technical personnel, procurement of traceable standards for routine equipment verification, and basic operations costs such as procurement of lab consumables. The structure has given officials a clearer picture of the proper cost of testing medicines, and PQM+ encouraged them to take the necessary administrative steps to officially revise its testing fees.

Supply. PQM+ is the only USAID-funded global health program that helps manufacturers achieve international quality standards by adopting current **good manufacturing practices** (GMP) in the production of quality-assured essential medicines. During Q4, PQM+ supported the India-based manufacturer Medopharm Pharmaceutical Private Limited to become the second manufacturer of praziquantel 600mg film-coated tablets to receive WHO prequalification(WHO PQ), a major accomplishment in expanding quality-assured sources for NTD medical products. Throughout PY2, PQM+ helped manufacturers work toward 52 medical product prequalifications or local market authorizations. Figure 2 shows that most of PQM+'s support focused on helping achieve WHO PQ (69 percent), and roughly half of the medicines manufacturing supported by PQM+ is for MNCH medicines. In PY2, PQM+ started supporting

production of quality-assured COVID-19 products, specifically remdesivir in Pakistan and personal protective equipment (PPE) in Bangladesh and Pakistan.

Figure 2. Progress on Achieving Quality Standards



In PY2, manufacturers supported by PQM+ completed the process of achieving WHO PQ orlocal market authorization for four important global public health products, as Table 1 details.

Table 1. WHO PQ and Local Market Authorization Achievements

Funding	Medicine	Use	Approval
Core NTD	Praziquantel 400 mg (finished pharmaceutical product / FPP)	Treat schistosomiasis	WHO PQ
Core TB	Clofazamine (FPP)	Treat drug-resistant TB	WHO PQ
Core TB	Clofazamine (active pharmaceutical ingredient / API)	Key ingredient to medicine totreat drug-resistant TB	WHO PQ
Pakistan COVID-19	Remdesivir	Treat severe COVID-19	Local authorization

In Pakistan during PY2, nine **private sector** manufacturers built the required systems to reliably produce quality-assured personal protective equipment (PPE) to fight COVID-19. As a result, they are now exporting quality-assured PPE to nine countries. Support from PQM+ included helping finalize the standards they would need to meet, assisting the manufacturers to improve their infrastructure and production areas (including by advising them on essential new equipment), building staff capacity, and creating a pathway by which an external QC testing laboratory could test the quality of their product, which formerly was not allowed in Pakistan. This work leveraged considerable investment by these manufacturers and enabled them to open export markets for these products, generating foreign exchange and creating jobs whilehelping protect health care workers and the public in Pakistan and elsewhere.

Finally, PQM+ is supporting five countries (Ethiopia, Kenya, Nigeria, Nepal, and Pakistan) in developing strategies to **grow their pharmaceutical sectors**. To that end, PQM+ helped counterparts solicit information on constraints to pharmaceutical production experienced by

manufacturers and/or helped form high-level working groups with public and private sector membership to collaborate on drafting long-term strategies.

Learning, Advocacy, and Awareness. PQM+ undertook several activities to broaden awareness of medical product quality at the country level. In Nepal and Nigeria, PQM+ fostered improved service delivery by helping create and distribute informational materials such as posters and job aids on the quality of medical products, including for **COVID-19**, and inspection processes for pharmacists and pharmacy customers. In Nigeria, materials provided to community pharmacies and patent medicine shops describe **good visual inspection practices**for medical products and good practices in handling medical products. These posters aim to inform, educate, and communicate key messages to practitioners and clients on steps to assurethe quality of medicines and consumables.

For its Asia Bureau work, PQM+ helped develop a GMP online course and provided mentorship support to its participants, in collaboration with MTaPS, World Health Organization (WHO) India, **JSS Academy of Higher Education & Research (JSS AHER), Mysuru,** Indian Pharmaceutical Alliance, Ministry of Health and Family Welfare, and the Government of India.

In addition to its activities at the country level, PQM+ continued its work developing global tools to **improve medical product quality**. PQM+ completed and disseminated a guidance document on the risk-based categorization of MNCH products in both English and French, explaining how to define probability and impact risks for priority RMNCH products. The document will facilitate countries' development of sampling plans using the Medicines Risk-based Surveillance (MedRS) tool.

During PY2, PQM+ completed development of an NTD global dashboard for active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs) and a user manual for the tool. PQM+ will pilot the **Neglected Tropical Disease Medicine Information Dashboard** (NTD MID) in a few program countries and make it available globally.

PQM+ provided ongoing technical guidance and monitoring during PY2 of Virginia Commonwealth University's (VCU's) development of an **alternative route to produce the API** for a priority TB product. During the laboratory phase, which ended in Q4, the team successfully identified a synthesis route and demonstrated each step of the target continuous manufacturing process.

As part of USAID's ongoing response to COVID-19, PQM+ is working with seven LMICs (Bangladesh, Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan, and Uzbekistan) to support their response to the pandemic. PQM+ completed the dissemination of the USP **quality control toolkits for the COVID-19 vaccine** in collaboration with the USP Science division and African Medicines Regulatory Harmonization (AMRH). In Ethiopia, PQM+ collaborated with government agencies to find ways to **increase local production** of priority medicines that the country's Ministry of Health (MOH) identified in support of the emergency response to COVID-19. An assessment there found that of 76 MOH-identified COVID-19 emergency response medicines, 62 (82 percent) could have been produced locally, indicating the potential of the local industry to supply critical medicines if it operates at full capacity. Under its **cross-bureau** portfolio, PQM+ completed dissemination of USP quality control toolkits for the COVID-19 vaccine in collaboration with the USP Science Division and African Medicines Regulatory Harmonization (AMRH). The program also hosted two webinars for 229 participants, who received complimentary access to the USP-National Formulary (NF) chapters for the COVID19 vaccine quality assessment toolkits.

Activities and Progress for Cross-Bureau Activities

PQM+ Cross-Bureau-funded activities in Q4 primarily focused on raising awareness about the importance of medical product quality and developing new approaches to strengthen medicines regulatory functions. Cross-Bureau activities funded by the Office of Health Systems (OHS) fall under the following program objectives:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors;
- Optimize and increase financial resources for medical product quality assurance (QA); and
- Advance a global medical products QA learning and operational agenda.

Highlights of Progress During PY2

During PY2, PQM+ achieved the following under the Cross-Bureau portfolio.

- Finalized the MedRS tool version 2 and made it available online for NMRAs to subscribe to and use it for RB-PMS protocol development and training. Continued to socialize the online MedRS v2 tool, resulting in eight regulatory authorities registering to use it.
- In collaboration with the University of Washington (UW), finalized the SF Medicine Burden Model tool. Countries and regions can use this tool to estimate the health and economic costs of the availability of SF medicines. PQM+ will pilot it in Kenya and Pakistan in PY3.
- Partnered with the Medicines, Technologies, and Pharmaceutical Systems (MTaPS) program to convert the in-person Medical Products Quality Assurance module of the USAID's Pharmaceutical Systems Strengthening ("PSS 101") course to an online eLearning course. This will improve the course's accessibility during the COVID-19 pandemic.
- Delivered two webinars: "What Are Regulatory and Quality Assurance Systems and How Do They Impact Health Programs?" and "Strengthening National Quality Control Laboratories (NQCL) to Ensure Quality Medical Products."

Progress in Quarter 4

In Q4, PQM+ continued to socialize the online MedRS version 2 (v2) tool, resulting in eight regulatory authorities registering for the tool, which helps medicines regulatory authorities develop risk-based sampling strategies to support national post-marketing surveillance (PMS) programs while maximizing available resources.

In collaboration with the University of Washington (UW), PQM+ finalized the substandard and falsified (SF) cost model tool and, as next steps, began engagement with local stakeholders in Kenya to pilot the model in Program Year 3, Quarter 1. Countries and regions can use the SF Medicine Burden Model tool to estimate the health and economic costs of using the SF medicines.

Risk-Based Inspection Methodology Framework

The risk-based inspection (RBI) methodology framework covers regulatory agencies' inspectorate activities in good manufacturing practice (GMP), good clinical practice (GCP) inspections for contract research organizations (CROs), bioequivalence (BE) center inspections,and good distribution practices (GDP) inspections. PQM+ is developing an RBI tool to help national medicines regulatory authorities (NMRAs) prioritize the selection and inspection of sites

based on risk-that is, directing limited resources to manufacturing sites that present the greatest risk to medical product quality assurance. This quarter, PQM+ worked on finalizing procurementof the RBI tool developer for two of the framework's modules: GMP and GDP. The contracting process for full engagement is underway.

PQM+ consulted with subject matter experts from Health Canada, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Expert Circle on Quality Risk Management, and the Market Compliance Department of Ireland's Health Products Regulatory Authority's on the tool'sGDP module. PQM+ drafted a preliminary guidance document on the structure of RBI distribution chains this quarter and conferred with the tool developer to determine the risk parameters (risk factor determination and calculation with score rating) and characterization (which risk factors belong to which categorization, such as distribution challenges, geography, facility, etc.) to guide the tool's development.

MedRS Tool

This quarter, PQM+ continued to socialize the online MedRS v2 tool as it supports countries in the adoption and implementation of RB-PMS and the use of the MedRS tool during PMS protocol development. Eight PQM+ countries' regulatory authorities have registered and are using the online MedRS v2 tool.

In coming quarters, PQM+ will continue to socialize and provide training on how to use this tool as part of RB-PMS technical assistance to countries. PQM+ expects more countries to register and adopt the tool based on their specific RB-PMS implementation timelines in PY3. In addition,PQM+ plans to meet with WHO in next quarter to share an overview of the MedRS tool version 2and seek its endorsement of the tool.

Model to Estimate the Economic and Health Impact of SF Medicines

PQM+ is developing a tool that countries or regions can use to estimate the health and economic costs of the availability of SF medicines on the market. This quarter, PQM+ organizedand facilitated the second and third Advisory Group (AG) meetings to review and finalize the SF Medicine Burden Model tool developed by the University of Washington (UW). Members of the Advisory Group play a critical role in reviewing major outputs, identifying relevant resources and data sources, helping resolve methodological challenges, and generally advising on the SF Medicine Burden Model tool and its application.

PQM+ also met with the Kenya Pharmacy and Poisons Board and Ministry of Health to share information on the model for determining the burden of SF medicines, introduced data needs fora Kenya case study, and shared the data parameters with Kenya partners. PQM+ plans to begin piloting the SF modeling tool in Kenya for oxytocin in PY3 Q1.

PQM+ also received concurrence from the Pakistan Mission for anti-tuberculosis medicine to pilot the model tool there in PY3.

The program drafted and shared a guidance document on the SF medicines burden model with Advisory Group participants for review and input before its finalization.

PQM+ is working with UW, UNC, and Harvard University to validate the SF costing model andto incorporate feedback received from the September 21 AG meeting to finalize the modeling tool and guidance document.

PQM+ also reviewed the "SF Model Literature Review Manuscript" drafted by the University of North Carolina (UNC) and facilitated USAID's review of the draft. UNC will submit the manuscript to the American Journal of Tropical Medicine and Hygiene (AJTMH) for publication.

Standards for Pharmaceutical Information Management

PQM+ and the Medicines Technologies and Pharmaceutical Services (MTaPS) program are working to identify and consolidate a repository of standards for pharmaceutical regulatory information management system (RIMS) for medicines regulatory authorities (MRAs). PQM+and MTaPS are leading a consultative process with key stakeholders to agree on a set of minimum common standards for RMIS for MRA adoption, streamline regulatory processes, improve information consistency, and enhance transparency for regulatory decision-making.

This quarter, PQM+ and MTaPS held the first virtual stakeholders consultative workshop on common standards for RIMS. Participants included MRA representatives, the World Health Organization (WHO), Gates Foundation regional economic communities for regulatory harmonization in Africa and Asia, USAID, Global Fund, World Bank, and implementing partners working in the regulatory space, as well as many others, to total 46 participants. The first consultative workshop discussed the current RIMS landscape and challenges in Africa and Asia, the role and scope of RIMS standards for LMICs, and the timeline for follow-up activities and meetings. The second consultative meeting is planned for October 27.

Pharmaceutical Systems Strengthening Course

PQM+ partnered with MTaPS to convert the in-person Medical Products Quality Assurance module of the USAID's Pharmaceutical Systems Strengthening ("PSS 101") course to an online eLearning course. This will improve the course's accessibility, as in-person trainings have not been possible during the COVID-19 pandemic.

This quarter, PQM+ reviewed the translated course module on the eLearning platform and provided feedback to improve information flow and clarity, as well as provided additional technical information to improve some sections. The course discussion and practice sections now align with a virtual setting. The final version of the course module is under development and will end in PY3 Q1.

Webinar Series

In PY2, PQM+ delivered two webinars, titled "What Are Regulatory and Quality Assurance Systems and How Do They Impact Health Programs?" and "Strengthening National Quality Control Laboratories (NQCLs) to Ensure Quality Medical Products."

In Q4, PQM+ planned a two-part webinar series on "Playing the Long Game: How Can Strengthening Medical Product Regulatory and Manufacturing Systems Help Countries Respond to COVID-19 and Future Health Crises?" The first webinar will be held on November8, 2021, and the second in December or January.

Priority Activities for Next Quarter

- Finalize development of the RBI tool and the guidance document;
- Expand use of the MedRS tool to additional countries;

- Pilot the SF medicines costing model in Kenya and finalize the model's guidance document;
- Finalize the draft report on Standards for Pharmaceutical Information Management Systems, and plan, coordinate, and deliver the second stakeholder consultative meeting; and
- Develop and deliver the next webinar.

Activities and Progress by Country and Regional Buy-Ins

Africa Region

Benin

As is the case in many French-speaking West African countries, the medicines regulatory system in Benin is fragmented. A single agency does not perform all regulatory functions. Moreover, the laws, ordinances, and decrees that make up the regulatory framework are largely outdated. In some cases, important regulatory functions such as post-marketing surveillance of products are lacking, not well defined, and/or not implemented. This allows falsified medical products to enter the supply chain, exposing unsuspecting consumers to illicit, unauthorized, or poor-quality medicines.

The main regulatory body is the Beninois Agency for Pharmaceutical Regulation, *l'Agence Béninoise de Régulation Pharmaceutique* (ABRP), formerly known as the Directorate of Pharmacy, Medicines, and Diagnostics. ABRP develops and implements national pharmaceutical policy and regulations, registers medicines, approves licenses, inspects pharmaceutical establishments, and controls the advertisement and promotion of medicines, including herbal and traditional medicines. The national quality control laboratory, *l'Agence Nationale de Contrôle de la Qualité des Produits de Santé et de l'Eau* (ANCQ), collects and testsmedicines at the points of entry into the country (land, sea, and air) or at the request of any national institution.

PQM+ activities in Benin began in PY2, Q2. PQM+ is helping ANCQ strengthen its quality management system (QMS) to achieve international recognition (ISO/IEC 17025 or WHO prequalification). This would assure the reliability of testing and increase the public's confidencein ANCQ test results.

In PY2, PQM+ worked to:

- Improve country and regional **regulatory systems** to assure the quality of medical products in the public and private sectors.

Highlights of Progress During PY2

During PY2, PQM+ in Benin achieved the following.

- Conducted a baseline assessment of ANCQ that led to the development of a roadmap toward ISO/IEC 17025 accreditation.
- Trained ANCQ on selected quality control techniques and quality management systems topics to close some gaps identified during the baseline assessment.
- Supported the establishment of a national multisectoral PMS-TWG that will serve as an instrument of ABRP to oversee PMS activities in the country.

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+ supported the establishment and inauguration of the new multisectoral Post-Marketing Surveillance Technical Working Group (PMS-TWG). The TWG includes members from ABRP, ANCQ, the national malaria, tuberculosis, and HIV/AIDS programs, the national orders of pharmacists and doctors, the association of private clinics, consumers association, and the customs department. The PMS-TWG officers include the president, from the medicines regulatory authority (ABRP); the vice president, from the national quality control laboratory (ANCQ); and the rapporteur, from the national malaria control program (NMCP. During the inaugural workshop, members reviewed and validated the terms of reference for the TWG, as well as draft national guidance for risk-based PMS, which ABRP had already revised and customized. In addition, PQM+ oriented the TWG on risk-based PMS and introduced the new MedRS tool, which the group will be expected to use in PY3 to develop an RB-PMS protocol for antimalarial medicines.

As follow-up to the baseline assessment conducted for ANCQ in Q2, as well as the internal audit conducted by ANCQ's quality assurance team in Q3 (using the Stepwise Assessment Tool Towards Accreditation, or SATTA, that PQM+ trained them on in Q2), PQM+ conducted a training on analytical method validation (AMV), Good Documentation Practices (GDP), and quality control techniques (pH, Karl Fischer titration, and titrimetry) to help close some of the gaps that both assessments identified. Ten analysts (six male, four female) learned to conduct AMV, a key requirement of the ISO/IEC 17025 standard that ANCQ was previously unable to perform. The training on the quality control (QC) techniques improved the capacity of 13 technical staff (eight male, five female) to conduct routine QC testing, per compendial requirements. This will be particularly useful as Benin prepares to conduct sampling and testing of antimalarial medicines in PY3 applying RB-PMS.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Train the national PMS-TWG on the online version of the MedRS Tool and
- Continue to build the capacity of ANCQ technical staff and coach them on specific quality control techniques for testing of antimalarials.

Burkina Faso

Malaria is one of Burkina Faso's primary causes of morbidity and mortality. In 2018, the Ministry of Health (MOH) confirmed 12 million cases and 3,974 deaths. The U.S. President's Malaria Initiative (PMI) supported Burkina Faso's National Malaria Control Program's (NMCP) implementation of its Malaria National Strategic Plan 2016–2020, which aimed for a 40 percent reduction in the incidence of and deaths from malaria by 2020.

The country's Directorate General of Pharmacy and Laboratory (ANRP) is the national pharmaceutical regulatory authority. It coordinates all regulatory actions in the pharmaceutical sector, including post-marketing surveillance of products. The Directorate of Market Surveillance and Quality Control of Health Products is the technical body in charge of QA/QC. A functional PMS program was established in the ANRP in 2018. ANRP is collaborating with the Directorate for the Control of Drugs and Non-Food Products (DCM/PNA), which falls under the *Laboratoire National de Santé Publique* (LNSP, the National Public Health Laboratory), to sample medical products for post-marketing surveillance.

PQM+ activities kicked off in Q2. The program is working with the main medicines quality stakeholders, ANRP and LNSP, and others to adopt a risk-based, sustainable approach to PMS; strengthening LNSP as it prepares for ISO 17025 accreditation; and assisting ANRP in improving collaboration among key stakeholders to strengthen regulatory systems and improve the quality of medicines on the Burkina Faso market.

In PY2, PQM+ worked to:

- Improve **governance** for medical product quality assurance systems and
- Improve country and regional **regulatory systems** to assure the quality of medical products in the public and private sectors.

Highlights of Progress During PY2

During PY2, PQM+ in Burkina Faso achieved the following.

- Kicked off implementation of the PY2 work plan in February 2021 in Ouagadougou.
- Supported the establishment of a national multisectoral PMS-TWG that now serves as an instrument of ABRP to oversee PMS activities in the country.
- Trained the PMS-TWG on the MedRS tool, provided supportive supervision to develop its first RB-PMS protocol, and supervised sampling and testing of antimalaria medicines.
- Supported the development of a collaborative framework between LNSP and ABRP to improve the efficiency of collaboration between LNSP and ANRP and foster accountability of both institutions.
- Provided training to LNSP on select quality control techniques and quality management systems topics to strengthen their capacity to conduct QC testing, per good laboratory practices and compendial requirements.

Progress by PQM+ Objective

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

The PMS-TWG, with supervision from PQM+, oversaw the completion of sampling of antimalarial medicines in Q4, including the collection of 320 samples from seven regions in Burkina Faso. LNSP screened these using MiniLabs™ procured by PQM+. After initial screening of all 320 samples, LNSP started the confirmatory testing of 82 samples using laboratory consumables procured by PQM+.

To help ANRP and LNSP sustain the implementation of the risk-based PMS approach, PQM+ drafted five standard operating procedure documents (SOPs) for implementing RB-PMS, sampling, storage of samples, analysis of PMS samples, and administrative actions to take based on PMS results. At a four-day workshop in Ouagadougou, the PMS-TWG reviewed theseSOPs and adapted them to the Burkina Faso context, with support from PQM+.

In August, PQM+ conducted a training on analytical method validation (AMV), a key advance requirement of the ISO/IEC 17025 standard. Thirteen analysts received training to conduct AMV and now have the capacity to meet this requirement, which was previously a non-conformity in LNSP's quality management system. To further strengthen the quality management system of LNSP and help institutionalize important elements of the ISO/IEC 17025 standard, PQM+ supported a workshop to supervise LNSP to develop key QMS SOPs on using SATTA to conduct internal audits and on measurement uncertainty and analytical method validation. The SOPs will ensure implementation of these key elements of the standard at LNSP's DCM.

To institutionalize the process of using the SATTA for internal audits, PQM+ supervised LNSP to conduct an internal audit using the SATTA and applying the internal SOP they developed and validated. Based on PQM+ observations and coaching, it is clear that the LNSP team of internal auditors have sufficient capacity to use the tool independent of further technical assistance. Results from the internal audit will help PQM+ carve out future technical assistance for LNSP as they prepare for an accreditation audit at the end of 2022.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Conduct the situational analysis for the development of a five-year strategic plan for LNSP;
- Conduct a baseline assessment of LNSP's DCM to guide the provision of technical assistance toward ISO 17025 accreditation; and
- Continue supervising testing and support ANRP to disseminate the RB-PMS results.

Democratic Republic of Congo (DRC)

Widespread availability and distribution of non-quality-assured artemisinin combination therapies (ACT) and non-artemisinin therapies in DRC underscore the necessity for strong medicines regulatory systems, including post-marketing surveillance. A ministerial decree of 2003 established the Directorate of Pharmacy and Medicines as the national medicine regulatory authority, which transformed to *Autorité Congolaise de Réglementation*

Pharmaceutique (ACOREP, the Congolese Pharmaceutical Regulatory Authority) in 2018. This transformation places the *Laboratoire National de Contrôle de Qualité – Laboratoire Pharmaceutique de Kinshasa* (LNCQ-LAPHAKI, the National Quality Control Laboratory – Pharmaceutical Laboratory of Kinshasa) under the management of ACOREP. In 2019, a ministerial decree mandated quality assurance of pharmaceutical and allied products manufactured, imported, and distributed in DRC.

In 2020, through a World Bank-funded project to strengthen the capacity of LNCQ-LAPHAKI, USP provided technical assistance to establish an ISO/IEC 17025-compliant quality management system within LNCQ-LAPHAKI, build the capacity of its technical personnel in quality assurance and quality control (QA/QC), and procure analytical equipment and laboratory consumables to enable the laboratory to conduct pharmacopeial testing. This project also developed a five-year strategic plan (2021–2026) for LNCQ-LAPHAKI; when operationalized, the plan will help ensure the lab's sustainability.

While ACOREP has a division of quality assurance and control of medicines that is responsible for post-marketing surveillance activities and conducts some PMS, it does not have a national PMS guidance document, and it has not adopted a risk-based approach to PMS. In PY2, PQM+ started providing technical assistance to ACOREP to strengthen its PMS function and facilitate its adoption of the risk-based PMS (RB-PMS) approach. In PY2, PQM+ worked to:

- Improve country and regional **regulatory systems** to assure the quality of medical products in the public and private sectors.

Highlights of Progress During PY2

During PY2, PQM+ in DRC achieved the following.

- Supported the establishment of a national multisectoral PMS-TWG that will serve as an instrument of the medicines regulatory authority (ABRP) to oversee PMS activities in the country.
- Trained the PMS-TWG on the online MedRS tool and provided supportive supervision to develop DRC's first risk-based PMS protocol for antimalaria medicines.
- Provided training to LNCQ-LAPHAKI analysts on selected quality control techniques to build their capacity to conduct confirmatory testing of PMS samples for the first time.

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+ collaborated with ACOREP to inaugurate the new PMS-TWG. The group comprises representatives from ACOREP; LNCQ-LAPHAKI; the national malaria control, tuberculosis, and AIDS control programs; the health inspectorate; the University of Kinshasa; the central medical stores (FEDECAME, the *Fédération des Centrales d'Achat des Médicaments*); the Congolese Federation of Businesses; the national center for pharmacovigilance; the National Order of Pharmacists; and three independent quality control laboratories (LACOMEDA, the *Laboratoire de Contrôle des Médicaments et Denrées Alimentaires*; LACOKIN, the *Laboratoire de Contrôle de Kinshasa*, and OCC, the *Office Congolais de Contrôle/Laboratoires*).

The TWG also elected its leadership, with ACOREP's director as president; the group will designate members as rapporteurs and moderators for each meeting. During the workshop, members also reviewed and validated a draft national guidance for risk-based PMS, which ACOREP had already revised and customized. In addition, PQM+ oriented TWG members on RB-PMS and introduced them to the new MedRS tool.

Later in the quarter, PQM+ supported the PMS-TWG to convene a training for 30 of its members on the MedRS tool. During that workshop, PQM+ provided supportive supervision to the PMS-TWG members to use the MedRS tool to conduct risk analysis to help develop the RB-PMS protocol for antimalarial medicines.

In addition, to prepare LNCQ-LAPHAKI to conduct confirmatory testing of the PMS samples for next quarter, PQM+ initiated a series of quality control trainings on various techniques that will be required to test the PMS samples. PQM+ has convened two training sessions for 14 analystson three quality control techniques—pH, Karl Fischer, and titrimetry—that are required to test the PMS samples. A high average post-test score and an appreciable knowledge gain (measured by comparing pre-training test scores to post-training scores) indicates the training was impactful. In addition, since LNCQ-LAPHAKI is new at applying these techniques, they will continue to be coached by PQM+ in PY3.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Monitor the sampling and testing of the RB-PMS samples as per the RB-PMS protocol developed in Q4 and
- Continue to build the capacity of LNCQ-LAPHAKI and coach them on specific quality control activities.

Ethiopia

In Ethiopia, authorized bodies at the federal and regional levels regulate medicines. At the federal level, the Ethiopian Food and Drug Authority (EFDA) registers all medical products; licenses and regulates the production, import, storage, and distribution of transregional medical products; and conducts quality-control testing and post-marketing surveillance of products circulating in the local market. All other regulatory activities that are not mandated to EFDA fall under the jurisdiction of regional government and city administration regulatory bodies. But the lack of clarity in mandates between EFDA and the regional regulatory bodies (RRBs), the absence of a formal reporting relationship between EFDA and those regulators, and the latter's poor capacity compromise proper regulatory oversight of medical products circulating in Ethiopia.

PQM+ has been working with EFDA and the regional regulatory bodies to build capacity to monitor medical product quality across the supply chain and strengthen their collaborative working relationship to create synergy in executing their respective mandates more efficiently. PQM+ also helps build local manufacturers' capacity to meet international standards, ensuring that locally produced medical products are of good quality and not harmful to end users.

In PY2, PQM+ worked to achieve four high-level objectives:

- Improve governance for medical product quality assurance systems;

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors;
- Increase the supply of quality-assured essential medical products of public health importance; and
- Optimize and increase financial resources for medical products quality assurance.

Highlights of Progress During PY2

During PY2, PQM+ in Ethiopia achieved the following.

- Following MOH's identification of priority medicines for the emergency response to COVID-19, PQM+ supported an assessment of local capacity to produce medicines and possible challenges facing the local industry and partnered with WHO to develop a policy brief.
- Supported training of trainers (TOT) for 32 inspectors, followed by cascaded trainings in four regions. An audit inspection after the training at 258 medicine retail outlets (from Addis Ababa, Oromia, Amhara, and SNNPR) found various practices that could compromise product quality and patient safety.
- Collaborated with EFDA to conduct supportive supervision of three branch laboratories, verifying the results of the self-assessment and identifying additional gaps. PQM+ developed a branch-specific roadmap toward ISO/IEC 17025:2017 accreditation and helped develop 20 SOPs for each lab, which will help improve their QMS and support accreditation.
- Supported EFDA to finalize a report on laboratory test results of 40 PMS samples of alcohol-based hand sanitizers collected during PY1. Nine of 40 samples (22.7 percent) failed to comply with requirements. EFDA issued a recall letter to all manufacturers that produced SF products.
- Provided technical assistance to develop five new SOPs and review/update 16 SOPs and supported the EFDA Inspectorate in compiling and submitting required documentation to ENAO for ISO 17020 accreditation. ENAO is expected to conduct an onsite inspection and evaluation before issuing a final decision on accreditation.
- Moderated a panel and presented at the 41st annual scientific conference of the Ethiopian Pharmaceutical Association. The PQM+ chief of party moderated a discussion titled "Pharmaceutical Sector Regulation in Ethiopia: Lessons Learnt from COVID-19 Response" and presented on "Challenges of Substandard and Falsified Medicines in the Era of COVID-19" to the continuing education session of the conference.
- Helped prepare the EFDA's branch laboratories for ISO 17025:2017 accreditation by providing two trainings in March to 12 laboratory analysts. The main topics covered were hands-on training on selected analytical test methods and QMS document preparation and implementation. PQM+ conducted pre- and post-tests for the training and measured the knowledge transfer achieved to participants. The average scores were 55 percent and 86 percent, respectively, indicating an aggregate knowledge gain of 31 percent.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

PQM+ works with EFDA and regional regulatory bodies (RRBs) to strengthen regulatory inspection with the objective of improving ethical practices, good storage, and good dispensing practices at private medicine retail outlets. In previous quarters, PQM+ supported a training of trainers (TOT) for 32 inspectors (12 women, 20 men) from EFDA and the regulatory authority in Addis Ababa to build inspectors' capacity. Cascaded trainings to regional inspectors followed at four locations: Amhara, Oromia, Addis Ababa, and the Southern Nation, Nationalities, and Peoples Region (SNNPR).

After the training, regional inspectors, supported by EFDA, conducted audit inspections at 258 medicines retail outlets (60 drug stores and 198 pharmacies). This far exceeded the plan for the

year of 100 retail outlets. A report on the findings of this inspection uncovered various practices that could compromise product quality and patient safety. (See Table 2 for details.)

Table 2. Findings at 258 Inspected Medicines Retail Outlets

Medical Outlet Locations and Types	% of Outlets
Region	
Addis Ababa	48
Oromia	23
Amhara	17
SNNPR	12
Type	
Pharmacy	76.7 (n=198)
Drug store	23.3 (n=60)

Characteristics/Observations	% of Outlets	# of Outlets
Dispensed medicines without a prescription	48.4	
Non-licensed professionals dispensed medicines	10.1	
No valid premises license	4	
Had unregistered medicines for sale	18.6	48
Had unfit-for-use (damaged/expired) medicines for sale	65.5	169
Reported these medicines to regulatory bodies	32	54
Did not segregate these medicines	17.8	30
Lacked proper documentation for these medicines	26.6	45
Had thermometers in place in storage/dispensingrooms	88	227
Possessed calibration certificates forthermometers	18.6	48
Had refrigerators in place for cold storage	92.6	239
Had back-up power supply in place	26.7	69

The inspection results helped identify some key downstream supply chain malpractices that facilitate the circulation of substandard and falsified medicines. Accordingly, regulatory authorities can use this information to devise evidence-based strategies to guide regulatory measures and strengthen routine inspections in a proactive manner.

As part of strengthening coordination between EFDA and RRBs, PQM+ supports EFDA and regional regulatory bodies to conduct a semiannual performance review meeting where more than 108 regulators participated from all regions and city administrations. In this quarter (Q4), PQM+ provided similar support. During this meeting, each of the regulatory bodies presented their performance against their plan and discussed it with all participants. More than 110 regulatory personnel (30 female, 80 male) from 10 regions (excluding Tigray) and Addis Ababa and Diredawa cities participated in the meeting.

Overall, these platforms are helping clarify roles and responsibilities between EFDA and RRBs, improving uniform implementation of national guidelines and standards, and creating consensus on information sharing and consistent enforcement of regulatory requirements for medical products, which is essential to safeguard the public from substandard and falsified products and illegal business practices.

During PY2, PQM+ also worked with EFDA and the Food, Beverage, and Pharmaceuticals Development Institute (FBPDI) to produce evidence on the barriers to importing critical inputs to

local manufacturers to help the government take informed and timely policy actions. The purpose of this support is to find ways to increase local production of priority medicines that the Ministry of Health (MOH) identified in support of the emergency response to COVID-19. The program gathered the evidence needed as part of the assessment on the status, capacity, and challenges of local manufacturers to produce essential medicines. Key stakeholders and partners received the report, which noted that the local industry has faced multiple hurdles to maintain optimal operation. (See findings box.) An initial consultative meeting took place in Q1 with government officials from eight critical stakeholders, including EFDA, Ethiopian Pharmaceuticals Supply Agency (EPSA), MOH, FBPDI, and the Ethiopian Pharmaceutical Manufacturers Association. The purpose of this meeting was to disseminate findings of the assessment to key government stakeholders and secure their commitment to address critical challenges that local manufacturers are facing.

Import Barriers Assessment Findings

Of 76 MOH-identified COVID-19 emergency response medicines, 62 (82 percent) could havebeen produced locally, indicating the potential ofthe local industry to supply critical medicines if it operates at full capacity.

In Q2, FBPDI presented the findings of the assessment to the national steering committee responsible for monitoring implementation of the National Strategy and Plan of Action for Local Production of Pharmaceuticals (NSPA-Pharma). In Q4, PQM+ led the development of a policy brief in partnership with WHO as part of the effort to consolidate the evidence and guide practical policy actions by responsible government bodies. The national steering committee received the brief for consultation before its dissemination to a wider audience. The evidence generated through the assessment and the policy brief, combined with the results of consultations, should help policymakers reach informed decisions that enable local manufacturers to produce priority medicines required for addressing critical public health needsin Ethiopia.

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

In Q4, PQM+ provided technical assistance to EFDA in developing guidance for exemption of on-site GMP inspection of manufacturing facilities based on reliance on assessment carried out by other strong regulatory authorities. Currently, the regulatory guidance document is under review by the inspectorate of EFDA. After approval, implementation of this guidance will contribute to speeding up the registration and import of medical products thereby helping to expand access to essential medicines. PQM+ also participated in a consultative workshop to enrich and finalize a directive drafted to guide the handling, storage, distribution and disposal of blood and blood products. This directive will have an important role in ensuring quality of blood and blood products across the supply chain, which is critical to saving lives, especially those of mothers and children.

In Q4, PQM+ followed up on the procurement of equipment for EFDA's branch laboratories to continue progress toward meeting the requirements for ISO 17025 accreditation. Delivery of these equipment is delayed due to the challenges of logistics associated with COVID-19, but it is expected to be shipped to Ethiopia soon. The presence of accredited laboratories at brancheswill substantially improve EFDAs capacity to detect falsified and substandard medical products circulating in the Ethiopian market by conducting regular PMS with a broader geographic and product coverage. Preventing poor quality products from reaching the public will in-turn have enormous public health outcomes.

PQM+ supported EFDA in Q4 to procure and deliver a MiniLab™ and other laboratory supplies for testing PMS samples through the three-level approach. The three-level approach consists of three successive, complementary, and increasingly complex levels of analysis. The first entails visual and physical inspections to assess the physical characteristics of the medicines; the second consists of rapid analytical tests that assess a limited number of quality attributes that less-trained personnel can easily perform in the field; and the third involves the full compendial testing in an appropriate laboratory setting using experienced and trained analysts. The approach offers regulators in limited-resource settings a cost-effective and more feasible methodology to monitoring the quality of medicines across the supply chain.

In addition, PQM+ trained 12 laboratory staff (one female and 11 males) of the main EFDA laboratory on use of the MiniLab™ technology. The staff then started testing the collected antimalarial and oxytocin samples as per the PMS protocol. Laboratory testing of the samples is complete and writing the PMS report and dissemination of the results will follow. The test resultsof these samples will give the regulatory authority insights into the current situation regarding the circulation of substandard and falsified medicines in the local market.

In addition, as part of introducing the RB-PMS approach to Ethiopia, PQM+ helped the EFDA to get free access to the online version of the MedRS tool, which helps regulatory authorities select medicines, geographical locations, and facilities based on their risk ranking and helps calculate the total number of samples to collect for each round of a PMS. Institutionalization of the RB-PMS using the MedRS tool and the three-level testing approach will help EFDA optimizeutilization of its limited resources and establish a sustainable PMS program.

As part of support to the central laboratory to maintain its accreditation, PQM+ has identified vendors that can provide maintenance and calibration service for the condom-testing machines and vendors that can provide proficiency test (PT) samples for the already accredited test methods, all of which are critical to fulfilling the international requirements for ISO 17025:2017 accreditation. PQM+ also helped EFDA secure maintenance and calibration services for its condom-testing machine. In the same quarter, the external accreditation body, the American National Accreditation Board (ANAB), audited EFDA's central laboratory to determine if the lab was meeting international requirements. The auditor found that the lab is compliant with ISO 17025:2017 standards and has fulfilled all requirements, thereby extending the lab's accreditation for the next two years.

In parallel, EFDA is working with the Ethiopia National Accreditation Office (ENAO) to transitionits ANAB accreditation to one from a local accrediting body. However, the progress from ENAOhas been slower than expected.

PQM+ provided technical assistance to establish a vaccine laboratory at EFDA as a member of the technical working group on this topic. The group developed its terms of reference (TOR) and proposed a draft lab design after discussing it with the engineering team at the federal Ministry of Health. The design is in its final stage of review by the engineering unit of the Ministry of Health.

In Q4, PQM+ procured and delivered five proficiency test (PT) samples to the EFDA's central laboratory to help it fulfill requirements for maintaining its accreditation status. EFDA has tested the PT samples and submitted the test results to the PT provider and is waiting for the PT report. This is a critical requirement to prove the laboratory's competency. PQM+ also helped EFDA secure maintenance and calibration services for its condom-testing machine by contracting with Enersol, an Australia-based supplier, per international requirements. Remote technical assistance has already been completed, and an Enersol technician will visit the lab

and provide the remaining services on site immediately after COVID-19 related travel restrictions are lifted.

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

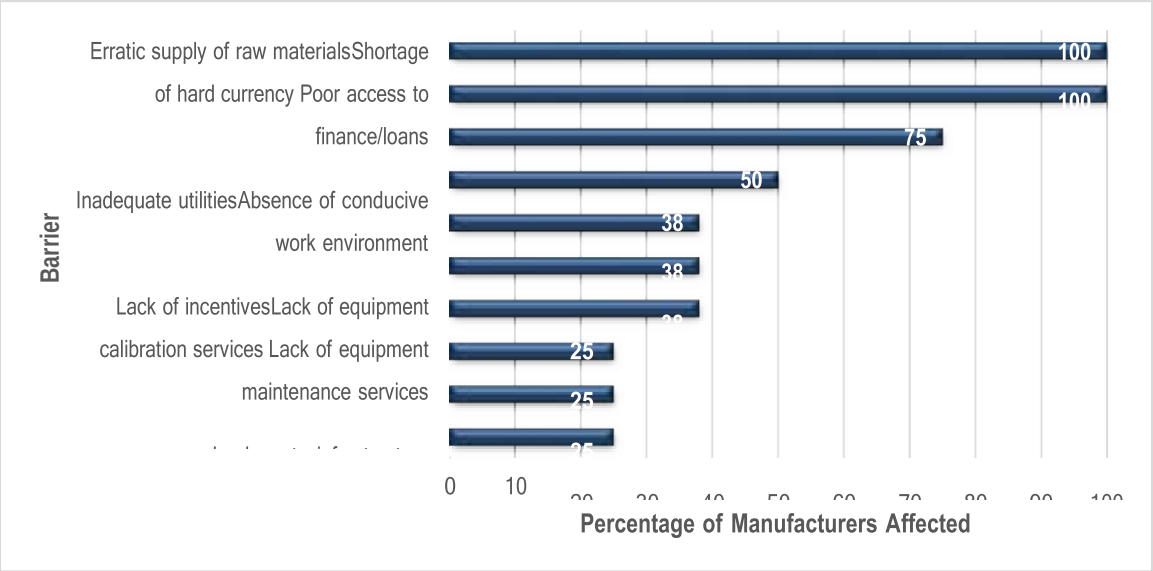
In support of the broader goal of financial sustainability for EFDA, PQM+ incorporated some key activities in the current work plan to address the agency's challenges in increasing its financial resources for ensuring medical product quality assurance. The activities focus on assisting EFDA in revising its fee structures, fee levels, and service fees regulation. A recent report on financial sustainability strategy, developed by McKinsey, identified gaps in this area.

Discussions with EFDA's director general (DG) indicated that the authority has asked the Ministry of Finance and Economic Development (MOFED) for authorization to retain fees it collects through its regulatory services to build its in-house capacity, instead of channeling the income to the government treasury. The DG indicated that the authority does not consider this awise investment of time and resources prior to receiving MOFED's approval. This government authorization process is expected to take considerable time, so the activity remains on hold until EFDA receives a positive response from MOFED.

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

During PY2, PQM+ worked with government counterparts to explore opportunities for boosting the local production of medicines, particularly amid the ongoing COVID-19 pandemic. As part of this effort, PQM+ supported FBPDI and EFDA in finalizing the assessment of available capacity and challenges local manufacturers face in producing MOH-identified priority medicines for the emergency response to COVID-19. The manufacturers indicated problems acquiring active pharmaceutical ingredients (APIs) during the previous six months, and all cited the lack of hard currency as the key bottleneck. Further, 88 percent of the responding manufacturers noted the challenges of price increases and transportation blockades. Top challenges that manufacturers mentioned to importing equipment and spare parts were lack of hard currency (89 percent), absence of skilled local labor (63 percent), travel restrictions (63 percent), and price escalation (50 percent). (See Figure 3 and findings box for more details.)

