Promoting the
QUALITY OF MEDICINES Plus

PQM+ Quarterly Report – Program Year 3, Quarter 2

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About PQM+

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

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Contents

Acronyms

4FDC	four-drug, fixed-dose combination
AEFI	adverse events following immunization
AMR	antimicrobial resistance
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	WHO Global Benchmarking Tool for evaluation of national regulatory systems
GMP	Good Manufacturing Practice
HPLC	high-performance liquid chromatography
HR	human resources
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission
LIF	laboratory information file
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

MSP	model strategic plan
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
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
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 Director

As PQM+ concludes Program Year 3 second quarter implementation and officially reached the midpoint of the five year program, this report demonstrates how countries and institutions have continued to leverage our program's technical support to sustainably strengthen their regulatory systems, expanding access to quality-assured medicines at the national and international levels over the years. Increasingly, the pandemic era underscores how critical strong and effective regulatory systems are in ensuring the quality, safety, and efficacy of medical products. In response to the increase in global initiatives aiming to accelerate COVID-19 vaccine manufacturing in lower-middle-income countries (LMICs), we have expanded our technical assistance beyond medicines and devices to include the strengthening of capacity for vaccine regulation and manufacturing. Our program supports COVID-19 prevention and response work in seven countries, all engaged in regulatory system strengthening activities; lab strengthening activities in five countries; and governance work in four countries.

PQM+ countries' work toward achieving WHO Maturity Level 3 demonstrates that a stable, well-functioning, and integrated regulatory system is in place. A key example is Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) recent achievement of Maturity Level 3, as affirmed by WHO. Since the beginning of the predecessor PQM program in 2009", our Nigeria team has partnered with NAFDAC on its journey that now boasts four ISO/IEC 17025-accredited drug laboratories in its Laboratory Services Directorate. One of these labs is ISO/IEC 17025 accredited for biologicals and rapid diagnostics testing. In this COVID-19 era, efforts to further expand the laboratory capacity will pave the way for timelier access to critically needed vaccines and biological products in Nigeria. An equally exciting highlight from Nigeria is the Pharmacists Council of Nigeria's (PCN) recent attainment of ISO 9001:2015 accreditation. In 2021, PQM+ partnered with PCN to build the capacity of community retail pharmacies in proper medicine handling and encourage registration of these outlets to ensure proper integration into the health care community. Bringing PQM+'s work closer to the patients and the frontlines of medicine delivery speaks directly to our mandate of strengthening health systems at all levels and more broadly aligns with USAID's Vision for Health System Strengthening 2030 goals of equity, quality, and resource optimization.

This report also highlights PQM+'s key role in Uzbekistan's pharmaceutical sector development. In March 2022, PQM+ and the American-Uzbekistan Chamber of Commerce hosted the inaugural U.S.-Uzbek Pharmaceutical Summit, in Rockville, MD, which aims to catalyze American pharmaceutical partnership, collaboration, and investment opportunities in the country. PQM+ is honored to partner with Uzbekistan in applying a multifaceted approach to developing its pharmaceutical sector, including through economic incentives, strengthening regulatory systems, and building workforce capabilities.

PQM+ remains dedicated to its goal of strengthening quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health. There is still work to be done, so we are eager to continue to build on these accomplishments. It is a great honor to do the work we do, and to have the opportunity to collaborate with committed partners at the global, regional, and local levels. Please continue to follow our progress.

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

Executive Summary

As of the second quarter of Program Year 3, the Promoting the Quality of Medicines Plus (PQM+) program is implementing 35 work plans, of which three are core-funded activities specifically supporting the offices of neglected tropical diseases (NTDs), tuberculosis (TB), maternal and child health (MCH). A fourth "cross-bureau" funding stream supports the Office of Health Systems. The remaining 31 work plans are Mission buy-ins implemented in 21 countries and the Asia Bureau, including nine COVID-19 work plans active in Q2. The goal from these activities is to sustainably strengthen medical product quality assurance (QA) systems in low- and middle-income countries (LMICs). PQM+ helps ensure access to quality-assured essential medicines for HIV/AIDS, TB, malaria, NTD, COVID-19, and other infectious diseases, as well as for MCH.