Figure 3. Local Manufacturers' Major Barriers to Utilizing Full Production Capacity



Manufacturers' Challenges Assessment Findings

- Most local manufacturers are operating far below their capacity, with a dramatic decline during the past two years. Until 2018, only one of six companies that responded to this question (17 percent) was operating below 25 percent of its capacity; in 2020, the number of companies that operate below 25 percent of capacity was five of seven responding (71 percent).
- Among the reasons for not operating at full capacity, all surveyed manufacturers cited the shortage of hard currency and an erratic supply of raw materials as the most significant challenges. Their most common reasons for not being able to import the quantity of raw materials needed or requested include:
  - Lack of access to hard currency due to COVID-19 (75 percent);
  - Delay in supplier shipment due to COVID-19 (75 percent);
  - Price increases (38 percent); and
  - Supplier sales restrictions (38 percent).
- The manufacturers highlighted several other challenges, including:
  - Three-fourths noted poor access to finance/loans (75 percent).
  - Half indicated problems with inadequate utilities (50 percent).
  - All rated improving access to hard currency as extremely critical (100 percent).
  - Half cited improved access to finance (50 percent).
- The spread of COVID-19 has negatively impacted local manufacturers in multiple ways, including a reduction in manufacturing capacity (operations) leading to a decrease in revenue; increased overall monthly cost (e.g., unexpected costs, including company fumigation and spraying, supply of sanitizer and face masks for employees, etc.); and a shortage of foreign currency due to COVID-19.

In Q4, PQM+ partnered with WHO to develop a policy brief summarizing available data on the status of local manufacturers and recommending ways for government stakeholders to implement the country's vision for local pharmaceuticals production. Overall, the evidence indicates that the existing few local manufacturers, despite working below their available production capacity, can contribute substantially to the supply of essential medicines to addressEthiopia's key public health priorities. However, this will require a concerted effort among the

government and other relevant stakeholders and partners to address industry challenges identified in the assessment, which severely affect local medicines production. This effort will ultimately contribute to improving the availability of quality-assured priority medicines from local sources.

In recent years, the local manufacturing industry has faced several hurdles, as indicated in a PQM+ assessment published in December 2020, titled “Available Capacity and Barriers to Local Production of Pharmaceuticals.” An assessment conducted in early 2021 sought to determine local manufacturing industries’ status in implementing the GMP roadmap after EFDA granted a deadline extension. The assessment was conducted based on the corrective and preventive actions (CAPA) plan submitted during a 2016 inspection. The assessment examined six of nine manufacturers that submitted the CAPA in 2016, rating results in terms of their progress. It found that only one manufacturer had cleared more than 80 percent of deficiencies listed in its CAPA plan, earning an “on track” rating. Two companies received a rating of “in progress,” clearing between 62 and 68 percent of the deficiencies their CAPA plans noted. The rest received a rating of “lagging,” scoring below 60 percent of deficiencies cleared. These challenges might have contributed to local manufacturers’ inability to fulfill the requirements stipulated in the GMP roadmap. Regardless, local manufacturers have considerable work aheadto meet the expected pace toward GMP compliance.

In Q4, PQM+ provided technical assistance to FBPDI to develop a document that provides guidance to select local manufacturers on the approaches for WHO prequalification and subsequent preparatory actions needed to acquire certification. This document will help FBPDI better understand the processes required to select and support a local manufacturer for WHO PQ in a manner that is transparent and leads to a successful outcome. Acquiring WHO certification (prequalification) by one or more manufacturers in Ethiopia will help demystify the contention that WHO PQ is unrealistic target and will set the example for other manufacturers tofollow suit. This will then pave the way for local production of quality assured medicines in Ethiopia and beyond thereby helping to improve public health through increasing timely access to quality and affordable medicines to the poor and vulnerable populations.

Addressing the gaps identified by WHO’s GBT is a key priority for EFDA to achieve WHO-listed authority status (Maturity Level 3 or higher). PQM+ is providing technical assistance to the authority by developing and revising relevant QMS documentation in compliance with the GBT requirements. This year, PQM+ provided technical assistance in the development of four new SOPs and review/updating of 10 SOPs. In Q2, PQM+ developed one new SOP and updated six others. The program also provided technical assistance to the Medicine Facility Licensing and Inspection Directorate of EFDA in compiling/preparing QMS documentation for submission to the Ethiopian National Accreditation Office (ENAO) for ISO/IEC 17020 accreditation.

PQM+ also assisted with an internal audit to determine the status of its compliance with ISO 17020, followed by development and implementation of corrective and preventive action to rectify the internal audit’s findings. PQM+ also helped the inspectorate identify and create a risk mitigation plan, which is a key requirement for ISO 17020 accreditation; revise/update its quality manual and compile 42 SOPs, assigning numbers per document control requirements; and compile and submit all required documents to ENAO as part of the application for ISO 17020 accreditation. ENAO already provided feedback on the noncompliance identified during evaluation of the documents and is expected to conduct an onsite inspection and evaluation before the final decision for certification.

This quarter, PQM+ provided technical assistance in the correction of non-compliance identified by the accrediting body on documents submitted to ENAO as part of application for ISO/IEC

17020 accreditation. PQM+ also supported the inspectorate on the drafting of one SOP on disposal of regulated products based on findings of internal audit and subsequent CAPA plan. In addition, PQM+ supported the inspectorate in the development/ updating and validation of different formats and checklists for incorporation into the electronic regulatory information system (eRIS), including GMP application formats, applications screening checklists for medicine GMP inspection, medicine GMP waiver and standard letter template for warning and suspension of medicines manufacturers following an inspection (post-inspection). Moreover, PQM+ assisted the inspectorate in drafting the medicine and medical device import and wholesale pre-licensing inspection strategy; the document is under evaluation by EFDA's management committee for approval.

Achieving compliance toward GBT requirements and becoming WHO listed authority providesthe signal that EFDA has the essential competencies needed to properly regulate medicines from product development and manufacture to use by the patient – which will ultimately contribute to safeguarding public health in Ethiopia.

The proper and timely conduct of clinical trials (CTs) is critical for priority health programs to improve their uptake of new treatments and ensure the safety/efficacy of new and existing products. The national regulatory authority is responsible for authorizing clinical trials, monitoring their adherence to good clinical/laboratory practices, evaluating their results, and authorizing use of their results or publishing them in a way that benefits the public. The regulatory authority can also suspend or withdraw approval for a clinical trial, if necessary.

As part of strengthening the quality management system of the clinical trial regulatory function, PQM+ also assisted in developing 12 SOPs to standardize procedures for the application, review, and approval of clinical trial applications. The SOPs cover screening clinical trial applications, review and authorization of new clinical trial applications, review of informed consent forms, review of amendments (both major and minor) to an approved CT application, importation of investigational medicinal products, evaluation of a reply to a request for further information, consideration of non-clinical data within the CT application review, safety reporting on clinical trials, engagement of relevant stakeholders in clinical trials, communication with clinical trial applicants, conditional approval of a CT application after review by the authority, andconducting Good Clinical Practice (GCP) in trial inspections.

In Q4, PQM+ supported the development of a new SOP on writing a clinical trial inspection report, which has been submitted for review. In addition, PQM+ supported EFDA in the organization of a workshop with relevant staff members to review the two directives developed in Q3. After a thorough discussion, a decision was made to merge the two directives into one clinical trial authorization directive. All participant input was incorporated, and a final draft is ready for wider consultation with external stakeholders. The practical implementation of these directives and SOPs will improve the consistency, transparency, accountability, and efficiency ofregulatory oversight of clinical trials. This will ultimately enhance uptake of new treatment options and ensure that treatments in Ethiopia are safe and effective.

Objective 5: Global medical product quality assurance learning agenda and operational agenda advanced

During PY2, the PQM+ chief of party (COP) participated at the 41st annual scientific conference of the Ethiopian Pharmaceutical Association in late July. This event attracts pharmacists from diverse sectors of the health and pharmaceutical systems, making it a perfect platform to disseminate information about medicine quality, which will contribute toward improving awareness and stimulating participation to prevent the circulation of poor-quality medicines.

Priority Activities for Next Quarter

- Clean data, compile, and write PMS report;
- Continue supporting EFDA to fulfill GBT requirements;
- Submit a policy brief on addressing the challenges of local pharmaceutical production in Ethiopia, and participate in discussions with policymakers as applicable; and
- Follow up and respond to any USAID feedback on the PY3 work plan.

Ghana

Malaria is endemic to Ghana and a major cause of illness and death in the country, particularly among children and pregnant women. Maternal mortality is another pressing health concern. Postpartum hemorrhage is the leading cause of maternal death in Ghana, one of 25 countries that account for more than 66 percent of the world's maternal and child deaths.[1]

WHO recommends oxytocin as a first-line treatment for postpartum hemorrhage. With technical assistance from the PQM+ predecessor program, PQM, USAID/Ghana worked on building the capacity of the Ghana Food and Drugs Authority (GFDA) to monitor the quality of maternal and child health commodities such as oxytocin. GFDA, now a WHO Maturity Level 3 medicines regulatory authority, has made great strides in surveying antimalarials, with a failure rate of less than 10 percent in the last survey. However, the challenge of substandard, falsified, and unregistered medicines, including those used to treat postpartum hemorrhage, persists.

PQM+ is working with GFDA and other stakeholders to adopt a risk-based sustainable approach to PMS; helping a local manufacturer achieve WHO prequalification for artemether/lumefantrine tablets to treat malaria; collaborating with GFDA to assess the progress of threeother manufacturers audited by PQM in 2019; identifying potential local manufacturers of oxytocin; and collaborating with the Ghana Health Supply Chain-Procurement and Supply Management (GHSC-PSM) to prepare the local pharmaceutical industry and GFDA to adopt GS1 standards.

In PY2, PQM+ worked to:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors and
- Increase the supply of quality-assured essential medical products of public health importance.

[1] https://www.usaid.gov/what-we-do/global-health/maternal-and-child-health/priority-countries

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Ghana achieved the following.

- Supported establishment of a national multisectoral PMS-TWG that will serve as an instrument of the medicines regulatory authority (FDA Ghana) to oversee PMS activities in the country.
- Trained the PMS-TWG on the online MedRS tool and provided supportive supervision to develop Ghana's first risk-based PMS protocol for antimalaria and MCH medicines.
- Trained medicines samplers and supervised the sampling and testing of products.
- Identified two new potential manufacturers of quality-assured antimalarials and two potential manufacturers of oxytocin injection and began technical assistance to improve their quality management systems to meet WHO prequalification requirements.

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

During Q4, PQM+ supported GFDA to train medicines samplers on the new risk-based PMS protocol and the best approaches for sampling and screening. PQM+ trained and prepared 19 samplers (13 male and six female) from five regions for the sampling missions. By the end of August, GFDA had completed antimalarial and MCH medicines sampling, including 378 samples:177 MCH (misoprostol tablets and oxytocin injection) and 201 antimalarial products (artemether/lumefantrine tablets, artemether injection and artesunate injection). Shipment and clearing challenges delayed Minilab™ screening, so to speed up testing, USP-Ghana is conducting confirmatory testing of oxytocin and misoprostol samples (which do not require screening), while GFDA will test the antimalarial samples. Screening is completed and GFDA has started confirmatory testing of the antimalarial samples that will continue through PY3, Q1.

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

PQM+ provided technical assistance to four local manufacturers at the beginning of Q4: three for quality-assured artemisinin-based combination therapy (ACT) and one for quality-assured oxytocin injection. Three new manufacturers and Entrance Pharmaceuticals developed roadmaps toward prequalification with PQM+ experts' support, and the program began work with these manufacturers to build their quality systems according to WHO GMP requirements. PQM+ experts from Nigeria and Ghana provided supportive supervision to help Entrance Pharmaceuticals, Ernest Chemists, and Amponsah Efah implement new quality management systems, product development, packaging and release, qualification and validation, and quality control measures as per the roadmaps that were developed.

Objective 5: Global medical product quality assurance learning agenda and operational agenda advanced.

PQM+ participated in the second meeting convened by a national TWG on GS1 supply chain standards during Q3, creating a draft pharmaceutical traceability strategy for Ghana. In Q4, PQM+ participated in a workshop organized by the GS1 TWG (with support from GHSC-PSM)to finalize the draft strategy. Next steps include development of an implementation plan. It is

also expected that industry will require at least two or three years to be able to adopt the GS1 standards for pharmaceutical products in Ghana after the adoption of the policy.

In August, PQM+ deployed a GS1 code adoption industry readiness survey to about 30 local manufacturers via Qualtrics. This survey will assess the industry's knowledge of GS1 codes and what they think they will need to adopt the standards for pharmaceuticals in Ghana. Based on the findings, PQM+ will collaborate with the national GS1 technical working group to convene a workshop to sensitize industry members on the GS1 code, what is required to implement the standard, and support that may be available to them through the process. As the implementation plan of the GS1 strategy has not yet been developed, future plans to support industry to adopt the GS1 standard will be scheduled to align with the dates in the implementation plan.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Continue to monitor the testing of the antimalarial and MNCH samples;
- Support GFDA to disseminate the results of PY2 RB-PMS;
- Provide technical assistance to three local ACT manufacturers, including training and QMS building, per the roadmaps developed in PY2; and
- Evaluate the GS1 survey results.

Guinea

Malaria is the top public health problem in Guinea, taking more lives than any other disease. PMI supports activities in line with the goal of reducing malaria-related mortality by 50 percent. This is because malaria is the primary cause of medical consultations, hospitalizations, and deaths, particularly for children under 5 years old. The maternal mortality rate in Guinea is one of the highest in the world. Through family planning and reproductive health (FP/RH) funding, USAID aims to integrate family planning services with maternal and neonatal health care, including emergency obstetric and newborn care. Through maternal and child health (MCH) funding, USAID seeks to scale up evidence-based interventions and contribute to a reduction inmaternal, newborn, and child mortality.

In collaboration with USAID's Systems for Improved Access to Pharmaceutical Services (SIAPS) program, PQM (the predecessor to PQM+) facilitated the process of revising the pharmaceutical law. Through this effort, Guinea's parliament enacted new legislation in June 2018 and the president signed it into law in July 2018. The National Directorate of Pharmacy and Medicines (DNPM) is installing regulatory provisions related to its mandate while strengthening its technical capacity to carry out regulatory functions.

In PY2, PQM+ worked to:

- Improve governance for medical product QA systems and
- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Guinea achieved the following. Kicked off

project work upon receipt of funding in April.

Supported establishment of a national multisectoral PMS-TWG that serves as an instrument of the medicines regulatory

authority (DNPM) to oversee PMS activities in the country.

Trained the PMS-TWG on the online MedRS tool and provided supportive supervision to develop Guinea's first risk- based PMS protocol for antimalaria, maternal and child health (MCH), and family planning medicines.

Worked with the PMS-TWG to finalize a national risk-based PMS guidance document.

Trained the national quality control laboratory staff on good laboratory practices and on six quality control techniques (pH, loss on drying, titrimetry, Karl Fischer titration, ultraviolet-visible spectrophotometry, and high-performance liquid chromatography). These training sessions strengthened the capacity of LNCQM to conduct key quality control techniques respecting good

Progress by PQM+ Objective

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

This quarter, PQM+ supported DNPM to convene a training workshop for members of its PMS-TWG on the use of the MedRS tool. This tool enables users to conduct a risk analysis to help the country identify the high-risk molecules/products to sample, geographic locations to target, facilities to sample from, and the representative sample size to collect. The output of that tool helps to develop RB-PMS protocols. In addition, during this workshop, PQM+ provided supportive supervision to the PMS-TWG to develop RB-PMS protocols for anti-malarial, MCH, and family planning medicines.

In July, PQM+ evaluated the equipment needs for LNCQM, taking into consideration key equipment that is required to conduct compendial testing to ascertain the quality of medicines. In terms of equipment required for quality control testing of medicines, LNCQM has 16 functioning pieces and eight that are damaged. As a result, it is unlikely that LNCQM will be ableto test all RB-PMS samples for PY2. PQM+ may have to ship some samples for testing to a laboratory outside Guinea. To put LNCQM on the path to future in-country testing of all PMS and other routine registration and investigation samples, PQM+ used an evaluation conducted this quarter to recommend 16 new pieces of equipment and five devices for procurement with funding from USAID. LNCQM and PQM+ will consider this equipment for procurement in PY3 based on funding availability and concurrence from USAID.

To build the capacity of LNCQM technical personnel for quality control testing, PQM+ conducteda training on quality control (QC) techniques that LNCQM can conduct with its existing equipment. These include high-performance liquid chromatography (HPLC), pH, ultraviolet (UV) spectrophotometry, loss on drying (LOD), Karl Fischer (KF), and titrimetry. The training showed 13 analysts (12 male and one female) to use this equipment and apply best practices while conducting these laboratory tests.

In pursuit of international recognition via ISO/IEC 17025 accreditation and WHO prequalification, LNCQM should periodically check its quality systems through internal audits. InQ4, PQM+ introduced LNCQM management to the Stepwise Assessment Tool Towards

Accreditation (SATTA) and trained 12 technical personnel (10 male and two female) on its use for internal audits. Using this tool to conduct routine audits at LNCQM will help the laboratory staff identify areas for improvement.

To help understand LNCQM's level of compliance with the ISO/IEC 17025 standard, PQM+ conducted a baseline assessment of the laboratory using the SATTA tool, per the ISO/IEC 17025 standard. LNCQM's overall score of 6 percent indicates very low adherence to the standard. PQM+ and LNCQM will develop and finalize a roadmap toward ISO/IEC 17025 accreditation detailing interventions. Support to LNCQM during subsequent program years willbe based on this roadmap.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Monitor the sampling and testing of the RB-PMS samples as per the RB-PMS protocol developed in Q4;
- Support a working visit for two analysts from LNCQM Guinea to the USP-Ghana laboratory to understudy quality control testing in an accredited environment; and
- Build the capacity of the MEDICRIME Brigade and work with the Brigade to develop relevant guidelines and SOPs.

Kenya

The PQM+ program aims to strengthen the quality of medical products in Kenya by improving governance structures and regulatory systems for medical product quality assurance. PQM+ delivers technical assistance to the Pharmacy and Poisons Board (PPB), NQCL, Division of National Malaria Program (DNMP), Department of Family Health (DFH), MOH's Division of Health Products and Technologies (HPT), and the counties to further strengthen stakeholders' capacity to ensure citizens' access to quality-assured medical products.

In PY2, PQM+ is working to:

- Improve governance for medical product QA systems;
- Strengthen regulatory systems for assuring quality of medical products;
- Optimize and increase financial resources for medical product QA systems;
- Increase supply of quality-assured essential medical products of public health importance; and
- Advance the global medical product QA learning and operational agenda.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Kenya achieved the following.

Procured and delivered a specialized laboratory tool, the Karl Fisher titrator, for the NQCL.

Began assisting the NQCL to analyze costs and fees of its medicines quality testing services to identify ways to make the laboratory financially sustainable.

Assisted the Division of Health Products and Technologies (HPT) of the Ministry of Health to develop brief informational packages for dissemination of the HPT supply strategy and related HPT guidelines and tools. PQM+ took the lead in designing and developing simple infographics and job aids on the quality assurance framework for HPTs.

Supported the DNMP to conduct a technical review of the draft QA framework for malaria commodities.

Conducted a human resources (HR) capacity assessment of the NQCL to identify its workforce's strengths and weaknesses

In Q4, PQM+ focused on improving governance for medical product QA systems, increasing supply of quality-assured essential medical products of public health importance and strengthening regulatory systems to assure the quality of medical products in Kenya.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

Regulatory rule-making procedure: As the national medicines regulatory authority for Kenya andin the course of its work, PPB develops various regulatory instruments to guide its work and interactions with the sectors they regulate. PPB's legal and regulatory instruments should be guided by good regulatory practices as recommended by the World Health Organization. In Q4, PQM+ worked with PPB to develop the Guideline for Development, Review and Approval of Regulatory Instruments. A draft of the guidelines is under review. Once the development process is completed and implemented, the rule making guideline will support PPB in development of regulatory tools and instruments that will ensure Kenyans have access to safe, quality, and efficacious medicines.

Malaria commodities quality assurance: Working with the Division of National Malaria Program (DNMP) in Kenya and other stakeholders, PQM+ program developed the Quality Assurance Framework of malaria products. During Q4, PQM+ submitted the developed QA Framework to the Director General of Health at the Ministry of Health for his approval. The document was approved, handed over to the DNMP and is now ready for dissemination and implementation. The framework will guide key stakeholders involved in ensuring the quality of malaria productsin the country by clarifying the roles and responsibilities of each stakeholder.

In addition, PQM+ participated in the Division of National Malaria Program's Commodities Management Committee of Experts (COE) virtual meeting in August, focusing on procurement and supply management (PSM) of malaria commodities. This multi-stakeholder forum discusses critical issues affecting malaria commodities' quality, procurement, and supplies. During the meeting, PQM+ presented on the risk-based approach for post-marketing surveillance of the quality of antimalarial medicines. Arising from the meeting, the committee recommended harmonization of the various PMS activities conducted by the program, especially those funded by USAID, the Global Fund, the Pharmacy and Poisons Board, and other sources of PMS funding.

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

Developing a PPB online platform for self-directed learning: PQM+ continued supporting the PPB to set up an online platform for self-directed learning. In Q4, the consultants developing theLMS system developed and installed the beta version of the developed system onto the PPB's servers. This version is undergoing testing and feedback by both the content developers and the users of the system. In addition, the consultants developing the course contents refined the drafts submitted by PPB subject matter experts, in readiness for uploading onto the system. PQM+ has now developed sample content that is currently undergoing final quality assurance before its upload to the online learning platform, which is ready for testing. This online platformis a cost-effective and sustainable strategy for improving the competence and technical skills capacity of the PPB staff to regulate and assure the quality of medicines used by the malaria, reproductive health, maternal and child health programs in the country.

Risk-based post-marketing surveillance of product quality: During Q4, PQM+ program worked with members of the pharmacovigilance and post-market surveillance technical working group (PV/PMS TWG) to undertake RB-PMS for malaria and RMNCH commodities. During the activity, the Pharmacy and Poisons Board (PPB) and National Quality Control Laboratory (NQCL) trained pharmaceutical experts who collected samples of medicines from the field for quality testing, using the protocol for RB-PMS that PQM+ helped develop in Q2. The trained experts sampled antimalarial and RMNCH products across 19 counties, with priority based on the overall MedRS risk scores of these two groups of medicines. At the end of Q4, PQM+ and the PPB team were waiting for the delivery of reagents, chemicals, and some equipment for MiniLab™ screening of the collected samples. The delay in screening resulted from vendors' procurement challenges in importing activity components due to COVID-19. The Pharmacy andPoisons Board contributed the vehicles and personnel for the activity.

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

Rationalizing fees for medicines quality testing: **The** PQM+ program is assisting the National Quality Control Laboratory (NQCL) to analyze costs and fees of its medicines quality testing services to identify ways of making the laboratory financially sustainable. During Q4, PQM+ identified, contracted, and inducted a financial costing consultant for the assignment. The consultant is expected to complete the work and submit a report within the next two months. The information gained from the assignment will be used to put in place measures to ensure financial sustainability of NQCL activities.

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

Local supply of essential medicines: PQM+ program continued collaborating with the PPB to strengthen its capacity for regulatory oversight of good manufacturing practices (GMP); and promoting GMP compliance by local manufacturers of antimalarial medicines, medicines used in the maternal and child program, and medicines for reproductive health and family planning. In Q4, the PQM+ program technical staff and the contracted GMP consultant interviewed key stakeholders, such as local manufacturers of medicines, the Federation of Kenya Pharmaceutical Manufacturers (FKPM), public and private procurement and supply agencies (Kenya Medicines Supply Authority and Mission for Essential Drugs and Supplies), the National Quality Control Laboratory, the Africa Leaders Malaria Alliance (ALMA), the Pharmacy and

Poisons Board, the Ministry of Health Division of Health Products and Technologies, and the Division of National Malaria control Program, to gather information about challenges and opportunities for improving the local manufacture and regulation of quality-assured antimalarials and MNCH medicines in Kenya. The interviews were completed in Q4, followed by analysis of the responses and compilation of a report to guide specific technical, managerial, regulatory, and policy-level interventions.

Objective 5: Global medical product quality assurance learning agenda and operational agenda advanced

Analysis and synthesis of local data from previous PMS activities to inform policy: PQM+ supported PPB to initiate the analysis of previous PMS data and review the PMS reports with the target of drafting and submitting a manuscript for publication in a scientific journal. PQM+ initiated the process of identifying a consultant to analyze the previous PMS data. In addition, PQM+ working together with PPB and National Quality Control Laboratory personnel developedan abstract on risk-based PMS that was submitted to the Pharmaceutical Society for Kenya for their upcoming annual scientific conference.

Integration of PPB PMS data into the PV system for safety and quality dashboard: PQM+ held a meeting with PPB's product safety department together with system developers to discuss how to comprehensively integrate the PMS data into the pharmacovigilance reporting system. The meeting identified the existing challenges for successful implementation and explored suggestions on how these could be addressed in the upgraded PPB safety and quality surveillance IT system.

Advocacy for product quality: PQM+ program in partnership with the Ecumenical Pharmaceutical Network (EPN) co-hosted a webinar addressing the negative perception aboutthe quality and cheaper prices of generic medicines. The webinar focused on managerial and regulatory strategies for assuring the quality of generic medicines during manufacture, procurement, distribution, and use. Presenters also underscored the importance and economicbenefits of using generic medicines for public health programs such as maternal and child health, family planning and reproductive health and malaria control programs.

Priority Activities for Next Quarter

Next quarter, Kenya plans to:

- Support the PPB to test the samples collected during the PMS survey based on the RB-PMS protocol developed for antimalarials and RMNCAH products;
- Assist PPB to complete the establishment of an online platform for self-directed learning;
- Strengthen the technical capacity of PPB and local pharmaceutical manufacturers in GMP to increase local the supply of quality-assured antimalarial and RMNCAH commodities;
- Advocate for inclusion of a medical product QA framework in select health coverage schemes in Kenya;
- Analyze and synthesize local data from previous PMS activities to inform policy direction for QA of malaria and RMNCAH products; and
- Continue to support PPB to integrate their PMS into the PV system to create a medicines safety and quality dashboard.

Liberia

PQM+ sustainably strengthens medical product quality assurance (QA) systems in LMICs. By sharing scientific expertise and providing technical support and leadership, PQM+ helps create resilient local health systems that ensure access to quality-assured essential medicines for HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases (NTDs), and other infectious diseases, as well as for reproductive, maternal, newborn, and child health (RMNCH).

In PY2, PQM+ worked to:

- Improve governance for medical product QA systems and
- Improve regulatory systems to assure the quality of medical products in the public and private sectors.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Liberia achieved the following.

- Supported the LMHRA to develop seven priority regulations.
- Provided technical assistance to help the LMHRA develop its five-year strategic plan.
- Supported the LMHRA to resume medicines registration by developing 13 SOPs for medicines registration, and provided dossier evaluation training to 13 senior assessors
- Supported the LMHRA QC lab to resume basic QC screening by donating MiniLabs™ and reagents, and reviewed a quality manual and 36 SOPs.
- Coordinated with the LMHRA to complete a GMP gap Assessment of a local pharmaceutical manufacturer
- Supported the LMHRA PQM+ to develop a costing template
- Coordinated with the LMHRA to establish a technical working group on post-marketing surveillance.
- Coordinated with the LMHRA to conducted one round of RB-PMS in five counties.
- Completed a human resources capacity assessment of the LMHRA.
- Coordinated with the LMHRA to complete an investigation on the diversion of PMI-procured antimalarial medicine in Monrovia.
- Competed an investigation on the diversion of PMI-procured antimalarial medicine in Monrovia.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

This quarter, PQM+ technical assistance enabled the LMHRA to draft seven priority regulations. The LMHRA submitted the following regulations to its board of directors:

- Treatment and Disposal of Unfit Medicines and Health Products,
- Donation of Medicines and Health Products,
- Import and Export of Medicines and Health Products,
- Labeling of Medicines and Health Products,
- Recall of Medicines and Health,
- Advertisement of Medicines and Health Products, and
- Registration of Medicines and Health Products.

Participants of the regulation review meeting included LMHRAManaging Director Keturah Smith (center).

PQM+ expects the LMHRA board of directors to approve the seven regulations. Since the establishment of the LMHRA in 2010, these constitutethe first sets of regulations drafted for the agency. “It took 11 years for regulations meant to govern the regulatory body to be developed,” said Keturah C. Smith, managing director of LMHRA. “Prior to the development of these regulations, decisions were made by individuals’ discretion, which may sometimesbe partial. … I am immensely grateful; now things will be more definite and discrete.”

From left to right: Theophilus Ndorbor of PQM+,Simmie Nyanfor of USAID, Keturah C. Smith of LMHRA, and Ben K. Botwe of PQM+.

PQM+ will facilitate a dissemination meeting following the board’s approval of the regulations.

In Q4, PQM+ also completed a human resources capacity assessment of the LMHRA, with 59 LMHRA staff participating. PQM+ interviewed 15 senior staff of the LMHRA during Q3. In September, PQM+ coordinated with the LMHRA to conduct an internal validation of the Human Resource Capacity Assessment Report with 11 LMHRA staff members and three PQM+ representatives attending. During the meeting, PQM+ presented findings and recommendations from the assessment. LMHRA Managing Director Keturah C. Smith lauded USAID for supporting PQM+ to conduct the assessment.

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

Medicines registration is one of LMHRA’s key regulatory functions. This quarter, PQM+ completed the review of 13 SOPs to facilitate medical products registration in Liberia. In August, PQM+ delivered a medicines registration process flow training to 17 LMHRA staff members, with a focus on receiving, processing, evaluating, and approving registration applications.

PQM+ also completed a review of seven QA SOPs in Q4; when operationalized, they will support the LMHRA toward ISO 17025 accreditation.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Support the LMHRA to resume laboratory testing activities;
- Continue drafting regulations;
- Complete the testing of PMS samples; and
- Conduct a stakeholder forum on the deployment of priority regulations.

Madagascar

The PQM+ program aims to strengthen the quality of medical products in Madagascar by improving governance structures and regulatory systems for medical product quality assurance. PQM+ delivers technical assistance to the *Direction de l'Agence du Médicament de Madagascar* (DAMM), the *Laboratoire de Contrôle de Qualité des Médicaments* (LCQM) and the Ministry of Health (MOH) to strengthen in-country stakeholders' capacity in ensuing access to quality-assured medical products for the Malagasy population. PQM+ will closely collaborate with the Global Fund Project Coordination Unit (UCP) in Madagascar.

In PY2, PQM+ began work to:

- Strengthen regulatory systems for assuring quality of medical products.

The workplan for Madagascar was approved in Q3. Immediately after its approval, PQM+ engaged two local consultants to lead provision of technical assistance to the DAMM, LCQM,and other stakeholders.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ began work on its Madagascar activities. Highlights of this work include:

Held program inception and technical activity implementation planning meetings with the head of DAMM to agree on and schedule detailed activities to strengthen DAMM's capacity for PMS of the quality of medicines and other medical products in Madagascar.

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

Due to suspended international travel, the PQM+ regional team was unable to travel to Madagascar to work on activities during Q4. Travel is expected to reopen in PY3, Q1.

Priority Activities for Next Quarter:

- Strengthen PMS of the quality of medicines in the country and
- Strengthen the capacity of the LCQM.

Mali

Over the past decade, the Government of Mali has engaged in widespread institutional reform. In 2019, however, the *Cellule de Développement Institutionnelle* (Institutional Development Unit,or IDU) rejected regulatory provisions for the creation of a national pharmaceutical regulatory agency, as proposed by the Directorate of Pharmacy and Medicines (DPM). According to the IDU, the provisions needed major revision. The DPM has yet to submit a revised proposal and is working to mobilize national support for the initiative. DPM hopes to share case studies of successful precedents in francophone Africa to convince the IDU of the need to establish a national pharmaceutical regulatory agency.

In PY1, PQM+ Mali supported *Laboratoire National de la Santé* (LNS, the National Health Laboratory) and DPM in establishing a PMS-TWG. The TWG includes representatives from the LNS, DPM, disease programs, *Pharmacie Populaire du Mali* (Popular Pharmacy of Mali), and private wholesalers' association. This was to address the lack of coordination in PMS activities. The working group adapted the *Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries* to the Mali context and developed a risk-based PMS protocol for antimalarial and MCH medicines.

PQM+ Mali also continued strengthening LNS's QC processes so the laboratory could achieve ISO/IEC 17025 accreditation. Thus, PQM+ implemented SATTA at LNS to help laboratory staff identify areas for improvement as they pursue accreditation and prequalification. PQM+ Mali trained staff on the techniques for its proposed accreditation scope in preparation for accreditation.

In PY2, PQM+ Mali is building the capacity of DPM's dossier evaluation committee to assess dossiers in the Common Technical Document (CTD) format, establishing a metrology team within LNS, and supporting implementation of PMS activities planned by the PMS-TWG.

In PY2, PQM+ worked to:

- Improve governance for medical product quality assurance systems;
- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors; and
- Increase financial resources for medical product QA optimization.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Mali achieved the following.

- Supervised the sampling and testing of antimalaria and MCH medicines as well as the dissemination of the first RB-PMS results in Mali.
- Provided supportive supervision to the PMS-TWG to develop the second RB-PMS protocol, which was implemented in Q4.
- Conducted a baseline assessment of LCQM and worked with LNS management to develop a roadmap toward ISO/IEC 17025 accreditation.
- Provided supportive supervision to close gaps identified during the baseline assessment and conducted practical quality control training to strengthen analysts' capacity to conduct the techniques identified in their proposed accreditation scope.
- Supported LCQM to calibrate its equipment and trained the in-house metrology unit on conducting basic equipment preventive maintenance to improve the management of equipment at LCQM and the reliability of test results.
- Provided training on the Common Technical Document (CTD) dossier format to build the capacity of DPM's technical committee to better evaluate dossiers in this format.
- Supported an OpERA assessment.

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

Using the risk-based PMS protocol developed in Q3 and applying the fixed-award agreement (FAA) mechanism established between PQM+ and LNS Mali, the PMS-TWG started samplingof antimalarial and MCH medicines from three of six planned regions in Mali. Sampling for theother three regions will continue into PY3.

PQM+ trained staff of Mali's Medicines Quality Control Laboratory (LCQM) within LNS during PY1 on quality control for each technique on their accreditation scope. This training was conducted virtually at the height of the COVID-19 pandemic, with the help of videos specifically created for this purpose. During Q4, PQM+ conducted a second series of hands-on refresher trainings in Bamako on the same accreditation scope techniques using LCQM's equipment. The training taught 15 technical personnel (six female and nine male) eight key analytical techniques: pH, loss on drying, dissolution, HPLC, UV-visible spectrophotometry, infrared spectrometry, uniformity of dosage units, and titrimetry. LCQM plans to apply for ISO/IEC 17025accreditation of these techniques, and this training helps to further strengthen the lab's capacityfor them. PQM+ also conducted advanced quality management systems training on measurement uncertainty and internal quality checks (IQCs) for 14 technical staff (six female and eight male), which will enable the LCQM to calculate uncertainties for measurements/tests they conduct and include them in the results they report, as required by the ISO 17025 standard.

In Q4, PQM+ conducted a mock audit of LNS's LCQM, seven months after the baseline assessment. Out of the 49 non-conformances noted during the baseline assessment, 31 had been closed and a corrective action plan was developed with LCQM's QA team to close the

remaining 18 gaps before December 2021, which is when LNS plans to have LCQM audited for ISO/IEC 17025 accreditation.

To improve the capacity of the DPM's dossier evaluation committee of experts to evaluate technical dossiers in the CTD format, PQM+ regulatory system strengthening experts delivered the training curriculum, which PQM+ customized to the Malian context with help from IntraHealth through a training needs assessment conducted in Q3. The training reached 17 committee of expert members (three female and 14 male) on several topics, including: introduction to CTD format; introduction to dossier evaluation; active pharmaceutical ingredient (API) data assessment in CTD; finished pharmaceutical product (FPP) data assessment in CTD; product information and labeling; bioequivalence; biopharmaceutical classification systems (BCS); and biowaivers and common deficiencies in dossier evaluation. The training willimprove the assessment method of product registration dossiers in Mali, enabling the committeeto identify deficiencies that could lead to the registration of poor-quality medicines and to act on these deficiencies to prevent this.

PQM+ also supported an OpERA assessment of DPM's medicines registration processes. The assessment questionnaire completed by the DPM has been evaluated by CIRS and the report is currently under development.

Objective 3: Increase financial resources for medical product QA optimization

Toward the end of Q4, PQM+ technical and financial experts convened a workshop to train LNS technical and administrative managers on applying a new costing model to determine a more accurate cost of quality control tests. This costing structure reflects the needs of LCQM's new ISO/IEC 17025 quality management system and takes into consideration expenses related to equipment calibration, requalification, preventive maintenance, reaccreditation fees, continuous professional development for technical personnel, procurement of traceable standards for routine equipment verification, and basic operations costs such as procurement of lab consumables, which they already routinely budget for. The structure has given LNS management a clearer picture of the proper cost of testing medicines at LCQM, and PQM+ encouraged the agency to take the necessary administrative steps to officially revise its testing fees.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Monitor the testing of RB-PMS samples;
- Support DPM and LNS disseminate the results of their second RB-PMS;
- Conduct the situational analysis for the development of a five-year strategic plan for LNSP; and
- Provide supportive supervision to LCQM to close the remaining 18 gaps identified during the mock audit.

Mozambique

Mozambique established its National Directorate of Pharmacy (DNF) in 2017 as a transitional organization, working toward becoming an autonomous National Medicines Regulatory Authority (NMRA). It was created from the Pharmacy Department of the Ministry of Health after

the promulgation of the revised pharmaceutical law. Further technical support is required to help the QC laboratory, known as the Department of Drug Quality Check (DCQ), attain ISO/IEC 17025:2017 accreditation, and for DNF to attain Maturity Level 3 in the WHO GBT program and ISO/IEC 9001:2015 accreditation.

In PY2, PQM+ worked to:

- Improve governance for medical product QA systems;
- Strengthen regulatory systems for quality medical products; and
- Optimize and increase financial resources for medical product QA systems.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Mozambique achieved the following.

- Evaluated the status of actions recommended during an audit conducted by PQM in 2018.
- Updated the roadmap toward ISO/IEC 17025:2017 accreditation and discussed it with the laboratory and DNF management.
- Trained DCQ staff to use the SATTA tool to conduct an internal quality audit of the laboratory.
- Conducted a mock assessment of the DCQ laboratory using the SATTA tool.
- Presented a draft quality risk management SOP to DCQ.
- Facilitated a five-day workshop for the DNF and key stakeholders to establish a the national (PMS-TWG).
- Discussed and finalized the TWG's TOR.
- Trained TWG members on the principles of RB-PMS and using the online MedRS tool.
- Developed a draft protocol for RB-PMS on HIV medicines.
- Procured essential reagents, proficiency testing samples, translation services, and two TRUSCAN machines, as well as replenished MiniLab™ supplies for testing HIV medicines.
- Supported procurement of essential equipment, reference standards, reagents, and supplies for DCQ's laboratory operations.

Progress by PQM+ Objective

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

In Q1, PQM+ reviewed and provided commentary to the DCQ on the current regulation for the medicine's quality control laboratory, which supersedes the previous one. Under the previous legal and regulatory framework, the NQCL was known as the Laboratório Nacional de Controle de Qualidade dos Medicamentos (LNCQM) and operated as an entity with a separate legal identity from the DNF. In the current legal framework, the laboratory has been reorganized to become the Department of Drug Quality Check (DCQ) under DNF. In Q4, PQM+ continued seeking feedback from DCQ in the effort to develop an updated, robust regulation for the department that will support and facilitate its implementation of good laboratory practices. During the quarter, PQM+ again shared the previously developed program implementation and sustainability frameworks with DNF for finalization and approval.

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

The DCQ plays a key role in assuring the quality of medical products in the country as the national quality control laboratory for medicines and other related medical products in Mozambique. Attainment of internationally recognized standards like the ISO/IEC 17025:2017 will showcase DCQ as a competent national institution for quality control testing of medicines. In preparation for the official ISO 17025 accreditation audit of the DCQ, PQM+ Mozambique secured visas for two staff members. The PQM+ staff visited the country in Q4 and implemented an approach to conducting internal audits at DCQ using the PQM-developed Stepwise Assessment Tool Towards Accreditation (SATTA).

In addition, PQM+ conducted a mock audit using the ISO 17025:2017 checklist. Based on findings from the mock audit, the program updated the roadmap toward ISO/IEC 17025:2017 accreditation and discussed it with the laboratory and DNF management, as well as trained DCQ staff on using the SATTA tool to conduct an internal quality audit of the laboratory. PQM+ continues to support DCQ/DNF to implement the activities and tasks from the roadmap for ISO 17025 accreditation.

A major activity on the updated ISO 17025 accreditation roadmap is for PQM+ to assist DCQwith developing, revising, and updating key QMS documents.

Another major activity on the updated ISO 17025 accreditation roadmap is DCQ's participation in a proficiency testing exercise. This quarter, DCQ participated in the proficiency testing (PT) round on the dissolution method and failed; thus, PQM+ generated a CAPA plan to address the gaps that led to the failure. A PQM+ selected PT provider delivered a second set of procured proficiency test samples to the lab. The samples are for HPLC, UV-spectroscopy, loss on drying, and pH.

DCQ requires an internet connection to communicate with customers, access essential information for its operation, and receive technical support from PQM+ during COVID-19 restrictions. This quarter, PQM+ procured and installed a network distribution device to enable the lab to maximize the high-quality internet bandwidth that PQM+ had procured for it. PQM+ included these recurrent expenses in the sustainability framework it shared with the DNF so that DNF may take over payment of these costs using its own funds.

The availability of supplies and reagents is pivotal to DCQ's operation. PQM+ continues to support the procurement of key reagents and supplies for DCQ. To ensure a sustainable supply of the reagents, PQM+ included these recurrent expenses in the sustainability framework it shared with the DNF so that DNF may increasingly take over payment of these costs using its own funds. In line with this recommendation, the DCQ has submitted to DNF management a budget for the essential laboratory reagents and supplies needed for its testing services. This quarter, to ensure that DCQ's laboratory equipment can produce accurate and precise QC test results, PQM+ secured a letter of invitation to enable an external vendor (who had been contracted to provide equipment calibration or performance verification services) to obtain his visa. In Q4, the vendor visited the laboratory and conducted calibration and maintenance on about 20 pieces of equipment. A second external vendor, contracted for maintenance and performance verification of the HPLCs, shipped spare parts that have arrived in Maputo and are awaiting clearance.

PQM+ worked to identify local custom brokers based in Mozambique to help with the clearance process for some lab supplies coming into Mozambique. PQM+ also procured translation services to support the translation of documents and a presentation, as well as aid simultaneous translation, during a workshop that took place during the PQM+ team's visit.

To build the capacity of the DNF's Department of Evaluation of Medicines, Vaccines, and Biological Health Products on dossier evaluation of medical devices, PQM+ finalized a training needs assessment report. The program continued designing and developing a course curriculum for a dossier evaluation of condoms. Weekly meetings are ongoing, in addition to interaction with DNF's Evaluation Department, to gather and share information needed to develop the course curriculum. Discussions with the department to schedule training dates arein progress.

A major activity planned in PY2 using funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funding was to build the DNF's capacity to conduct RB-PMS of HIV medicines circulating in the country. To achieve this target, PQM+ worked with the DNF to establish the first national technical working group (TWG) for PMS. PQM+ collaborated with DNF to hold a five-day workshop, during which TWG members representing six stakeholder organizations (including the DNF) received training on the principles of RB-PMS. PQM+ developed a draft terms of reference (TOR), which the TWG reviewed and customized to suit the Mozambique landscape, then adopted as an official TWG document. The group selected itspresident (from the MRA), vice president (from the laboratory), and secretary (from the HIV program). Workshop participants included 11 women and 10 men. PQM+ provided hands-on training for TWG members on using the online MedRS tool. The TWG used the tool to score thequality risk of medicines, the geographical regions, cities, and facilities. Finally, the group used the collected results from the MedRS tool to draft the RB-PMS protocol for HIV medicines surveillance.

PQM+ also provided technical and operational support to procure two TRUSCAN machines and replenish MiniLab™ supplies for strengthening the DNF's testing capacity. PQM+ identified vendors and contacted them to provide price quotes and delivery times.

The PQM+ team assisted the program's technical resource partners (the University of Washington and the Global Health Impact Group/London School of Hygiene and Tropical Medicine) in conducting a rapid assessment of emergency regulatory processes and procedures for COVID-19 in Mozambique.

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

In Q4, PQM+ continued to support DCQ's ISO 17025 accreditation quest, since attainment of this standard will help DCQ generate additional revenue from rendering QC testing services to other donors like the Global Fund. The revenue generated from this sustainability strategy will enable DCQ to procure supplies and services required for operation.

Priority Activities for Next Quarter

Next quarter, PQM+ Mozambique plans to:

- Perform a maintenance and performance verification service for DCQ's laboratory equipment;

- Help with DCQ's participation in proficiency testing for selected test methods under the proposed scope of accreditation;
- Deliver a training on condom dossier evaluation and provide follow-up support;
- Assist DNF with finalizing the TOR and PMS guidelines that the TWG drafted; and
- Work with the TWG to finalize the PMS protocol.

Nigeria

According to the 2018 Nigeria Demographic and Health Survey, one in eight children die before turning 5 years old. Maternal mortality caused by prolonged obstructed labor, unsafe abortion, septicemia, hemorrhage, and eclampsia is a serious problem in Nigeria. Malaria remains the country's leading public health problem, disproportionately affecting children younger than 5 years and pregnant women. Nigeria also has a high incidence of communicable and noncommunicable diseases.

PQM+ is focused on helping ensure the quality of medicines and other medical products with an emphasis on USAID and Government of Nigeria priority malaria and MCH medicines and family planning commodities. PQM+ collaborates with stakeholders in the public and private sectors to increase local pharmaceutical manufacturing capacity and to sustainably strengthen regulatory systems at the national and state levels. PQM+ also is strengthening quality management systems and building laboratory capacity in quality control testing in compliance with international standards.

In PY2, PQM+ worked to:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors;
- Optimize and increase financial resources for medical product QA; and
- Increase the supply of quality-assured essential medical products of public health importance.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Nigeria achieved the following.

- Conducted a gap assessment of PCN headquarters, which led to development of an ISO 9001:2015 roadmap for the council.
- Supported the National Institute for Pharmaceutical Research and Development (NIPRD) to reduce its annual accreditation fees by subscribing to local accreditation body the Nigeria National Accreditation System (NiNAS) instead of paying the high fees required by the American National Accreditation Board (ANAB).
- Helped NIPRD determine how to generate additional revenue to cover the cost of future reaccreditation efforts.
- Assisted manufacturers of malaria and MNCH medical products in in submitting dossiers for sulfadoxine+ pyrimethamine tablets and zinc sulfate dispersible tablets to the WHO PQ team and upgrading production facilities.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

During Q4, PQM+ concluded the pharmaceutical industry stakeholder survey initiated earlier in the year. Respondents included 37 stakeholders and manufacturers who provided insights on trends, issues, and challenges in the industry. The responses will inform updates to the GMP roadmap report and all industry stakeholders will receive a copy afterward.

PQM+ is also working on the TOR for the national technical working group for the developmentof the national pharmaceutical sector strategy (NPSS) and will fully inaugurate the group in thenext quarter.

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

In Q4, PQM+ continued to collaborate with the Pharmacists Council of Nigeria (PCN) to implement activities to strengthen state-level regulatory and quality assurance systems. The target beneficiaries are pharmaceutical inspectors, for-profit retail outlets (community pharmacies [CPs] and proprietary patent medicine vendors [PPMVs]) involved in selling medicines and consumables and providing essential primary health care services. PQM+ implemented the following activities during the quarter:

- Finalized the reports of the capacity building session held in three states after input and review by applicable stakeholders.
- Conducted capacity building workshops with the theme “Pharmaceutical Inspection – Need for Excellence in Pharmaceutical Services Delivery” for inspectors from the Nassarawa state in Northern Nigeria and Lagos state in the South. The workshops aimed to build the inspectors’ capacity in terms of skills, expertise, and competencies, as well as acquainting pharmaceutical inspectors with new and emerging trends in inspectorate activities. PQM+ staff presented on three topics: regulatory and quality assurance case studies of pharmaceutical retail outlets in Bauchi, Ebonyi, and Sokoto states; the importance of QMS in medical products regulatory system strengthening; and inspection of cold chain facilities. Attendees at the workshop included the chairperson of the board; the registrar; PCN staff; directors of pharmaceutical services at state ministries of health (or their representatives) from all 36 states and the capital, Abuja; selected non-PCN pharmaceutical inspectors; a representative of Pharmaceutical Society of Nigeria (PSN); and a representative of Association of Community Pharmacists of Nigeria (ACPN). The workshops provided an opportunity for PCN to discuss gaps in the quality assurance and regulatory systems with the intent of improving these systems.
- Finalized and printed job aids for CPs and patent medicine shops (PMSs) in Q4, PY2. PQM+ developed the content of the job aids in previous quarters. The posters contain useful information on good visual inspection practices for medical products with a version for community/retail pharmacies and another version for patent medicines shops (PMSs). PQM+ also designed posters on good practices in handling medical products for both pharmacies and PMSs. These posters aim to inform, educate, and communicate key messages to practitioners and clients on steps to assure the quality of medicines and consumables. They will act as information, education, and communication materials and job aids. Various stakeholders provided input into the design and delivery of the

poster before final approval. In PY3, the posters will be distributed to Bauchi, Ebonyi,and Sokoto states. The target is to allocate two posters on different topics to each registered community pharmacy and PMS across the local governments of the respective states.

- Facilitated and participated in a meeting between USAID and the PCN management team to discuss strategies that will enhance the quality of medical products, supply chain, quality assurance, and regulatory systems.
- Organized and facilitated a meeting between USAID-funded implementing partners and PCN to discuss issues and challenges encountered in engaging CPs and PMSs during implementation. The meeting ended with a key agreement on the set-up of a technical working group (TWG) comprising PCN, PQM+ and other implementing partners (IPs) to improve synergy and cooperation among the IPs, ensure quality medical products and health services for the communities they serve, and achieve the subobjectives under USAID's Development Objective 2, to which they contribute through their activities.

In Q4, PQM+ continued to support PCN to institute a quality management system toward attainment of ISO 9001:2015 certification by closely monitoring the implementation of selected activities in the 1SO 9001 certification implementation plan.

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

PQM+ assists manufacturers of malaria and MNCH medical products. A summary of tasks completed in Q4 follows.

For Swipha:

- Provided further support for the zinc sulfate dispersible tablet dossier review in respect of additional product data related to the primary packaging, which led to update and submission of the dossier to the WHO PQ team for evaluation.
- Following a successful review of the bioequivalence study report of their sulfadoxine/pyrimethamine (500/25) mg tablet, the Swipha team updated the SP dossier and submitted it to the WHO PQ team for review and subsequent evaluation.

For Emzor:

- The National Agency for Food Drug Administration and Administration (NAFDAC) conducted an advisory audit of the ready-to-use therapeutic food (RUTF) plant with a positive outcome. Consequently, NAFDAC has granted Emzor the necessary permits to import starting materials for production of scale up batches of the RUTF.
- Supported the development of a project plan for WHO PQ of Emzor's artemether/lumefantrine (20/120) mg following the delivery of the API from a WHO PQ manufacturer. PQM+ provided guidance on formulation optimization; initial lab scale samples correspond to the pharmacopeial specifications. PQM+ also reports that the bioequivalence study of SP began.

For Juhel:

- Provided support in selection of an accredited laboratory to conduct a test of magnesium sulfate 50%w/v injection to determine the risk label adhesive and ink migration into the product.

Priority Activities for Next Quarter

Next quarter, PQM+ in Nigeria plans to:

- Inaugurate the TWG for the NPSS.
- Continue to implement activities approved in the PY3 workplan that will further strengthen the quality assurance and regulatory systems.
- Continue to support PCN in its quest to attain ISO 9001:2015 certification and WHO Maturity Level 3 status in collaboration with NAFDAC.
- Continue to support Juhel to address the request by the WHO PQ team for product data on magnesium sulfate injection.
- Continue to support Juhel in dossier compilation of oxytocin injection and other related documentation.
- Continue to provide support in the revalidation of air handling units in Emzor's expanded oral dosage facility.
- Continue to monitor the progress of the bioequivalence study of Emzor's SP tablet
- Provide support to Emzor technical staff in product development of artemether/ lumefantrine 20/120 tablets and the compilation of submodules of the AL (20/120) mg tablet dossier in the CTD format.
- Support Swipha to submit their zinc sulphate dossier for WHO PQ.
- Continue to support Swipha to address queries/request for additional product data for the SP dossier by the WHO/PQ team.
- Build the capacity of co-inspectors and new inspectors of the Directorate of Drug Evaluation and Research (DER) on GMP inspections.
- Support in the implementation of GMP roadmap report.

Rwanda

The PQM+ program aims to strengthen the quality of medical products in Rwanda by improving country and regional regulatory systems for medical product quality assurance. PQM+ delivers technical assistance to the Rwanda Foods and Drug Authority (Rwanda FDA), Rwanda Medical Supply and University of Rwanda, Regional center of excellence for vaccines immunization and health supply chain management to further strengthen in-country stakeholders' capacity in ensuring access to quality-assured medical products for the population in Rwanda.

In PY2, PQM+ worked to:

- Strengthen regulatory systems for assuring quality of medical products; and
- Increase supply of quality-assured essential medical products of public health importance

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Rwanda achieved the following.

- Supported the Rwanda FDA quality control laboratory to attain access to the U.K. and U.S. pharmacopeias.
- Collaborated with the Rwanda FDA to initiate a training needs assessment and develop a training plan.

Progress by PQM+ Objective

Objective 1: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved

Procuring online reference documents and chemical standards: In Q4, PQM+ supported the Rwanda FDA quality control laboratory to attain access to the U.K. and U.S. pharmacopeias. These online reference documents will function as standards for the quality testing of medical products sampled during post-marketing surveillance or routine testing for registration purposes. PQM+ also procured 19 chemical reference standards for the Rwanda FDA QC laboratory to use in testing the quality of maternal and child health, family planning, and reproductive health commodities.

Objective 2: Supply of quality-assured essential medical products of health importance increased

Training needs assessment and capacity development plan: This quarter, PQM+ collaborated with the Rwanda FDA to initiate a training needs assessment and develop a training plan. This included recruiting two consultants to support the Rwanda FDA in collectingdata for the assessment and proposing a capacity development plan. PQM+ completed the scope of work, inception report, and data collection tools this quarter.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Strengthen PMS of medicines quality in Rwanda;
- Strengthen the capacity of the Rwanda FDA's Drug Quality Control Laboratory;
- Strengthen the GMP regulatory inspection and quality-assurance systems of local essential medical products manufacturers; and
- Review and strengthen the quality assurance policies and guidelines of Rwanda Medical Supply Limited (RMS LTD).
- Collaborate with University of Rwanda to introduce course modules on quality assurance of medical products

Senegal

The Government of Senegal has developed a five-year (2019–2023) integrated strategic plan for the DPM and the *Laboratoire National de Contrôle des Medicament* (LNCM, the National Medicines Control Laboratory). The government's vision is to build "an efficient system of regulation and control, which ensures the development and application of quality standards and

which guarantees access to medicines and other quality health products that are effective and safe for the entire population."

The plan cites areas of weakness of the DPM and LNCM. These 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, the strategic plan outlines seven general objectives. PQM+ is contributing to the first, "Establish an appropriate institutional framework for the optimal implementation of pharmaceutical regulatory and control functions," and the third, "Evaluate and control the qualityof drugs." PQM+ is also addressing two sub-objectives under those general objectives: "Meet the conditions for WHO certification and ISO 17025 accreditation of LNCM" and "Ensure PMS of medical products."

During PY1, PQM+ facilitated the establishment of a national PMS unit that includes DPM, LNCM, the health inspectorate, all disease programs, the procurement agency, the pharmaceutical wholesalers' association, and other allied professional bodies. PQM+ worked with the PMS unit to develop national guidelines and a protocol on RB-PMS for the MedRS tool for antimalarial medicines. During PY2, PQM+ continued to build on this progress.

In PY2, PQM+ worked to:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Senegal achieved the following.

- Supervised the sampling and testing of antimalaria and MCH medicines as well as dissemination of the first RB-PMS results in Senegal.
- Supported the development of five SOPs for RB-PMS to be adopted by DPM and LNCM.
- Supported the LNCM to calibrate its equipment and trained the in-house metrology unit on conducting basic equipment preventive maintenance.

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

Following a workshop that PQM+ supported in Q3 to review and validate five standard operating procedures (SOPs) for conducting risk-based PMS, PQM+ supported dissemination of results of this first risk-based approach to post-marketing surveillance, as adopted by Senegal's DPM and LNCM, at a workshop in Dakar. The dissemination workshop followed months of technical assistance provided by PQM+ using USAID PMI funding, with strong collaboration between various stakeholders who work to assure the quality of medicines in the country.

The workshop opened with Dr. Cheick Camara, president of the PMS Unit at DPM, with about30 participants representing health sector entities including: LNCM; DPM; TB control program; malaria control program; Department of Maternal and Child Health; pharmaceutical manufacturers association; private wholesalers association; *l'Association des pharmaciens*

hospitaliers du Sénégal (APHS, the clinical pharmacists association); and *Pharmacie National de l'Approvissionement* (PNA, the procurement agency).

Health sector stakeholders in attendance made strong recommendations for corrective and preventive regulatory actions, and the group delineated clear next steps and assigned responsibilities for DPM management. Of 301 samples collected (artemether/lumefantrine, artesunate, sulfadoxine/pyrimethamine, and sulfadoxine/pyrimethamine/amodiaquine) from five regions—Dakar, Kolda, Djourbel, Kaolack, Kedougou, and Tambacounda—2 percent did not conform to specifications and failed testing, while about 75 percent of the samples collected were registered.

During Q4, with support from PQM+, LNCM identified qualified (ISO 17025-accredited) metrology service providers in the region and selected the vendor with the largest accreditation scope. The vendor was then recruited, with support from PQM+, to calibrate all equipment and measurement devices within the LNCM to solve a major gap in the laboratory's QMS. LNCM management now has the actual cost of this service and all contact details of this vendor, whomthey plan to include in their approved vendor's list. A second training session on equipment preventive maintenance in Q4 built on the work of the Dakar-based equipment maintenance consultant, who provided technical assistance for equipment preventive and breakdown maintenance and worked with the internal metrology team to develop protocols for basic equipment preventive maintenance.

As DPM plans on embarking on a process toward ISO 9001 certification by the end of 2021, PQM+ provided an initial virtual training on the requirements of the standards for 12 technical personnel of DPM. This will be a foundation for technical assistance PQM+ will provide in PY3to support DPM in achieving this milestone.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Train the PMS Unit on the online version of the MedRS tool and
- Conduct a baseline assessment of the DPM as per the ISO 9001:2015 standard.

Asia Region

Asia Bureau

PQM+'s technical assistance, funded by USAID's Asia Bureau, aims to promote regional regulatory convergence and reliance. PQM+ works through regional health networks that include the Association of Southeast Asian Nations (ASEAN) Pharmaceutical Product Working Group (PPWG) and the South-East Asia Regulatory Network (SEARN) to strengthen regulatoryand quality assurance systems. This work builds on support provided through the PQM program, as well as leverages the current PQM+ work in Southeast and Central Asia. USAID approved the PY2 workplan in November 2020, including work on the current GMP (cGMP) online training course, which received approval earlier.

In PY2, PQM+ is working to:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors.

Highlights of Progress by PQM+ During PY2

During PY2, the PQM+ Asia Bureau achieved the following.

- Engaged partner Mahidol University in Thailand to conduct a regulatory landscape analysis of the medical product quality assurance system for SEARN and ASEAN member countries.
- Helped develop and provided mentorship support to participants of a GMP online course in collaboration with MTaPS, WHO India, **JSS Academy of Higher Education & Research (JSS AHER), Mysuru**, Indian Pharmaceutical Alliance, Ministry of Health and Family Welfare, and the Government of India.
- Developed two course modules for a WHO-led online current Good Manufacturing Practices course in India.

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 PY2, PQM+ worked with its core field-led extension partner, Mahidol University, to conduct a landscape analysis of the medical product quality assurance systems for SEARN and ASEAN member countries. PQM+ expects to complete this assessment and final report in the first quarter of PY3. Furthermore, in collaboration with MTaPS and USAID, the program started to coordinate with ASEAN and SEARN secretariats and member states' NMRAs to identify the priority areas for technical assistance. The assessment report, along with a final agreement on priority areas for technical support, will serve as the basis for development of regional and country-specific plans of action to strengthen regulatory systems.

In collaboration with USAID implementing partner, MTaPS, PQM+ developed two course modules for the WHO-led online cGMP course in India. WHO organized and implemented the course in collaboration with **JSS Academy of Higher Education and Research in Mysuru**, the Indian Pharmaceutical Alliance, the Ministry of Health and Family Welfare, the Government of India, MTaPS, and PQM+. The team successfully rolled out the course and conducted six back-to-back, 12-day workshops, with representatives of 33 pharmaceutical companies from India attending. The program expects to continue its advocacy and collaboration with stakeholders for its rollout in other member countries in PY3.

This quarter, PQM+ received feedback from the ASEAN PPWG on the concept note that PQM+ and MTaPS jointly proposed regarding areas of potential support. The working group preliminarily selected priority areas to receive technical assistance for formal discussion and agreement at a planned meeting next quarter. In addition, in collaboration with Mahidol, the team has made great progress in the landscape analysis of the medical product quality assurance systems, with 11 NMRAs assessed to date. The team expects to finalize the report next quarter.

Priority Activities for Next Quarter

Next quarter, the Asia Bureau plans to:

- Finalize the landscape analysis and report in collaboration with Mahidol University.
- Participate in an ASEAN PPWG meeting to seek necessary approvals from member countries on priority technical areas for support and agree on communication protocols between PQM+ and PPWG.

Bangladesh

In Q4, PQM+ focused on implementing activities of all five program objectives in the PY2 approved work plan and on completing activities from the last quarter of PY1. PQM+ Bangladesh is helping the Directorate General of Drug Administration (DGDA) to institutionalizegood governance practices related to transparency, accountability, and communication with stakeholders; the National Control Laboratory (NCL) to strengthen its medicines quality monitoring systems focusing on vaccines; and manufacturers to increase production of quality-assured first-line anti-TB medicines and their good manufacturing practice.

In PY2, PQM+ Bangladesh worked to:

- Improve governance for medical product quality assurance systems.
- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors.
- Increase and optimize financial resources for medical product quality assurance.
- Increase the supply of quality-assured essential medical products of health importance; and
- Advance the global medical product quality assurance learning and operational agenda.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Bangladesh achieved the following.

- Worked with DGDA to move the agency toward PIC/S membership.
- Supported ACI Pharmaceuticals in addressing the CAPAs identified during PQM's inspection of the company in 2019.
- Advised DGDA on steps to achieve WHO Maturity Level 3 designation for the vaccine testing laboratory.
- Helped strengthen the NCL's capacity to sustain its achieved international standards.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

Activity 1.1, Support institutionalization of good governance practices relating to transparency, accountability, and stakeholders' communications at DGDA: DGDA and PQM+ jointly organizeda dissemination workshop titled "National Quality Assurance Guideline (NQAG) and Risk-Based post marketing surveillance for Medical Products" in September in the Sylhet division. Participants included key leaders, experts, and division government and nongovernmental agency representatives. The workshop's objective was to disseminate contents of the NQAG to stakeholders who have a direct or indirect role in ensuring that quality-assured medicines are available to the public. The workshop highlighted quality measures and elements to ensure the manufacture, registry, procurement, storage, and distribution of quality, safe, and efficacious medicines before they reach consumers.

Th m DGDA; the divisional director of the Directorate General of Health Se e superintendent engineer of the Health Engineering Department; the civ l Association (BMA); the Bangladesh Association of Pharmaceutical In d Druggist Samiti; president of the Bangladesh Chemists & Druggists Sa on; president of the Sylhet press club; Customs; the police force; the Ph ty of Science and Technology; MAG Osmani Medical College; ma d others.

T , PQM+ started working with the committee members to ence to institutionalize the reporting systemas a routine p A review.

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

Activity 2.1.1, Continue support to DGDA for attaining WHO Maturity Level 3 of its market surveillance and control, laboratory testing, lot release, clinical trial, and marketing authorization: PQM+ is leading support for all nine functions of DGDA to strengthen the national regulatory system for medical products, including vaccines, biologicals, and medical devices. DGDA is moving forward to achieve Maturity Level 3 (ML3). To accomplish this, DGDA participated in a WHO formal assessment in July. In August, DGDA received the final assessment report from WHO assessors with 274 observations, including 67 recommendations.

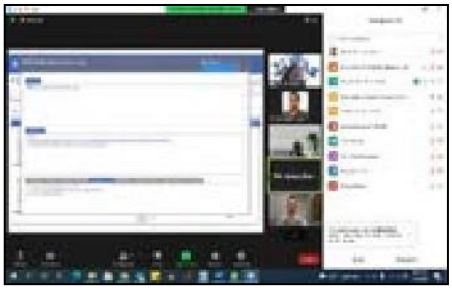
PQM+ provided TA to DGDA's functional teams to develop a corrective and preventive actions (CAPA) plan. Later in August, DGDA submitted the CAPA plan to WHO for acceptance. In parallel, PQM+ started working with the functional team to address the CAPA. The successful completion of the CAPA plan will be a significant step toward achieving WHO ML3. This recognition will prove that DGDA is a fully functional regulatory agency, capable of providing quality-assured services to the pharmaceutical sectors and securing public health with quality monitoring throughout the product lifecycle.

WHO Assessment preparatory meeting

In Q4, PQM+ supported DGDA in developing documents, assisting implementation, generating evidence, providing input to the GBT, and conducting a mock assessment, a self-assessment, and reporting. Following NRA input on the self-assessment, PQM+ provided technical assistance by generating evidence for each input/ answer against sub-indicators. All the evidence documents have been uploaded to

WHO's SharePoint server, with a link generated and provided in the relevant section of the GBT. PQM+ supported coordination and generation of a final report and shared it with WHO headquarters on behalf of DGDA for WHO to conduct a desk-based formal assessment. WHO readied the assessment tool for verification and performed the assessment. The mock assessment and self-assessment took place in June, with all evidence prepared, uploaded, and linked to the GBT at the end of that month. DGDA has a well-established legal framework, despite some gaps following the previous act and rules, and arranged the gazette notification, policy decisions, and guidelines to comply with all legislative requirements.

During this period, PQM+ provided technical support for the legislative gap analysis; regulatory gap analysis; input into the new drug act; development of the official notification and gazette, guidelines, SOPs, manuals, procedures, protocols, record log, registrars, checklist, forms, presentations, and reports; training plan development; and monitoring and evaluation.



WHO's assessment is ongoing.

The desk-based formal assessment took place in July, after which WHO provided a draft report and PQM+ developed the formal institutional development plan (IDP) with 274 observations. Of the 274 observations for nine functions, 206 observations were either not implemented (NI), partially implemented (PI), or ongoing implementation (OI); the other 67 observations needed further improvement, though those sub-indicators have already been implemented. During the formal assessment, PQM+ directly participated as an observer to the assessment program and provided support to DGDA to give feedback and generate evidence, including the translation of several documents, to make the assessment more compliant.

Of the 274 observations, 20 are from Maturity Level 1 (ML1), 22 are from ML2, 172 are from ML3, and 60 are from ML4. Of the ML3 observations, 151 are pending implementation.

Following the IDP observations, PQM+ provided technical support to develop a draft corrective and preventive actions (CAPA) plan, which has been sent to WHO HQ for feedback. To implement the CAPA plan, DGDA issued an office order in September, assigning technical officers from the involved development partners.

PQM+ provided support to DGDA with the following activities:

1. Updated IDP following the mock assessment and self-assessment.
2. Facilitated NRA input, developed documents, assisted with implementation and evidence generation; uploaded documents to the WHO SharePoint and input link to the WHO GBT.
3. Observed response documents to ensure compliance during the assessment.
4. Conducted strategic plan monitoring and evaluation.
5. Monitored implementation of the National Drug Policy of 2016.
6. Developed 11 presentations for bilateral session of formal assessment.
7. Translated major documents from Bangla language.

8. Developed corrective and preventive actions (CAPA) plan following observations from formal assessment.

Areas for further improvement:

1. Improve National Regulatory Framework and develop regulatory framework documents.
2. Develop risk management plan for regulatory action.
3. Implement a monitoring and evaluation (M&E) framework, including output measurement.
4. Develop competency framework and competency matrix.
5. Continuously improve QMS and IMS to ensure sustainable implementation of regulatory activities.
6. Facilitate risk-based regulatory inspection planning, conducting, monitoring, and reporting.
7. Improve good governance system.
8. Improve good review practice.
9. Improve transparency, accountability, reproducibility, and monitoring.
10. Use IT-based database/platform/software for HR, product, and service management, asset management, records management, process implementation, monitoring, etc.
11. Facilitate approval of New Drug Act.
12. Mobilize and optimize human resources through an online application evaluation system to minimize workload.

Activity 2.1.2, Introduce the OpERA program to integrate tracking and measure of regulatory performance and continuous improvements: The Centre for Innovation in Regulatory Science (CIRS) developed the Optimising Efficiencies in Regulatory Agencies **(**OpERA) tool. A technical officer from PQM+ took part in a training on OpERA in June. The tool can help regulators "integrate a practice of tracking and measuring regulatory performance focused on the medicine authorization process" within their agencies. This global program is available to all regulatory agencies, regardless of size, mission, or maturity level.

DGDA is following the WHO GBT as part of its target to reach Maturity Level 3. The CIRS OpERA tool is complementary to support DGDA. PQM+ is continuing the OpERA tool work in PY3.

Activity 2.1.3, Assist Bangladesh in becoming a participating country in the WHO CPAR and provide technical assistance to the DGDA to ensure establishment and use of the procedure: In September, PQM+ met with DGDA about the Collaborative Procedure for Accelerated Registration (CPAR). PQM+ reviewed the WHO CPAR guideline and provided advocacy to DGDA for their independent participation. Through this support, DGDA will be a participating member and subsequently operationalize the process, which would allow expedited registration of WHO-pre-qualified medicines. In PY3, PQM+ will provide technical support to develop and implement the guidelines, principles, and procedures for the WHO CPAR.

Activity 2.1.5, Support DGDA toward achieving PIC/S membership: The Pharmaceutical Inspection Co-operation Scheme (PIC/S) has a worldwide membership of 54 participating medicines authorities, including more than 2,000 inspectors, and is preparing its strategic plan

for 2022 to 2026. DGDA participated in a consultation program for developing the plan, and PQM+ supported by giving feedback on the consultation responses that the director general of DGDA sent in July.

PIC/S pre-accession membership of DGDA has been suspended, per a letter from PIC/S in April. DGDA's two-year timeframe of pre-accession applicant status expired at the end of February 2021 and the PIC/S committee closed the Bangladesh DGDA application. The PIC/S Sub-Committee on Compliance (SCC), which is in-charge of accession and pre-accession applications, noted that in February, DGDA requested an extension for the pre-accession application but had not met its financial obligations. As a result, the SCC recommended, and the committee endorsed, closure of the pre-accession process and invited DGDA to re-apply after securing funding and committing to respond to the rapporteur's requests related to the pre-application. DGDA subsequently expressed plans to re-apply, and the PIC/S secretariat has proposed a meeting on the topic. PQM+ supported DGDA in all relevant communications and provided technical support in the PIC/S pre-accession process.

Activity 2.1.6, Facilitate the implementation of RB-PMS: Based on the sampling plan, field inspectors continued to perform sampling and testing of medical products. In July, five medicines: (amoxicillin, cefpodoxime, isoniazid, clavulanic acid, and ceftriaxone) underwent testing, followed by another five in August (levofloxacin, rifampicin, lamivudine, chloroquine, andalbendazole) tested. Field inspectors tested more than 100 samples at MiniLab™ sites. Among the samples, two were found suspicious and are under NCL confirmatory testing. Another five medicines (dexamethasone, metronidazole azithromycin, doxycycline, cefuroxime, and moxifloxacin) were under surveillance in September.

In late September, DGDA and PQM+ visited the newly established MiniLab™ Sylhet divisional sites to oversee the RB-PMS implementation. Also in September, PQM+ provided hands-on training on visual inspection and MiniLab™ screening techniques to the remaining candidates of new Sylhet divisional sites, including Sylhet city, and Sunamganj and Moulvibazar district inspectors at the Dhaka divisional MiniLab™ site office. Four inspectors attended, including the Shariatpur District inspector, who is working under the Dhaka divisions. This completed the PQM+ cycle of training divisional site inspectors, and DGDA is now ready to run the RB-PMS system at all eight of its targeted divisions.

Activity 2.1.8, Rapid assessment on SF anti-TB medicines: PQM+ is conducting a rapid assessment of SF anti-TB medicines in Bangladesh that includes development of a draft terms of reference (TOR) in consultation with Dr. Md. Ziaul Islam, head of the Community Medicine Department at the National Institute of Preventive and Social Medicine (NIPSOM), and Professor Syed Masud Ahmed of BRAC University.

Left: Hands-on training on Balance before demonstration.

Below: WHO ML-3 virtual auditat NCL

*Activity 2.2.2, Provide technical assistance to NCL to increase the vaccine laboratory's capacity for testing:*In July, PQM+ supported DGDA's virtualWHO formal benchmarking audit.
WHO's audit committee evaluated

Bangladesh's vaccine regulatory system against the WHO NRA Global Benchmarking Tool (GBT) and measured the system's maturity. PQM+ observed and took notes during the audits. Afterward, PQM+ helped prepare a CAPA plan based on the auditors' observations and started activities to resolve the CAPA within the timeline.

To help build the capacity of NCL's vaccine laboratory staff, PQM+ provided guidance and training on the following topics:

- Helped NCL's QA staffer conduct an internal audit of the vaccine chemical laboratory.
- Assisted with preparation of an analytical method validation/ verification protocol of the thiomersal content of vaccines.
- Helped prepare a checklist for CMC (Chemistry, Manufacturing and Controls), dossier, and analytical method review of Marketing Authorization documents by NCL and total Standard Testing Procedure list of vaccines.
- Provided hands-on training and demonstration to vaccine chemical staff on the pH meter, weighing balance, and ELISA as part of audit preparation.
- Helped finalize the equipment specification for the COVID-19 emergency response and pandemic preparedness in NCL's vaccine unit.
- Provided hands-on training on limes flocculation test for identification of toxins in the tetanus vaccine.

Hands-on training on ELISA beforedemonstration

- In September, facilitated hands-on training on glycoprotein content determination of human rabies vaccine by single radial immunodiffusion (SRID) method.
- Helped prepare an in-house method list for vaccine analysis.
- Assisted with review of the "Customer Satisfaction Survey" SOP.
- Supported preparation of the analytical method validation protocols for meningococcal, typhoid, rabies, tetanus, and influenza vaccines.
- Prepared the required equipment list for analysis of all available vaccine.

Hands-on training on limes flocculation test oftetanus vaccine

To enrich vaccines knowledge, PQM+ facilitated an advanced vaccinology course training in India in September. Participants included the deputy director of DGDA, deputy chief of NCL, the NCL bacteriologist and government analyst, and two PQM+ technical officers.

Activity 2.2.3, Continue support to increase capacity for compendial testing of priority medicines (e.g., TB, MCH, FP) in the NCL: In August, a virtual ANAB reaccreditation audit of NCL's

physicochemical laboratory took place. PQM+ staff observed and took notes. Afterward, PQM+ assisted with preparation of a CAPA plan based on the auditor's observations and helped close the CAPA in the recommended timeframe.

This quarter, PQM+ also assisted NCL to arrange the proficiency test (PT) from the provider on time and helped the physicochemical lab staff analyze the PT sample within the scheduled time. PQM+ provided guidance and assistance on the following activities:

- Assisted with review of the "Operation, Cleaning, and Calibration of PerkinElmer Gas Chromatography (GC) with Headspace Sampler" SOP and revised it according to a gap analysis.
- Supported the testing of samples during GC analysis in the physicochemical laboratory.
- Provided hands-on training on the general procedures of GC.

Activity 2.2.4, Magnify impact of previous technical assistance through supporting NCL's mentoring of Chattogram Drug Testing Laboratory (CDTL): For CDTL to fully function as a modern regional drug testing laboratory and achieve ISO 17025 accreditation or WHO PQ, PQM+ supported DGDA in developing a five-year roadmap for 2020 through 2025. Accordingly, PQM+ is working with DGDA to follow up on CDTL's progress with periodic visits.

In September, NCL's deputy chief and technical officer conducted a joint visit to review progress on RB-PMS sample testing and lab functioning in pursuit of CDTL's full functioning as a modern regional drug testing laboratory for achievement of ISO 17025 accreditation or WHO-PQ by 2025.

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

Activity 3.1, Support NCL to adopt an in-house costing tool and prepare a proposal for the Ministry of Health and Family Welfare to rationalize fees for medicines quality testing: PQM+ collaborated with NCL management to perform a cost analysis on medicine quality testing and developed a proposal to rationalize medicines quality testing fees. PQM+ provided training to relevant NCL staff on this tool.

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

Activity 4.1, Continue to provide technical support to a local manufacturer of priority first-line TB medicines to progress toward achieving WHO PQ: In August, PQM+ conducted an online technical session with ACI Pharmaceutical's technical staff focusing on the GMP compliance for production of BE batches, with 18 people attending. PQM+ experts from USP headquarters continued providing technical assistance to ACI to produce bio batches of first-line anti-TB medicines.

Online technical session

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Develop a CAPA plan to address observations from WHO's formal assessment.
- Collaborate with WHO for Coalition of Interested Parties (CIP) meeting.
- Conduct a mock inspection and onboarding of Avatour tools for ACI Healthcare Ltd., in collaboration with PQM+ HQ.
- Continue providing technical support to ACI Healthcare Ltd. toward prequalification BA/BE study of first-line TB medicines.
- Arrange a consultative meeting to finalize the scope of work to conduct a rapid assessment of SF anti-TB medicines in the private sector.
- Collaborate with WHO on support for DGDA on the World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) activities.
- Implement COVID-19 vaccine technical assistance, including emergency use authorization (EUA) and RB-PMS. Emergency use authorization is a special procedure for granting equitable access to life-saving vaccines in the case of a public health emergency when less certainty about the efficacy and safety of products is tolerated.
- Support DGDA to attend 2021 PIC/S virtual seminar in November.

Burma

The PQM+ Program in Burma is working to build the capacity of Burma's Department of Food and Drug Administration (DFDA) toward a resilient medical product quality monitoring system. PQM+ aims to assure the quality of medicines in the country, with focus on antimalarials, and thereby contribute to the National Malaria Control Program's effort to eliminate malaria by 2030.

In PY2, PQM+ worked to:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors.

Highlights of Progress by PQM+ During PY2

During PY2, work in Burma required navigating the challenges of a military coup for a couple of weeks in February, but effects from the coup continued to affect programming. PQM+ achieved the following.

Facilitated the ISO 17025:2017 reaccreditation assessment of DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory.

Assisted DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory (PCL) to resume its QMS functions and maintain a stable output of medicine quality testing. The Ministry of Health and Sports (MOHS) and DFDA dismissed around two- thirds of its staff who joined the civil disobedience movement following the military coup. QA team members and trained analysts from the Nay Pyi Taw PCL were among the dismissed staff.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

PQM+ planned to provide technical assistance to DFDA to assess and regulate private laboratories in Burma. However, the program could not implement the activity due to delays in parliamentary approval for the National Laboratory Law, which grants the authority to DFDA.

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

In Q4, PQM+ delivered a remote training on the QMS, covering an introduction to ISO/IEC 17025:2017, the internal auditing program, the corrective and preventative action program, anda root cause analysis to the Pharmaceutical Chemistry Laboratory (PCL) of DFDA Myanmar. Participants included eight QA team members from PCL and 20 observers from other laboratories under DFDA in Nay Pyi Taw, Yangon, and Mandalay. PQM+ designed the training with activities organized through digital platforms so that participants and observers, regardlessof their location, can take part in training activities and learn from them. This training provided the opportunity for participants to improve their understanding of the ISO 17025:2017 requirements and strengthen the QMS in the laboratory. Skills and expertise learned from this training will help the newly formed QA team prepare for the annual surveillance assessment byANAB in November 2021.

PQM+  team members fromPCL and 20 observers from other labora

PQM collaboration with USP Ghana and IntraHealth. The filming process for metrology training modules is ongoing at the USP Ghana facility.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Coordinate the ISO 17025:2017 annual surveillance by ANAB at the Pharmaceutical Chemistry Lab, Nay Pyi Taw.
- Identify and onboard private manufacturers to strengthen their GMP and prepare for WHO PQ of locally manufactured chloroquine.
- Identify and onboard private laboratories to prepare for ISO 17025:2017 accreditation.
- Conduct, in collaboration with USP Ghana and IntraHealth, a virtual metrology training for the core team at DFDA Nay Pyi Taw PCL.

Nepal

PQM+ provides technical assistance to Nepal's Department of Drug Administration (DDA) to strengthen medical product QA and QC systems at the province-level central and branch offices. In addition, PQM+ is strengthening the capacity of laboratories to conduct quality testingat the National Medicines Laboratory (NML). PQM+ also works with local manufacturers, both public and private, to increase the supply of quality-assured medicines locally. Finally, PQM+ works across all stakeholders—including the National Health Research Council, the Logistics Management Section of Ministry of Health and Population (MoHP), the Association of Pharmaceutical Producers of Nepal (APPON), and others—to build awareness of the health and economic threats posed by SF medical products and the need for strong regulatory systems.

In PY2, PQM+ worked to:

- Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors and
- Increase the supply of quality-assured essential medical products of public health importance.
- Increase the awareness of substandard and falsified medicines

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Nepal achieved the following.

Coordinated with the NML to perform a desk review of the lab's policies, procedures, and tools related to governance, HR, service delivery, information management, finance, performance management, and more, and drafted a report on the findings.

Conducted a seven-day SATTA assessment at the NML to identify areas for improvement and design a path to ISO 17025 accreditation.

Reviewed the Nepali GMP code for inspection of medical product manufacturers, importers, and distributors to determine gaps and inconsistencies with international standards, and supported DDA in revising the code.

Invited local manufacturers to submit expressions of interest for technical assistance for WHO prequalification and worked with DDA to short-list six companies for the next step of rapid assessment.

Used the SATTA to conduct an inventory of NML capacity and assessed the lab's strengths and weaknesses in compliance with the international best practices approach to quality management systems requirements of ISO/IEC 17025:2017. The inventory identified several major deficiencies.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

PQM+ supported the DDA in organizing a high-level group comprising representatives of national health organizations, professional bodies and councils, academia, and private sector entities such as drug importers and manufacturers. The group will support DDA's regulation of medical products by providing consultations, as well as advocating on behalf of DDA to ensure the supply of quality medical products in the country. The group will form subcommittees to discuss specific regulatory and medicines quality assurance issues as needed. Seventeen

representatives attended the group's first meeting. PQM+ presented the group charter to the participants and with minor suggestions to the charter, members agreed to adopt it.

PQM+ is coordinating with another USAID partner, MTaPS, on revising the Drug Act to ensure that the new draft adequately incorporates provisions related to risk-based inspection, post-marketing surveillance, and quality control/assurance. In the coming year, PQM+ will continue to work with MTaPS by participating in relevant technical meetings and providing expert recommendations in continuing work on the new Drug Law and a new draft of the National Medicines Policy.

High-level group's first meeting

PQM+ Nepal supported the DDA in its response to the COVID-19 pandemic. DDA faced pressure to support the government's COVID-19 response, especially on granting EUA and facilitating the import of COVID-related medications into Nepal. PQM+ collaborated with DDA onproviding EUA templates in English and connecting with pharmaceutical manufacturers in other countries with which PQM+ was working.

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

PQM+ continued to work in various areas to strengthen the institutional capacity of the DDA and NML. Introducing risk-based approaches within DDA's PMS function was a key activity during PY2. First, PQM+ supported DDA to form an RB-PMS TWG. Collaborating with the TWG, PQM+ assessed the DDA's PMS function and recommended steps to incorporate risk-based approaches. With the TWG taking the lead, PQM+ facilitated a workshop and meetings to help DDA and NML understand the steps and requirements, including resources for RB-PMS. PQM+ also organized a training workshop on the MedRS tool to DDA and NML staff, with help from USP experts. In addition, PQM+ separately trained a DDA staff member whom the agency designated to be a focal person for MedRS. Taking into account the RB-PMS approaches in other countries and adapting them to the local context, PQM+ helped draft Nepal-specific RB- PMS guidelines and framework, which DDA is reviewing.