This report summarizes activities during Quarter 2 (January 1 to March 31, 2022) 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).

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. PQM+ supports national pharmaceutical QA systems through the adoption of sound policies, the development of strategic QA plans, and by implementing coordination mechanisms that promote efficiency, accountability, transparency, and partners' coordination. Through this process, stakeholders become more effective in ensuring the quality and safety of medical products, increase public trust, and free up valuable resources to expand health service coverage to their populations.

During this quarter, PQM+ engaged in governance-strengthening technical assistance in 10 countries. Our participation spanned numerous areas: 1) strategic plan drafting/development

and review (including in **Nigeria**, **Kazakhstan**, **Uzbekistan**, and **Nepal**); 2) establishing systems to promote transparency and collaboration between key stakeholders (notably in **Guinea**, **Kenya**, **Liberia**, **Nigeria,** and **Mozambique**); and 3) continued support for policy and regulatory framework implementation (such as our achievements in **Pakistan**).

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. As of the second quarter, we supported 20 countries to address eight regulatory functional areas, totaling 90 institutional development activities.

Regulatory agencies need sufficient capacity to apply tools to inspect pharmaceutical manufacturing facilities to ensure they follow Good Manufacturing Practices (GMP) and to grant market authorization. This capacity is critical to an agency's inspection function. Similarly, national medical regulatory authorities (NMRAs) need to be able to inspect and monitor the quality of medical products throughout the supply chain, from manufacture to delivery, to minimize the circulation of substandard or falsified medicines or degraded medical products. PQM+ continued its development of the **online risk-based inspection (RBI) tool, and the RBI guidance document.** These are intended to support key regulatory activities during GMP and Good Distribution Practices (GDP) inspections. An expert advisory group provided further inputs on the scope of the tool and its guidance document. Based on that feedback, PQM+ revised both. The new RBI tool should reduce costs associated with planning, scheduling, execution, reporting, and follow-up actions, which will increase inspection efficiency and effectiveness.

To ensure that medical product quality is maintained throughout the system and until it reaches the patient, NMRAs must establish adequate post-marketing surveillance (PMS) programs to monitor medicines quality. Using risk-based methods can significantly reduce both sampling and testing costs. We are supporting **risk-based post-marketing surveillance (RB-PMS)** of medical products in 18 countries: **Bangladesh, Benin, Burkina Faso, DRC, Ethiopia, Ghana, Guinea, Kazakhstan, Kenya, Liberia, Madagascar, Mali, Mozambique, Nepal, Nigeria, Rwanda, Senegal,** and **Uzbekistan**. Each one is making progress in building and/or strengthening their PMS programs. For example, PQM+ supported the Ghana FDA in disseminating results of its first RB-PMS of antimalarials and MNCH medicines, which reflects the organizations' commitment to using this advanced approach to optimize health resources.

Establishing guidelines for evaluating each lot of a licensed vaccine before allowing its release to the market, known as "lot release," helps manufacturers and regulators assure the quality, efficacy, and safety of vaccines before their administration to patients. In **Bangladesh**, PQM+ collaborated with the National Control Laboratory (NCL) of the Directorate General of Drug Administration (DGDA) in developing the "Vaccines Lot Release Guideline in Bangladesh," posting the document on the DGDA's website for public opinion, and disseminating it to relevant stakeholders for feedback.

This quarter, PQM+ also helped strengthen the regulatory system in **Uzbekistan** through our promotion of **emergency use authorization (EUA)**, leading to the mechanism's inclusion in an updated draft of a Cabinet resolution. PQM+ reviewed the EUA provisions of the resolution and provided feedback for improvement toward its approval by the Agency on Development of the Pharmaceutical Industry. Similarly, the program supported the DGDA in **Bangladesh** to implement appropriate mechanisms for using the WHO Collaborative Procedure for Accelerated Registration (CPAR).