Table 3. Training and Workshops for Regulatory Bodies

Dates	Training / Workshop Type	Participants
May 3-7, 2021	GMP training to regulators (remote)	DDA: 16; NML: 18 MTaPS: 1
April 16, 2021	RB-PMS kick off meeting (in-person)	DDA: 7; NML: 1 PQM+ (Nepal): 5
May 17-18, 2021	Med-RS focal person training (remote)	DDA: 1 PQM+ (Nepal): 1
May 24-27, 2021	Med-RS workshop (remote)	DDA: 18; NML: 9

PQM+ conducted a remote GMP training to DDA and NML staff to enhance inspection capacities in the regulatory bodies. Participants found the training useful, especially in the areasof cleaning validation, water purification, HVAC systems, and premises maintenance.

PQM+ supported the formation of an inspection TWG with the head of DDA's inspection division as its focal person. The TWG, with support from PQM+, is working to institutionalize risk-based methods in its inspection function.


Inspection TWG meeting

Collaborating with the TWG, PQM+ helped review the Nepali GMP code of 2015 for the inspection of pharmaceutical manufacturers to determine gaps and inconsistencies with international standards and revised the code to align with WHO GMP guidelines. The TWG suggested updating the Nepali GMP code by adding sections on a pharmaceutical quality system (PQS), quality risk management (QRM), and product quality review (PQR). DDA's Inspection Division will submit the revised GMP code to the Drug Advisory Committee for approval in the next fiscal year.

PQM+ assessed complaint-handling practices at the DDA by reviewing and revising the Inspection Division's SOP on complaint handling, then developed an assessment report. The division reviewed the assessment report and realized the need for a more comprehensive approach in the form of a guideline along with the same SOP.

PQM+ worked with NML to assess its technical capabilities and compliance with ISO/IEC 17025:2017 standards using USP-developed tools. Based on the assessment, PQM+ and NML have developed an IDP to lay the course for NML's ISO accreditation. The IDP is a multi-year document that sets out timelines and specifies roles for NML and PQM+ to achieve accreditation by 2024. NML sees the SATTA report and IDP as suitable mediums to advocate to MOHP for more resources for its underfunded laboratory activities. PQM+ provided the NML with access to pharmacopeias and reference materials to support the laboratory's testing capacity and supported NML to register for proficiency testing. PQM+ continued to support NML to develop standard formats and key procedures to strengthen quality management systems according to ISO requirements. The box that follows contains highlights from the SATTA.


SATTA assessment

PQM+ used the SATTA to conduct an inventory of laboratory capacity and assessed the lab's strengths and weaknesses in compliance with the international best practices approach to quality management systems requirements of ISO/IEC 17025:2017.

It identified several major deficiencies:

- Structural requirement, with no quality manager assigned to lead implementation of the quality system.
- Management system requirement, with underdeveloped and not yet implemented key documents (quality policy, objective, and manual) and critical SOPs.
- Resource requirement, with key laboratory equipment requiring calibration, inadequate facilities, and insufficient infrastructure, especially for environmental conditions, storage areas, and adequate separation.
- No personnel competency training program in place to maintain the competency of NML staff.

NML's overall rating was 37 percent.

PQM+ collaborated with DDA and NML to conduct a workforce assessment of the regulatory authorities in December 2020 and January 2021. The program administered a survey to all DDA and NML staff and interviewed eight DDA/NML officials, including DDA's leadership. PQM+ presented the assessment findings and solicited feedback during a workforce data validation workshop, at which DDA and NML leadership expressed a commitment to improving the working environment for their staffs. Some major findings included: unstaffed positions, lack of regulatory competencies and development plan for the staff, inadequate physical amenities to support day-to-day jobs, and lack of an incentivized mechanism linked to performance, transfers, and career development. PQM+ finalized the workforce assessment report and an IDP after another round of review by DDA and NML in July. DDA and NML suggested that PQM+ align their activities with the developed workforce IDP. With this feedback, PQM+ finalized the report with the IDP, and the IDP will feed into PQM+ workforce activities in the nextfiscal year.

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

To improve the local supply of quality-assured essential medicines, PQM+ worked with DDA to publish an expression of interest (EOI) for Nepali pharmaceutical manufacturers to receive technical assistance on WHO PQ of selected medicines. Prior to its publication, PQM+ identified and finalized MNCH and FP/ reproductive health (RH) medicines for the EOI after consulting with relevant stakeholders. Thirteen manufacturers applied for technical assistance and submitted the required documentation. PQM+ conducted a preliminary review of their documents and consulted with DDA to shortlist six manufacturers. PQM+


Invitation to manufacturers in Nepal to submit an Expression of Interest (EOI) for Technical Assistance

First Date of publication: February 07, 2021

To support national and global efforts to increase access to the affordable quality assured products for Maternal, Neonatal and Child Health (MNCH) and Family Planning (FP), the Department of Drug Administration (DDA), with technical assistance from the Promoting the Quality of Medicines Plus (PQM+) program implemented by United States Pharmacopeia (USP) and with funding from the U.S. Agency for International Development (USAID), invites Nepali pharmaceutical manufacturers to submit an Expression of Interest (EOI) for evaluation of their manufacturing sites to assess compliance with Good Manufacturing Practices (GMP) for production of essential medicines for MNCH and FP products to attain the WHO Prequalification requirement.

1. PROCEDURE FOR THIS INVITATION TO SUBMIT EOI

The current invitation is published in accordance with the provision of Drug Act 2035 to prevent the misuse or abuse of drugs and allied pharmaceutical substances and false or misleading information relating to the efficacy

Published EOI for technical assistance

coordinated with DDA to conduct a rapid assessment of five manufacturers. Table 4 describes the manufacturers expressing interest in technical assistance by product type.

Table 4. Requests for WHO PQ Technical Assistance

Prioritized Medicines	Disease/Condition	Number of Interested Pharma Companies	Number of Shortlisted Companies
Oxytocin injection (5 IU/ 10 IU per ml)	Postpartum hemorrhage	2	1
Zinc sulfate (10 mg/ 20 mg dispersible tabletor other zinc salts, i.e., gluconate, acetate, and citrate, containing 10mg or 20mg elemental zinc)	Diarrhea inchildren	6	2
Amoxicillin (dispersible tablet 125 mg/ 250mg, scored)	Pneumonia in children	4	2
Azithromycin (500 mg tablet)	Respiratory tract infections	11	2

PQM+ Nepal received a request from the public medicines manufacturer, Nepal Ausadhi Limited, to support them toward national GMP compliance. PQM+ assessed the manufacturer and jointly developed a CAPA plan to meet national GMP requirements. The PQM+ Nepal PY3 work plan lays out specific plans for strengthening the public medicine producer.

In coordination with APPON, PQM+ conducted a training needs assessment to get insight into contents for the GMP training to private manufacturers in support of their GMP compliance. PQM+ organized a remote GMP training for 133 industry technical personnel (pharmacists, chemists, and microbiologists) in July, focusing on subjects such as self-inspection, the pharmaceutical quality system, and water for pharmaceutical use. Pre- and post-training assessments showed an increase in participants' knowledge, further verified in their remarks during the training evaluation.

PQM+ is working to develop the Nepal Pharmaceutical Strategy and engaged consortium partner IQVIA to carry out a landscape analysis of the Nepali medicines market. The desk review is complete and PQM+ Nepal is facilitating primary information collection with a public health stakeholder. With input from DDA, PQM+ is facilitating a working group that will supportdrafting the concept for a manufacturing strategy. The working group will be a sub-group withinthe high-level group mentioned under Objective 1. PQM+ also signed a memorandum of understanding (MOU) with APPON to sustainably build and strengthen the capacity of pharmaceutical industries in Nepal, as well as to contribute to developing a manufacturing strategy.

To assure the quality of medicines in the public medicine supply chain, PQM+ is reviewing current public procurement practices and policies at the federal, provincial, and local levels. PQM+ also met with the National Health Insurance Board (NHIB) to discuss the quality of medicines that participating health institutions procure and that the health coverage scheme

pays for. Both parties met to identify courses of action to develop procurement guidelines and detailed activities for next year.

PQM+ Nepal and the Nepal Health Research Council (NHRC) have signed an MOU to jointly work on documenting research-based evidence related to quality medicinesand advocating for policy change to promote quality medicines. To prevent the public from accessing SF medicines, PQM+ and DDA collaborated to design messages on posters that, following approvals, were disseminated to nearly 3,000

Two posters on display for visitors at a hospital pharmacy in western Nepal

retail pharmacies in Nepal's major cities. DDA and PQM+, with support from professional organizations, distributed the posters to pharmacies across Nepal. The messages aim to inform pharmacy visitors about SF medicines and procuring quality-assured medical products.

Priority Activities for Next Quarter

In PY3, PQM+ Nepal plans to:

- Provide technical assistance to DDA in updating, institutionalizing, and disseminating the GMP and Good Sales and Distribution Practices (GSDP) code.
- Operationalize and institutionalize the stakeholder consultation mechanism (drug advisory group and committees).
- Support DDA to strengthen the risk-based inspection system and sustainable risk-based post-marketing surveillance program system in Nepal.
- Strengthen medical product quality control laboratory capacity toward ISO 17025 accreditation.
- Deliver technical assistance to DDA and NML to identify staffing needs and strengthen technical and management competencies.
- Improve the quality of both public and private local manufacturers.
- Develop a pharmaceutical manufacturing strategy for Nepal.
- Support improved procurement processes and logistics to reduce the availability of SF medicines.
- Raise public awareness of the dangers of SF medicines.

Pakistan

Pakistan's regulatory system has limited capacity for medicines quality surveillance, contributingto the proliferation of SF medical products. Lack of regulatory enforcement and availability of centers to conduct reliable bioequivalence studies reduces confidence in the efficacy of generic medical products manufactured in the country. Inconsistent government policies for the pharmaceutical sector have undermined the private sector's potential role in improving health

outcomes. The PQM+ Pakistan program is addressing these challenges through four areas: improving governance of medical product QA systems; strengthening medical product regulations; enhancing private sector engagement; and reducing the availability of SF medical products. PQM+ works closely with the Drug Regulatory Authority of Pakistan (DRAP).

In terms of specific country objectives, the PQM+ work plan focuses on advancing medicines quality assurance elements to enhance Global Health Security Agenda initiatives; curbing antimicrobial resistance; promoting maternal, neonatal, and child health; addressing communicable diseases; and engaging the private sector in achieving better health outcomesand contributing to economic development.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Pakistan achieved the following.

- Assisted nine private sector manufacturers to build the required systems to reliably produce Pakistan's needed volume of quality-assured PPE. Previously, the country imported most of its PPE, a significant expense as the COVID-19 pandemic hit. After this assistance, Pakistan began exporting PPEs to at least eight other countries.
- Conducted a gap assessment of the appellate laboratory, NIH in Islamabad, against the ISO 17025: 2017 standard, followed by developing a CAPA plan and more than 50 new SOPs and drafting a quality manual and application for proficiency testing.
- Developed an antimicrobial consumption dashboard for PIRIMS.
- Drafted a concept note to formulate a national pharmaceutical development strategy, including increasing private sector engagement.
- Established a partnership with the WHO Prequalification Team for peer audits to strengthen the country's quality control lab system.

Progress by PQM+ Objective

In PY2, PQM+ Pakistan's program activities focused on using an integrated approach to improve the quality of medical products and systems through the following areas.

Objective 1: Governance for medical product quality assurance systems improved

Activity 1.1: Develop risk-based regulations for market authorization of high-risk medical devices: Medical devices regulations in Pakistan are comparatively new, and currently there areno regulations in place to standardize refurbished equipment for medical devices. Guidelines and regulations are required for good practices, which would help to ensure the quality, safety, and effectiveness of medical equipment, without changing the equipment's or system's performance safety specifications, and/or changing their intended use.

To initiate the process, PQM+ conducted a gap assessment, for the review of DRAP's medical devices regulations, reflecting international regulations on aspects including regulatory structure, device classification, device approval, and post-marketing surveillance. For this purpose, the PQM+ team used the Global Benchmarking Tool (GBT) to conduct the assessment and provided DRAP with a rating of medical devices according to WHO GBT performance maturity levels.[2] PQM+ assistance helped to lay out short, medium, and long-term

[2] The WHO GBT represents the primary means by which the WHO objectively evaluates regulatory systems. WHO GBT four performance maturity levels are an expression of the extent to which a

recommendations for DRAP, based on the assessment, including human resource capacity related to medical equipment and devices, development of integrated information management systems, establishment of conformity assessment bodies (to evaluate medical devices, planning for high-priority equipment protocols, and protocols for refurbished and remanufactured equipment.

PQM+ experts meet with the CEO of DRAP and other officials about regulations for refurbished medical device equipment.

PQM+ finalized the ***procedures and guidelines for refurbished equipment***[3] after incorporating feedback provided by stakeholders (including manufacturers, importers from pharmaceutical industry, etc.) and has submitted these guidelines to DRAP for approval.

Activity 1.2: Support DRAP in developing/ revising its policy on contract manufacturing: While contract manufacturing can provide cost savings for the originator company and create a solid business opportunity for the contract manufacturer, it also necessitates regulation. To expand opportunities for contract manufacturing in Pakistan, PQM+ Pakistan conducted a desk review of best practices in contract manufacturing, using lessons learned from reference countries. The review helped DRAP to establish a working group on contract manufacturing with representation from all relevant stakeholders (government, multinational pharmaceutical manufacturers, and domestic manufacturers) to consider findings from the desk review. PQM+ Pakistan and DRAP incorporated comments and feedback from the working group deliberations into a draft contract manufacturing policy (regulations/guidelines), and then reconvened the working group to consider these regulations/guidelines.

To be published in the extra ordinary Gazette of Pakistan, Part-II

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)

Islamabad, the 4th June, 2021

NOTIFICATION

S.R.O. 423(I)/2021.— The following draft of further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXII of 2012), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published for the information of all persons likely to be affected thereby and, as required by sub-section (3) of section 43 of the said Act (XXXI of 1976), notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Federal Government, be sent within fourteen days of the publication of this Notification in the official Gazette.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Federal Government.

Excerpt from draft amendments on contractmanufacturing that PQM+ provided

With PQM+ support, DRAP published a draft of amendments proposed to be made by DRAP in the Drug (Licensing, Registering and Advertising) Rules, 1976, with further approval of the Federal Government.[4] The key amendments included regulations for the contract manufacturer, production, analysis, quality control, quality assurance, QMS, supply chain, pharmacovigilance, recalls and compliance to Drug Act 1976 and DRAP Act 2012.

1.3: Support DRAP for the development of institutional developmental plans (IDPs): In 2018, upon DRAP request, the USAID-funded Promoting Quality of Medicine (PQM) project extended its technical support to DRAP for the development of institutional developmental plans (IDPs)

regulatory system has been formalized as stable, well-functioning and integrated (https://www.who.int/tools/global-benchmarking-tools).

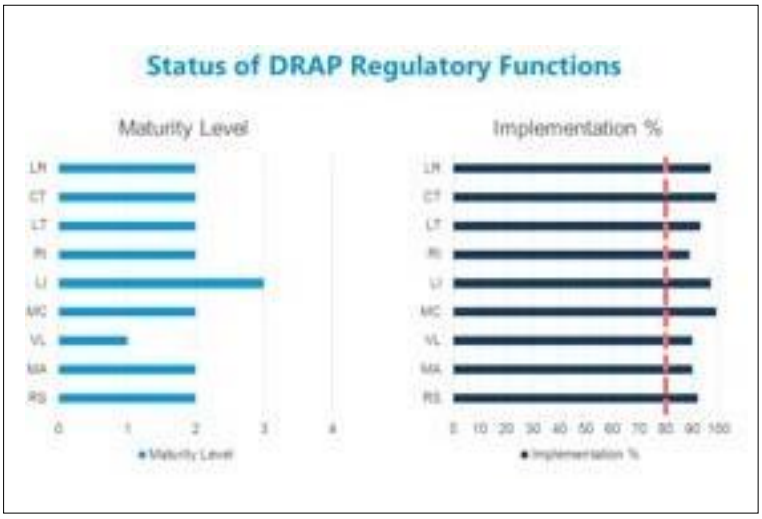
[3] Refurbished Equipment (https://drive.google.com/file/d/1wTi4HvPcqZ_zFmFDETm6i0GP4gJ3g2UW/view)

[4] Notification for draft amendments (June 2021). Weblink: Notification for Draft Amendments on Contract Manufacturing

based on self-assessment gaps. One of the major gaps identified during the self-assessment exercise was the lack of an organizational QMS. PQM provided technical assistance to DRAP to achieve ISO 9001:2015 certification. This certification is helping DRAP develop and implement a QMS, a set of coordinated activities to direct and control an organization to continually improve the effectiveness and efficiency of its performance. In short, by virtue of QMS in DRAP,for the first time, job descriptions for each position are defined, documented, and controlled as per ISO standards. Moreover, QMS assisted in the development of key performance indicators, redefining process workflows with timelines, risk management, and mitigation of critical processes, as well as transparency and accountability in all processes.

After the implementation of QMS and other major IDPs, which include implementation of the common technical document (CTD) for market authorization application, adaptation/revision of policies/guidelines, GMP Inspection (checklist) including PIC/s requirements, 2D Barcode implemented to check SF products in the Supply Chain, development of the prototype for Integrated Regulatory Information Management System and risk-based post-marketing surveillance. These interventions improved the maturity level score of all nine regulatory functions, listed below.

1. National Regulatory System (RS)
2. Registration and Marketing Authorization (MA)
3. Vigilance (V)
4. Market Surveillance And Control (MC)
5. Licensing Premises (LI)
6. Regulatory Inspection (RI)
7. Laboratory Access and Testing (LT)
8. Clinical Trial's Oversight (CT)
9. Lot Release (LR)



PQM+ will continue its technical assistance on the effort to position DRAP as the first stringent regulatory authority in this region. This will help improve the availability of quality-assured medicines for basic health services and infectious disease control programs. The table that follows shows the status of PQM+ assistance to DRAP for GBT and plans for PY3.

Table 5. Activities Related to GBT Findings

RegulatoryFunction	Major Challenges	PY2 Activities	PY3 Proposed Activities
National Regulatory System	● Annual plan reporting not yet established ● Lack of competent regulatory workforce for performance monitoring ● Training plans not well documented ● Organizational quality management system just developed and requires more advancements for implementation across all functions	Support DRAP in developing: ● Developed annual objectives (targets) for all technical divisions ● Draft training need assessments based on the competency framework developed ● Review and revised organizational QMS SOPs and work instructions across all functions	Support DRAP in: ● Risk assessment and management ● Guidelines for dissemination of information to public and relevant stakeholders have been developed and implemented. ● Guidelines for complaints from general public related to different regulatory decisions ● Approval of communication document (Communication policy)
Registration and Marketing Authorization (MA)	● Internal guidance on the MA assessment procedures require improvement	● Developed internal guidance for assessors on the assessment of MA submissions ● Developed internal guidance for assessors on the assessment of MA submissions ● Draft MA timelines process developed	● Optimize MA regulatory flows/pathways along with guidance document ● Develop a summary of product characteristics database ● Assessment and evaluation of process validation data ● Assessment and evaluation of stability data as per ICH Guidelines ● Product assessment as per Common Technical Document (CTD) ● Post registration variation requirements ● Drug registration; local and international practices ● Update of draft document on policy for reliance including criteria for selection of NRAs and mechanism to utilize reliance information in decision making

RegulatoryFunction	Major Challenges	PY2 Activities	PY3 Proposed Activities
Market Surveillance and Control	• Lack of a risk-based approach for conduction of post-marketing surveillance	• Piloting completed for implementation of risk-based post-marketing surveillance • Held a consultative meeting to review and approve the national RB PMS sampling and testing plan in consultation with provinces that will shift the focus from QC to QA by increasing GMP compliance at the manufacturing level and premarket measures • Draft developed for national recall guidelines including how to manage SF medical products • Draft developed for the annual risk-based PMS	• Dissemination of national action plan on Risk-Based Post-Marketing Surveillance (RB-PMS) • Procedure for destruction of recalled/withdrawn products to be elaborated in recall SOP. • Approval of draft guidelines on conditions and requirements of promotion and advertising of medical products. • Guideline for import authorization of therapeutic goods • Guidance on reporting suspected medical products
LicensingPremises	• Scope of licensing needs expansion and updating	• Supported DRAP in drafting amendments to regulations based on the new proposed establishment licensing and inspection systems	• Support DRAP to develop international guidelines for evaluation and approval for basic manufacturing • International guidelines for evaluation of layout plan of pharmaceutical industry • Procedure to upload information of suspended, cancel and revoked manufacturing license in the form official bulletin, and website. • Approval and Publication of guidelines for licensing applications, including instructions or guidelines for applicants explaining licensing requirement. • SOP for internal and external communications with stakeholders related to licensing activities
Regulatory Inspections	• No National GMP guidelines exist • Training and capacity building of GMP inspectors requires improvement	• First draft developed to support DRAP for national GMP guidelines based on PIC/S and WHO standards • Initial training held on MedRS tool	• Assessment of GMP compliance for therapeutic Goods manufacturing facility (for local and foreign manufacturers) • Approval of Draft Guidelines on reporting and investigation of quality defects in therapeutic goods • Development of Good Distribution Practices • Development of Good Cold Chain Management Practices • SOPs for inspections (onsite verification, investigation inspection, I&E inspection, consumption verification inspection, Panel inspection) • SOPs for follow-up inspections, evaluation and decision making on inspection outcome and enforcement activities thereof. • Training of inspectors on categorization of findings according to quality risk management

RegulatoryFunction	Major Challenges	PY2 Activities	PY3 Proposed Activities
Laboratory Testing	● Poor interaction and communication between labs other regulatory function ● Lack of Quality Management system at Central Drug Testing Laboratory	● Draft is ready to implement communication strategy among laboratories, inspectorate, and registration division ● Prototype developed for Integration of lab results on one dashboard.	● Develop a policy on reference standards ● Evaluation of Site Master File (SMF) ● Development of a Guidance Document for all quality control laboratories on method validation, verification and transfer of methods / analytical procedure ● Mechanism to be devised to grant CDL and NCLB access to Marketing Authorization (MA) documentation.
Clinical Trial Oversight	● National Bio studies rules require revisions		● Revise national bioequivalence studies rules as per international best practices ● Best practices in clinical trials and adaptation of international guidelines ● Good Clinical Practices (GCP) ● Assessment and evaluation of pre-clinical and clinical trial data ● Assessment of bio-similarity data ● Guidance for CT stakeholder (DRAP, NBC, GCP Inspectorate etc) to define procedure for sharing and feedback mechanisms in the information and documentation
NRA Lot Release	● Release on the lot by lot for some biological products that do not require to be released by NRA ● Weak implementation ofthe Quality Management System at National Control Laboratory for Biologicals	● Provided technical support to DRAP in revising list of biologicals as per international best practices	● Support NCLB in implementing CAPA plans ● Development of National Guidelines on Lot Release ● Recognition mechanism for acceptance of lot release certificate issued by other NRAs. ● Mechanism and SOP to share Biological Marketing authorization relevant files to NCLB. ● Maintenance of MA dossier library at NCLB

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

Activity 2.1: Development of ISO 17025:2017 QMS system SOPs for National Appellate Laboratory, Islamabad: The Appellate Lab at the National Institute of Health, Islamabad is the only lab in Pakistan that has been designated for conducting re-testing/confirmatory testing if results from other testing labs are challenged by a manufacturer or importer. The results of re-testing from the Appellate Lab are considered final under the law, and no further challenge can be made against their results.

PQM+ supported the Appellate Laboratory to achieve ISO 17025 accreditation. PQM+ completed a gap assessment of the lab against the ISO 17025:2017 standard, followed by the development of a CAPA plan. Afterward, PQM+ developed the quality manual and all required quality management documentation for ISO 17025 certification. As a result of PQM+ assistance,all QMS documents are in the final execution stage. [5] PQM+ will submit the application to the Pakistan National Accreditation Council (PNAC) for ISO 17025 accreditation once proficiency testing samples have been received for execution (proficiency testing results are required for the application filing process for PNAC).

Activity 2.2: Improve the laboratory quality system by preparing additional laboratories for international certification: The Public Health Laboratory (PHL) at the Institute of Public Health (IPH) in Lahore, provided services for COVID-19 and its related testing.

PQM+ completed the gap assessment of the IPH for the achievement of ISO 15189 accreditation (an international standard for QMS at Medical Diagnostic Laboratories). PQM+ also developed a list of procedures and two policy documents on quality and ethical policy, required for the IPH lab for Pakistan National Accreditation Council (PNAC) accreditation. As a result of PQM+ assistance, Pakistan National Accreditation Council (PNAC) completed the pre-audit on September 15, 2021. Achievement of ISO 15189 accreditation will enable PHL to improve its lab testing reliability going forward.

ISO 17025 achieved by Lahore DTL. In PY2, PQM+ and the WHO prequalification team established a partnership for peer audits to strengthen the quality control lab system in Pakistan. PQM+ team conducted a three-day peer audit for DTL, Lahore from August 23-25,2021, with PQM+ serving as the lead auditor.

ISO 17025 achieved by Multan DTL. PQM+ assisted Multan DTL to achieve ISO 17025 certification, and its laboratory information file (LIF) has been submitted and approved. PQM+ team visited Multan DTL to prepare for peer audits. In addition, the PQM+ team also helped to address queries on the LIF against ISO 17043 standards on proficiency testing [6] from PNAC.

[5] Lab staff also conducted final uncertainty measurement calculations for HPLC and pH on their internal control templates and have issued method verification protocol for execution.

[6] Proficiency testing (PT) is interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel.

PQM+ assistance will help build the capacity of external quality assurance schemes, which area requirement to maintain accreditations.

At this moment, quality control laboratories are dependent on international resources for proficiency testing, which are both expensive and time-consuming. Attainment of ISO 17043 by Multan DTL will ensure availability of proficiency testing services to other quality control labs in and outside of Pakistan. With thesupport received from the PQM+ program, the Multan DTL will be in the position to offer these services to other quality control laboratories nationally and internationally going forward.

ISO 17025 achieved by Bahawalpur DTL. PQM+ also assisted Bahawalpur DTL to review and submit the LIF for WHO prequalification, which WHO has been accepted and approved.

ISO 17025 achieved by Rawalpindi DTL. PQM+ assisted Rawalpindi DTL to submit its LIFwhich has been approved. From April 26-28, 2021, PQM+ provided technical assistance to Rawalpindi DTL during the WHO prequalification audit. As a follow up activity, PQM+ assisted the DTL for CAPA preparation and submission to WHO. The CAPA plan is currently under review by WHO.

WHO prequalification audit visit at DTL, Rawalpindi

WHO Peer audit at CDL, Karachi

Central Drug Laboratory (CDL) Karachi, Peer Audit – WHO Prequalification: The PQM+ team visited the CDL Karachi to prepare for peer audits. WHO pre-qualification will ensure quality control for drug testing. With the support received from the PQM+ program, CDL Karachi will be in the position to offer these services to other quality control laboratories nationally and internationally going forward**.**

Table 6. Status of Labs Accreditation

Lab	Accreditation sought	Initial Gap Assessment	CAPA	QMS	PT/LT	Official Inspection/ Pre-assessment
IPH Lab	ISO 15189	Completed	Completed	Completed	Completed	Completed
Appellate lab	ISO 17025	Completed	Ongoing	Developed, under implementation and PT pending	Ongoing	
Ferozsons	PIC/s	Completed	Ongoing	Will be followed up by CAPA.		

Lab	Accreditation sought	Initial Gap Assessment	CAPA	QMS	PT/LT	Official Inspection/ Pre-assessment
DTL, Rawalpindi	WHO PQ	Completed	Completed	Under review		
DTL Multan	WHO PQ	Completed	Completed	Completed	Submitted/ approved	Completed
DTL, Lahore	WHO PQ	Completed	Completed	Completed	Submitted/ approved	Completed
CDL, Karachi	WHO PQ	Completed	Completed	Completed	Submitted/ approved	Completed
DTL, Bahawalpur	WHO PQ	Completed	Completed	Completed	Submitted/ approved	Scheduled for October 11-13

Activity 2.3: Consultative meeting on the development of integrated laboratory results from allfive Drug Testing Laboratories (DTLs): Punjab is Pakistan's second largest and most densely populated province, and thus has five DTLs. Drug-testing activities, however, are not well coordinated among the different DTLs, resulting in duplication of efforts. In addition, data is often siloed, and thus cannot be used to readily inform regulatory activities and decisions.

To facilitate regulatory oversight by improving coordination, reducing duplication of efforts, and ensuring integration of drug testing results, PQM+ Pakistan held a consultative meeting on the development of integrated laboratory results from all five DTLs. PQM+ Pakistan plans to designa dashboard interface to integrate drug testing results into the Pakistan Integrated Regulatory Information Management System (PIRIMS), starting with results from all Punjab DTLs. An information systems specialist will develop the dashboard interface, create a dashboard to display harmonized data from the laboratories, and integrate the new DTL results module with the PIRIMS laboratory and company profile interface. PQM+ Pakistan then will develop a manual on the dashboard and train DTL and DRAP staff to use the new dashboard. PQM+ technical assistance will facilitate integrating lab results from all five DTLs in Punjab and providemore accurate data to the Government of Punjab for effective decision-making and regulatory activities.

Activity 2.4: Support DRAP in benchmarking the pharmaceutical industry: In the past, DRAP has taken a one-size-fits-all approach to its regulatory activities, providing the same level of oversight regardless of the level of risk presented by a medical product or manufacturer. Thus, all 629 Pakistani pharmaceutical manufacturers are to be inspected twice a year, irrespective of their GMP status.

PQM+ meets with the chief executive of DRAP.

This diverts some of DRAP's limited resources from areas where they would be most efficiently used: to ensure the quality of medical products with a higher risk profile. Benchmarking would categorize the manufacturer according to level of risk (high, medium, low and no risk), based on level of cGMP compliance, technologies, and expertise. Risk could be variable in different manufacturing sections, according to complexity of the manufacturing process and product. With regulatory action guided by benchmarking, lower- or no- risk medical products and/or manufacturers could be inspected perhaps once every three years, while those posing moderate or high risk would be inspected more frequently.

Benchmarking will help in prioritizing frequency of inspection, registration of new products and development of a risk-based post marketing surveillance plan.

In PY2, the PQM+ team drafted a guidance document on risk-based GMP audits of manufacturing facilities, and a checklist for inspection and benchmarking has been developed. Moreover, the PQM+ team supported DRAP to develop terms of reference for the risk-based GMP assessment committee. DRAP inspectorate completed piloting of risk-based GMP audits of five pharmaceutical establishments. DRAP has developed risk profiling of all establishments followed by the development of an annual plan for GMP inspections of manufacturing facilities to optimize the available resources and reduce the number of GMP inspections without compromising the quality using a risk-based approach.

Objective 3: Supply of quality-assured essential medical products of health importance increased

Activity 3.1: Development of Antimicrobial Consumption (AMC) dashboard in PIRIMS: AMC data helps quantify the consumption of antimicrobial agents, conduct comparative analysis at the country level, and evaluate the impact of regulatory interventions, therefore it plays a key role in AMR surveillance. Access to AMC data, however, remains challenging in Pakistan.

Through this representation, DRAP can easily assess the geographical consumption of antimicrobials at the consumer level in Pakistan.

PQM+, in collaboration with DRAP, developed an AMC dashboard to link with the PIRIMS portal, which will help pharmaceutical industry users submit data relating to production/batch details, sale details, and distributor, reseller, and patient details. For this purpose, PQM+ will train manufacturers, retailers, and distributors once the data input process is complete.

Activity 3.2: Development of a National Pharmaceutical Strategy: In PY2, a key area of focus for PQM+ was to help foster a business enabling environment that encourages private sector investment. At present and compared to a global market of more than $1.2 trillion, Pakistan exports approximately $230 million in pharmaceutical products.[7] With careful planning, strategic policy making, and investments, as well as strong commitment from the government and the pharmaceutical industry, Pakistan's share of the global pharmaceutical market can increase exponentially. Not only will this bolster Pakistan's economy in terms of the resulting foreign exchange, but it will also ensure the provision of safe, effective, and quality assured drugs in Pakistan.

As a result of interactions with the government, PQM+ helped identify the need for developing a comprehensive pharmaceutical sector strategy. PQM+ developed a concept note to map out a plan to develop the strategy and engage all the key stakeholders for an inclusive and government-owned and led process, that would ensure the uptake of the recommendations driven by the strategy. The focus of the strategy is on identifying key constraints faced by the private sector and co-creating interventions (including fostering a business enabling

[7] Pakistan Exports of pharmaceutical products: https://tradingeconomics.com/pakistan/exports/pharmaceutical-products

environment and regulatory reforms, and incentive structures) that can help attract investments from the private sector to grow high-quality domestic manufacturing. In addition, the strategy will help Pakistan to capture a larger share of the global pharmaceutical market, with a special focus on the global pharmaceutical generic medicines market, which is expected to grow to $700 billion by 2025.[8]

PQM+ held a high-level meeting with the Chairman and senior leadership of the Board of Investment (BOI) in October 2020, at the Prime Minister's Office in order to discuss the need fora pharmaceutical sector strategy. The BOI Chairman agreed to support the development of a ten-year National Pharmaceutical Sector Growth Strategy, in addition to nominating a focal person at the BOI to coordinate the way forward for this exercise. Following the inception meeting, PQM+ conducted several planning meetings with key BOI officials, nominated by the Secretary to facilitate the development of the National Pharmaceutical Strategy.

Led by an internal strategy working group, PQM+ started work on a desk review focused on gathering key data points around the current state of the pharmaceutical industry, mapping key stakeholders, identifying challenges to the growth of the industry, and consolidating recommendations to promote investment and create a business enabling environment in the pharmaceutical sector. The first round of interviews and consultations with Chief Executive Officers and senior management from 12 leading pharmaceutical companies was concluded. Following a second round of consultations with a similar number of pharmaceutical companies, the findings will be consolidated and shared with a panel of experts to ensure their accuracy and practicability.

In parallel, PQM+ has also started working on advocating for the uptake of the recommendations from the strategy once these are finalized. PQM+ has been engaging with thekey stakeholders including the Ministry of National Health Services, Regulation and Coordination (MoNHSR&C), and DRAP. A detailed meeting was conducted with the DRAP CEOregarding the need for and the objectives of the pharmaceutical strategy-building exercise. This was a key step in ensuring buy-in from the regulatory body for the strategy building process, given the final recommendations will include proposals for further regulatory reforms. The PQM+ team has also started actively raising awareness of the strategy development exercise with development partners working on public health-related initiatives in the country to actively seek out opportunities for leveraging their work and identifying opportunities for synergistic partnerships.

During PY2, the progress on national pharmaceutical strategy included the development of a concept note, engagement of BOI to support and lead the development of the strategy, formation of a working group to lead the strategy development, nomination of the DRAP CEO tothe working group, development of a terms of reference for the working group, completion of a desk review, and initiation of a stakeholder mapping and consultations.

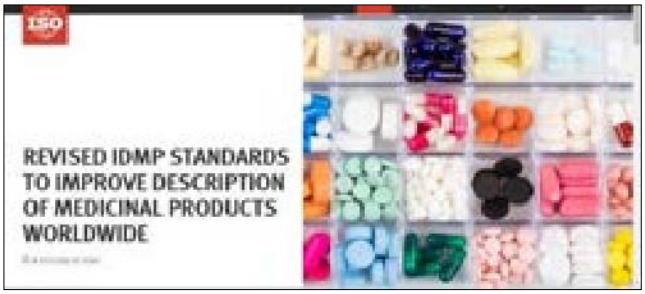
Objective 4: Reduce the availability of SF medical products to advance the Global Health Security Agenda

*Activity 4.1: Support the adoption of data standards, including the Common Technical Document format, to facilitate dossier review and information management with manufacturers:*The ISO Identification of Medicinal Products (IDMP) standards specify the use of standardized definitions to identify and describe medicinal products for human use. The purpose of these

[8] Unleashing the Potential of Pharmaceuticals in Pakistan. https://www.pbc.org.pk/research/unleashing-the-potential-of-pharmaceuticals-in-pakistan/

standards is to facilitate the reliable and consistent exchange of medicinal product informationby providing a common product language for stakeholders to use in their interactions.

PQM+ provided technical assistance to DRAP to adopt and implement IDMP standards. PQM+ shared the five IDMP ISO standards and the draft roadmap with DRAP for the implementation of these standards, including:



1. Drug substances (ISO 11238)
2. Pharmaceutical dose forms, units of presentation, routes of administration, and packaging (ISO 11239)
3. Units of measurement (ISO 11240)
4. Regulated pharmaceutical product information (ISO 11616)
5. Regulated medicinal product information (ISO 11615)

In PY2, with the support of PQM+, DRAP has adopted three ISO standards and incorporated them into the PIRIMS portal. In addition, PQM+ has developed guidance documents for DRAPon two ISO standards, i.e., ISO 11239 – Pharmaceutical dose forms, units of presentation, routes of administration, and packaging and ISO 11240 – Units of Measurement. PQM+ has also conducted two, one-day training sessions for DRAP staff on implementation of IDMP standards, while another training session on implementation of IDMP standards is planned forAugust 2021.

Due to the COVID-19 pandemic and travel restrictions, some PQM+ activities are in process and a few activities will carry forward to PY3. See Table 7.

Table 7. Status of PY2 Activities

Sr	Activities/Sub Activities	Status
1.	Develop National Medicines Policy (NMP) implementation plan and guidelines for quality assurance of medical products (including antimicrobials)	Will begin in PY3
2	Develop a regulatory framework to handle regulatory actions based on the National AWaRE list	Will begin in PY3
3	Prepare potential labs to acquire ISO 17043 (Proficiency Testing) and ISO 17025 (calibration) to reduce the dependency on international labs	Ongoing

Europe and Eurasia RegionCentral

Asia/Kazakhstan

PQM+ is strengthening the medicines regulatory system in Kazakhstan by providing technical assistance to the National Center for Expertise of Medicines and Medical Devices (NCEM). The main objectives are to improve the medicines registration system; support medicines quality control laboratories (MQCLs) so they can test the quality of medicines reliably and accurately according to international standards; strengthen the GMP inspectorate; and prepare the country for accession to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

In PY2, PQM+ worked to:

- Improve country regulatory systems to assure the quality of medical products and
- Increase the supply of quality-assured medical products.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ in Central Asia/Kazakhstan achieved the following.

- Assisted Karaganda laboratory to maintain the status of WHO pre-qualification and helped Almaty laboratory prepare for WHO prequalification. PQM+ conducted a virtual assessment of Almaty laboratory and submitted a peer audit report to WHO.
- Provided trainings on validation of computerized systems (CSV).
- Completed procurement of laboratory equipment for Karaganda and Almaty laboratories.
- Introduced the RB-PMS concept and provided technical assistance to develop corresponding regulatory documents and procedures, resulting in NCEM conducting a first round of PMS sampling and testing. The report is pending.
- Assisted the Pharmaceutical Inspectorate's progress toward preparation for PIC/S accession, according to the roadmap developed with PQM+ support.
- Provided comprehensive support to prepare the GMP Inspectorate for distant assessments of manufacturers, particularly amid COVID-19 travel restrictions.
- After the first assessment, conducted with PQM+ support, the inspectorate performed distant assessments of three pharmaceutical manufacturers and 25 manufacturers of medical devices.
- Initiated work with the Medical Devices Inspectorate, identified key areas of technical assistance, and started providing capacity building technical assistance to inspectorate staff.
- Began assisting the NCEM's scientific-educational center, including help in obtaining local accreditation of the educational institution and increasing the staff capacity by providing trainings tailored to the center's needs.

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 technical assistance to the Almaty and Karaganda MQCLs to help them achieve and maintain WHO prequalification (PQ). PQM+ finalized a report on the virtual assessment of the Almaty laboratory and submitted it to the WHO prequalification team (PQT). WHO PQT agreed to accept the assessment as a peer review audit. PQM+ expects a response from WHO PQT about the dates for the laboratory audit for WHO PQ. Meanwhile, the Almaty laboratory developed a CAPA plan and PQM+ has been working with the laboratory on its implementation following the virtual assessment.

PQM+ began processing the delivery of three analytical instruments (pH meter, conductometer, and Karl Fischer titrator) for the Karaganda laboratory and completed the delivery of safety showers for the Almaty laboratory to improve each lab's compliance with WHO guidelines. PQM+ also conducted a hands-on training on computerized system validation (CSV) for Karaganda and Almaty laboratories and the Pharmaceutical Inspectorate. WHO identified this area as needing further capacity building for prequalification of the Karaganda laboratory.

PQM+ is supporting Kazakhstan in strengthening the Pharmaceutical Inspectorate and preparing for ascension to PIC/S membership. This will facilitate reliance and open access to

the GMP inspection mechanism with other PIC/S member countries, assure the availability of resources for further capacity development, and eventually support access to quality-assured medicines in the country. Kazakhstan's membership in PIC/S and using the PIC/S GMP guidelines in inspecting the local industry will also facilitate the export of medicines. In Q3, PQM+ provided extensive support to the GMP Inspectorate to prepare for its first distant GMP assessment of a pharmaceutical manufacturer; it took place successfully, and the inspectorate used this experience in Q4 to conduct three distant assessments of medicines manufacturers and 25 distant assessments of medical device manufacturers.

In Q4, PQM+ also provided training for 37 inspectorate staff from the Committee for Medical and Pharmaceutical Control and NCEM on shared facilities and cleaning validation. The training covered GMP requirements; cleaning validation approach, limits, and analytical methods; and typical problems of shared facilities.

NCEM requested PQM+ assistance in strengthening the capacity of the Medical Devices (MD) Inspectorate. PQM+ identified four main areas of technical assistance: developing an MD inspectors' group, developing a QMS, training inspectors, and evaluating dossier applications. In Q4, PQM+ administered training on medical device quality system inspections with a focus on in-vitro diagnostic devices (IVDs). Thirteen people from the Inspection Department of NCEM attended. The training included an overview of quality standards with an emphasis on design and development requirements to assist the inspectorate with premarket requests for facility inspections of diagnostic manufacturers. The facilitator encouraged participants to use specific ISO standards or other global regulatory guidance to help identify quality system deficiencies.

The 2018 WHO GBT assessment identified gaps in Kazakhstan's market surveillance and control. In Q3 and Q4, NCEM conducted a first round of PMS sampling and testing. In the first PMS round, NCEM applied elements of risk-based PMS by selecting products, geographical regions, and outlets based on risk assessment and analyzed the collected data. As a follow-up, PQM+ provided technical assistance to NCEM in preparation for the PMS report, helping develop a report template and providing relevant guidance. NCEM will prepare the PMS report by the end of 2021. NCEM also developed a PMS process map based on the rules of sampling from the market and PQM+ recommendations; the map includes all PMS stakeholders and theirroles. In Q4, PQM+ started translation of the online RB-PMS tool, MedRS, into Russian. In PY3,PQM+ will provide training on using the tool, after which NCEM will be able to use the tool for scientifically sound identification of specific samples to select from the market based on risks.

In Q4, PQM+ continued work with NCEM's scientific-educational center (SEC). The center is important to ensure the sustainability of PQM+'s efforts to build the capacity of the medicines regulatory workforce in Kazakhstan. In Q4, PQM+ assisted the SEC in preparation for accreditation from a local accrediting body; SEC's goal is to achieve accreditation by the end of 2021. As one accreditation requirement, the SEC must prepare training programs for the courses under its scope. SEC shared a draft program on the Eurasian Economic Union (EAEU) rules of GMP inspections developed for pharmaceutical manufacturers. PQM+ reviewed the draft and provided recommendations on the program template and the content of the training. PQM+ continues preparation for the workshop on competency-based learning and adult learning. PQM+ is preparing training materials and will use the program on EAEU rules of GMP inspections as an example of applying principles of competency-based and adult learning. The training will include several sessions; it is scheduled for October 2021.

In Q4, WHO conducted a follow-up remote assessment of Kazakhstan's regulatory system and assigned GBT Maturity Level 2 to all eight GBT functions based on the document review. The results of the remote assessment will be confirmed during an on-site visit in September 2021.

However, Kazakhstan has neither worked on nor been assessed on GBT Function 9, lot release. In Q4, PQM+ provided an orientation session on the GBT lot release function for the staff of NCEM and the Committee for Medical Pharmaceutical Control. PQM+ provided an overview of GBT lot release indicators and sub-indicators and explained the requirements to comply with this function. PQM+ also developed a position paper that explains key regulatory considerations regarding the development of vaccines during a public emergency, as well as thelot release program. The document highlights three areas: 1) regulatory requirements, including the risk-based approach, 2) the development and data requirements for manufacturing vaccines, and 3) the lot-release program, with a focus on regulatory compliance. NCEM will coordinate with PQM+ for any technical support needed after the WHO GBT team's visit.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Address findings related to good regulatory practices from the GBT follow-up assessment in collaboration with NCEM and the Committee for Medical and Pharmaceutical Control.
- Continue technical assistance to the NCEM on developing approaches and procedures for RB-PMS.
- Assist in implementing CAPAs resulting from the virtual audit of the Almaty MQCL to prepare the laboratory for WHO PQ.
- Continue technical assistance to the PIC/S working group in the areas outlined in the PIC/S accession roadmap.
- Provide technical assistance to the medical devices inspection group to operate in compliance with international standards.
- Continue technical assistance to the scientific-educational center to ensure it becomes a main element of the system for continuous education of NCEM staff.

Uzbekistan

Uzbekistan is graduating from the Global Fund-supported procurement of TB medicines to domestically funded procurement, and the country plans to gradually increase the funding it allocates to procure second-line TB medicines. The government's strategy is to ensure that domestically produced, quality-assured medicines are available for procurement. In recent years, the Government of Uzbekistan introduced several initiatives to strengthen the local production of quality-assured medicines in the country. In support of this strategy, and generallyto ensure the quality of medicines on the local market, PQM+ is assisting the Agency on Development of the Pharmaceutical Industry ("the Agency") around medicines regulatory systems strengthening. This includes improving the medicines review and registration system, supporting MQCLs to test the quality of medicines reliably and accurately, and preparing the GMP inspectorate for PIC/S accession. The program also focuses on increasing the supply of locally manufactured, quality-assured TB medicines by providing technical assistance to pharmaceutical manufacturers.

In PY2, PQM+ helped to:

- Improve country regulatory systems to assure the quality of medical products and
- Increase the supply of quality-assured medical products.

Highlights of Progress by PQM+ During PY2

During PY2, USAID and the Agency signed an MOU about PQM+, signifying political commitment and collaboration between the two institutions on PQM+ scope. During the program year, PQM+ in Uzbekistan achieved the following.

- Conducted a technical review of a new Cabinet of Ministers decree No. 213, which regulates the procedure for registration of medicines, medical devices, and equipment, and provided detailed recommendations for improvement.
- Facilitated the development of guidelines and SOPs and oriented the Agency and manufacturers on the WHO CRP fast-track registration process for WHO prequalified medicines. Although Uzbekistan was a member of the WHO CRP, it had not yet registered any medicine using the process.
- Coordinated between the State Center, Global Fund, National TB program, and Global Drug facility to facilitate the registration of WHO prequalified medicines in Uzbekistan.
- Supports the Agency in advocating for the reduced fee approval for WHO CRP, with two major milestones:
  - MoH approved a reduced fee for registration of WHO PQ medicines through WHO CRP (about 55 percent of the regular registration fee).
  - The country's first dossier for a WHO-prequalified medicine, cycloserine, was submitted to the Agency for registration through WHO CRP.
- Worked closely with the Agency's working group on streamlining to a single GMP Inspectorate to review legislation and regulations to address the gaps in current GMP inspection procedures, develop new inspection procedures, and recommend options on an effective organizational structure of the inspectorate.
- Advocated for and provided technical assistance in establishing the Good Practice (GxP) Center within the Agency, which will be responsible for GMP inspections. The formation of one GMP inspectorate in Uzbekistan will develop manufacturers' capacity to comply with GMP requirements and prepare Uzbekistan for accession tothe PIC/S.
- Provided technical assistance to manufacturer, Nobel Pharmasanoat, enabling it to further prepare for submission of levofloxacin for WHO prequalification. Nobel completed all outstanding issues related to cross-contamination risk management, sourced WHO prequalified API for the product, started development of the product, and began dossier compilation.

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+ hit two important milestones in advocating and providing technical assistance for using the collaborative registration procedure (CRP) for accelerated registration of WHO-prequalified medicines in Uzbekistan. First, the Cabinet of Ministers approved a reduced cost (55 percent of the regular fee) for registering WHO-prequalified medicines through the WHO CRP. Second, two manufacturers have submitted their first dossiers of WHO-prequalified products (cycloserine and protionamide) for registration in Uzbekistan through the WHO CRP. Currently, these dossiers are undergoing review by the Agency through the WHO CRP process.Once approved, they will be the first WHO-prequalified products registered in Uzbekistan through the system. This important milestone means that WHO CRP is starting to work in Uzbekistan, which will help accelerate the registration of WHO-prequalified, quality-assured medicines and in removing registration-related obstacles in procuring or importing these products.

PQM+ is working with the stakeholders to ensure that other manufacturers of WHO-prequalified products also submit corresponding dossiers to the Agency to register their products in Uzbekistan through WHO CRP. The Agency has started reviewing the dossiers. This

achievement is a result of PQM+ technical assistance through facilitating the operationalizationof the WHO CRP in Uzbekistan. PQM+ supported in developing corresponding procedures (SOPs and guidelines) and training the staff. PQM+ also advocated and coordinated with the international and national stakeholders (Gold Dried Fruit Export LLC; the Global Fund to Fight AIDS, Tuberculosis, and Malaria/ GFATM; the National Tuberculosis Program/ NTP; and the Agency) to ensure that manufacturers of WHO Prequalified medicines understand the requirements for registration through WHO CRP in Uzbekistan and to motivate them to work on submission of their dossiers.

In Q4, PQM+ continued to provide technical assistance to strengthen the medicines registration system. The priority is to develop appropriate SOPs that will meet international standards. PQM+ is providing guidance to develop 47 relevant SOPs; the program assisted in reviewing the SOPs and provided recommendations to the members of the working group for finalization.

In Q4, the resolution of the Cabinet of Ministers established the Good Practice (GxP) Center within the Agency as a separate legal entity with 40 staff units. This is an important milestone as until now there were several structural units responsible for GMP inspections with an unclear delineation of responsibilities. Now, the new center will be solely responsible for GMP inspections. The formation of one GMP inspectorate in Uzbekistan will support the development of the capacity of the manufacturers to comply to GMP requirements as well as prepare Uzbekistan for accession to the PIC/S. PQM+ provided technical assistance to the Agency by advising on the options for the organizational structure to meet PIC/S membership requirements for the GMP inspectorate which helped in the decision making process when the GxP center was established based on the resolution to the Cabinet of Ministers. In addition, in Q4, PQM+ also conducted a training with ten participants on distant assessment of manufacturers for the newly established GxP center.

This quarter, the local accreditation body completed the Tashkent laboratory re-accreditation assessment for ISO 17025. Tashkent laboratory has developed a corrective action plan and PQM+ is providing guidance on addressing the observations. PQM+ provided two trainings for 18 Tashkent laboratory staff: one on decision rule and another on risk-based management in a quality control laboratory (QCL). PQM+ also visited the Andijan laboratory to provide technical assistance on site and to follow up on a few outstanding activities in preparation for their re-accreditation assessment. An HPLC machine procured by PQM+ for the Andijan laboratory has arrived in country. Adding the HPLC capability will help strengthen the infrastructure to test the quality of medicines.

In Q4, the government introduced a clause into a protocol on the development of a roadmap for introduction of PMS. This is a good development because this indicates the government’s desire to transition into a PMS system. PQM+ started working with the respective working groupat the Agency. As a result, a draft roadmap for introduction and piloting of the PMS system in Uzbekistan was developed and is undergoing an internal review at the Agency.

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

PQM+ continued technical assistance to Nobel Pharmsanoat towards prequalification of their TB product levofloxacin. In Q4, PQM+ technical assistance included training of the staff on some specific topics related to dossier development in common technical document (CTD) format. Also, guidance was provided on some specific topics related to product development, aswell as on biowaiver, product formulation, dissolution profile, and bio batch production.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Review the newly developed SOPs to support strengthening of the medicine's registration system.
- Provide technical assistance to develop the integrated information management system for medicines registration.
- Continue facilitation of registration of WHO-prequalified TB medicines through the WHO CRP mechanism.
- Conduct an assessment of at least one additional regional MQCL.
- Continue technical assistance to the PIC/S working group in its preparation for the PIC/S accession, including strengthening QMS and building the GxP inspectorate staff's capacity.
- Complete delivery of HPLC equipment to the Andijan MQCL.
- Provide technical assistance to MQCLs as they prepare for local ISO 17025 accreditation.
- Continue technical assistance on strengthening the post-marketing surveillance system including finalization and approval of the roadmap.
- Continue technical assistance to Nobel Pharmsanoat in its preparation for WHO PQ for levofloxacin production.

COVID-19

COVID-19 Response Activities

Cross-Bureau

PQM+ received funds from the Office of Health Systems (OHS) to support COVID-19 pandemic-related activities that contribute to Objective 2 of the PQM+ results framework: Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors. USAID approved the work plan in March 2021, with two main activities to implement:

- Develop an operational guide on emergency regulatory procedures for COVID-19 medical products and
- Disseminate the USP quality control toolkit for COVID-19 vaccines.

PQM+ is implementing the two activities with its partners, the University of Washington and the Global Health Impact Group (GHIG)-London School of Hygiene and Tropical Medicine (LSHTM). Activity updates for this quarter are:

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ achieved the following Cross-Bureau COVID response activities.

- Completed dissemination of the USP quality control toolkits for the COVID-19 vaccine in collaboration with the USP Science Division and African Medicines Regulatory Harmonization (AMRH).
- A series of two webinars drew 229 participants who received complimentary access to the USP-National Formulary (NF) chapters for the COVID19 vaccine quality assessment toolkits.

Emergency regulatory procedures for COVID-19 medical products: PQM+ engaged two of its technical partners, the University of Washington (UW) and Global Health Impact Group (GHIG) to support the development of an operational guide for EUA for vaccines and for in vitro diagnostic devices (IVD), respectively.

PQM+ organized working sessions between GHIG and UW to jointly develop MRA country readiness assessment questionnaires. This was an effort to ensure that questions for vaccines and IVDs were not duplicative, and to make sure MRAs' engagement occurred at the same time to reduce responder fatigue. The country readiness assessment aims to collect information on current MRA practices, experiences, and readiness for emergency pathway approvals for COVID-19 medical products. The questionnaires were translated into French for French-speaking countries. PQM+ field offices administered the questionnaires to MRA focal points. Sixteen PQM+ countries responded to the diagnostics questionnaire and 17 answered the vaccine questionnaire. The final country assessment report is under development.

Next quarter, PQM+ will host a webinar titled "Model Practical Emergency Use Authorization (EUA) Guidance to Expedite the Availability of COVID-19 Vaccines and Diagnostics." The main purpose of this webinar is to conduct a soft launch of the EUA guidance for vaccines and diagnostics and to solicit feedback from stakeholders that participated in content improvement. UW and GHIG will use the feedback from this webinar to finalize the vaccine and diagnostics EUAs, respectively. Next steps after finalizing the deliverables include translating the EUA into French and disseminating it widely to stakeholders.

Dissemination of the USP Quality Control Toolkit for COVID-19 Vaccines: PQM+ collaborated with USP and AMRH to plan and host two webinar sessions to disseminate the USP quality control toolkits for COVID-19 vaccines. In preparation for the webinars, PQM+ developed webinar advocacy and invitation materials and shared them with New Partnership forAfrica's Development (NEPAD) to share with regional technical working group platforms in Africa and MRAs. PQM+ also promoted the webinars on various social media platforms and listservs. The main target audiences included technical working group members of AMRH, mainly African Vaccine Regulatory Forum (AVAREF) and African Medicines Quality Forum (AMQF). PQM+ engaged a consultant to translate the webinar invitation and concept note into French. PQM+ also engaged both French and Portuguese simultaneous interpreters for both webinars.

Part one of the webinar titled "Safeguarding the Population from Access to Poor Quality COVID-19 Vaccine Products: Toolkits for the Assessment of Quality Attributes" was held on July 27, 2021. A total of 114 people attended this webinar. Part two of the webinar, which focused on assessing the quality attributes of mRNA vaccines and the quality attributes of inactivated vaccines, took place on August 3. The webinar conducted in collaboration with the New Partnership for Africa's Development (NEPAD) targeted the Africa region; 111 people attended.

All attendees received complimentary access to the USP-National Formulary (NF) chapters for the COVID-19 vaccine quality assessment toolkits.

Pakistan

In PY2, the PQM+ program supported DRAP, the pharmaceutical industry (manufacturers and importers), CROs, and BE centers through the following major activities:

PQM+ conducted a virtual one-day training in August in collaboration with DRAP on EUA Guidelines for Medical Devices for key

EUA regulatory approvals from DRAP: In the beginning of the COVID-19 pandemic, DRAP was unable to grant emergency approvals or practice EUA due to a lack of legal provisions and procedures, especially for medical devices (such as PPE) and pharmaceuticals (remdesivir). To address this issue, the PQM+ Pakistan COVID-19 program developed EUA guidelines per international best practices, in consultation with DRAP and stakeholders. DRAP will convert the EUA guidelines into regulations for implementation going forward, through the following stages:

1. Converting the EUA guidelines for medical devices into policy,
2. Conducting a legal review of the policy, and
3. Presenting the policy to the Cabinet for approval.

PQM+ assistance in this area will ultimately strengthen DRAP's regulatory systems, enabling Pakistan to respond to the COVID-19 and future public health emergencies.

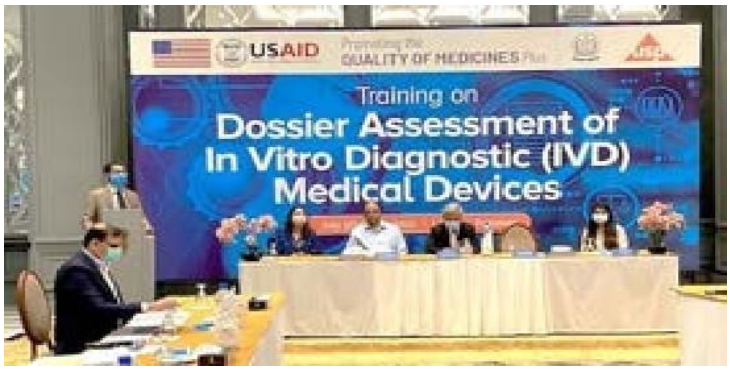
PQM+ developed draft EUA guidelines for medical devices and held a virtual consultative meeting with various stakeholders. Participants from the Pakistan Pharmaceutical Manufacturing Association, Pharma Bureau, Chairman of the Healthcare Devices Association ofPakistan, President of the Federation of Pakistan Chambers of Commerce and Industry, regulatory affairs managers from Abbott and Roche pharmaceutical companies, and the Director of Medical Devices from DRAP, along with DRAP staff attended the session. PQM+ submitted the draft EUA guidelines to DRAP for final approval after the inclusion of feedback provided by the stakeholders.

Finally, in August, PQM+ conducted a one-day training on finalized EUA guidelines for medical devices, in collaboration with DRAP, for key stakeholders such as manufacturers and importers of medical devices. Representatives of DRAP's Medical Devices Division, medical devices manufacturers/importers, and pharmaceutical companies actively participated.

The training on EUA guidelines can help build the capacity of stakeholders on required EUA application procedures for medical devices, in addition to training DRAP staff on effectively managing and processing requests for EUA and ensuring a more responsive regulatory systemin Pakistan during the pandemic and for future health emergencies.

Capacity building of DRAP on dossier assessment of medical devices: After the training needs assessment of DRAP staff on dossier assessment of medical devices, PQM+ hosted a three-

day extensive training session on Dossier Assessment of In-Vitro Diagnostics (IVD) Medical Devices, leveraging technical expertise of a US-based diagnostic manufacturer.



PQM+ conducted a three-day training in Lahore for DRAP staff on Dossier Assessment of In-vitro Diagnostic (IVD) Medical Devices in July.

The DRAP Chief Executive Officer (CEO) and the director of DRAP's Medical Devices Division, attended the session. Training topics included international regulations on In-Vitro Diagnostics, WHO pre- qualification criteria for IVDs, technical documentation requirements, preparing a high-quality dossier, and other topics.

Engaging local private sector to manufacture quality-assured remdesivir: PQM+ supported Remdesivir manufacturer, BF Biosciences (Pvt.) Ltd. (Ferozsons), to build their capacity for compliance with GMP, in line with Pharmaceutical Inspection Cooperation Scheme (PIC/S) standards, International Organization for Standardization (ISO) 17025:2017 standards for quality control testing laboratory, and a supply chain assessment for products, to ensure end toend quality of the product, while also providing support to increase remdesivir production for local use and exports.

Regarding Ferozsons' compliance with GMP under PIC/S standards, PQM+ led a detailed five-day onsite audit to conduct a gap assessment of the facility. The assessment included the manufacturingsite, its ancillary areas, and the pharmaceutical QMS against the PIC/S standards and has identified and documented areas for improvement. PQM+ developed a detailed gap assessment report, which includes key observations and findings noted during the visit and shared it with the Ferozsons management team. Ferozsons will prepare a CAPA plan and share it with PQM+ for review

PQM+ aid enabled Ferozsons to locally produce the COVID- 19 medicine remdesivir.

PQM+ is engaging Ferozsons to produce remdesivir (a COVID-19 treatment medicine) in accordance with PIC/S and ISO 17025:2017 standards, in addition to ensuring the facility's compliance with current GMP. With PQM+ support, Ferozsons has increased its production and is supplying remdesivir to local markets in Pakistan and globally through exports. In addition, this activity contributes to the Global Health Security Agenda (GHSA) by developing/implementing national multi-sectoral, multi-hazard emergency preparedness measures and saving lives during the pandemic.

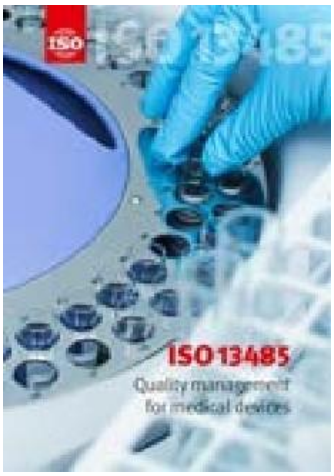
With PQM+ support, Ferozsons increased its production and is supplying remdesivir to local markets in Pakistan and globally through exports. Table 8 details remdesivir batch production.

Table 8. Production of Remidia

Product	Std. Batchsize	Number of Batches Produced (As of Aug 13, 2021)	Total Number of Vials Produced (As of Aug 13, 2021)
Remidia solution for Infusion 100mg/20ml	3780	37	142,115 Packs
Remidia Lyophilized powder for Infusion 100mg	4800	48	222,261 Packs

Ferozsons exported Remidia Infusion to 16 countries: Angola, Aruba, Belarus, Dominican Republic, Honduras, Indonesia, Mozambique, Jamaica, Kenya, Philippines, Tanzania, Uganda, Ukraine, Uzbekistan, St. Maarten, and Libya, translating into the export and timely provision of urgent COVID-19 treatments globally, saving lives during the pandemic.

Engaging local private sector to manufacture quality-assured PPE: To cope with and control the spread of the COVID-19 pandemic, it is necessary to ensure the proper tools and measures are available and in place. One of the most crucial tools is the supply and use of quality PPE for the public. Higher-quality PPE is more effective at containing the pandemic and saving lives. The use of quality- assured PPE will also contribute to infection prevention and control (IPC).



PQM+ assisted nine PPE manufacturers to produce high-quality PPE according to international standards, for both local use and export. PPE manufacturers have been selected through an advertised expression of interest (EOI) to receive support on ISO 13485 accreditation and, for one product, the *Conformité Européenne* (CE) mark, signifying that the product can be sold in theEuropean Union (EU).

PQM+ has started visits to PPE manufacturers to identify gaps related to environment, health, and safety (EHS) and compliance issues in manufacturing practices. Following this gap analysis, PQM+ will support development of a CAPA plan to address existing gaps at the facility, in addition to providing technical assistance for ISO 13485 accreditation and CE mark certification for one product.

The CE mark and ISO 13485 accreditation would encourage PPE manufacturers in Pakistan to design quality management systems and maintain the effectiveness of their processes per international standards, as well as export PPE globally.

Increased regulatory capacity to handle in-country biostudies as per international best practices: As a result of the current pandemic, many new medical products are introduced internationally. However, some are still under review, meaning data on safety and quality is under investigation,

and this development stage requires extra vigilance and expertise to review before DRAP allows market authorization in Pakistan.

To assist with this process, PQM+ developed guidance documents on conducting biostudies (clinical studies/trials) to build the capacity of DRAP staff on biostudies and helpDRAP develop and implement national biostudies guidelines to ensure reliable, evidence-based, clinical data on new treatments during the pandemic.

PQM+ hosted a two-day interactive training in Islamabad on Good Clinical Practices (GCP) and Good Lab Practices (GLP) for the DRAP staff in July.

To sensitize and build capacity on biostudies (clinical studies/trials), the PQM+ program provided a two-day interactive training session on Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) for staff from DRAP Pharmacy Services Division, including the Director of Pharmacy Services, while provincial staff based in other cities across Pakistan attended the training session virtually.

As a continuation of PQM+'s series of activities on biostudies (clinical studies/trials), the PQM+ program also conducted a training session on Discussion on Best Practices in Clinical Trials & Adaptation of International Guidelines, with the session facilitated by the US-based PQM+ bioequivalence consultant. Over 100 participants attended the session in-person and virtually, from the DRAP Pharmacy Services Division, Bioavailability/Bioequivalence (BA/BE) Centers, and Contract Research Organizations (CROs) from all across Pakistan.

These sessions help DRAP, Bioavailability/ Bioequivalence (BA/BE) Centers, and Contract Research Organizations (CROs) to adapt international best practices and guidelines for improving the practices of clinical trials and studies in Pakistan, especially for COVID-19 medicines and vaccines.

In addition to the above series of activities in clinical trials/studies, PQM+ conducted a training on “Submission, Review, and Disposal of Clinical Trial/Bioequivalence (BE) Study Applications” for DRAP staff, CROs, and provincial officials. The PQM+ Bioequivalence Consultant presented details about clinical trial/bioequivalence study applications, as well as the necessary procedures and regulatory requirements, as per best international practices.

PQM+ administered an in-depth virtual training session on Submission, Review, and Disposal of Clinical Trial/BE Study Applications for DRAP, provincial officials, and CROs in August.

The PQM+ Bioequivalence Consultant shared a **Guidance Document on Clinical Protocols and proposed SOPs** for DRAP to adopt, for overseeing clinical trial study applications as per best international practices going forward. This USAID-funded training will help to guide CROs regarding application and submission requirements for clinical trials, in addition to enhancing the capacity of DRAP staff to review and dispose of BE applications effectively in future; thus increasing regulatory capacity to handle in-country biostudies as per international best practices, as well as improving the quality of clinical trial study applications in Pakistan.

Regulatory support to DRAP to reduce the risk of shortages of quality-assured and evidence-based COVID-19 medical products and supplies: In the case of public-health emergencies, such as the COVID-19 pandemic, medicines andtheir ingredients are often in short supply, and it is necessary to identify and arrange for alternative sources of APIs and FPPs, to prevent medicine shortages and guarantee timely access to both COVID-19 medicines and regular supplies of essential medicines.

PQM+ has procured a one-year subscription [9] for providing DRAP with access to an online global database of APIs, for developing local resources to identify and arrange for alternate API sources for manufacture of COVID-19 and other essential medicines, in case of shortages.

Cover Page of PQM+ Guidance Document for Monitoring of DrugShortages, developed for DRAP

[9] PQM+ is purchasing this one-year subscription and is providing support to develop a database dashboard for DRAP to monitor API shortages. DRAP will pay for the subscription charges after PQM+ ends, ensuring sustainability.

The PQM+ IT consultant has developed a prototype dashboard for DRAP. When it's finished, use of this dashboard will allow DRAP to effectively monitor API shortages and allow the agencyto easily use the global online API database going forward. A demo/test run on the prototype dashboard will be conducted for DRAP staff. In addition, the PQM+ team has developed a guidance document for DRAP to ensure effective monitoring and prevention of drug shortages using a proactive approach. Thisactivity contributes to the Global Health Security Agenda (GHSA) priority of developing/implementing risk communication systems for unusual/ unexpected events and emergencies.

Consultative meeting on RB-PMS for COVID-19 products.

National Action Plan for risk-based post-marketing surveillance (RB-PMS) for COVID-19 supplies in Pakistan: To protect patients from substandard and falsified medical products, PQM+ worked with regulators to implement risk-based quality surveillance and inspection by developing and implementing a national action plan for risk- based post-marketing surveillance (RB-PMS) for COVID-19 medical products in Pakistan.

PQM+ developed a RB-PMS plan based on the existing RB-PMS framework during a three-day consultative meeting in Islamabad. Senior officials from health departments from all provinces and the Azad Jammu and Kashmir (AJK) region participated in the meeting. At its conclusion, all provincial and regional health authorities unanimously endorsed two declarations and an action plan:

- Declaration on a national action plan for RB-PMS
- Declaration to establish a national quality control laboratories (NQCLs) technical forum
- A national action plan for RB-PMS of COVID-19 medical products

DRAP's Quality Assurance Division has shared the RB-PMS National Action Plan with provinces for final comments before implementation.

The CEO of DRAP addresses provincial and regional stakeholders during the PQM+ Dissemination Seminar on a National Action Plan for RB-PMS for COVID-19 products, in Islamabad on July 28-29.

In another meeting, provincial stakeholders and DRAP staff worked to develop a province-specific RB-PMS National Action Plan in a two-day "Dissemination Seminar on the National Action Plan for Risk-Based Post-Marketing Surveillance (RB-PMS) for COVID-19 products," in collaboration with DRAP. Participants from DRAP, provincial and regional health department stakeholders from all provinces attended the seminar. Furthermore, this intervention works

towards the Global Health Security Agenda (GHSA) priority of developing/ implementing surveillance systems.

PQM+ staff conduct an on-site training session for Central Drug Laboratory (CDL), Karachi staff on Sterility Testing onJuly 14.

Provision of PPE testing equipment for public sector PPE testing lab: During the COVID-19 pandemic, there is a greater demand for masks and other PPE in Pakistan. Due to the increase in demand, there is subsequently an increased risk of poor-quality PPE circulating in the local market. In Pakistan, the public sector lacks the capacity to conduct quality testing and post-marketing surveillance of PPE.

The PQM+ team finalized the procurement for 11 types of equipment for conducting testing of personal protective equipment (PPE) at the Central Drug Laboratory (CDL) in Karachi and initiated the procurement process for additional types of equipment[10] and consumables required for PPE testing.

In addition, a three-person PQM+ team at CDL Karachi finalized the layout design to establishthe PPE testing lab at CDL, in consultation with the lab director; in addition to reviewing requirements for upgrading the heating, ventilation, and air conditioning (HVAC) system for the microbiological lab in coordination with the PQM+ technical team. The lab layout includes sections for physical testing, flammability, and a micro-lab for personal protective equipment.

PQM+ staff conduct onsite training for staff of the Central Drug Laboratory (CDL), Karachi, on Emergency Response Procedures, Lab Chemical Safety, and Safe Waste Disposalin August.

The PQM+ team at CDL Karachi also developed a weekly training plan (based on a training needs assessment) to build the capacity of CDL staff on various technical areas and conducted the following trainings:

- Calibration and Preventive Maintenance for lab equipment
- Bacterial Endotoxin Test (Microbiological Test, Test for Injection)
- Sterility Testing
- Documentation Practices for Quality Control (QC) Labs
- Emergency Response Procedures, Lab Chemical Safety & Safe Waste Disposal

PQM+ developed and finalized 13 SOPs for equipment operations and lab testing [11] in collaboration with the director of CDL Karachi. PQM+ worked to strengthen public sector

[10] These include the following additional instruments: Water Impact Penetration Tester, Synthetic Blood Penetration Tester, and Dry Microbial Penetration Tester, and a Conditioning Chamber.

[11] These include the following SOPs: 1. Emergency Response Procedures; 2. Lab Safety Rules; 3. Waste Disposal; 4. HSE Inspection; 5. Autoclave Maintenance; 6. Autoclave Operations & Cleaning; 7. Generator Maintenance & Operations; 8. Inspection and Receiving Equipment; 9. Calibration & Maintenance of PH Meter; 10. Calibration and Maintenance of Fourier Transform Infrared Spectroscopy (FTIR); 11. Calibration & Maintenance of High Performance Liquid Chromatography (HPLC); 12. Calibration & Maintenance of Gas Chromatography (GC); 13. Calibration & Maintenance of Microscopes.

laboratories, such as DRAP's public sector lab and the Central Drug Laboratory (CDL) inKarachi, by supporting their PPE testing facilities and capacity building to help ensure uninterrupted access to quality-assured COVID-19 medical products.

Engage local private sector laboratories to test PPE: As part of its PSE strategy, PQM+ is engaging private sector PPE-testing laboratories inPakistan. To facilitate and improve the regulatory environment for PPE manufacturers, PQM+ worked with the DRAP to develop and implement aguidance document which lays out required conditions and accountability criteria for private sector testing labs to qualify as independent testing laboratories for PPE manufacturers.

PQM+ Private Sector Partner Lab for PPE Testing

PQM+ provided support to DRAP for finalizing national PPE standards, to ensure that all PPE products available in the market are safe and quality-assured. In this regard, PQM+ hosted a seminar in collaboration with DRAP and the private sector for Dissemination of National Personal Protective Equipment (PPE) Standards in Islamabad with key stakeholders.

The session was chaired by the Executive Director, National Institute of Health (NIH), International Health Regulations (IHR) focal person from the World Health Organization (WHO), the DRAP Chief Operating Officer (CEO), and the DRAP Director Medical Devices.

Seminar sessions included dissemination of PPE standards, an overview of DRAP's inspection system for PPE manufacturers, and a session on PPE testing by a private third-party, ISO 17025 accredited, PPE testing lab laboratory (Tti Testing Laboratories) to equip PPE manufacturers in Pakistan to manufacture quality PPE during COVID-19 as part of PQM+'s private sector engagement (PSE) strategy. Dissemination of national PPE standards will help to ensure the supply and use of quality-assured PPE in Pakistan during the pandemic, contributing towards infection prevention and control accordingly.

PQM+ conducts a seminar on Dissemination of National Personal Protective Equipment (PPE) Standards on July 15 in Islamabad for stakeholders.

Engage local private sector laboratories to test PPE: ISO 17025 accreditation of Tti lab: PQM+ team finalized the Gap Assessment report on the Quality Management System for Tti Testing Laboratory, which will be shared with the laboratory for development of a corrective and preventive action (CAPA) plan, along with PQM+ provision of additional assistance for implementation of required improvements. PQM+ team identified gaps and shared 24 observations on the calibrations and its status labeling, qualification of HVAC system in microbiology lab, good documentation practices, training of technical staff, in accordance with ISO 17025.

Implementation of QMS at Pakistan Institute of Medical Science (PIMS) 's public diagnostic laboratory: In PY2, PQM+ strengthen the public sector hospitals diagnostic laboratories' testing

quality by implementing a QMS at public sector PIMS hospital laboratory for International Organization for Standards (ISO) 15189 accreditation.

PQM+ conducted a gap assessment of the PIMS lab and implemented all major SOPsdeveloped for the laboratory quality management system (LQMS) at PIMS, in addition to implementation of QMS forms, to ensure the lab's compliance with ISO 15189 standards.

PQM+ trains Pakistan Institute of MedicalSciences (PIMS) laboratory staff on ISO 15189 requirements.

PQM+ conducted several trainings at PIMS under the ISO 15189 Project:

1. Awareness Session
2. Advanced Training on ISO 15189, which covered the following key topics:
   a. Implementation of SOPs
   b. Risk Management
   c. Corrective Action
   d. Participation in PT
   e. Measurement Uncertainty
3. Internal Auditing Training (to be conducted)

PQM+ provided support to PIMS for acquisition of proficiency testing and equipment calibration services. PIMS has submitted its first proficiency testing results after conducting required tests in its chemistry laboratory (for Hepatitis B and C). Equipment calibration will also be conducted after completion of proficiency testing at the PIMS lab. The proficiency testing plan will also be attached with PIMS's application to PNAC for pre-assessment for ISO 15189 accreditation.

PQM+ also supported PIMS to update its application to the Pakistan National Accreditation Council (PNAC) for ISO 15189 accreditation, in line with changes in its scope of accreditation, with submission of the application Laboratory Information File (LIF) to PNAC.

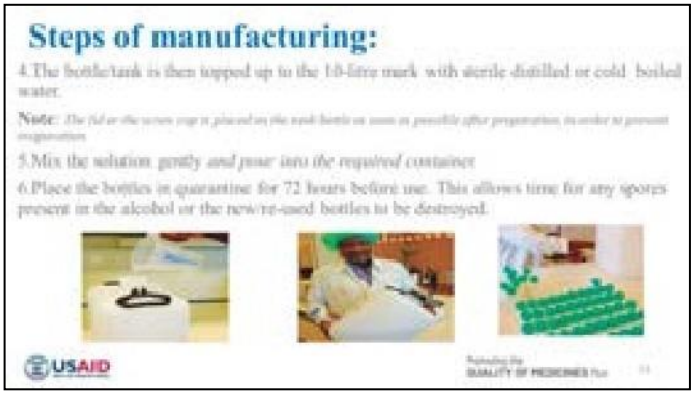
Achievement of ISO 15189 certification by the PIMS lab as a result of PQM+ efforts would helpto improve the lab's testing reliability during the COVID-19 pandemic, and in the future as well.

ISO 15189 accreditation will help to ensure quality and reliable testing for PIMS Hospital laboratory and aid the Pakistan government in effectively managing COVID-19 cases. Implementation of laboratory quality systems is also a priority area for PQM+ to focus on under the Global Health Security Agenda (GHSA).

In-house manufacturing of alcohol-based hand rub (ABHR) for public sector hospitals: In Pakistan, consumption of ABHR/ sanitizer has increased significantly due to the COVID-19 pandemic, particularly in tertiary care hospitals, where the daily utilization is over hundreds of

liters. As costs increase, there is a pressing need for public sector hospitals in Pakistan to increase sustainability in the production of quality ABHR/sanitizer.

PQM+ trained 30 lab staff in a virtual training for public sector hospital staff across Pakistan on in-site production of ABHR/Sanitizer. The training included key recommendations by WHO and USP, and topics on formulations, manufacturing steps, labelling, and quality control testing.



PQM+ hosted a virtual training on In-house Manufacturing of Alcohol-Based Hand Rub (ABHR/sanitizer) on June 2 for public sector hospitals across Pakistan.

In addition, PQM+ team developed a quality control plan, along with guidance for ensuring regular quality testing of in-house manufacturing of ABHR/ sanitizer by public healthcare hospitals. The guidance document has been reviewed and finalized by the PQM+ technical team and shared with all public sector hospitals [12] for future guidance and quality monitoring of in-house manufactured sanitizer; consequently contributing towards ensuring infection prevention and control in Pakistan.

ABHR training will help to build the capacity of public sector tertiary care hospitals in Pakistan to manufacture sanitizer in-house and help them to ensure infection prevention and control during COVID-19.

Planned Activities for PY3, Q1

- Training on Global Lessons Learned from COVID-19 for Regulatory Best Practices;
- Consultative meeting with DRAP to finalize API shortages monitoring policy;
- Installation of remaining testing equipment for post-marketing surveillance of PPE;
- Submission of EOI application for Pakistan Institute of Medical Sciences (PIMS) to PNAC for pre-assessment for ISO 15189 and subsequent assessment audit;
- Support for Remdesivir Local Production - BF Biosciences (Pvt) Ltd (Ferozsons);
- Five-day training session for government medical diagnostic lab staff on Assessor Training Course based on ISO 15189 in partnership with PNAC; and
- ISO 13485 and CE mark awareness training for PPE manufacturers for PPE Manufacturers and DRAP.

[12] PQM+ previously conducted training for public sector labs on in-house production of sanitizer, and nowis providing the final guidance document, which includes details of required standards according to best international practices, and a monitoring mechanism for ensuring regular quality testing for sanitizer manufactured in-house at public hospitals. The main beneficiaries would be public sector hospitals at the federal and provincial levels, who could maintain a continuous supply of quality sanitizer at their facilities.

COVID-19 Vaccine Activities

Bangladesh

Policy, Planning, and Coordination

Objective 1: Support DGDA to develop and implement a plan for monitoring quality of COVID-19 vaccines as part of the overall COVID-19 vaccine safety surveillance system

Background: As part of USAID's COVID-19 response efforts in Bangladesh, PQM+ received funding to support the Directorate General of Drug Administration (DGDA), Bangladesh's national regulatory authority, on policy, planning, and coordination. The program has been providing technical support to DGDA, its National Control Laboratory (NCL), and other relevant stakeholders to (i) strengthen safety surveillance systems in support of COVID-19 vaccine introduction and ensure patient safety; and (ii) revise and adopt expedited market authorization procedures, such as EUA/no-objection certificate (NOC) with appropriate requirements for product safety, efficacy, and quality monitoring through the following activities.

Progress this quarter:

Activity 1.1: Conduct desk review and stakeholder interviews to understand proposed suppliers, distributions chain, and AEFI systems

1. Completed a desk review for updating the draft plan and testing protocol for COVID-19 vaccines and reviewed the following documents:
    a. USP COVID-19 Vaccine Quality Assessment Toolkits, July 2021
    b. USP COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners, Version 4.0, June 2021
    c. DGDA Standard Operating Procedure (Ideal Procedures of Sample Collection of Medicines for Testing and Analysis), July 2017
    d. Vaccine Storage and Handling Toolkit, US Department of Health and Human Sciences, CDC, March 2021
    e. USP International COVID-19 Vaccine Handling Guide, Version 1.0, July 2021
    f. COVID-19 vaccines: development, evaluation, approval, and monitoring: European Medicines Agency, September 2021
    g. Journal article- Human Cell (2021) COVID-19 Vaccines: rapid development, implications, challenges, and future prospects
    h. COVID-19 vaccines: Modes of immune activation and future challenges; Nature Reviews/Immunology- Volume 21, April 2021

i. The COVID-19 Vaccines: Recent development, challenges, and prospects. (Vaccines 2021, 9, 349)

2. Completed interviews with relevant stakeholders, listed below:

   a. Dr. Md. Harun-Or-Rashid, Deputy Chief, NCL/DGDA. This meeting focused on risk-based testing at NCL. The Deputy Chief recommended to include specific vaccines in the risk-based protocol namely identification tests,potency tests, sterility tests, and endotoxin tests.

   b. Prof. Liaquat Ali, Ex-VC, Bangladesh University of Health Sciences, and member of technical expert committee of DGDA.

   c. Dr ASM Alamgir, Principal Scientific Officer, IEDCR involved in different government process of COVID-19 vaccination program.

   d. Mr. Ashraf Hossain, Deputy Director, DGDA: This meeting focused on the logistics of on PMS. Mr. Hossain provided recommendations on challenges related to sample collection, storage, and transportation.

3. Continued to support the Pharmacovigilance and Safety Surveillance for COVID-19 working group:

   a. Participated in meetings on July 19 and August 23.

   b. Followed up with the focal points for adverse events following immunization (AEFI) management at different levels.

Activity 1.2: Stakeholder consultation meeting to present categorization and propose plan for RB-PMS

1. Drafted the Risk-Based Post-marketing Surveillance (RB-PMS) Plan for COVID-19 Vaccines. The PQM+ technical team has reviewed the draft and provided initial feedback.
2. Held a consultative meeting with DGDA in September to discuss the first draft of the Risked-Based Post-Marketing Surveillance (RB-PMS) Plan for COVID-19 vaccines. During the discussion, the team received feedback to make the document applicable for all vaccines, with a focus on COVID-19 vaccines; make the plan introduction more conciseand focused on PMS; expand the scopeto include industry and depot, as recommended for inclusion of all vaccines in the plan/guideline; and involve key stakeholders including WHO, USP, and the European Medicines Agency (EMA).