Also, supporting **registration/market authorization**, PQM+ provided technical assistance to the **Liberia** Medicines and Health Products Regulatory Authority (LMHRA) to expediate and clear its backlog of 52 dossiers on antimalarial medicines. This will allow new antimalarials to reach the market, improving product availability and reducing product costs. These improvements should in turn contribute to the reduction of malaria mortality and morbidity.

National quality control laboratories (NQCLs) play a critical function in the regulatory quality assurance system. Accurate, reliable testing results inform decision-making across multiple areas, from market authorization to investigating product complaints. Our support to NQCLs aims to assist their implementation of processes that allow them to meet international standards for testing medicines quality. During Q2, PQM+ provided support and system strengthening activities to NQCLs in 19 countries (12 in **Africa**, four in **Asia**, and three in **Central Asia**) as well as two private laboratories. Activities included guided supervision of quality management system (QMS) document development, trainings, and support for pre-assessments by two countries' regional accreditation bodies. PQM+ also guided **Mali's** Medicines Quality Control Laboratory (LCQM) to implement corrective actions, such as preparations for its preliminary audit in March by a West African accreditation body. The next step is an official accreditation visit. This quarter, our teams in **Bangladesh** and **Burkina Faso** actively assisted their NQCLs in drafting and reviewing their strategic plans.

Optimize financial resources for QA systems. This quarter, PQM+ worked with quality control laboratories in two countries to establish a fee-for-service structure. The goal is to ensure the adequate financing of national laboratory operations and help to ensure the labs' sustainability. In **Guinea**, we trained NQCL staff on the use of a new laboratory tests costing tool that takes into consideration key drivers to arrive at realistic testing fees that could help to finance the lab's operations. In **Kenya**, we helped rationalize fees for testing services to help cover the costs of conducting quality testing of antimalarial, reproductive, and MNCH products.

Supply. This quarter, PQM+ supported 22 manufacturers in 10 countries, including three new manufacturers, located in **Burma, Liberia,** and **South Africa**. Figure 2 lists the medical products that PQM+ supports to improve their manufacturing process. We had significant achievements with collaborative registration process (CRP) registrations, expressions of interest (EOIs), and product dossier submissions. At the end of March, we hosted a delegation from **Uzbekistan** to meet with U.S. pharmaceutical manufacturers with the goal of bolstering the Uzbek pharmaceutical industry. We solicited or evaluated manufacturers using EOIs for **Ethiopia, Ghana, Nepal,** and for the **Core NTD** portfolio. PQM+ is also supporting country efforts to prepare 14 dossiers for WHO submission in **Nigeria, Bangladesh, Pakistan, Uzbekistan,** and for the **Core NTD** and **Core TB** programs. With PQM+ backing, a manufacturer in **Burma** is seeking national regulatory authority (NRA) product approval.

Figure 2. Medical Products Supported by PQM+

Malaria
Artemether lumefantrine
Chloroquine
Sulfadoxine pyrimethamine
TB
4FDC
Isoniazid API
Levofloxacin
NTD
Albendazole
Praziquantel

MNCH
Amoxicillin
Azithromycin
Magnesium sulfate
Oxytocin
Ready-to-use-therapeutic foods
Zinc
Zinc sulfate
Zinc sulfate with ORS

The efforts of PQM+ and its predecessor, PQM, to increase supply of important medicines continues to pay off. To illustrate, during the Q2 period (from January 1 through March 31), manufacturers in Nigeria that had received PQM and PQM+ support in developing products that achieved market authorization produced the following treatments:

- Enough chlorhexidine gel to prevent 1.26 million umbilical cord infections in newborns;
- Enough amoxicillin dispersible tablets (amoxicillin DT) to treat 600,000 severe pneumonia infections in children ages 2 months to 1 year; and
- Enough co-trimoxazole to treat 75,000 opportunistic infections in children under 5 years who are living with HIV/AIDS.

PQM+ is collaborating with several countries to build their capacity to **manufacture medical products**. In **Ethiopia**, we developed a database template to capture data findings from prior GMP inspections conducted by the regulatory authority. This information will help to determine the future needs for manufacturer risk inspections and fulfill a requirement for meeting WHO Maturity Level 3; that is, regularly publishing inspection findings and making them publicly available. To assure quality in medicines procurement in **Nepal**, PQM+ completed an assessment of the process and is developing a standard procurement guideline. In **Kazakhstan**, PQM+ continues to help assess the greatest needs in the manufacturing sector and is developing targeted GMP trainings. In addition, we organized a knowledge and experience exchange between our teams in Kenya and Kazakhstan regarding the development and sustainability of an open-source learning management system. In **Bangladesh**, we conducted an organizational training needs assessment of a state-owned manufacturer to identify areas for capacity development.

To support the safe deployment of COVID-19 vaccines, PQM+ is working with countries to strengthen their adverse events following immunization (AEFI) systems. To date, PQM+ has assisted six countries (**Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan**, and **Uzbekistan**) to develop procedures, enhance information and adverse event reporting systems, strengthen active surveillance, and generate evidence to support regulatory actions. We continue to support the Drug Regulatory Authority of **Pakistan** (DRAP) to **strengthen surveillance** through COVID-19 vaccine vigilance reporting and AEFI and **establish QA linkages** through guidance documents/procedures for AEFI surveillance and vaccine vigilance. To this end, we are assisting DRAP in establishing a national vaccine vigilance committee to ensure review of and action on AEFI data, developing guidance documents for COVID-19

vaccine PMS for quality monitoring, and conducting capacity building activities for DRAP staff on guidance documents for AEFI and PMS and integrity of the supply chain.

Learning, Advocacy, and Awareness. In Q2, PQM+ worked to advance the use of evidence-based tools and approaches, as well as promote awareness, advocacy, and collaboration.

Evidence-Based Tools/Approaches. PQM+ has developed new tools and approaches that regulatory authorities or other stakeholders can adopt to better assure medical product quality. Use of such tools in the first half of PY3 includes:

- Seventeen countries subscribed to the RB-PMS tool to assist them in developing sampling plans for their post-marketing surveillance activities.
- Two regulatory authorities (**Ghana** and **Liberia**) reported using the "Guidance Document for Developing and Implementing a Risk-Based PMS for Maternal, Neonatal, and Child Health Products." Both identified significant issues with the quality of some MNCH products in their recent post-marketing surveillance.
- Users completed 627 modules from the eGMP course.
- Sixty participants from about 40 USAID Missions and USAID/Washington completed the PQM+ module on the role of quality assurance in pharmaceutical systems strengthening (PSS) for the PSS 101 course through USAID University. This marked the first time the training modality for this course was offered online.

In addition, we continued developing and enhancing the **NTD Medicines Information Dashboard (NTD|MID)** that will be available for governments, regulators, manufacturers, procurement agencies, suppliers, donor communities, and other interested parties planning for procurement, supply, and use of NTD medical products.

In the course of our product development work to produce the active pharmaceutical ingredient (API) for a priority TB product, PQM+ is seeking the opportunity to incorporate pharmaceutical continuous manufacturing as a platform. This will help to lower API production costs, remove nitrosamine impurities, improve efficiency, and reduce environmental impact. Our partner on this effort completed the laboratory phase of the development project, successfully identifying a synthesis route and demonstrating each step of the continuous manufacturing process for this important API.

PQM+ is working on several fronts to improve the availability of quality-assured MNCH medical devices. From an informal assessment in countries we support, our teams identified a dearth of information on how countries regulate and test medical devices. This finding will inform planning for future activities to strengthen regulation and testing of these devices.

Awareness, Advocacy, and Collaboration: PQM+ collaborated actively with our partners and globally to advance medical product quality assurance during Q2. Some important collaborations this quarter include working with:

- Newborn Essential Solutions and Technologies 360 (a program developing and delivering a bundle of high-quality products and services to reduce preventable neonatal deaths in sub-Saharan Africa).
- USAID-funded Medicines, Technologies, and Pharmaceutical Systems program (MTaPS) and Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) programs on consultative meetings that the Commodities Sub-group of the Child Health Task Force, which is co-chaired by UNICEF and USAID.

- Suppliers of data for the NTD|MID dashboard, including the U.S. Food and Drug Administration and the regulatory authority of Tanzania.