Co

PQM+ will continue its review of the RB-PMS plan and incorporate the feedback from the consultative meeting. After the

feedback from DGDA and other stakeholders is incorporated, PQM+ will hold a second consultative meeting to validate, finalize, and disseminate the plan in November.

Activity 1.4: Map NQCL needs for carrying out testing of vaccines (i.e., vaccine division of NQCL lab in Dhaka)

1. Mapped the current capability of staff and availability of needed equipment and supplies for testing COVID-19 vaccine samples in NQCL's vaccine wing.
2. After the mapping, PQM+ will support the lab to develop its human resource capacity in the testing of COVID-19 vaccines.

Interview with Dr. Md. Harun-Or-Rashid, NCL deputy chief

Activity 1.5: Develop protocol for testing COVID-19 vaccines

1. Drafted the protocol for testing COVID-19 vaccines and shared it with the PQM+ team inearly August. The PQM+ technical team reviewed the protocol and provided inputs.

Objective 2: Review existing DGDA emergency use authorization (EUA)/ No Objection Certificate (NOC) guidelines and alignment of vaccine marketing authorization process in response to COVID-19 vaccine introduction.

Background: The COVID-19 pandemic has posed a challenge to Bangladesh's public health system, including the national medicines regulatory authority, the Directorate General of Drug Administration (DGDA). DGDA is responsible for EUA of COVID-19 medical products in Bangladesh. As part of its regulatory preparedness, DGDA is working to transition its regulatory pathways and practices from a traditional, reactive control system to a proactive, risk-based approach. Access to life-saving vaccines will be accelerated by allowing national regulatory decision-making to be completed in a timely way. The USAID-funded PQM+ program is providing technical assistance to DGDA by reviewing DGDA's existing EUA/NOC processes to identify and prioritize the required data for obtaining EUA for COVID-19 vaccines to strengthen the regulatory decision making in a time efficient manner and align the DGDA's EUA procedureswith global standards.

Progress this quarter:

1. Conducted a gap assessment of Bangladesh's current EUA/NOC system. The team conducted interviews of relevant stakeholders online, over the phone, and in person. PQM+ Bangladesh then worked on compiling the results of the gap assessment in a report to be with DGDA and to be the basis of any new EUA guidelines.
2. Drafted EUA guidelines and submitted them to the technical team for review.
3. Held a consultative meeting on the draft EUA of COVID-19 Vaccines in Bangladesh guideline in September where DGDA provided its feedback.After this feedback is incorporated, PQM+ will hold another consultative meeting for

Interview with Dr. Md. Akter Hossain,deputy director of DGDA

review and finalization of the guideline in October. After the guideline is finalized, PQM+will provide a training on the EUA/NOC guidelines to DGDA staff in October.

Ghana

Policy, Planning, and Coordination

Activity 1: Support the optimization of Ghana Food and Drugs Authority (FDA) laboratory services for the quality control testing of COVID-19 vaccines

Background: To enable FDA Ghana to conduct all quality control tests required for COVID-19 vaccines – both universal tests required for parenteral drug products and specific product quality tests – PQM+ will provide training for analysts at the FDA Ghana Laboratory and procure needed consumables to conduct these tests. The Ghana FDA microbiology laboratory is currently at Biosafety Level II; however, vaccine testing should be conducted in a Biosafety Level III environment. While supporting FDA Ghana to test in the current conditions, PQM+ will conduct an assessment of the current FDA facilities to identify what is required to have the laboratory upgraded to a Biosafety Level III in the future.

Progress this quarter:

This quarter, PQM+:

1. Strategized with PQM+ counterparts in Bangladesh on approach for training the FDA Ghana lab on the potency assay, given this is also part of the scope of the PQM+ Bangladesh COVID-19 vaccines technical assistance. As PQM+ Bangladesh has a microbiologist with vaccines testing experience, both countries considered collaboration for the development of the training curriculum together.
2. Worked with FDA Ghana to outline the specifications for the list of accessories/ consumables required for the vaccine potency testing.
3. Developed and shared the Request for Quotation for the required laboratory consumables with a short list of laboratory reagent and consumables suppliers.
4. PQM+ evaluated quotations received from suppliers of laboratory consumables required for testing of the COVID-19 vaccines and selected a vendor. The bid evaluation was shared with Ghana FDA to (1) confirm all specifications and items before PQM+ issues a purchase order and (2) identify which of the consumables they would be able to procure as the funding for this procurement is limited and cannot cover all that is required by Ghana FDA.

Pharmacovigilance and COVID-19 Vaccines Quality

Activity 2: Support Ghana FDA to enhance its COVID-19 vaccine safety monitoring and supportive supervision

Background: A cohort event monitoring (CEM) study has been designed as a prospective effort in 16 sentinel sites across Ghana, with one site in each region. Approximately 10,000 participants are expected to be enrolled and followed on predetermined days after receiving firstand second doses; 2,500 people are already enrolled from the March and May 2021 deployment (distribution of vaccines). However, during June and July, Ghana could not secure

additional vaccines, halting the deployment and the CEM study. In August, Ghana received 149,000 doses of the Johnson & Johnson vaccine, but since the delay created urgency in that deployment, no new study sites were included and study participants were not recruited. Also, in August, Ghana received 249,000 doses of Covidshield, but this was deployed for study participants who had been waiting for their second dose since March and May 2021; again, no new study participants were recruited.

The CEM study team will require training and support with the needed logistics to manage the study, including tablets (electronic devices) for data entry, airtime for follow-up, and periodic allowances. A monitoring team made up of officers from Ghana FDA and the Expanded Program on Immunization (EPI) will undertake supportive supervisory visits to ensure that the cohort event monitoring is being implemented according to the protocol and data collection is asplanned. The study is expected to last eight months. PQM+ will provide support to Ghana FDA to implement this study by assisting with the enrollment of at least 3,000 additional participants, development, and implementation of training programs for site coordinators and the study team,development of job aides, and participation in the supportive supervisory visits. PQM+ will also assist FDA Ghana with the necessary logistics to facilitate the study for its duration.

In September, Ghana received 1,229,620 doses of the Moderna COVID-19 vaccine; FDA and EPI planned to enroll participants during the deployment of this vaccine. Since the vaccine deployment of this vaccine has started, PQM+ will provide technical assistance by co-facilitating training for the CEM study team, scheduled for October, and providing support for the required logistics during participant enrollment in the seven established study sites in the Greater Accra, Central, Volta, Ashanti, and Northern regions.

Progress this quarter:

This quarter, PQM+:

1. Procured 10 tablets to use in collecting real-time data on adverse events following immunization. Two tablets will be provided to each of five sites to be covered under the PQM+ Ghana COVID-19 TA. This handover of tablets to beneficiary regions for use in reporting has not yet occurred.
2. Recruited a consultant to review the CEM protocol for optimization, develop job aids, and create work instructions for the cohort study. The consultant will also support training of the study team and participate in the supportive supervision of the study.
3. Reviewed the CEM protocol and made revisions to optimize it for use in the upcoming deployment. Selected revisions have been adopted by FDA Ghana.
4. Developed training materials to be used for training the study team before the next deployment.
5. Drafted job aides for the CEM study team.
6. Strategized with FDA Ghana and EPI on the expected deployment in September and who will be targeted for recruitment of additional study participants.
7. Facilitated two virtual sessions with three Ghana FDA staff and one EPI representative to review the CEM training materials and job aides for the study team.
8. Revised the CEM study training materials and job aides to reflect new changes in the CEM protocol - such as in the schedule of follow-up of enrolled participants, images used in the job aides, and data collection methodology - and finalized the materials.

9. Facilitated discussions with the World Health Organization Regional Office for Africa (WHO AFRO) and Ghana FDA on the possibility of utilization of the Open Data Kit (ODK) platform for CEM data collection. ODK is a platform for data collection using handheld devices. It enables transfer of data submission to an online server and does not require an internet connection at the point of data collection. It can therefore be downloaded onto the tablets that have been procured for Ghana FDA for data collection during the enrollment of study participants. [13] As of October, Ghana FDA has decided to move forward with using the platform and will be trained on it by WHO AFRO.

Pakistan

Pharmacovigilance and COVID-19 Vaccines Quality

Activity 1: In collaboration with national stakeholders, support the revision and dissemination of the National Action Plan for Adverse Event Following Immunization (AEFI) surveillance for COVID-19 Vaccines

Background: Although the Ministry of National Health Services, Regulations & Coordination (MoNHSR&C) has developed national guidelines for surveillance of adverse events following immunization (AEFI) for the COVID-19 vaccine, these guidelines have not been officially announced by the Pakistan Government through any statutory regulatory order (SRO), nor do the existing guidelines include roles/guidelines for key AEFI stakeholders such as the Drug Regulatory Authority of Pakistan (DRAP), Provincial Healthcare Commissions, and the Expanded Program on Immunization (EPI). To address this issue, and to ensure effective pharmacovigilance of AEFI data, the USAID-funded PQM+ program is collaborating with national stakeholders (federal and provincial governments, WHO, and others) to support the revision of existing AEFI guidelines, in order to formulate and disseminate a National Action Plan for AEFI surveillance for COVID-19 vaccines.

PQM+ held an inception meeting with the CEO of the Punjab Healthcare Commission (PHC) in Lahore on June18 regarding development of an AEFI reporting system.

Progress this Quarter:

1. Met with the Director General (DG) of Health in July regarding the current AEFI reporting system and gaps within the existing system. The team also identified synergies with WHO and UNICEF for AEFI activities. In addition, the PQM+ team discussed developments on the National AEFI Action Plan with DRAP and WHO.
2. Worked on recruiting one federal and four provincial AEFI coordinators, conducting interviews for the federal AEFI coordinator. Recruitment is in process, while applications for provincial coordinators are at the review and short-listing stage.
3. Conducted an initial meeting with the EPI director and team in August. During this meeting, participants discussed the National AEFI Action Plan and proposed including PQM+ in the AEFI review committee. EPI later confirmed it submitted a proposal to the

[13] https://getodk.org/

AEFI review committee chair for formal notification in this regard. In addition, PQM+reviewed and shared feedback with EPI and WHO on the National AEFI Guidelines.

4. PQM+ also shared a draft concept note with WHO, DRAP, and EPI regarding a joint meeting with federal & provincial authorities for the review of AEFI guidelines and formulation of a National AEFI Action Plan.

Activity 2: Support the Drug Regulatory Authority of Pakistan (DRAP) to ensure that COVID-19 vaccine emergency use authorization (EUA) holders are engaged in vigilance systems

Background: As DRAP has issued EUA for COVID-19 vaccines, it is still collecting the limited data for existing COVID-19 vaccines in Pakistan. As COVID-19 vaccines are so new, it is important to monitor and record all adverse events following immunization (AEFI), in addition to creating a system to reduce such events. For this purpose, the PQM+ program is supporting DRAP to ensure that COVID-19 vaccine EUA holders are engaged in vigilance systems, by developing guidance documents for EUA holders on AEFI reporting requirements and COVID-19 vaccine risk-management plans, in addition to developing an online portal that integrates with the national AEFI reporting system currently in use (VigiFlow) and conducting trainings for federal and provincial DRAP staff on AEFI data collection, analysis, and reporting.

Progress to date:

1. Met with DRAP to discuss a proposed revision to the EUA holder letter, as per best practices. The PQM+ team shared the first draft of EUA holder requirements regarding AEFI for COVID-19 vaccines with DRAP for review.
2. The EUA document includes clauses regarding a quarterly review of the vaccine with respect to its safety, efficacy, and quality. An EUA holder firm must submit periodic AEFI data to the National Pharmacovigilance Centre, Pharmacy Services Division at DRAP.
3. Worked closely with the government to ensure vaccine disclaimer certificates (which mention side effects of the vaccine) were provided to and being completed by citizens receiving the AstraZeneca vaccine. PQM+ is advocating for similar disclaimer certificates to be used for all COVID-19 vaccines.

Activities 4 and 5: Establish/reinforce vaccine safety surveillance systems through revitalization of existing provincial causality assessment committees to expand their scope to include COVID-19 vaccine safety data review. Support the provincial Healthcare Commissions to ensure that private sector healthcare facilities are engaged in Vaccine Vigilance & AEFI Surveillance Reporting

Background: Limited safety data is available for current COVID-19 vaccines in Pakistan, meaning an increased chance of AEFI occurring. In this scenario, coordination with both the private and public sectors is necessary to develop a comprehensive system for AEFI reporting. PQM+ is engaging with stakeholders such as Provincial Healthcare Commissions to ensure that private sector healthcare facilities are engaged in vaccine vigilance and AEFI surveillance. Furthermore, PQM+ is collaborating with the WHO to provide technical support to strengthen provincial committees for COVID-19 vaccine safety data review; establish coordination mechanisms at the provincial level among key stakeholders in the AEFI surveillance systems;

revise procedures for causality assessment of serious AEFI cases in collaboration with stakeholders; and train causality assessment committees on revised procedures.

PQM+ met with WHO, DRAP, and PHC in August to discussongoing AEFI activities.

Progress to Date

1. The PQM+ team conducted a joint meeting with the Punjab Healthcare Commission, WHO, and DRAP on August 5, 2021. The PQM+ AEFI Pharmacovigilance consultant presented a brief introduction of the current situation in Pakistan regarding COVID-19 vaccines vigilance and guidelines.

Key discussion and action points from the meeting are provided below:

- DRAP will formally request all provincial healthcare collaborate to promote ownership of provincial AEFI data.
- A joint meeting will be scheduled by MoNHRS&C to review AEFI guidelines by early September 2021.
- An MoU will be signed between DRAP, WHO, and PQM+ for collaboration on the AEFI national policy development.
- Punjab Healthcare Commission (PHC) will build the capacity of the private sector with the support of PQM+ and WHO, with the main objective of motivating the private sector to identify, report, and investigate AEFI cases.
- An AEFI assessment checklist will be shared with all private and public hospitals.
- Causal assessment committees will be activated at the provincial level.

2. Punjab Healthcare Commission (PHC) officials endorsed and agreed to support the above activities. They also PHC has shared the PQM+ AEFI activities with the Secretary of the Specialized Healthcare and Medical Education Department in Punjab. Finally, as a result of this joint meeting, DRAP has issued a letter for ensuring AEFI reporting by the provinces and provincial healthcare commissions, as no AEFI cases are currently being reported by private hospitals. In this regard, DRAP has also advised provincial healthcare commissions to mobilize assessment committees for evaluation of AEFI cases.

Policy, Planning, and Coordination

Activity 3: Support DRAP to strengthen COVID-19 vaccine vigilance reporting and AEFI surveillance and establish linkages to quality assurance

Background: PQM+ is also supporting DRAP to strengthen COVID-19 vaccine vigilance reporting and AEFI surveillance and establish linkages to quality assurance, through developingof guidance documents/procedures for AEFI surveillance and vaccine vigilance; establishing a national vaccine vigilance committee to ensure review of and action on AEFI data; developing

guidance documents for COVID-19 vaccine post-marketing surveillance (PMS) for quality, and conducting capacity building of DRAP staff on guidance documents for AEFI and PMS, and integrity of supply chain i.e. cold chain.

Progress to Date:

The PQM+ team is providing support to DRAP's National Control Laboratory for Biologicals (NCLB). The PQM+ team met with NCLB in August to discuss the PQM+ gap assessment report and corrective and preventive action plan developed as part of earlier program support. PQM+ will be working to develop a complete QMS for the NCLB lab going forward.

Planned Activities for PY3, Q1:

- Joint Consultative Meeting on Review of National AEFI Guidelines and Formulation of National Action Plan for COVID-19 Vaccines;
- Finalization of National AEFI Guidelines in collaboration with stakeholders (Federal and Provincial EPI, NADRA, NCOC, UNICEF, health care commissions, and private sector health care providers, etc.);
- Development of PIRIMS dashboard to capture link vigiflow with NIMS;
- Formal notification of AEFI technical committee and inception of fortnightly meetings;
- Preparation of guidance document for industry for AEFI data collection, assessment and reporting for EUA holders;
- Development of AEFI training materials for provinces as requested by PHC;
- Training manual preparation for causal assessment committees; and
- Development of SOPs for DRAP on EUA review and reporting of safety data.

Uzbekistan

Policy, Planning, and Coordination

Objective 1: Provide technical assistance to operationalize the emergency use authorization (EUA) for COVID-19 vaccine(s)

Background: As the number of COVID-19 cases rises in Uzbekistan, it is critical to ensure that COVID-19 vaccine(s) are made available faster for the country's population. Facilitating the establishment of EUA for COVID-19 vaccine(s) provides an expedited regulatory pathway for approval, allowing health authorities to make the product available for medical use. Under Activity 1, the USAID-funded PQM+ program is providing technical assistance to the Development of the Pharmaceutical Industry (the Agency) including the State Center on Expertise and Standardization of Medicines, Medical Equipment and Medical Devices (State Center) in developing a system for EUA by conducting a preliminary assessment of existing in-country guidelines and procedures, developing standard operating procedures (SOPs) and guidelines, and providing trainings to Agency staff. The guidelines will serve as regulatory tools to prepare the Agency for future public health emergencies as part of Uzbekistan's plan to ensure access to quality, safe, and effective medical products during emergencies. Under this activity, PQM+ is tasked with the following sub-activities:

- Activity 1.1: Conduct a desk review of existing in-country guidelines and documentation of best practices (in-country, regional, and international) for EUA for COVID-19 vaccine(s).

- Activity 1.2: Support the Agency to develop/update guidelines for EUA and corresponding standard operating procedures (SOPs), including public-facing information and guidance to industry.
- Activity 1.3: Train Agency staff on the guidelines and SOPs for EUA of COVID-19 vaccines including EUA review and oversight of EUA conditions.

Progress this quarter:

1. Developed an implementation plan and Gantt chart on activities related to developing a practical guide and checklist adapted to low- and middle-income countries (LMICs) to facilitate the establishment and operationalization of a EUA regulatory pathway for the planned COVID-19 vaccines and medical products. This includes developing a questionnaire to assess existing emergency use authorization regulatory processes and procedures for COVID-19 vaccines. The questionnaire was completed by the Head of Laboratory for Toxicological Research at the State Center, and PQM+ is now analyzing the responses to guide next steps.
2. As requested by the Agency, drafted a provision to include EUA in the Resolution No. 213 of the Cabinet of Ministers. The drafted provision was shared with top management, and they will work to include it in the next revision of the resolution.
3. Received, analyzed, and completed a questionnaire to understand the current regulatory processes that enable introduction and implementation of EUA for vaccines and pharmaceuticals. The analyses identified specific needs for the introduction of EUA. PQM+ shared the plan with the deputy director of the Agency, who will work on appointing a responsible working group for the implementation of EUA activities.
4. Shared a previously drafted provision to include EUA in Resolution No. 213 of the Cabinet of Ministers with top management, who confirmed that they will include it in the next iteration of the resolution.

Pharmacovigilance and COVID-19 vaccines quality

Objective 2: Provide technical assistance to improve coordination between the Agency and the National Immunization Program (NIP) to strengthen the vaccine safety surveillance system

Background: With the increasing availability of COVID-19 vaccines in Uzbekistan, it is critical to monitor the safety of authorized COVID-19 vaccines through an active safety surveillance system. PQM+ is supporting the Agency in strengthening vaccine surveillance systems to ensure the system can detect, investigate, and analyze adverse events following immunization (AEFIs) and adverse events of special interest (AESIs) to ensure an appropriate and rapid response. According to an assessment, collaboration between the NIP and the medicines regulatory authority (MRA) is weak on AEFI surveillance and there is a need to define clear roles and responsibilities, to avoid duplication of efforts or gaps in the information on the AEFI for regulatory decisions from the MRA. Under this activity, USAID/PQM+ will work to improve coordination between the MRA and the National Immunization Program by defining roles and responsibilities, information flow and developing procedures for coordination between the MRA, NIP, and other institutions involved in AEFI surveillance.

Under this activity, PQM+ is tasked with the following sub-activities:

- Activity 2.1: Review the current processes and procedures in place for coordination between the NIP and the MRA on AEFI surveillance through document review and consultation with stakeholders to identify gaps that will help in developing targeted interventions (see activity 2.2). Familiarize the staff of the Agency with the WHO guidance for COVID -19 Pharmacovigilance and provide support in defining needs for further technical assistance.
- Activity 2.2: In consultation with national stakeholders, support the Agency to define roles, responsibilities, and information flow and to develop procedures for coordination between MRA, NIP, and other institutions involved in AEFI surveillance. Based on the rapid assessment conducted under sub-activity 2.1, PQM+ will address the gaps in ensuring effective coordination between the NIP and the MRA by defining clear roles and responsibilities for each party; and developing corresponding procedures for coordination and information exchange on AEFI. In addition, PQM+ will provide technical assistance to the MRA to secure mechanisms to share COVID-19 vaccine safety data with the relevant international partners (e.g., WHO).

Progress this quarter:

1. Developed a pharmacovigilance (PV) comprehensive assessment tool that looks at structure, process, and indicators related to PV in the country. The questionnaire is being translated and will be used to assess the maturity and existing tools and guidelines of pharmacovigilance system in Uzbekistan. Once translated, PQM+ will interview identified persons at the NIP and MRA and their responses will be analyzed to assess gaps and prepare next steps. PQM+ is also preparing for a virtual workshop for the stakeholder that will include an orientation on PV and vaccine safety surveillance, this workshop will also be used to gather information on vaccine safety surveillance, supplementing the assessment questionnaire.
2. PQM+ is in discussions with the Agency to establish a pharmacovigilance working group, who will coordinate closely with PQM+ and disseminate information within the Agency related to the implementation of activities.
3. In September, PQM+ developed and translated a tool for assessment of the status of the pharmacovigilance system in Uzbekistan. The results of the assessment will help identify needs for PQM+ technical assistance to strengthen the pharmacovigilance and vaccines surveillance systems. To begin the assessment, PQM+ will need to engage with the pharmacovigilance working group that the Agency is currently developing. There have been delays in assigning members to the working group due to staff reorganizations in the Agency. In the meantime, PQM+ is conducting a desk review of the available literature, strategic documents, polices, and other relevant documents on pharmacovigilance and immunization for Uzbekistan.

New Buy-Ins

Table 9. Summary of New Work under the PQM+ Program

USAID Team	Summary and Next Steps
COVID-19 America Rescue Plan (ARP) Activities	PQM+ received funding for COVID-19 work from the American Rescue Plan for Bangladesh, Burkina Faso, Ethiopia, Ghana, Kazakhstan, and Uzbekistan in August 2021. As of the end of September, all work plans were drafted and submitted to USAID for review, and Uzbekistan, Kazakhstan, and Ghana received approval.
Tajikistan	PQM+ received approval for work plan activities in September 2021. PQM+ is now working on scheduling a meeting with the Ministry of Health to kick off activities.

Progress by Health Elements

Maternal and Child Health

PQM+'s support to USAID's directed core MCH work focuses on assisting medicine regulatory authorities and manufacturers to improve their systems. PQM+ also supports global leadership efforts in collaboration with other MCH partners to continue to advance USAID's, global, and country MCH agendas and to increase access to quality-assured lifesaving medicines for women and children in LMICs.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ achieved the following under the Maternal and Child Health area.

- Completed and disseminated the English and French versions of a guidance document on the risk-based categorization of MNCH products; it explains how to define probability and impact risks for priority MNCH products and will facilitate countries' development of sampling plans using the MedRS tool.
- Completed and disseminated the English and French versions of Product Information Reports to support registration and inspection of chlorhexidine digluconate (7.1%) gel, oxytocin injection, and amoxicillin for NMRAs.
- Hosted a medical devices regulatory workshop for USAID field office staff and headquarters staff. The workshop delivered an overview of the regulatory framework and quality system for medical device development and manufacturing, followed by a panel discussion with medical device innovators about challenges in interpreting regulations and requirements to gain market authorization in LMICs.
- Completed the amoxicillin dispersible tablet (DT) manufacturing landscape analysis in Africa in partnership with Muhimbili University in Tanzania.

Progress This Quarter

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

With support from Muhimbili University in Tanzania, PQM+ completed the amoxicillin dispersible tablet (DT) manufacturing landscape analysis in Africa. The analysis identified 540 manufacturers of amoxicillin DT (as well as manufacturers who may be capable of producing the product) [14] on the continent. Only 34 of these perform direct manufacturing; the rest conduct import, repacking, and other activities. Nine of 30 manufacturers in PQM+ countries responded to the survey questionnaire, yielding a 30 percent response rate. This low response rate resulted from generalized versus specific contact information accessed from company websites,staffing shortages, lack of interest, business closures, company focus on high-volume products, and acquisitions. COVID-19 may have affected the response rate. Some firms found it difficult toset times for interviews amid staff layoffs. Others indicated that they were not operating full time and, thus, could not devote time to the survey.

The survey highlighted barriers to local production that manufacturers face, such as: the lack of contract research organizations for bioequivalence (BE) studies; the high cost of conducting BE studies; high product registration costs and annual registration retention fees; a reluctance of

[14] Potential manufacturers are those that have the facilities and technical capability to produce any beta lactam, such as penicillin and amoxicillin, in any dosage form.

API manufacturers to provide documentation (e.g., API master files needed for registration); NMRA's requirement of a compilation of dossiers in the CTD format; delayed regulatory product evaluations; mandatory pre-registration laboratory testing (e.g., an NMRA required a product to be tested in their facilities, but did not possess the proper equipment to carry out the testing); inconsistent assessments and reporting by local and regulatory authorities in other countries; and low patronage of in-country suppliers.

PQM+ is developing a redacted version of the amoxicillin dispersible tablet (DT) manufacturing landscape analysis report to remove the manufacturers' confidential information prior to dissemination, which will occur primarily through consultative meetings planned with the Commodities Sub-group of the Child Health Task Force, in coordination with USAID and UNICEF, in early 2022.

Neglected Tropical Diseases

The November 2020 WHO NTD global roadmap, Ending the Neglect to Attain the Sustainable Development Goals: A Roadmap for Neglected Tropical Diseases 2021 – 2030, sets goals for an integrated approach across all NTD diseases and sets targets to reduce the number of people requiring treatments for NTDs by 90 percent. WHO has been instrumental in coordinating NTD medicine donations from manufacturers for use in affected populations globally. However, shortfalls remain compared to the demand for some medicines. 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 overall goal of the PQM+ NTD work is to ensure the availability of affordable, quality-assured NTD medicines for the patients in need.

PQM+'s NTD activities fall under the program's Objective 4. PQM+ uses a systems strengthening approach to build the local organizational and individual capacity of pharmaceutical manufacturers.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ achieved the following under the Neglected Tropical Diseases area.

- Supported manufacturer Medopharm Private Limited in India to achieve approval by WHO's Prequalification of Medicines Program for praziquantel 600mg film-coated tablets.
- Completed development of the NTD global dashboard for NTD APIs and FPPs and its user manual. PQM+ will pilot the tool, called the Neglected Tropical Disease Medicine Information Dashboard (NTD MID), in a few PQM+ countries and make it available globally.
- Repackaged the GMP e-learning course to make it easier for users to complete, to include offline modules, and to enable the collection of more data on user feedback. The revised version is available and PQM+ disseminated it through several platforms, including the PQM+ website, social media, and the USAID Health Systems Strengthening (HSS) distribution network.

Progress This Quarter

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

PQM+ supported the India-based manufacturer Medopharm Pharmaceutical Private Limited to become the second manufacturer of praziquantel 600mg film-coated tablets to receive WHO

PQ, a major accomplishment in expanding quality-assured sources for NTD medical products. The GMP of the manufacturing plant received conditional approval based on a desk assessment developed using prior inspection reports by other agencies. With global travel restrictions lifted, the WHO PQ team plans to visit the manufacturer for an onsite inspection to verify site compliance with cGMP next quarter. PQM+ is planning a mock audit of the facility to prepare for the upcoming WHO PQ inspection.

PQM+ continued supporting a manufacturer of albendazole tablets for WHO PQ. In Q4, the manufacturer completed the compilation of a product dossier, including the BE study, and submitted the application for WHO PQ. PQM+ is awaiting WHO feedback.

PQM+ engaged two core-FLEX partners, Muhimbili University in Tanzania, and Mahidol University in Thailand, to conduct an NTD market landscape analysis in Africa and Asia to better understand the local supply and demands of NTD API and FPP in the two regions. Multiple unexpected factors resulted in a series of delays with data collection; these included COVID-19 and its effect on manufacturers' facilities (e.g., staff layoffs, facility closures, operations at reduced capacity, and changes in priorities), lack of incentives for manufacturers to participate, and challenges with obtaining information from procurement agencies, largely driven by changing priorities due to the pandemic. As of the end of September, 54 of 169 contacted manufacturers (32 percent) had responded to outreach about the analysis, with eight (5 percent)declining to participate. To improve response to the surveys, PQM+ and Mahidol offered a GMPe-learning course to manufacturers, which provides an overview of essential GMP principles and requirements and covers key principles of the WHO and PIC/S standards. However, this incentive's impact on survey uptake was minimal. The team is continuing outreach to increase the rate of response, and the data analysis, finalization of assessment reports, and global dissemination will carry over into PY3, Q1.

In Q4, PQM+ continued to engage the IT consultant to finalize development of the Neglected Tropical Disease Medicines Information Dashboard (NTD MID) and user manual. The PQM+ technical team is conducting user testing and will recommend enhancements to improve the user experience for the NTD MID and user manual. Once finalized, the tool will be available online to the public. PQM+ continued to engage the WHO NTD PQ team, UNICEF, Drugs for Neglected Diseases Initiative (DNDi), and UNITAID for data the NTD MID could use and to avoid duplication of efforts. NTD MID will serve procurement agencies, NMRAs, health professionals, manufacturers, suppliers, donor communities, and other interested parties.

To identify and provide support to new manufacturers of NTD medical products toward increasing the global supply of quality-assured products, in Q4 PQM+ drafted and finalized EOIsfor eight NTD products (diethylcarbamazine tablet, azithromycin tablets, azithromycin powder for oral solution [POS], ivermectin tablet, praziquantel tablet, albendazole tablet, mebendazole tablet, and tetracycline eye ointment). PQM+ reached out to the Federation of African Pharmaceutical Manufacturers Associations (FAPMA), Federation of East African Pharmaceutical Manufacturers (FEAPM), and West African Pharmaceutical Manufacturers Association (WAPMA) to publish the EOIs. In PY3, PQM+ will review responses to the EOI, identify manufacturers for technical assistance toward cGMP, and conduct a rapid assessment of shortlisted manufacturers for GMP of the facilities.

PQM+ continued efforts to promote and disseminate the repackaged GMP e-learning course to make it more user-friendly and boost the course completion rate. In Q4, PQM+ updated the pre-course questionnaire to include questions that will support data analysis to better target participants and plan outreach efforts.

Tuberculosis (TB)

PQM+ is working to ensure an uninterrupted supply of lifesaving quality-assured TB medicines by providing direct support to the manufacturers of priority TB products, as well as providing technical leadership by exploring innovative manufacturing processes for priority TB medicines, developing technical documents such as product information reports, and working with partners to ensure the medicines registration processes does not create hurdles for the introduction and scale-up of the new TB medicines.

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ achieved the following under the Tuberculosis area.

- Provided technical assistance to one manufacturer of 4FDC TB medicine in Pakistan to submit the dossier for WHO review. When the product is WHO prequalified, it will help ensure access to locally produced quality-assured TB medicine in Pakistan.
- Issued a subaward to VCU to optimize the manufacturing of API for a priority first-line TB medicine. VCU completed Phase I and demonstrated the feasibility of low-cost API at the laboratory scale. The VCU subaward was extended for PY3 to include the Phase II for scaling up the synthesis process and integrating the individual steps demonstrated successfully under Phase I. If successful, this could help with development of a more optimal and cost-effective manufacturing process, which eventually affect the cost of the finished product.
- Completed the initial evaluation of the GC-MS/MS method to quantify two nitrosamine impurities in the rifapentine drug substance and drug product. The team will start an alternate LC-MS/MS method development in conjunction with additional work on the GC-MS/MS method. Based on the LC-MS/MS method developed, a comparison between both methods will be performed. A final method or a choice of methods will be presented.

Progress This Quarter

Objective 2. Country and regional regulatory systems to ensure access to quality-assured TB products improved

The development and introduction of new TB medicines and novel TB treatment regimens are essential for achieving the Sustainable Development Goals and ending the TB epidemic. Recent years saw the introduction of three new TB medicines (bedaquiline, delamanid, and pretomanid), while a large pipeline of new TB medicines and regimens are in varying stages of clinical research. In this evolving situation, it is important for NMRAs to stay engaged and ensure timely review and approval of new TB medicines to enable access to these life-saving products. In recent years, NMRAs in some countries occasionally have faced challenges in timely reviews and approval of new products due a lack of corresponding experience and procedures.

To address this, PQM+ started collaborating with the U.S. Food and Drug Administration (U.S. FDA) to organize an online workshop for representatives of MRAs from high-burden TB countries, at which the agency will share experiences on the regulatory review of new TB medicines. In Q3, PQM+ developed a questionnaire and engaged NMRAs in select LMICs to identify topics of interest for the workshop. In Q4, PQM+ compiled topics and developed a draft program and shared it with the U.S FDA. PQM+ met with the agency and discussed plans for organizing the workshop, which is tentatively planned for February 2022.

In Q4, PQM+ continued to support two pharmaceutical manufacturers of first-line, fixed-dose combination (4FDC) TB medicines in Pakistan. In Q3, PQM+'s technical assistance to one manufacturer enabled the finalized compilation of a dossier, including the report on a completed stability study. This was an important milestone toward prequalification of the product and ensuring that TB patients in Pakistan have access to locally produced quality-assured TB medicines. PQM+ will continue to provide technical assistance through full prequalification of the product. WHO is reviewing the dossier and the manufacturer is preparing for a WHO onsite inspection for prequalification.

Another Pakistani manufacturer is undergoing stability studies for 4FDC products that have demonstrated stability over the first three months. Continued demonstrated stability over six months would suggest that the product is stable. This manufacturer will submit the results to WHO for a potential review of the dossier, and PQM+ will continue to provide technical assistance through full prequalification of the product.

During Q4, work progressed in the validation of methods to test for nitrosamines impurities in rifapentine and rifampicin TB medicines. However, USP lab staff identified issues in accuracy and sensitivity with the selected gas chromatography-mass spectroscopy/mass spectroscopy (GC-MS/MS) method. As a result, the lab staff investigated and found an alternative method utilizing liquid chromatography-mass spectroscopy/mass spectroscopy (LC-MS/MS) to have acceptable sensitivity and accuracy. They are further evaluating the latter method and will assess its use on similar instruments. Efforts will also continue using the GC-MS/MS method to resolve the accuracy and sensitivity issues identified, which could result in two validated methods and provide more flexibility to stakeholders.

In Q4, PQM+ provided ongoing technical guidance and monitoring of the Virginia Commonwealth University (VCU) subaward for the laboratory phase on developing an alternative route to produce API for a priority TB product. During the laboratory phase, which ended in Q4, the team successfully identified a synthesis route and demonstrated each step of the target continuous manufacturing process. During Phase II, further development will take place to optimize, scale up, and integrate the steps of the synthesis process. PQM+ developeda concept note and outlined budgetary needs for the next phase; USAID has approved the concept note. PQM+ extended the VCU agreement through September 2022 (the end of PY3) to include Phase 2. In Q4, PQM+ also worked on developing the criteria to identify a manufacturer for technology transfer, the next step after Phase 2.

Priority Activities for Next Quarter

Next quarter, PQM+ will:

- Follow up with the manufacturer in Pakistan to ensure the finalization of the stability study reports and the submission to WHO.
- Follow up with the manufacturer in Pakistan to respond to WHO questions and queries as needed while WHO reviews the dossier.
- Continue joint work with VCU on Phase 2 the manufacturing process optimization for a priority TB product. Continue to refine the criteria for technology transfer, on scaling up the proposed synthetic process.

- Prepare for the U.S. FDA workshop with the pharmaceutical regulatory authorities to share the agency's experience on the review and registration of new TB medicines.

Program Support

Communications

Highlights of Progress by PQM+ During PY2

During PY2, PQM+ achieved the following in its Communications efforts.

- Produced a success story about Pakistan's PPE manufacturing that Jeremy Konyndyk (executive director of USAID's COVID-19 Task Force) shared as part of an National Security Council update on broader COVID-19 commitments and expanding PPE production.
- Launched PQM+'s webinars and held two successful webinars for global audiences.
- Institutionalized the program newsletter, sending out issues on a quarterly basis.

Newsletter: In August, PQM+ sent its fourth newsletter, which featured Mali's RB-PMS approach to medicines. The open rate for the August newsletter was 60 percent, the highest to date. The click rate was 10 percent. This year, PQM+ doubled the number of newsletter subscribers from 312 to 630, with many of the new contacts being either USAID field staff or country stakeholders.

Social media: The program's presence on social media expanded over the year, as PQM+ shared more than 160 social media posts across LinkedIn, Facebook, and Twitter. LinkedIn posts received the most engagement of the three platforms, with as many as 71 likes for some posts. The content is clearly resonating with audiences in PQM+ countries such as Pakistan and Kenya.

USP also has a new Twitter handle, @USPGlobalHealth, which is aimed at the international development audience rather than USP's traditional audience. The handle launched in July 2021 and reflects USP's PQM+ work and other donor-funded activities. USP's main handle will retweet all posts sent using this handle.

Success stories: This quarter, PQM+ developed a success story highlighting Pakistan's manufacture of quality-assured PPE. HQ also worked with the Mali field office to develop a story on RB-PMS, which the Mission liked and subsequently published on its website. USAID Central Asia developed two success stories about PQM+'s work with input from the field office. The first discussed PQM+'s support to Uzbekistan's Nobel Pharmsanoat during COVID-19 and the second covered PQM+ support to the Karaganda lab to achieve WHO PQ. In addition, this year,PQM+ developed four short success stories as "spotlight" pieces for its newsletter, as well as a new MNCH fact sheet.

Webinars: This quarter, PQM+ secured approval for two webinars on "How Strengthening Medical Product Regulatory and Manufacturing Systems Helps Countries Respond to COVID-19 and Future Health Crises." The first will occur in November and the second will follow in December or January. PQM+ launched its webinar series earlier this year; the first was an overall instruction on strengthening medical product quality assurance systems (November 2020) and the second discussed strengthening NQCLs (April 2021). More than 100 people attended both webinars.

Website: This year, PQM+ made substantial progress developing the new program website. This quarter, USP IT's team has built the new site using Drupal 9. They also migrated all of PQM resources to the new site while preserving the old site for archival purposes. The AOR team approved the site map and content. PQM+ submitted the majority of the new text for AOR reviews. The final site will be sent to USAID's governance board as soon as it is ready, which should be by the end of 2021.

Staff: In September, PQM+ onboarded a new communications specialist, Angela Pashayan, whose experience includes working with USAID's Bureau for Resilience and Food Security. She and Kristina Campbell, who joined PQM+ in January as the program's editor, support Senior Communications Manager Megan Meline. In addition, HQ assists communications points of contact in the PQM+ field offices to identify content, liaise with Mission DOCs, and take COVID-appropriate photos.

Annex 1: FY2021 Monitoring Results

PQM+ reports on its performance monitoring indicators twice a year. Annex Table 2, the M&E Results Table, shows results from PY2021 for PQM+ country and directed core buy-ins. Results are organized by PQM+ objectives and sub-objectives. Country and directed core buy-ins do not report on all PQM+ indicators, but on selected indicators that reflect the focus of their programs (please refer to Annex 1A for the set of buy-ins that report on the various PQM+ indicators). Annex 1B shows the start dates of all PQM+ buy-ins.

How to Read the M&E Results Table

Below is background information on the M&E Results Table overall and for specific indicatorsthat merit explanation.

Buy-ins and indicators. Buy-ins listed under indicators in Annex 1B appear in the M&E Results Table under those indicators unless they have no data to report. Similarly, if an indicator from Annex 1B is missing from the M&E Results Table, no buy-ins had data to report. Because start-up activities could take up to two quarters, relatively new PQM+ buy-ins may not have data to report until about Q3. For this reason, Rwanda, Madagascar, and several COVID-19 vaccine buy-ins will begin reporting in PY3.

Policy status (1.1a and 4.4a [Kenya]). PQM+ supports counterparts in developing new or improved regulatory and medicines policies. The program captures the status of these policies each quarter to track progress toward adoption and implementation. Results for the indicator 4.4a, which tracks ***medicine*** policies, laws, and regulations and which is included in Kenya's MEL Plan, are subsumed under the indicator 1.1a, policies, laws, and regulations related to medical product quality.

Institutionalization indicators. PQM+ works to institutionalize medical product quality assurance approaches and tools so counterparts (MRAs and QC laboratories) can continue using them after the project ends. To determine institutionalization, PQM+ tracks whether the counterpart: (1) has adopted SOPs that require use of the approach/ tool or detail how to use it; (2) is able to train its own staff on the approach or tool; and (3) uses an information system to track use and/or outcomes of the approach/tool. To each factor, a score of "0" is given if it is not yet being developed for adoption; "1" if work on it is underway but not yet finished; and "2" if it has been instituted. Thus, a total score of 6 (100%) means the tool/approach has been fully incorporated into national and/or counterpart practices. Once 100% has been achieved, PQM+ will continue monitoring use of the tool/approach to increase its chance for sustainability.

Milestone indicators. Generally, it takes years for quality control laboratories to achieve ISO accreditation or WHO prequalification (**2.2h**) or for manufacturers to achieve local market authorization or WHO prequalification (**4.1c**). Each of these outcomes requires completion of a set of activities, as shown in Annex Table 1. To summarize and systematically report progress on these long-term efforts, PQM+ uses "milestone" indicators that correspond with each of these major stages and activities. As laboratories and manufacturers make progress against each stage, PQM+ reports on the percentage of milestones met. Manufacturer milestones are reported for *each* medical product for which the manufacturer is seeking authorization with PQM+ support. For each of the milestones outlined in Annex Table 2, a score of "0" is given if no work has begun, a "1" if work is underway, and a "2" if work is completed. As milestones varyin the length of time they take to complete, some are weighted more than others. Laboratories'

QMS development and implementation is weighted four times that of the other laboratory activities. Similarly, manufacturers' product/dossier development and CAPA close-out are weighted one and a half times, and dossier compilation two times more than the other manufacturing activities. The total possible score for each set of activities is 20 (100%). Once this goal (100%) is achieved, the laboratory will be accredited or prequalified, or the manufacturer will have its dossier/market application approved by the MRA (for local market authorization) or WHO (for prequalification). Those major achievements are captured as distinctindicators (indicator 2.2b.1 for lab accreditation or prequalification; indicator 4c for market authorization or prequalification of a manufacturer's product).

Annex Table 1. Milestones Toward ISO Accreditation, Market Authorization, and WHO Prequalification

Laboratory Activities (ISO accreditation/WHO prequalification) - 2.2h	Manufacturer Activities (market authorization/ WHO prequalification) - 4.1c
Gap assessment / roadmap toward accreditation/ prequalification	GMP assessment and gap analysis
Institute a quality management system (QMS)	Product and dossier development
Lab equipment and facilities readiness	Close out GMP CAPAs
Analytical methods readiness	Dossier compilation
Proficiency testing	Dossier acceptance
PQM+ mock audit / interim assessment	PQM+ mock audit
Inspection/audit by the accreditation/inspection body	MRA or WHO audit
	MRA or WHO dossier review

Scores and weights are used to calculate the overall percentage of milestones achieved.

Training (2.5b). PQM+ buy-ins generally do not maintain databases of all trainees who participate in PQM+ training programs. Rather, buy-ins track the number of trainees (disaggregated by sex) in each major segment of the workforce who participate in each PQM+ training. So as not to duplicate the number of individuals trained in any given quarter, PQM+ counts trainees from each identifiable segment of the workforce (e.g., lab staff) only once each quarter, even though those staff may have benefited from multiple trainings that quarter.

Tracking other outcomes. PQM+ is especially interested in tracking certain project outcomes; thus, it includes the following indicators in every buy-in's MEL plan: [15]

- Standard operating procedures developed by the project for MRAs (**2.1k**) and national quality control laboratories (**2.2i**);
- Adoption of new project tools, namely SATTA (**5.1b.1**) and MedRS (**5.1b.2**); USP's Good Manufacturing Practices (GMP) online training modules (**5.1b.3**); and the project-created resource, *Guidance Document for Developing and Implementing a Risk-Based PMS for MNCH Products* (**5.1b.4**);

[15] There are a few exceptions, notably, buy-ins that deliberately limit the number of indicators so as to minimize the burden of reporting and focus on outcome-level indicators.

- Technical publications and presentations that focus on strengthening medical product quality assurance systems produced by the project (**5.2a**); and
- Media coverage of project activities (**5.3b**).
- This ensures that these outcomes—whether explicit foci or inadvertent results of buy-ins—are captured.

Contextual factors. In PY 2021, many PQM+ buy-ins dealt with disruptions that affected implementation of planned activities. In February 2021, a coup in **Burma** interrupted PQM+'s work with laboratories. Many laboratory staff who joined a national civil disobedience campaign were fired and PQM+ had to train a new QA team. Restructuring of **Uzbekistan's** MRA in the summer of 2021 slowed PQM+'s work in that country. Many countries also continued experiencing slow-downs in work plan implementation due to COVID-19 restrictions on travel or meetings, or counterparts' prioritization of emergency responses.

Annex Table 2. PQM+ FY2021 Monitoring Results

Table Legend

n/a: Not applicable. Buy-in is new to PY2, hence, there are no PY1 totals.

N/A: PQM+ cannot access the data or they are not available.

- (dash): No data as either no work was done or activity has not yet begun.

Not PY1/PY2 indicator: Buy-in did not have the indicator in the year referenced.

0: No results achieved.

No target: Target not set since results could not be predicted.

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
OBJECTIVE 1: GOVERNANCE FOR MEDICAL PRODUCT QUALITY ASSURANCE SYSTEMS STRENGTHENED								
Overarching Outcome								
1a. Number of enforcement actions taken by MRA and other authorized entities to address substandard and falsified medical products, by quarter								
Bangladesh DGDA	N/A	0	No target	0	0	0	N/A	N/A
Ethiopia EDFA	0	n/a	No target	6	0	0	1	**7**
Liberia LMHRA	0	n/a	No target	0	0	6	1	**7**
Nepal DDA	64[a]	0	No target	8	13	4	32	**57**
Total 1a				**14**	**13**	**10**	**34[b]**	**71[b]**
Government enforcement action in response to regulatory violations is a sign that the government is committed to keeping its citizens safe. PQM+ is tracking MRA enforcement actions in 6 countries (those listed as well as in the relatively new buy-ins, Guinea and Rwanda). In Ethiopia, 1 MNCH product was recalled in Q4 due to a complaint through EFDA's pharmacovigilance center about its quality. In Bangladesh, 6 (including 2 FP/RH) products were found to be suspicious in Q3 and, although PQM+ is aware that the government took action in Q4, there has been no official reporting as yet (PQM+ will confirm this in PY3). The Liberian government seized 6 (2 MNCH and 4 anti-malarial) unregistered products in Q3 and an anti-malarial product in Q4. Nepal's DDA identified and recalled 4 substandard products in Q3 (1 FP/RH, MNCH, and NTD product each) and 32 (22 of which were hand sanitizers) in Q4. **Notes:** [a] Nepal's baseline comes from the government's annual report. The 64 enforcement actions include product recalls and the filing of legal cases due to violations of the Drug Act 2035. The baseline covers the period July 2019-July 2020, which overlaps with the start of PQM+. As the fiscal years of the U.S. and Nepal's governments are different, there will be an overlap or gap in the reporting periods for this baseline. [b] Totals for Q4 and PY2 are likely higher due to DGDA's (Bangladesh) action.								
1.1. Evidence-based medical product quality assurance legislation, policies, and regulations developed, updated, and/or implemented								
1.1a. Number of policies, laws, regulations, and guidelines on medical product quality assurance developed or revised with PQM+ support and submitted for adoption, by quarter								
Bangladesh	0	1	1	0	1	0	0	**1**
National Quality Assurance Guidelines (drafted in PY1)				Submitted		Adopted		

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Legislation for Laboratory Service Sub-Contracting in Bangladesh					Drafted			
Burkina Faso	0	n/a	1	0	1	0	0	**1**
Collaborative Framework between ANRP and LNSP					Drafted	Stakeholder consultation		
Ethiopia	0	0	5	1	2	3	3	**9**
Medicines and Medical Devices Import, Export, and Wholesale Directive				Drafted & submitted				
Directive for Medicines GMP Inspection Procedures					Drafted & submitted			
Guidance for Cold Supply Chain					Drafting			
Directive-Medicine Packaging, Repackaging, and Labeling						Drafting		
Directive-Good Clinical Practice						Drafting		
Directive-Clinical Trial Application, Review, and Authorization						Drafting		
Directive-Clinical Trial Authorization							Drafting	
Addressing the Challenges of Local Pharmaceutical Production in Ethiopia							Revised/ Adopted	
Guidance on Waiver of GMP Inspection based on SRA Procedure							Drafting	
Kazakhstan	0	Not PY1 indicator	2	1	1	0	0	**2**
Rules of Expertise of Medicines/Medical Devices					Adopted			
Rules for Risk-Based Sampling of Medicines & Medical Devices from the Market				Adopted				
Kenya	0	1	2	0	0	1	1	**2**
QA Framework for Malaria Commodities (drafted in PY1)				Stakeholder consultation	Submitted		Adopted	
Guideline for Development, Review and Approval of Regulatory Instruments							Drafted	
Health Products and Technologies Supply Chain Strategy (drafted in PY1)				Submitted	Adopted			
RB-PMS Guideline						Revising	Revising	
Liberia	0	n/a	3	0	0	6	1	**7**
Regulations on Importation and Exportation of Medicines and Health Products						Drafted	Submitted	
Regulations for Advertising and Promotion of Medicines and Health Products						Drafted	Submitted	
Regulations for Donation of Medicines and Health Products						Drafted	Submitted	

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Regulations for Treatment & Disposal of Unfit Medicines and Health Products						Drafted	Submitted	
Regulations for Medicines & Health Products Product Recall, Withdrawal, & Seizure						Drafted	Submitted	
Regulations for Labeling of Medicines and Health Products						Drafted	Submitted	
Regulations for the Registration of Medicines & Health Products							Drafted & Submitted	
Mali	0	1	Not Y2 indicator					
National Guidance for RB-PMS (drafted in PY1)				Adopted				
Mozambique	0	n/a	1	1	0	0	0	**1**
Regulations for Medicines and Lab Quality Assurance				Revised				
Nepal	0	0	N/A	0	1	1	0	**2**
GMP Code					Revising	Revising	Revising	
Risk-Based PMS Guideline						Drafting	Drafting	
Pakistan	0	4	N/A	0	3	2	1	**6**
Guidance for Identification of Medicinal Products (IDMP) (API and Drug Products)					Submitted for review			
Procedures/Guidelines for Refurbished Equipment					Stakeholder consultation		Drafted & submitted	
Contract Manufacturing						Official requestfor comment		
National Pharmaceutical Sector Growth Strategy				Stakeholder consultation	Stakeholder consultation	Stakeholder consultation	Stakeholder consultation	
National Action Plan on Risk-Based PMS				Concept	Concept approved			
Establishment of National QC Laboratory Forum				Concept	Concept approved			
Emergency use authorization procedures/guidelines				Stakeholder consultation	Drafted	Stakeholder consultation		
PPE Standards						PQM+ reviewing client draft		
Guidelines for Bioequivalence Studies						Drafted	Submitted	
Guidance on Monitoring API and Medicine Shortages						Drafted		

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Conditions and Accountability Criteria for Private Sector QC Testing					Drafted	Submitted for review		
Guidance on Risk-based Post Marketing Drug Quality Surveillance							Adopted	
Senegal	0	1	Not Y2 indicator					
National Guidance for RB-PMS (drafted in PY1)				Submitted	Adopted			
Uzbekistan	0	1	3	1	1	1	1	**4**
Guideline on WHO collaborative procedure in accelerated registration of WHO prequalified pharmaceutical products				Drafted &Adopted				
Regulations related to inspections (drafted in PY1)				Reviewed	Revising	Revising	Revising	
Resolution of Cabinet Ministers #213 (registration of medical products)					Drafted	Submitted		
Organigram, MQCL						Revised & Adopted		
Resolution of Cabinet Ministers #486 (establishment of independent inspectorate)							Drafted & Adopted	
Total 1.1a				**4**	**10**	**14**	**7**	**35**
A national policy and regulatory framework is essential to ensuring the quality of medical products in countries. PQM+ is helping 15 countries (those listed, plus Guinea, Nigeria, and Rwanda) develop or revise and submit for adoption medical product quality assurance legislation, policies, and regulations. During PY2, the program supported a total of 35 new policies, laws, regulations, and guidelines. Twelve regulations (including six drafted and submitted in PY1) were adopted during the year (7 in Q3 and Q4); another 14 were submitted for adoption (11 in Q3 and Q4); and 15 new policies were drafted or revised (9 in Q3 and Q4). Policy work during the year took place mostly in Ethiopia, Liberia, and Pakistan. In Liberia, these seven new policies drafted and submitted in Q3 and Q4 constitute the first set of regulations drafted for LMHRA since it was established in 2010.								
1.2. Systems that facilitate transparency and accountability promoted								
1.2c.1 PQM+-supported MRA disseminated inspection results, by quarter								
Kazakhstan NCEM	Yes	Not PY1 indicator	Yes	Yes	Yes	Yes	Yes	**Yes**
1.2c.2. PQM+-supported MRA disseminated registration results, by quarter								
Kazakhstan NCEM	Yes	Not PY1 indicator	Yes	Yes	Yes	Yes	Yes	**Yes**
Uzbekistan Agency	Yes	Not PY1 indicator	Yes	Yes	Yes	Yes	Yes	**Yes**
1.2c.3. PQM+-supported MRA disseminated licensing results, by quarter								
Kazakhstan NCEM	Yes	Not PY1 indicator	Yes	Yes	Yes	Yes	Yes	**Yes**
1.2c.4. PQM+-supported MRA disseminated PMS results, by quarter								
Bangladesh DGDA	No	No	Yes	No	Yes	Yes	Yes	**Yes**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Mali DPM	Partial	n/a	Yes	No	No	Yes	No	**Yes**
Senegal DPM	Yes	n/a	Yes	No	No	No	Yes	**Yes**
PQM+ promotes transparent and accountable systems in countries to increase public trust. The program encourages MRAs to disseminate (or continue disseminating) results of their regulatory activities (inspection, registration, licensing, and post-marketing surveillance). In Kazakhstan, the MRA continued disseminating the results of its inspection, registration, and licensing activities throughout the year as results became available. Uzbekistan's Agency also continued disseminating its registration results. To complement its extensive PMS support, PQM+ assists 10 other countries in disseminating their PMS results. Two countries (Burkina Faso and Ghana) have not yet reported PMS results as the process is ongoing. Guinea and DRC, as newer buy-ins, have not yet begun PMS activities, and dissemination of the results of Ethiopia, Kenya, and Liberia's PMS activities is pending. The remaining three countries completed and disseminated the results of their PMS in Q3 and Q4. In Bangladesh, PQM+ assisted the DGDA in developing and releasing its annual 2019-2020 report, which included results for PMS as well as other regulatory functions.								
1.3. Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted								
1.3a PQM+-supported MRA's score on coordination and communication with other authorities involved in medical product regulatory oversight, by quarter								
Burkina Faso ANRP	N/A	n/a	Develop & operationalize a framework	0	0	2-implemented	0	**2-implemented**
Regular coordination and information-sharing among stakeholders involved in assuring the quality of medicines is poor in some countries. In PY2, PQM+ helped the ANRP of Burkina Faso develop a QA/QC stakeholder list and convene a two-day national medicines QA/QC workshop in Q3. More than 20 stakeholders from the MoH and private sector deliberated on QA issues and exchanged information. A second workshop scheduled for Q4 was postponed to PY3, Q1.								
1.4. Links among the medical product quality assurance systems and other sectors developed and fortified								
1.4a Percent of core functional components in place for a multisectoral group supported by PQM+ to advance medical product quality assurance, by quarter								
Technical Working Groups—Post-Marketing Surveillance								
Benin	0%	n/a	20%	0%	0%	10%	90%	**90%**
Burkina Faso	0%	n/a	50%	0%	80%	90%	90%	**90%**
DRC	0%	n/a	50%	n/a	0%	50%	90%	**90%**
Ghana	0%	n/a	25%	0%	10%	90%	90%	**90%**
Guinea	0%	n/a	50%	-	0%	70%	90%	**90%**
Kenya	0%	70%	90%	90%	90%	90%	90%	**90%**
Liberia	0%	n/a	25%	70%	70%	90%	90%	**90%**
Mali	0%	90%	90%	90%	90%	90%	90%	**90%**
Mozambique	0%	n/a	N/A	0%	0%	0%	70%	**70%**
Senegal	0%	90%	90%	90%	90%	90%	90%	**90%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
PQM+ promotes collaboration among the various counterparts and sectors (e.g., health programs, regulatory agency, laboratories, industry, civil society) involved in medical product quality. In 12 countries, PQM+ is supporting the development of Technical Working Groups (TWGs) to establish priorities for, oversee, and report results of RB-PMS activities, and make recommendations for enforcement action to the MRA. To determine multisector collaboration, PQM+ tracks whether TWGs have: (1) a coordination framework (terms of reference or TOR), and (2) chairperson in place; whether they (3) hold regular meetings per the TOR, and (4) distribute meeting minutes; and whether (5) the majority of TWG members attend the majority of meetings. Each component is given a "0" if it is absent, a "1" if PQM+ is still assisting, and a "2" if the component is established and documented. The total possible score is 10 (or 100%). In PY2, PQM+ helped establish 7 new groups in Benin, Burkina Faso, DRC, Ghana, Guinea, Liberia, and Mozambique, and continued strengthening the capacity of TWGs instituted in PY1 (in Kenya, Mali, and Senegal). All TWGs now have TORs and elected officials in place. This year, all TWG members convened for PQM+ training on RB-PMS tools and methods and planned the PMS–the first ever for some of the countries. All TWGs still rely on PQM+ to fund their meetings, however, which is why they do not yet score 100%. Counterparts in some countries are facilitating meetings, which is a step in the right direction. Nominated rapporteurs in all TWGs have kept and distributed meeting minutes. In Nigeria, PQM+ has discussed with officials in three states the formation of state-level multisector QA committees. As enormous progress has been made in establishing these TWGs, PQM+ will monitor their potential for sustainability, tracking whether they become fully independent in convening/running meetings and whether a majority of their members maintain active participation.								
OBJECTIVE 2: COUNTRY AND REGIONAL REGULATORY SYSTEMS TO ASSURE THE QUALITY OF MEDICAL PRODUCTS IN THE PUBLIC AND PRIVATE SECTORS IMPROVED								
Overarching Outcome								
2a. Percent of medical product samples assessed by PQM+-supported MRA through post-marketing surveillance that failed during the year								
Bangladesh DGDA	N/A	-	No Target	0%		3%		**3%**
Mali DPM	5%	n/a	No Target			3%		**3%**
Nepal DDA	12%	12%	No Target				10%	**10%**
Senegal DPM	N/A	-	No Target				1%	**1%**
Notes: Areas of the table are left blank to highlight PMS results that are, in fact, 0%. Note that each PMS quality survey has its own focus. Given the interest in assessing the quality of multiple medicine classes, the results below may be nationally representative of the percent of medicines that are SF in the country, but would not be nationally representative of the percent of **specific** medicines that are SF. In PY2, seven countries conducted at least one round of PMS. (Bangladesh held two and Kenya also conducted PMS for other essential medicines). The status and results of those PMS activities are as follows: Bangladesh–3% of 187 FP/RH and other samples failed. Mali–3% of 262 malaria and MNCH products sampled failed; 69% of products sampled from four regions were unregistered. Nepal–10% of 185 samples (including 32 MNCH and 4 NTD) medicines failed. (Note: PQM+ supported development of a PMS TWG in Nepal this year but did not support this PMS survey.) Senegal–1% of 301 malaria samples collected failed. Ethiopia–The shortage of medicines in the country at the time and the inaccessibility of some sites meant the team could only collect 70 of the planned 250 malaria and MNCH samples per the PMS protocol. Sample results are not yet available. Kenya–Collected 285 malaria and MNCH samples; results are not yet available.								

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Liberia–Collected 303 malaria and MNCH samples; results are not yet available. PMS in Burkina Faso and Ghana is beginning, while in Nigeria and in the relatively new buy-ins (DRC, Guinea, and Rwanda), PQM+ support for PMS has not yet begun.								
2.1. Sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies improved								
2.1a. Number of recommendations in the country's WHO GBT Institutional Development Plan addressed with PQM+ support during the year								
Bangladesh	0	0	51	0	0	0	206	**206**
Ethiopia	0	0	5	4	-	-	-	**4**
Kazakhstan	0	Not PY1 indicator	11	0	0	0	12	**12**
Pakistan	0	0	N/A	0	10	-	-	**10**
The regulatory functions of many MRAs in LMICs have been benchmarked against global standards per the WHO Global Benchmarking Tool. Thus, institutional development plans (IDPs) are developed with recommendations on how to improve each regulatory function (and its score). PQM+ is helping MRAs in several countries address these recommendations. In PY2, PQM+ helped MRAs complete: • 206 out of 274 IDP recommendations in Bangladesh; • 4 out of 4 agreed-upon inspection recommendations pertaining to SOPs in Ethiopia; • 12 of 26 inspection recommendations in Kazakhstan; [PQM+ also partially implemented 3 of 4 outstanding recommendations pertaining to registration and 3 of 6 remaining PMS recommendations]; and • 10 (3 regulatory systems, 3 registration, 1 inspection, 1 licensing, and 2 other) out of 14 recommendations in Pakistan.								
2.1b.1. Score on institutionalization of quality checklist for dossier review by PQM+-supported MRA, by quarter								
Uzbekistan NCEM	12.5%	16.7%	50%	16.7%	33.3%	33.3%	33.3%	**33.3%**
2.1b.4. Score on institutionalization of Good Review Practices by PQM+-supported MRA, by quarter								
Bangladesh DGDA	0%	0%	33.3%	0%	0%	33.3%	33.3%	**33.3%**
2.1d. Score on institutionalization of use of an inspection checklist by PQM+-supported MRA, by quarter								
Bangladesh DGDA	0%	0%	50%	0%	0%	33.3%	33.3%	**33.3%**
Ethiopia EFDA	0%	0%	100%	0%	0%	100%	100%	**100%**
PQM+ works to institutionalize the use of new approaches and tools to strengthen MRAs' regulatory functions. A score of 6 (or 100%) means the tool/approach has been fully incorporated into MRA practices (see scoring convention on p. 117). In Uzbekistan, PQM+ is helping the Agency institutionalize use of a dossier quality checklist to ensure consistent and high-quality assessment of dossiers submitted by manufacturers for market authorization. In Bangladesh, PQM+ is helping DGDA institutionalize Good Review Practices and inspection checklists. In Ethiopia, EFDA fully institutionalized the use of the inspection checklist.								
2.1i. Percent of milestones to prepare for PIC/S accession achieved by the MRA with PQM+ support in the reporting period								
Kazakhstan NCEM	10%	22%	59%	27%	27%	27%	32%	**32%**
Uzbekistan Agency	0%	0%	38%	10%	14%	14%	19%	**19%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Both Kazakhstan and Uzbekistan seek to accede to PIC/S. This will indicate that their inspectorates meet PIC/S' harmonized GMP standards and quality systems. PQM+ tracks progress along the protracted journey toward meeting all accession requirements. Kazakhstan is about a third of the way to PIC/S accession. Uzbekistan is nearly one- fifth of the way.								
2.1k. Number of standard operating procedures and quality assurance manuals developed or updated and adopted by project-supported MRA, by quarter								
Bangladesh DGDA (licensing, regulatory systems, registration, inspection, PMS, others)	0	0	2	0	1	45	1	**47**
Burkina Faso ANRP (PMS)	0	n/a	1	0	0	0	5	**5**
Ethiopia EFDA (registration, inspection, PMS, laboratory testing)	0	0	10	4	19	15	2	**40**
Kazakhstan NCEM (inspection)	0	Not PY1 indicator	15	4	2	4	1	**11**
Liberia LMHRA (licensing)	0	n/a	10	0	0	0	10	**10**
Mali DPM (PMS)	0	0	1	0	0	3	0	**3**
Senegal DPM (PMS)	0	0	No target	0	0	5	0	**5**
Uzbekistan Agency (inspection, laboratory testing)	0	Not PY1 indicator	2	3	1	2	0	**6**
Total 2.1k				**11**	**23**	**74**	**19**	**127**
PQM+ helps MRAs develop or update and adopt SOPs to carry out regulatory functions, depending on their needs. SOPs help MRAs achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and noncompliance with regulations or requirements. In FY2, MRAs in 7 countries adopted 127 SOPs (see above for types of procedures dealt with).								
2.2a. PQM+-supported QC laboratory score on SATTA in the year								
Benin ANCQ	-	n/a	No target	-	-	12%	-	**12%**
Burkina Faso LNSP	-	n/a	No target	-	-	-	3%	**3%**
Ethiopia Diredawa	-	-	No target	22%	-	-	-	**22%**
Ethiopia Bahirdar	-	-	No target	23%	-	-	-	**23%**
Ethiopia Jimma	-	-	No target	5%	-	-	-	**5%**
Guinea LNCQM	-	n/a	No target	-	-	-	6%	**6%**
Liberia LMHRA QCL	-	n/a	No target	-	-	64%	-	**64%**
Mali LNS	-	-	No target	-	21%	-	-	**21%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Mozambique DCQ	-	n/a	No target	-	-	-	14%	**14%**
Nepal NML	-	-	No target	-	37%	-	-	**37%**
PQM+ strengthens QC laboratories so they can generate accurate and consistent test results for medical products. The program usually commences support for a laboratory by conducting a detailed baseline assessment using the SATTA tool to identify areas that are weak (i.e., not compliant with WHO prequalification or ISO 17025:2017 standards). In Q3 and Q4, PQM+ completed SATTAs for 5 additional new laboratories (a total of 10 for the year). Baseline scores ranged from lows of 3-6% (Burkina Faso's LNSP, Ethiopia's Jimma branch laboratory, and Guinea's LNCQM) to a high of 64% (Liberia's LMHRA QCL). PQM+ uses these results to develop roadmaps to address gaps.								
2.2b.1. Number of PQM+-supported laboratories that were WHO prequalified or ISO/IEC accredited during the year								
Bangladesh Physiochemical Lab	ISO 17025 accreditation (10 methods)	ISO re-accredited (10 methods)	ISO & PQ				ISO17025 re-accredited (12 methods)	**ISO17025 re-accredited (12 methods)**
Burma Nay Pyi Taw PCL	ISO 17025:2017 (10 methods)	ISO re-accredited (10 methods)	ISO re-accreditation (10 methods)	ISO re-accredited (10 methods)				**ISO 17025:2017 re-accredited (10 methods)**
Ethiopia PQAD	ISO 17025:2017 accreditation (16 methods)	ISO re-accredited (16 methods)	ISO re-accreditation (16 methods)			ISO re-accredited (16 methods)		**ISO re-accredited (16 methods)**
Nigeria NAFDAC zonal lab, Agulu	ISO 17025:2017 accreditation (7 methods)	ISO re-accredited(7 methods)	ISO 17025:2017 re-accreditation (7 methods)	ISO re-accredited (16 methods)				**ISO 17025:2017 re-accredited (16 methods)**
Nigeria NAFDAC zonal lab, Kaduna	ISO 17025:2017 accreditation (7 methods)	ISO re-accredited (7 methods)	ISO 17025:2017 re-accreditation (7 methods)	ISO re-accredited (16 methods)				**ISO 17025:2017 re-accredited (16 methods)**
Nigeria NAFDAC zonal lab, Yaba	ISO 17025:2017 accreditation (7 methods)	ISO re-accredited(7 methods)	ISO 17025:2017 re-accreditation (7 methods)	ISO re-accredited (17 methods)				**ISO 17025:2017 re-accredited (17 methods)**
Nigeria NIPRID NQCL	ISO 17025:2017 accreditation (6 methods)	ISO re-accredited(6 methods)	ISO 17025:2017 re-accreditation (6 methods)	ISO re-accredited(6 methods)				**ISO 17025:2017 re-accredited (6 methods)**
Nigeria NAFDAC NCL, Vaccines & Biologics, Yaba	ISO 17025:2017 accreditation (10 methods)	ISO re-accredited (10 methods)	ISO 17025:2017 re-accreditation (10 methods)	ISO re-accredited (14 methods)				**ISO 17025:2017 re-accredited (14 methods)**
Pakistan Drug Testing Lab, Lahore	ISO 17025:2017 accreditation, 2018 (10 methods)	n/a	ISO 17025:2017 accreditation			ISO re-accredited, scope extension of 46 parameters		**ISO re-accredited, (scope extension 46 parameters)**
Uzbekistan Andijan	ISO 17025:2017 accreditation (56 methods)	ISO re-accredited (56 methods)	ISO 17025:2017 re-accreditation				ISO re-accredited (118 methods)	**ISO re-accredited (118 methods)**
Total 2.2b.1				**6**	**0**	**2**	**2**	**10**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
PQM+ helps laboratories achieve international accreditation or WHO prequalification as evidence of their quality and competence. Having to renew accreditation means that laboratories must remain at the top of their game in competency and data quality. In PY2, 10 QC laboratories in 6 countries (listed) received ISO 17025:2017 re-accreditation. Seven expanded their scope (i.e., the number of methods for which they are accredited).								
2.2c.1. Score on institutionalization of training program at PQM+-supported QC laborator, by quarter								
Kazakhstan Almaty	18%	66.7%	83.3%	66.7%	66.7%	66.7%	100%	**100%**
Kazakhstan Karaganda	18%	100%	100%	100%	100%	100%	100%	**100%**
Liberia LMHRA QCL	17%	n/a	100%	0%	0%	83.3%	83.3%	**83.3%**
2.2c.2. Score on institutionalization of preventive maintenance program at PQM+-supported QC laboratory, by quarter								
Kazakhstan Almaty	18%	66.7%	83%	66.7%	66.7%	66.7%	100%	**100%**
Kazakhstan Karaganda	18%	100%	100%	100%	100%	100%	100%	**100%**
Liberia LMHRA QCL	0%	n/a	50%	0%	0%	50%	50%	**50%**
Mali LNS	0%	0%	N/A	0%	0%	0%	83.3%	**83.3%**
Senegal LNCM	0%	0%	N/A	0%	0%	0%	83.3%	**83.3%**
Uzbekistan Andijan	0%	16.7%	50%	16.7%	16.7%	16.7%	16.7%	**16.7%**
Uzbekistan Tashkent	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
2.2c.3. Score on institutionalization of calibration program at PQM+-supported QC laboratory, by quarter								
Burma Nay Pyi Taw PCL	50%	66.7%	N/A	66.7%	-	66.7%	83.3%	**83.3%**
Kazakhstan Almaty	18%	66.7%	83%	66.7%	66.7%	66.7%	100%	**100%**
Kazakhstan Karaganda	18%	100%	100%	100%	100%	100%	100%	**100%**
Liberia LMHRA QCL	0%	n/a	50%	0%	0%	33.3%	33.3%	**33.3%**
Mali LNS	0%	0%	N/A	0%	0%	0%	83.3%	**83.3%**
Senegal LNCM	0%	0%	N/A	0%	0%	0%	83.3%	**83.3%**
Uzbekistan Andijan	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
Uzbekistan Tashkent	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
2.2c.4. Score on institutionalization of analyst competency assessment program at PQM+-supported QC laboratory, by quarter								
Burma Nay Pyi Taw PCL	37.5%	50%	N/A	50%	-	50%	83.3%	**83.3%**
Kazakhstan Almaty	18%	66.7%	83%	66.7%	66.7%	66.7%	100%	**100%**
Kazakhstan Karaganda	18%	100%	100%	100%	100%	100%	100%	**100%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Liberia LMHRA QCL	0%	n/a	50%	0%	0%	16.7%	16.7%	**16.7%**
Uzbekistan Andijan	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
Uzbekistan Tashkent	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
2.2c.5. Score on institutionalization of internal performance review at PQM+-supported QC laboratory, by quarter								
Benin ANCQ	0%	n/a	33.3%	0%	0%	16.7%	66.7%	**66.7%**
Burma Nay Pyi Taw PCL	50%	66.7%	N/A	66.7%	-	50%	66.7%	**66.7%**
Kazakhstan Almaty	18%	66.7%	83%	66.7%	66.7%	66.7%	100%	**100%**
Kazakhstan Karaganda	18%	100%	100%	100%	100%	100%	100%	**100%**
Liberia LMHRA QCL	0%	n/a	50%	0%	0%	16.7%	16.7%	**16.7%**
Mali LNS	0%	66.7%	Not PY2 indicator	66.7%	66.7%	66.7%	66.7%	**66.7%**
Uzbekistan Andijan	0%	16.7%	50%	16.7%	16.7%	16.7%	16.7%	**16.7%**
Uzbekistan Tashkent	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
2.2c.6. Score on institutionalization of quality management system at PQM+-supported QC laboratory, by quarter								
Burma Nay Pyi Taw PCL	37.5%	50%	50%	66.7%	-	83.3%	83.3%	**83.3%**
Guinea LNCQM	TBC	n/a	N/A	n/a	0%	0%	83.3%	**83.3%**
Kazakhstan Almaty	18%	66.7%	83%	66.7%	66.7%	66.7%	100%	**100%**
Kazakhstan Karaganda	18%	100%	100%	100%	100%	100%	100%	**100%**
Liberia LMHRA QCL	0%	n/a	50%	0%	0%	50%	100%	**100%**
Uzbekistan Andijan	0%	16.7%	50%	16.7%	16.7%	16.7%	16.7%	**16.7%**
Uzbekistan Tashkent	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**

The sustainability of PQM+'s laboratory strengthening work depends, in part, on whether laboratories "own" the new quality programs and systems PQM+ has introduced. Having the capability to continually evaluate operational procedures, staff, and equipment allows a more reliable laboratory environment capable of producing accurate results in the most efficient way. PQM+ tracks institutionalization of these programs using the scoring rule on p. 117. A score of 6 (or 100%) means that the program has been fully incorporated into QC laboratory practices. Both PQM+-supported laboratories in Kazakhstan have now fully institutionalized training, preventive maintenance, calibration, and competency assessment programs, as well as internal performance review and quality management systems. Karaganda maintained its status in PY2. Institutionalization at the Uzbekistan laboratories effectively ceased as the MRA underwent substantial restructuring in the middle of the year. Following the Burmese coup and loss of laboratory staff in Q2, all PQM+ work was directed at building the capacity of the Nay Pyi Taw PCL. Mali's LNS has SOPs in place, but no internal capacity to train on preventive maintenance or calibration or to perform an internal audit. Likewise, Benin's ANCQ has institutionalized SOPs, but does not have the capacity as yet to train. Senegal's LNCM is in the early stages of institutionalization, while Guinea's LNCQM has not yet begun work on institutionalizing systems for internal performance reviews. It has fully instituted SOPs and a tracking system, and partially a training program in QMS.

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
2.2g. Number of proficiency tests or inter-laboratory tests completed by the QC laboratory, by quarter								
Bangladesh Physiochemical Lab	0	7	2	0	1	4	0	**5**
Bangladesh Vaccine Lab	0	n/a	N/A	0	1	0	0	**1**
Burma Nay Pyi Taw PCL	2	2	2	0	0	2	1	**3**
Ethiopia NQCL	N/A	0	N/A	0	0	0	5	**5**
Ethiopia PQAD	N/A	0	N/A	0	0	2	0	**2**
Kazakhstan Almaty NQCL	N/A	3	No target	4	0	4	1	**9**
Kazakhstan Karaganda NQCL	N/A	5	No target	4	0	3	5	**12**
Total 2.2g				**8**	**2**	**15**	**12**	**37**
PQM+ tracks the number of proficiency or inter-laboratory tests (PTs/ILTs) completed by supported laboratories in seven countries (those listed, plus Nigeria). Proficiency/inter-laboratory testing is an external assessment of a QA laboratory's testing or measurement capabilities. It supplements the internal quality control system of a laboratory, allows laboratories to compare their performance with that of others in the same program, and indicates whether a laboratory is performing to acceptable standards. In PY2, 37 such tests were completed by supported laboratories. Mozambique failed a PT (dissolution method) in Q4 and currently has 4 PT samples, which it will work on in PY3. Nepal's NML is in the process of registering for PTs.								
2.2h. Percentage of milestones toward accreditation/WHO PQ achieved by a PQM+-supported laboratory, by quarter								
Bangladesh Chattogram DTL (ISO 17025)	0%	n/a	100%	5%	10%	10%	30%	**30%**
Bangladesh Vaccine Lab (WHO PQ)	0%	0%	100%	55%	55%	55%	55%	**55%**
Ethiopia Bahirdar branch (ISO17025)	0%	0%	41.7%	0%	0%	40%	40%	**40%**
Ethiopia Diredawa branch (ISO 17025)	0%	0%	41.7%	0%	0%	40%	40%	**40%**
Ethiopia Jimma branch (ISO 17025)	0%	0%	41.7%	0%	0%	40%	40%	**40%**
Kazakhstan Almaty (WHO PQ)	78%	Not PY1 indicator	92%	85%	85%	90%	90%	**90%**
Liberia LMHRA QCL (ISO 17025)	0%	n/a	35%	0%	0%	35%	35%	**35%**
Mali LCQM/LNS (ISO 17025)	0%	0%	N/A	5%	45%	45%	90%	**90%**
Mozambique DCQ (ISO 17025)	30%	5%	N/A	n/a	n/a	30%	30%	**30%**
Nepal NML (ISO 17025)	0%	0%	35%	0%	40%	45%	45%	**45%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Pakistan Appellate Lab (ISO17025)	10%	10%	100%	10%	10%	65%	65%	**65%**
Pakistan Institute Public Health(ISO 15189)	0%	0%	N/A	0%	0%	55%	55%	**55%**
Pakistan Institute Med. Sciences(ISO 15189)	0%	0%	N/A	0%	0%	10%	10%	**10%**
Pakistan DTL, Multan (WHO PQ)	95%	95%	100%	95%	95%	95%	95%	**95%**
Pakistan DTL, Multan (ISO 17043)	N/A	N/A	N/A	-	-	75%	75%	**75%**
Pakistan DTL, Bahawalpur (WHOPQ)	95%	95%	100%	95%	95%	95%	95%	**95%**
Pakistan DTL, Rawalpindi (WHOPQ)	N/A	N/A	100%	-	-	100%	100%	**100%**
Uzbekistan Andijan NQCL (ISO 17025)	35%	Not PY1 indicator	64%	35%	35%	35%	35%	**35%**
Uzbekistan Tashkent NQCL (ISO 17025)	35%	Not PY1 indicator	64%	35%	35%	35%	35%	**30%**
International accreditation enhances a laboratory's technical competence and reputation and assures compliance with established standards. Achieving ISO accreditation/ WHO PQ is a lengthy process. As a general rule, the closer a buy-in is to 100%, the more activities (referred to in Annex Table 1, p. 110) they have completed. In PY2, PQM+ began preparing 9 new labs (those with a baseline of 0%) for their first ISO accreditation. PQM+ is also helping 9 labs pursue re-accreditation or WHO PQ. Kazakhstan's Almaty laboratory–which was recertified in PY1–is now seeking WHO PQ.								
2.2i. Number of standard operating procedures and quality assurance manuals developed or updated and adopted by PQM+-supported laboratory, by quarter								
Bangladesh (3 labs)	0	14	5	11	10	10	3	**34**
Benin ANCQ	0	n/a	1	0	0	0	1	**1**
Burkina Faso LNSP	0	n/a	1	0	0	0	3	**3**
Kazakhstan (2 labs)	0	Not PY1 indicator	10	0	20	1	3	**24**
Liberia LMHRA QCL	0	n/a	11	0	0	28	8	**36**
Mali LNS	0	1	3	0	0	2	0	**2**
Senegal NQCL	0	1	2	0	0	1	0	**1**
Uzbekistan Tashkent	0	Not PY1 indicator	10	0	0	1	0	**1**
Total 2.2i				**11**	**30**	**43**	**18**	**102**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
SOPs help ensure that accepted procedures are followed consistently so as to ensure consistent performance and results. SOPs underpin many efforts to strengthen laboratories and are essential for accreditation. In PY2, laboratories in 8 countries adopted a total of 102 SOPs with PQM+ support.								
2.3. Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported								
2.3c.1 Score on institutionalization of use of WHO collaborative procedure for accelerated registration at PQM+ supported MRA, by quarter								
Uzbekistan NCEM	25%	33.3%	83.3%	50%	66.7%	83.3%	83.3%	**83.3%**
PQM+ is helping the MRAs in Bangladesh, Liberia, and Uzbekistan institutionalize use of the WHO collaborative procedure for registration. This will enable them to use assessment and inspection outputs from the WHO prequalification process to reduce duplicative regulatory work and save time. Uzbekistan's MRA now has a SOP, can offer training, and is developing an information system to track the use and results of CRP. A score of 100% means the procedure has been fully incorporated into counterpart practices (see p. 117 for scoring convention).								
2.4. Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported								
2.4b. # of data standards adopted by PQM+-supported MRA in the year								
Pakistan DRAP	0	0	N/A	0	0	0	4	**4**
Pakistan has adopted the Common Technical Document for medical product dossiers (which counts as one data standard) and three of the five ISO Identification of Medicinal Product (IDMP) standards. It is in the process of incorporating these into PIRIMS.								
2.5. Competence, efficiency, and expansion of the medical product quality assurance workforce improved								
2.5a. Number of in-service training programs that address quality assurance/quality control topics delivered with PQM+ support, by quarter								
Asia Bureau	0	0	N/A	1	0	0	0	**1**
Bangladesh	0	5	7	5	13	8	9	**35**
Benin	0	n/a	1	0	1	1	2	**4**
Burkina Faso	0	n/a	5	0	3	4	1	**8**
Burma	0	2	5	1	-	0	1	**2**
DRC	0	n/a	4	n/a	0	0	4	**4**
Ethiopia	0	1	4	1	3	1	1	**6**
Ghana	0	n/a	1	0	0	3	1	**4**
Guinea	0	n/a	8	n/a	0	1	5	**6**
Kazakhstan	0	5	3	4	1	1	3	**9**
Kenya	0	0	5	1	1	0	0	**2**
Liberia	0	n/a	4	0	3	6	2	**11**
Mali	0	2	4	1	0	4	2	**7**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Mozambique	0	n/a	N/A	0	0	0	2	**2**
Nepal	0	0	N/A	0	0	3	1	**4**
Nigeria	0	0	Not PY2 indicator	2	0	5	1	**8**
Pakistan	0	N/A	N/A	0	1	4	13	**18**
Senegal	0	2	3	1	0	1	1	**3**
Uzbekistan	0	4	5	2	3	2	4	**11**
Total 2.5a				**19**	**29**	**44**	**53**	**145**
2.5b. Number of individuals who successfully completed a PQM+-supported in-service training program during the year								
				Female / Male	Female / Male	Female / Male	Female / Male	Female / Male
Asia Bureau	0			127 (sex unknown)				
Bangladesh	0	81		5 / 10	32 / 152	16 / 29	25 / 42	
Benin	0	n/a			6 / 8	6 / 7	5 / 8	
Burkina Faso	0	n/a			7 / 8	17 / 21	5 / 8	
Burma	0	41		93 / 12			7 / 1	
DRC	0	n/a	n/a				18 / 35	
Ethiopia	0	0			6 / 14	12 / 20	1 / 11	
Ghana	0					3 / 10	5 / 17	
Guinea	0	n/a	n/a			1 / 12	8 / 20	
Kazakhstan	0	5		94 / 37	35 / 16	43 / 19	45 / 17	
Kenya	0	0		7 / 11	6 / 9			
Liberia	0	n/a			10 / 31	18 / 36	10 / 27	
Mali	0			8 / 6		13 / 19	10 / 28	
Mozambique	0	n/a					17 / 13	
Nepal	0	0				7 / 14	16 / 56	
Nigeria	0	0		34 / 40		332 / 972	65 / 100	
Pakistan	0				6 / 31	13/ 30	75 / 107	
Senegal	0	30		4 / 8		17 / 9	13 / 9	**See note below**
Uzbekistan	0	21		33 / 46	27 / 38	20 / 20	16 / 16	