Operations. After fully remote work since March 2020, headquarters staff returned to USP's Rockville office one day a week and limited international travel resumed. Staff continued to use creative approaches to navigate the pandemic, using blends of in-person and remote technical assistance to achieve program goals. Examples of our remote work include a human resources (HR) assessment in **Madagascar,** which applied best practices in remote implementation, and a remote staffing needs assessments in **Liberia** and **Nepal**.

The accomplishments highlighted here are illustrative of the extensive work PQM+ performed during the second quarter of our third year. We invite you to read a more detailed accounting of our achievements in the report that follows.

Cross-Bureau Activities and Progress

PQM+ cross-bureau-funded activities primarily focused on raising awareness about the importance of medical product quality and developing new approaches to strengthen medicines regulatory functions. PQM+ cross-bureau activities funded by the Office of Health Systems 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.

Progress This Quarter

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

PQM+ is collaborating with the WHO to develop a model strategic plan for NMRAs to operationalize their institutional development plans derived from country Global Benchmarking Tool[1] (GBT) assessments. The model strategic plan, called the CIP Support Plan, is a critical component of the CIP Global RSS Network to guide and define roles and responsibilities of each CIP member in supporting and monitoring progress, milestones, and accomplishments to NMRAs based on its competencies, specific activities, expected outcomes, priorities, timelines, and identified available resources. This quarter, WHO and PQM+ agreed on the third version of the concept note, titled "Coalition of the Interested Parties (CIP) Support Plan Template." The CIP Support Plan Template aims to 1) ensure cohesion with the requirements set out in the CIP Global RSS Network terms of reference; 2) facilitate IDP implementation as supported by CIP members, and 3) contribute to the CIP Implementation Toolkit that WHO is developing to assist NRAs as they move forward with IDP implementation with support from CIP membership (for which USP, and by extension PQM+, has applied). Finalization of the toolkit is anticipated in Q3. On March 16, 2022, PQM+ participated in the kickoff meeting for CIP network members organized by WHO.

This quarter, USAID approved a collaboration activity between WHO and PQM+ to develop a model local production and health products security strategy to strengthen local manufacturing. This endeavor will help countries boost infrastructure for local production to supply essential medical products at the local and regional levels. PQM+ shared the concept note of the activity with WHO to secure their buy-in, leading an agreement on the major tasks to be completed under this activity.

Building on the last quarter's progress, PQM+ continued the development of a risk-based inspection (GMP and GDP) framework and tool this quarter. This framework will address the

[1] The GBT is a globally accepted assessment tool to rank a country's national medicine regulatory authority maturity level on a scale of 1 (lowest) to 4 (highest) and to undertake reforms following an institutional development plan (IDP) that involves country-led stakeholder/donor coordination. The GBT represents the primary means by which performance of regulatory systems across countries is objectively evaluated to determine their strength. For PQM+, aligning its support to meeting the GBT requirements provides assurance that the investments are ultimately tuned to creating a regulatory pathway that ensures the safety of patients.

key regulatory inspectorate activities in GMP and GDP inspections. This quarter, PQM+ extended the contract with the IT developer to add interim hosting, testing environment, and maintenance support as preparations are underway to transfer hosting support to USP IT. The basic functionalities of the tool were developed and shared with an expert advisory group on February 2 to seek inputs on the scope of the tool and the guidance document. The expert advisory group consists of global experts representing the Pharmaceutical Inspection Co-operation Scheme's (PIC/S) Quality Risk Management Committee, U.S. Food and Drug Administration, the U.K. Medicines and Health Care Products Regulatory Agency, Australia's Therapeutic Goods Administration, WHO, and selected NMRAs from Africa and Asia regions. Based on the feedback received, PQM+ revised the tool and the guidance document. The final version of the tool and guidance document will be ready by the end of next quarter.