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Total (disaggregated)	0			**278 / 170**	**135 / 307**	**518 / 1,218**	**341 / 515**	
Grand total 2.5b				**448**	**442**	**1,736**	**856**	
Despite constraints on travel and in-person meetings experienced in many countries, PQM+ maintained a robust program of training for its various counterparts in all countries. The very high numbers of people trained are driven by some very large-scale trainings associated with state-level work in Nigeria. Specifically, in Q3, PQM+ trained 1,194 (of the 1,304 listed in the table) staff from patent medicines shops on best practices in medicines supply chain management. Also in Nigeria, in Q4, PQM+ trained 165 PCN zonal inspectors on "Pharmaceutical Inspection - Need for Excellence in Pharmaceutical Services Delivery." The percentage of female trainees are as follows: Q1–62.1%; Q2– 30.5%; Q3–29.8%; and Q4–39.8%. **Note: There are no quarterly or annual totals as doing so would count the same trainee multiple times.**									
2.5c. Number of training or academic programs that address quality assurance/quality control topics developed or revised with PQM+ support, by quarter								
Burma	0	0	2	1	-	0	0	**1**
Kazakhstan	0	Not PY1 indicator	2	4	1	1	2	**8**
Kenya	0	Not PY1 indicator	3	1	0	0	0	**1**
Mali	0	0	1	0	0	2	0	**2**
Uzbekistan	0	Not PY1 indicator	1	1	2	0	0	**3**
Total 2.5c				**7**	**3**	**3**	**2**	**15**
2.5d.1. Score on institutionalization of staffing program adopted by PQM+ supported MRA, by quarter								
Nepal DDA	0%	0%	N/A	33.3%	33.3%	33.3%	33.3%	**33.3%**
2.5d.2. Score on institutionalization of skills program adopted by PQM+ supported MRA, by quarter								
Liberia LMHRA	0%	n/a	No target	0%	0%	0%	50%	**50%**
Nepal DDA	0%	0%	N/A	33.3%	33.3%	33.3%	33.3%	**33.3%**
2.5e.1. Score on institutionalization of staffing program adopted by PQM+ supported QC laboratory, by quarter								
Kenya NQCL	0%	0%	No target	0%	33.3%	83.3%	83.3%	**83.3%**
2.5e.2. Score on institutionalization of skills program adopted by PQM+ supported QC laboratory, by quarter								
Kenya NQCL	0%	0%	No target	0%	33.3%	83.3%	83.3%	**83.3%**
2.5e.3. Score on institutionalization of working conditions program adopted by PQM+ supported QC laboratory, by quarter								
Kenya NQCL	0%	0%	No target	0%	33.3%	83.3%	83.3%	**83.3%**
2.5e.4. Score on institutionalization of staff motivation program adopted by PQM+ supported QC laboratory, by quarter								
Kenya NQCL	0%	0%	No target	0%	33.3%	83.3%	83.3%	**83.3%**
Mali LNS	0%	n/a	No target	0%	0%	33.3%	33.3%	**33.3%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
To improve the sustainability of its interventions, PQM+ promotes workforce development approaches that help counterparts (MRAs and laboratories) build, retain, and adequately support and motivate their workforce over the long run. PQM+ begins by (1) conducting a comprehensive assessment of counterparts' human resources across four pathways: staffing, skills, working conditions, and staff motivation. PQM+ then works with the counterpart to (2) design interventions to strengthen areas prioritized for support, and to (3) develop and utilize a central tracking system to monitor implementation of/or results from the intervention. PQM+ scores each of these components (see scoring convention on p. 117) on the pathways selected for improvement to determine how much the counterpart has institutionalized. A total score of 6 (or 100%) means the program has been fully incorporated into national and/or counterpart practices. In PY2, PQM+ completed human resources assessments of Liberia's LMHRA, Nepal's DDA, Kenya's NQCL, and Mali's LNS. In addition, the program is now helping LMHRA and Kenya's NQCL develop a tracking system. Work on developing an intervention in all four areas is also ongoing at Kenya's NQCL. No further work was carried out in Nepal or Mali.								
2.5f. Number of membership organizations strengthened in advancing members' understanding of medical product quality assurance by PQM+ during the year								
Bangladesh	0	0	1	0	0	0	2	**2**
Independent University & Plasma Plus Laboratory as well as Essential Drugs Co. received GMP training.								
Kenya	0	0	2	0	0	0	1	**1**
Federation of Kenya Pharmaceutical Manufacturers								
Nigeria	0	Not PY1 indicator	Not PY2 indicator	2	0	0	0	**2**
Pharmacists Council of Nigeria (PQM+ worked with and trained PCN throughout PY2); Pharmaceutical Manufacturing Group of the Manufacturers' Association of Nigeria (PQM+ trained member companies on several QA/QC topics throughout PY2).								
Uzbekistan	0	1	Not PY2 indicator	1	0	0	0	**1**
Pharmaceutical Association (from PY1), training for members on CTD								
Total 2.5f				**3**	**0**	**0**	**3**	**6**
OBJECTIVE 3: FINANCIAL RESOURCES FOR MEDICAL PRODUCT QUALITY ASSURANCE OPTIMIZED AND INCREASED								
3.1. Allocation and use of investments for medical product quality assurance systems strengthening optimized								
3.1a.2. Score on institutionalization of risk-based approach to inspection at PQM+-supported MRA, by quarter								
Kazakhstan NCEM	0%	Not PY1 indicator	37.5%	50%	50%	50%	50%	**50%**
Nepal DDA	0%	0%	35%	16.7%	16.7%	33.3%	33.3%	**33.3%**
Uzbekistan Agency	0%	Not PY1 indicator	33%	0%	16.7%	16.7%	16.7%	**16.7%**
3.1a.3. Score on institutionalization of risk-based approach to post marketing surveillance at PQM+-supported MRA, by quarter								
Bangladesh DGDA	33.3%	33.3%	50%	33.3%	33.3%	33.3%	83.3%	**83.3%**
Burkina Faso ANRP	0%	n/a	N/A	0%	0%	0%	83.3%	**83.3%**
DRC ACOREP	0%	n/a	16.7%	n/a	0%	0%	33.3%	**33.3%**
Ethiopia EFDA	0%	33.3%	100%	33.3%	33.3%	50%	50%	**50%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Ghana GFDA	0%	n/a	25%	0%	0%	0%	50%	**50%**
Guinea DNPM	0%	n/a	50%	n/a	0%	0%	50%	**50%**
Kenya PPB	0%	0%	50%	0%	66.7%	66.7%	66.7%	**66.7%**
Liberia LMHRA	0%	n/a	50%	0%	0%	33.3%	33.3%	**33.3%**
Mali DPM	0%	0%	50%	0%	0%	50%	50%	**50%**
Nepal DDA	0%	0%	12%	16.7%	16.7%	33.3%	33.3%	**33.3%**
Senegal DPM	0%	16.7%	50%	16.7%	16.7%	16.7%	66.7%	**66.7%**

To optimize financial resources, PQM+ promotes the use of risk-based approaches to regulatory activities. Such approaches focus on the facilities, products, or locations that pose the greatest risks to public health. PQM+ is helping launch and institutionalize risk-based inspections in 4 countries (listed, plus Rwanda in FY3). [Please refer to scoring of institutionalization factors on page 117. A total score of 6 (or 100%) means the tool/approach has been fully incorporated into MRA practices.

In PY2, the MRAs in Kazakhstan (NCEM), Nepal (DDA), and Uzbekistan (Agency) began developing training programs to train staff on the RB-inspection approach/tools. NCEM and DDA are also developing SOPs, and NCEM is creating an information system to track use and/or outcomes of the RB-inspection approach/tools. PQM+ is also working to institutionalize RB-PMS in 11 countries. In all MRAs, PQM+ facilitated RB-PMS training throughout the year. Seven countries either have RB-PMS SOPs in place (Bangladesh, Burkina Faso, Mali, Senegal) or are developing them (Ethiopia and Kenya). All but two countries (Mali and Nepal) use or are setting up an information system to track RB-PMS activities and outcomes. Notably, although PQM+ is still assisting Kenya's PPB with RB-PMS, the MRA has already demonstrated independent use of the MedRS tool/approach (in Q2, PPB designed a protocol for assessing the quality of other medicines) and financial independence (PPB fully funded the TWG workshop to develop the protocol and fully funded the activity in Q3). PPB has also engaged in cost-sharing, providing human resources, vehicles, fuel for transporting staff and samples, and its field offices as MiniLab screening sites.

3.2. Sustainable resources mobilized

3.2b.1. PQM+-supported MRA analyzed its costs in the reporting period to support review of the fee structure or to improve budgeting & planning for market authorization/registration								
Liberia LMHRA	No	n/a	Yes	No	No	Yes	-	**Yes**
3.2b.4. PQM+-supported MRA analyzed its costs in the reporting period to support review of the fee structure or to improve budgeting & planning for PMS								
Ethiopia EFDA	No	No	Yes	No	No	No	Yes	**Yes**
3.2b.5. PQM+-supported MRA analyzed its costs in the reporting period to support review of the fee structure or to improve budgeting & planning for laboratory testing								
Bangladesh DGDA	No	Yes	Yes	No	No	No	Yes	**Yes**
Ethiopia EFDA	No	No	Yes	No	No	No	Yes	**Yes**
Kenya PPB	No	No	Yes	No	No	No	Ongoing	**Ongoing**
Liberia LMHRA	No	n/a	Yes	No	No	Yes	-	**Yes**
Mali DPM	Yes	n/a	Yes	No	No	No	Yes	**Yes**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
PQM+ supports MRAs and their QC laboratories in analyzing and reporting their costs. MRAs and QC laboratories can use these cost analyses to justify budget requests or changes in user fees. In PY2, PQM+ helped five countries' QC laboratories analyze the costs of laboratory testing. It also helped Liberia analyze the costs of market authorization activities, and Ethiopia analyze the costs of its PMS.								
OBJECTIVE 4: SUPPLY OF QUALITY-ASSURED ESSENTIAL MEDICAL PRODUCTS OF PUBLIC HEALTH IMPORTANCE INCREASED								
4c. Number of priority medical products that received market authorization with PQM+ support, by quarter								
Core NTD, Praziquantel 600 mg (WHO PQ)	0	n/a	No target	0	0	1	0	**1**
Core TB, Clofazamine API and FPP (WHO PQ)	0	n/a	No target	0	1	0	1	**2**
Pakistan Covid-19, Remdesivir (local authorization)	0	n/a	No target	1	0	0	0	**1**
Total 4c				**1**	**0**	**1**	**0**	**2**
In Q3, under the Core NTD program, the PQM+-supported Indian manufacturer, Medopharm, achieved WHO PQ for its praziquantel 600mg film-coated tablet, which is used to treat schistosomiasis. Dong A Pharma, a South Korean manufacturer, achieved WHO PQ for its drug-resistant TB medicine, clofazimine (FPP and API) in PY2. Finally, the PQM+ COVID-19 Pakistan buy-in worked with Ferozsons to produce quality-assured remdesivir. The Government of Pakistan has approved use of this product and Ferozsons has received approval and is exporting remdesivir to 16 countries.								
4.1. Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/dossiers supported								
4.1b. Number of product dossiers submitted by PQM+-supported manufacturers for a USAID-priority medical product, by quarter								
Core NTD, Albendazole FPP	0	0	1	0	0	1	0	**1**
Core TB, 4FDC	0	0	2	0	0	0	1	**1**
Nigeria, SP and Zinc sulfate	0	0	1	0	0	0	2	**2**
Total 4.1b				**0**	**0**	**1**	**3**	**4**
PQM+-supported manufacturers submitted dossiers for four medicines for WHO PQ in Q3 and Q4– for the NTD medicine albendazole chewable tablet (from Mepro of India); the anti-TB medicine 4FDC (from Schazoo of Pakistan); the malaria medicine SP tablets (from Swipha of Nigeria); and for zinc sulphate dispersible tablets and SP tablets (from Swipha of Nigeria).								
4.1c. Percentage of milestones toward market authorization or WHO prequalification achieved by PQM+-supported manufacturer, by quarter								
Bangladesh ACI Ltd., 2DC anti-TB medicines	n/a	n/a	30%	25%	32.5%	32.5%	37.5%	**37.5%**
Core NTD/Mepro (India), Albendazole chewable 400 mg	n/a	n/a	N/A	N/A	N/A	65%	65%	**65%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Core NTD/Medopharm (India), Praziquantel 600 mg	n/a	n/a	N/A	0%	0%	100% (achieved WHO PQ)	-	**100%**
Core TB/Schazoo (Pakistan),4FDC anti-TB medicine	n/a	n/a	70%	N/A	N/A	70%	75%	**75%**
Core TB/Pacific Pharmaceuticals (Pakistan) 4FDC anti-TB medicine	n/a	n/a	65%	N/A	N/A	N/A	17.5%	**17.5%**
Ghana Ernest Chemists, ALu 20/120 mg	0%	n/a	N/A	0%	10%	10%	15%	**15%**
Ghana Amponsah Efah Ltd., ALu 20/120 mg	0%	n/a	N/A	0%	10%	10%	15%	**15%**
Ghana Atlantic Life Science Pharmaceutical, Oxytocin 10iu/mL	0%	n/a	N/A	0%	10%	10%	15%	**15%**
Ghana Entrance Pharmaceuticals,ALu 20/120 mg	0%	n/a	N/A	0%	7.5%	10%	15%	**15%**
Nigeria Nemel Pharmaceuticals, Amoxicillin DT 250 mg	n/a	n/a	N/A	0%	0%	50%	50%	**50%**
Nigeria Nemel Pharmaceuticals, Amoxicillin DT 125 mg	n/a	n/a	N/A	0%	50%	50%	50%	**50%**
Nigeria Emzor Lagos, ALu 20/120 mcg)	n/a	n/a	N/A	0%	0%	15%	23%	**23%**
Nigeria Emzor Lagos, RUTF	n/a	n/a	N/A	10%	27.5%	27.5%	27.5%	**27.5%**
Nigeria Emzor Lagos, SP 500+25	n/a	n/a	N/A	0%	0%	22.5%	22.5%	**22.5%**
Nigeria Juhel, Oxytocin 10iu/mL	n/a	n/a	N/A	0%	55%	42.5%	50%	**50%**
Nigeria Juhel, Magnesium sulphate injection	n/a	n/a	N/A	0%	80%	80%	80%	**80%**
Nigeria DailyNeed Industries, Amoxicillin DT 250 mg	n/a	n/a	N/A	0%	0%	25%	25%	**25%**
Nigeria DailyNeed Industries, Amoxicillin DT 125 mg	n/a	n/a	N/A	0%	0%	25%	25%	**25%**
Nigeria Swiss Pharma, ALu 20/120 mcg	n/a	n/a	N/A	0%	0%	42.5%	42.5%	**42.5%**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Nigeria Swiss Pharma, Zincsulphate 20 mg	n/a	n/a	N/A	0%	25%	50%	65%	**65%**
Nigeria Swiss Pharma, SP 500+25	n/a	n/a	N/A	0%	0%	50%	65	**65%**
Nigeria May & Baker, ALu 20/120mcg	n/a	n/a	N/A	0%	0%	10%	10%	**10%**
Pakistan Covid-19-1, Ferozsons, Remdesivir	n/a	n/a	N/A	27.5%	27.5%	27.5%	27.5%	**27.5%**
Pakistan American Safety PowerTool (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	31.25%	**31.25%**
Pakistan AKC (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Pakistan Blitzkrieg Defense Solution (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Pakistan Chawla Enterprises (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Pakistan Fashion Villaz (ISO13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	31.25%	**31.25%**
Pakistan Maheen Textile Mills (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Pakistan Mundia Exports (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Pakistan Samad Rubber (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Pakistan Tecno Trend (ISO 13485 for PPE)	0%	n/a	N/A	N/A	N/A	N/A	25%	**25%**
Uzbekistan Nobel, 2FDC anti-TB	n/a	n/a	42.5%	25%	25%	25%	40%	**40%**

Achievement of market authorization or WHO prequalification for a new medical product is a long process with many stages. In PY2, PQM+ made considerable progress toward market authorization, WHO prequalification, or ISO 13485, with 26 manufacturers producing 12 priority medicines and PPE (2 malaria; 5 MNCH, 2 NTD, 2 TB; and 1 COVID-19 treatment plus PPE). PQM+ started working with manufacturers in Ghana and the COVID manufacturers in Pakistan this year. PQM+ and/or PQM started supporting the other manufacturers earlier. Because the milestones indicator was introduced at the beginning of PY2 and because it is not possible to reconstruct this complex indicator retroactively, the program cannot report the milestones' status for many previously supported manufacturers since the start of PY2.

Notes: (1) The process for achieving ISO 13485 (pursued by the PPE manufacturers) has many, but not all the same milestones as that for achieving market authorization or WHO PQ and is faster. (2) This is a relatively new indicator, first piloted with manufacturers in Nigeria. PQM+ teams are now beginning to track progress with all supported manufacturers. Milestone scores, therefore, are not available for many manufacturers from earlier time points.

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
OBJECTIVE 5: GLOBAL MEDICAL PRODUCT QUALITY ASSURANCE LEARNING AND OPERATIONAL AGENDA ADVANCED								
5.1. Evidence-based approaches and tools developed and/or applied								
5.1a. Number of new medical product quality assurance or regulatory tools with tested efficacy supported by PQM+, by quarter								
Bangladesh	0	8	1	3	1	0	2	**6**
Excel database of registered medical devices, online GMP training modules, inspection checklist for inspecting PPE manufacturing facilities, specifications and QC parameters for N95 and KN95 masks, COVID-19 medical product information sheets (multiple)								
Core MNCH	0	n/a	3	2	5	0	0	**7**
Amoxicillin lab and dossier aids in English & French; Chlorhexidine Gel 7.1% lab and dossier aids in English & French; Oxytocin Injection lab and dossier aids in English & French; *Guidance Document for Developing and Implementing a Risk-Based PMS for MNCH Products*								
Cross Bureau	0	0	N/A	0	0	1	1	**2**
MedRS online tool, SF medicine burden model tool (draft)								
Ghana	0	0	N/A	0	0	0	1	**1**
Tools for Vaccine Cohort Monitoring Team								
Total 5.1a				**5**	**6**	**1**	**4**	**16**
PQM+ develops new approaches and tools to improve medical product quality, enhance efficiency, or improve sustainability. In PY2, PQM+ rolled out 16 new tools. One such tool from the Core MNCH project, *Guidance Document for Developing and Implementing a Risk-based PMS for Maternal, Neonatal, and Child Health Products*, published in Q2 in English and French, was immediately used by Liberia's LMHRA to inform development of its plan for risk-based PMS of MNCH products. Since then, counterparts in 4 other countries have used the document to plan PMS (see 5.1b.4). Several of the COVID-19 buy-ins developed tools for immediate use in their countries as they deal with COVID-19 and for repurposing in other countries. Also, in PY2, several tools for global application moved forward in their development: the MedRS online tool and a tool to estimate the burden of use of substandard and falsified medicines (to be piloted in PY3).								
5.1b.1. Number of PQM+-supported entities that adopted SATTA during the year								
Benin NQCL	0	n/a	1	0	0	0	1	**1**
Burkina Faso NQCL	0	n/a	1	0	0	0	1	**1**
Ethiopia NQCL	0	0	1	1	0	0	3	**4**
Guinea LNCQM	0	n/a	1	n/a	0	0	1	**1**
Liberia LMHRA QCL	0	n/a	1	0	0	1	0	**1**
Total 5.1b.1				**1**	**0**	**1**	**6**	**8**
Eight PQM+-supported laboratories adopted the SATTA tool in PY2. That includes 4 of Ethiopia's EFDA's branch labs (Northwest, Bahirdar, Diredawa, and Jimma). Training in the use of SATTA is part of PQM+'s lab strengthening strategy. Adoption of the tool will help laboratory staff conduct internal, routine audits to identify areas for improvement.								

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
5.1b.2. Number of PQM+-supported entities that adopted MedRS during the year								
Burkina Faso	0	n/a	2	0	0	0	1	**1**
DRC	0	n/a	1	n/a	0	0	1	**1**
Ethiopia	0	0	1	0	0	0	1	**1**
Ghana	0	n/a	2	0	0	1	0	**1**
Guinea	0	n/a	1	n/a	0	0	1	**1**
Kenya	0	0	2	0	0	1	0	**1**
Liberia	0	n/a	1	0	0	1	0	**1**
Mali	0	n/a	1	0	0	1	0	**1**
Mozambique	0	n/a	1	0	0	0	1	**1**
Senegal	0	0	1	0	0	0	1	**1**
Total 5.1b.2				**0**	**0**	**4**	**6**	**10**
The MedRS tool is one of the keys to PQM+'s RB-PMS approach. It helps MRAs and TWGs develop risk-based sampling strategies to support national PMS while maximizing available resources. Adoption of the tool in 10 countries will help ensure effective and efficient PMS in those countries. PQM+ offers an online version of the tool (MedRSv2). So far, nine countries have subscribed to the online tool, four of which have used it, with PQM+ support, to develop PMS protocols.								
5.1b.3. Number of PQM+-supported entities that adopted GMP online training modules during the year								
Bangladesh	0	0	2	0	0	0	2	**2**
Kenya	0	0	1	0	0	0	1	**1**
Total 5.1b.3				**0**	**0**	**0**	**3**	**3**
Kenya's PPB plans to adopt all 10 modules of USP's GMP course. In Q4, it began including the GMP's foundational training module in its online learning platform. In Bangladesh, the pharmaceutical company EDCL as well as the private lab Plasma Plus also adopted GMP online modules in Q4.								
5.1b.4. Number of PQM+-supported entities that used *Guidance Document for Developing and Implementing a Risk-Based PMS for MNCH Products* during the year								
Bangladesh	0	0	No target	n/a	n/a	0	1	**1**
Ethiopia	0	n/a	No target	n/a	n/a	1	0	**1**
Ghana	0	n/a	No target	n/a	n/a	0	6	**6**
Kenya	0	0	No target	n/a	n/a	0	4	**4**
Liberia	0	n/a	No target	n/a	n/a	1	0	**1**
Total 5.1b.4				**n/a**	**n/a**	**2**	**11**	**13**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
The *Guidance Document* (which was published in PY2 Q2) has been used by MRAs in all the above countries, as well as Kenya's QC laboratory, Kenya's Division of Family Health at the Ministry of Health, and a procurement agent in Kenya. In Ghana, it has been used by the National Health Insurance Authority; national malaria, TB, and AIDS control programs; as well as the MRA and pharmacy staff.								
5.1b.Bang-1. Number of PQM+-supported entities that used database of registered medical devices during the year								
Bangladesh	0	0	1	0	0	0	1	**1**
Total 5.1b.Bang-1				**0**	**0**	**0**	**1**	**1**
Bangladesh's DGDA utilized the database in Q4.								
5.2. Research and analysis to support medical product quality assurance systems strengthening conducted								
5.2a. Number of technical publications or technical presentations authored by PQM+, by quarter								
Bangladesh	0	2	3	0	3 pres.	1 pres.	2 pres.	**6**
Burkina Faso	0	n/a	2	0	1 pub.	0	0	**1**
Burma	0	0	5	1 pres.	-	0	0	**1**
Ethiopia	0	1	2	2 pub.	2 pres.	0	0	**4**
Core MNCH	0	n/a	0	0	0	1 pres.	0	**1**
Core TB	0	n/a	4	0	1 pub.	0	0	**1**
Cross Bureau	0	0	No target	0	0	1 pres.	1 pub., 1 pres.	**3**
Kazakhstan	0	4	1	0	1 pres.	1 pres.	1 pres.	**3**
Kenya	0	0	2	2 pres.	0	0	3 pres.	**5**
Liberia	0	n/a	2	0	1 pub.	1 pub.	0	**2**
Pakistan	0	N/A	N/A	1 pres.	1 pres.	0	1 pres., 1 pub.	**4**
Uzbekistan	0	0	1	1 pres.	0	0	0	**1**
Total 5.2a				**7**	**10**	**5**	**10**	**32**
PQM+ conducted 24 conference and workshop presentations and produced 8 new technical reports during the year. Of note in Q3 was a technical publication on QAS20-864 guidance on the shelf life for the supply and procurement of emergency health kits (Cross Bureau).								
5.2e. Number of modules in the Foundations of GMP eLearning course that were completed, by quarter								
Core NTD	4,000	n/a	2,700+	760	1,043	509	1,157	**3,469**
Users completed over 3,400 USP online GMP training modules (more than 1,600 in Q3 and Q4) in PY2. Of all PQM+-supported countries, Pakistan has the most users.								

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
5.3. Advocacy on the importance of medical product quality assurance for public health, including the link between medical product quality and AMR								
5.3a. Number of awareness raising or advocacy events around medical product quality supported by PQM+, by quarter								
Bangladesh	0	0	N/A	0	1	0	2	**3**
GXP training for the state-owned company EDCL and its staff to build awareness, seminar on NQAG and RB-PMS for medicinal products, public dissemination of NQAG guideline								
Core MNCH	0	n/a	1	0	0	1	0	**1**
Workshop for USAID's global staff on QA of medical devices								
Cross Bureau	0	0	N/A	1	0	2	0	**3**
Virtual sessions on RQAS and how they impact health programs, strengthening NQCLs to ensure quality medical products, and EUA for timely and safe access to medical products during health emergencies								
Ethiopia	0	0	N/A	0	0	0	1	**1**
Ethiopian Pharmaceutical Association 41st annual conference-presentation on pharmaceutical sector regulation during Covid-19								
Kazakhstan	0	1	1	0	0	1	0	**1**
Webinar on GMP distant assessment of manufacturers-Sharing NCEM's experience								
Uzbekistan	0	0	N/A	0	1	1	2	**4**
World TB Day, International TB Conference, remote inspection advocacy event, USAID visit to Nobel Pharmsanoat								
Total 5.3a				**1**	**2**	**5**	**5**	**13**
5.3b. Number of instances of media coverage of PQM+-supported medical product quality assurance-related events or topics, by quarter								
Bangladesh–social & digital/print media, TV news, newsletter	0	4	No target	5	5	1	2	**13**
Burkina Faso–digital & social media, newsletter, events	0	n/a	No target	0	8	1	0	**9**
Burma–social media, newsletter	0	5	1	2	0	1	1	**4**
Core MNCH–social media, newsletter	0	0	No target	0	0	3	0	**3**
Core NTD–digital & social media	0	n/a	No target	0	0	3	0	**3**
Core TB–social media, newsletter	0	n/a	No target	0	0	2	3	**5**
Ethiopia–social media, webinar, newsletter	0	0	No target	1	2	3	0	**6**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Ghana–digitial media	0	0	No target	0	0	2	0	**2**
Kazakhstan–social media, newsletter, webinar, success story	0	1	2	0	1	5	2	**8**
Kenya–social & digital media, webinar, newsletter, fact sheet	0	1	1	1	0	1	5	**7**
Liberia–social & digital media, success story, newsletter	0	n/a	1	1	1	1	5	**8**
Mali–social media, video, newsletter	0	0	No target	0	0	1	2	**3**
Mozambique–social media, newsletter, webinar	0	n/a	No target	1	0	2	0	**3**
Nepal–social media, newsletter, webinar	0	4	1	4	4	6	5	**19**
Nigeria–social media, TV show	0	0	No target	0	0	4	1	**5**
Pakistan–social, digital, & print media,	0	1	16	16	6	5	4	**31**
Senegal–social media	0	0	No target	0	0	1	0	**1**
Uzbekistan–social media, video, TV show, webinar	0	0	4	1	3	3	2	**9**
Total 5.3b				**32**	**30**	**45**	**32**	**139**
STIR-10. Number of innovations supported through USG assistance (Nepal indicator), by quarter								
Nepal	0	0	3	0	0	3	0	**3**
In Q3, PQM+ began implementing the RB-PMS approach in Nepal; worked with the DDA on institutionalizing risk-based inspection; and started developing a roadmap for ISO 17025 accreditation for the NML.								
CBLD-9. Number of USG-assisted organizations with improved performance during the year								
Nepal	0	0	N/A	0	0	0	3	**3**
PQM+ has improved the performance of the DDA, NML, and Nepal Ausadhi Ltd.								
CORE-FLEX PARTNERSHIPS								
CC.CF.a. Core-FLEX partner score on participating in studies, technical assistance activities, or training events during the year								
Asia Bureau - Mahidol University, landscape analysis of the medical product quality assurance systems for SEARN and ASEAN member countries						2	2	**2**

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
Core MNCH – MUHAS, landscape analysis of amoxicillin DT manufacturing in Africa						2	2	**2**
Kenya – Ecumenical Pharmaceutical network (EPN), organized/co-hosted webinar on medicines' quality						2		**2**
PQM+ engages core-FLEX partners in technical activities. The Core-FLEX partner's role is scored as "1" if the partner *supported* PQM+ on studies, technical assistance activities, or training events and "2" if the partner *led* the work. In Q3 and Q4, both Mahidol University and MUHAS are conducting landscape analyses of medical product quality assurance systems in Asia and amoxicillin DT manufacturing in Africa. In Kenya, EPN organized and held a webinar on the quality of medicines in Q3.								
External Partnerships								
CC.PPP.a. Number of external partnerships that PQM+ helped establish during the year; and CC.PPP.b. Outcomes of interest								
Bangladesh	0	0	1	0	0	1	0	**1**
In Q3, PQM+ gave advanced GMP training to staff at Independent University's Plasma Plus Research & Testing Lab. PQM+ is building the lab's capacity to be a potential partner for NCL and DGDA.								
Core TB	0	0	N/A	0	0	0	1	**1**
In Q4, PQM+ and the U.S. FDA organized and conducted a joint webinar for targeted PQM+ countries on topics related to the regulatory review of bedaquiline and pretomanid.								
Ethiopia	0	1	8	0	0	0	1	**1**
In collaboration with the Pharmaceutical Manufacturers' Association (a partnership established in PY1) and other stakeholders, PQM+ completed the assessment of challenges facing pharmaceutical manufacturers. The assessment was shared with association members for feedback. In Q4, Ethiopia's Covid-19 Scientific Advisory Council, a PQM+ partner, gave advisory support to the Ministry of Health on the prevention and treatment of Covid-19.								
Ghana	0	n/a	3	0	4	0	0	**4**
In Q4, PQM+ established partnerships with 4 manufacturers–Entrance Pharmaceuticals, to manufacture Alu 20/120 mcg; Atlantic Life Science Pharmaceutical, to manufacture oxytocin; Amponsah Efah, to manufacture ACT; and Ernest Chemists, to manufacture ACT and oxytocin.								
Kenya	0	0	2	0	0	1	1	**2**
PQM+ established a partnership with the Association of Kenya Insurers in Q3 (no outcomes as yet) and with the Federation of Kenya Pharmaceutical Manufacturers in Q4. The program is providing TA/training to the latter.								
Nigeria	0	0	No target	2	2	0	0	**2**
PQM+ is collaborating with the Pharmaceutical Society of Nigeria and the Association of Community Pharmacists of Nigeria to improve the quality of medicines sold to the public in three states. PQM+ also facilitated linkages between two manufacturers (Emzor and Swipha) and two state governments (Zamfara and Sokoto states, respectively) for the supply of essential drugs for their Drug Revolving Fund Schemes. This latter activity was done in collaboration with the USAID-funded GHSC-PSM activity implemented by Chemonics.								
Pakistan	0	0	2	0	5			**5**
Pfizer Pakistan (pharmaceutical manufacturer). Trained NQCL staff on standards and analytical techniques for azithromicin.								

Indicator Code and Name	Baseline	PY1 Total	PY2 Target	Q1	Q2	Q3	Q4	PY2 Total
US-based diagnostic manufacturer provided training on Dossier Assessment of IVD Medical Devices								
Asia Pacific Medical Technology Association (APACMed) helped provide the "COVID-19 In-Vitro Diagnostic Technologies and Good Laboratory Practices (GLP)" training								
Ferozsons (manufacturer of remdesivir). Private sector investment; Ferozsons ordered a large-capacity lyophilizer; trained NQCL staff on standards and analytical techniques for remdesivir); and started earning foreign exchange for Pakistan (through export of remdesivir to Indonesia).								
AKC (manufacturer of PPE). Through engagement with PQM+, AKC is now earning foreign exchange for Pakistan by exporting KN95 and surgical masks to the United States and Spain.								
Adsell (manufacturer of PPE). This private sector engagement leveraged private investment in HVAC and other changes to the facility so it could manufacture PPE.								
Titi lab (private testing lab). The Titi lab purchased equipment for PPE testing contract (leverage of private investment) and created new jobs in Pakistan from the testing contract it then was able to secure with Honeywell. Also, PQM+ policy work that allowed manufacturers to outsource testing of their product in Pakistan opened the way for Titi to provide those services, which opened the way for Pakistani manufacturers to start producing quality-assured PPE for sale in Pakistan, Spain, the United States, and many other markets.								
Total CC.PPP.a				**0**	**11**	**2**	**3**	**16**

Annex 1A. Mission and Directed Core Buy-Ins by PQM+ Indicator

Mission and Directed Core Buy-Ins by PQM+ Indicator					
1a	1.4a	2.1d	2.2a	2.2c.4	2.2h
Bangladesh	Benin	Bangladesh	Benin	Burma	Bangladesh
Ethiopia	Burkina Faso	Burma	Burkina Faso	Kazakhstan	Burkina Faso
Guinea	DRC	Ethiopia	Ethiopia	Liberia	Ethiopia
Liberia	Ghana	Rwanda	Guinea	Rwanda	Guinea
Nepal	Guinea		Liberia	Uzbekistan	Kazakhstan
Rwanda	Kenya	2.1g	Mali		Liberia
	Liberia	Guinea	Mozambique	2.2c.5	Madagascar
1.1a	Mali	Kazakhstan	Nepal	Bangladesh	Mali
Bangladesh	Mozambique	Liberia	Rwanda	Benin	Mozambique
Burkina Faso	Nigeria	Uzbekistan		Burma	Nepal
Ethiopia	Rwanda		2.2b.1	Guinea	Nigeria
Guinea	Senegal	2.1i	Bangladesh	Kazakhstan	Pakistan
Kazakhstan		Bangladesh	Burma	Liberia	Uzbekistan
Kenya	2a	Kazakhstan	Ethiopia	Mali	
Liberia	Bangladesh	Uzbekistan	Nigeria	Rwanda	2.2i
Mali	Burkina Faso		Pakistan	Uzbekistan	Bangladesh
Mozambique	DRC	2.1j	Uzbekistan		Benin
Nepal	Ethiopia	Bangladesh		2.2c.6	Burkina Faso
Nigeria	Ghana		2.2c.1	Bangladesh	Burma
Pakistan	Guinea	2.1k	Burma	Burma	DRC
Rwanda	Kenya	Bangladesh	Kazakhstan	Guinea	Ethiopia
Senegal	Liberia	Benin	Liberia	Kazakhstan	Ghana
Uzbekistan	Mali	Burkina Faso		Liberia	Guinea
	Nepal	Burma	2.2c.2	Uzbekistan	Kazakhstan
1.2c.1 - 1.2c.3	Rwanda	DRC	Burma		Kenya
Kazakhstan	Senegal	Ethiopia	Kazakhstan	2.2f.1	Liberia
Uzbekistan		Ghana	Liberia	DRC	Madagascar
	2b.2 - 2b.5	Guinea	Madagascar	Ethiopia	Mali
1.2c.4	Rwanda	Kazakhstan	Mali	Rwanda	Mozambique
Bangladesh		Kenya	Rwanda		Nepal
Burkina Faso	2.1a	Liberia	Senegal	2.2g	Nigeria
DRC	Bangladesh	Madagascar	Uzbekistan	Bangladesh	Pakistan
Ethiopia	Ethiopia	Mali		Burma	Rwanda
Ghana	Kazakhstan	Mozambique	2.2c.3	Ethiopia	Senegal
Guinea	Pakistan	Nepal	Bangladesh	Kazakhstan	Uzbekistan
Kenya	Rwanda	Nigeria	Burma	Mozambique	
Liberia		Pakistan	Kazakhstan	Nepal	2.3a
Mali	2.1b.1	Rwanda	Liberia	Nigeria	Bangladesh
Senegal	Uzbekistan	Senegal	Mali	Rwanda	Rwanda
		Uzbekistan	Rwanda		Uzbekistan
1.3a	2.1b.4		Senegal		
Burkina Faso	Bangladesh		Uzbekistan		2.3c.1
Guinea					Bangladesh
Mali					Liberia
					Uzbekistan

Mission and Directed Core Buy-Ins by PQM+ Indicator

2.4b
Pakistan

2.5a/2.5b
Asia Bureau
Bangladesh
Benin
Burkina Faso
Burma
DRC
Ethiopia
Ghana
Guinea
Kazakhstan
Kenya
Liberia
Madagascar
Mali
Mozambique
Nepal
Nigeria
Pakistan
Rwanda
Senegal
Uzbekistan

2.5c
Burma
Kazakhstan
Kenya
Mali
Mozambique
Rwanda
Uzbekistan

2.5d.1, 2.5d.3, 2.5d.4
Nepal

2.5d.2
Liberia
Madagascar
Nepal
Rwanda

2.5e.1, 2.5e.3
Kenya

2.5e.2
Kenya
Madagascar
Mozambique
Rwanda

2.5e.4
Kenya
Mali

2.5f
Bangladesh
Kenya
Nigeria

3.1a.1
Rwanda

3.1a.2
Kazakhstan
Nepal
Rwanda
Uzbekistan

3.1a.3
Bangladesh
Burkina Faso
DRC
Ethiopia
Ghana
Guinea
Kazakhstan
Kenya
Liberia
Mali
Nepal
Rwanda
Senegal

3.1b.1
Ethiopia
Guinea

3.1b.2
Rwanda

3.1b.3
Mali
Rwanda
Senegal

3.2b.1
Liberia

3.2b.3
Rwanda

3.2b.4
Ethiopia
Guinea
Rwanda

3.2b.5
Bangladesh
Ethiopia
Kenya
Liberia
Mali
Rwanda

4a
Nigeria

4c
Core NTD
Core TB
Nepal
Nigeria
Pakistan

4.1a.7
Rwanda

4.1b
Bangladesh
Core NTD
Core TB
Nigeria

4.1c
Core NTD
Core TB
BangladeshGhana

Nepal
Nigeria
Pakistan Covid-19
Uzbekistan

4.1d
Rwanda

4.3a
Core MNCH
Core NTD
Ghana
Nepal

4.4a
Kenya
Rwanda

5.1a
Asia Bureau
Bangladesh
Bangladesh Covid-19

Core MNCH
Core NTD
Cross Bureau
Kenya
Mali
Mozambique
Nigeria
Pakistan
Rwanda

5.1b.1
Benin
Burkina Faso
DRC
Ethiopia
Guinea
Liberia
Madagascar
Mali
Mozambique
Nepal
Rwanda

5.1b.2
Bangladesh
Benin
Burkina Faso
DRC
Ethiopia
Ghana
Guinea
Kazakhstan
Kenya
Liberia
Madagascar
Mali
Nepal
Pakistan
Rwanda
Senegal

5.1b.3
Bangladesh
Ethiopia
Kenya
Nepal
Nigeria
Pakistan
Uzbekistan

5.1b.4
Bangladesh
Ethiopia
Ghana
Guinea
Kenya
Liberia
Mali
Nepal
Nigeria
Pakistan

5.2a
Asia Bureau
Bangladesh
Benin
Burkina Faso
Burma
Core MNCH
Core NTD
Core TB
Cross Bureau
Ethiopia
Ghana
Kazakhstan
Kenya
Liberia
Mali
Nepal
Nigeria
Pakistan
Rwanda
Senegal
Uzbekistan

5.2e
Core NTD

5.3a
Bangladesh
Core MNCH
Cross Bureau
DRC
Ethiopia
Ghana
Kazakhstan
Uzbekistan

5.3b Bangladesh Benin Burkina Faso Burma Core MNCH Core NTD Cross Bureau DRC Ethiopia Ghana Guinea Kazakhstan Kenya Liberia Madagascar Mali Mozambique Nepal Nigeria Pakistan Rwanda Senegal Uzbekistan	5.3c Cross Bureau STIR-10 Nepal CBLD-9 Nepal Nigeria	CC.CF.a Asia Bureau Kenya Core MNCH Core NTD Core TB Cross Bureau CC.CF.c Cross Bureau	CC.PPP.a/b Bangladesh Core MNCH Core NTD Core TB Cross Bureau Ethiopia Ghana Kenya Nigeria Pakistan Pakistan Covid-19 Rwanda Uzbekistan		

Annex 1B. Start Dates by PQM+ Funding, Including for Covid-19

		PY1 (October 2019 through September 2020)				PY2 (October 2020 through September 2021)			
Buy-Ins		**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Burma	27-Sep								
Cross Bureau	27-Sep								
Kazakhstan	27-Sep								
Uzbekistan	27-Sep								
Nepal		1-Oct							
Bangladesh		1-Dec							
Kenya			1-Jan						
Nigeria			1-Jan						
Pakistan			1-Jan						
Senegal			1-Mar						
Mali			1-Jan						
Core MNCH				1-Apr					
Ethiopia				1-Apr					
Bangladesh Covid-19				10-Jun					
Mozambique					1-Jul				
Pakistan Covid-19-1					1-Jul				
Core NTD					1-Aug				
Burkina Faso					15-Aug				
Ghana					15-Aug				
Benin					1-Sep				
Asia Bureau						1-Oct			
Core TB						1-Oct			
Liberia						1-Oct			
Serbia Covid-19						1-Oct		Ended 4/30	
Guinea							1-Jan		
Cross Bureau Covid-19							1-Feb		
DRC							1-Mar		
Madagascar							1-Mar		
Bangladesh COVID-19 Vaccine								1-Apr	
Ghana COVID-19 Vaccine								1-Apr	
Pakistan COVID-19 Vaccine								1-May	
Uzbekistan COVID-19 Vaccine								1-Apr	
Rwanda (PY2/PY3 work plan)								1-May	