PQM+ continues to collaborate with USAID's MTaPS program on the common minimum standards for regulatory information management system activity. This quarter, PQM+ and MTaPS held the third consultative meeting with the national medicine regulatory authorities (NMRAs). The purpose of this meeting was to share the selection criteria for identifying the common minimum standards for the regulatory information management system and solicit feedback. Sixty stakeholders from global and national programs participated in this meeting. PQM+ and MTaPS teams made proactive efforts to reach out to the NMRAs and stakeholders to seek feedback on the common minimum standards and on an advocacy brief to gain concurrence on standards selection with stakeholders and collaborating with WHO on standards review. The next consultative meeting is dependent on receiving complete feedback from the NMRAs and stakeholders and is tentatively slated for May 2022. PQM+ and MTaPS also finalized the third consultative meeting report and the advocacy brief that will accompany the final products from this activity.

Objective 3: Optimize and increase financial resources for medical product quality assurance

In program year 2, PQM+ worked with three academic partners (the University of Washington, University of North Carolina, and Harvard University) to develop a generalizable model for estimating the health and economic burden of substandard and falsified (SF) medicines to patients and the health system. PQM+ and our partners are piloting the model in Kenya and Pakistan this program year.

This quarter, PQM+ facilitated the Pilot Core Working Group meeting on January 6, 2022, and a larger working group meeting with key Kenya stakeholders to orient them on the model and the activity. The core Kenya team also began data collection. PQM+ and the University of Washington drafted and presented a PowerPoint orientation on the model and a frequently asked questions document for the larger working group.

PQM+ also began planning the Pakistan pilot and met the program's country team to orient them on the tool and the activity work plan on February 17, 2022. The orientation meeting identified a need to consider a different medicine class for the pilot as TB treatment follow-through is a bigger concern than quality of anti-TB medicines in country. .PQM+ is currently working on identifying the medicine class with the country team.

PQM+ refined the guidance document on the model, revising language around how users should handle data gaps in parameters and addressing several remaining comments from USAID.

The University of North Carolina finalized a journal article on the literature review of other models used to estimate the cost of SF medicines that it completed in PY2. PQM+ revised the university's contract to add the cost of publishing the journal article, "Modeling the Health and Economic Impact of Substandard and Falsified Medicines: A Review of Existing Models and Approaches," in the American Journal of Tropical Medicine and Hygiene.

Objective 5: Advance a global medical products QA learning and operational agenda

PQM+ collaborated with MTaPS to plan and deliver USAID's Pharmaceutical Systems Strengthening ("PSS 101") blended course titled "Virtual Pharmaceutical Systems Strengthening 101" for 67 participants from 40 Missions and various units within USAID's Global Health Bureau. PQM+ delivered a module on Medical Product Quality Assurance: Global and Country Perspectives on March 25. This one-week instructor-facilitated blended format course seeks to broaden USAID health personnel's knowledge of pharmaceutical systems, including regulation, pharmacy practices, financing and priority setting, appropriate use, and combating antimicrobial resistance.

Priority Activities for Next Quarter

In Q3, PQM+ plans to:

- Conduct an NMRA engagement meeting for the common minimum standards for the regulatory information management system activity.
- Revise and develop the content of the model strategic plan for IDP implementation.
- Conduct testing of the beta version of the risk-based inspection tool, incorporate changes, and complete the online version of the tool. Commence offline tool development.
- Conduct the following sub-activities for the SF modeling activity:
    - Complete orientation of the full pilot core group and the working group in Pakistan.
    - Support data collection process in Kenya and Pakistan as needed.
    - Revise the orientation materials to reflect lessons from Kenya.
    - Launch the pilot in Pakistan.
    - Complete the assessment approach and tool.

Activities and Progress by Country and Regional Buy-Ins

Africa Region

Benin

PQM+ works with Benin's main regulatory body, the Beninois Agency for Pharmaceutical Regulation, *l'Agence Béninoise de Régulation Pharmaceutique* (ABRP). 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 (NQCL), *l'Agence Nationale de Contrôle de la Qualité des Produits de Santé et de l'Eau* (ANCQ), collects and tests medicines at the points of entry into the country (land, sea, and air) and at the request of any national institution. PQM+ is helping ANCQ strengthen its QMS to achieve international recognition (ISO/IEC 17025 or WHO prequalification). This would improve the reliability of testing and increase the public's confidence in ANCQ test results.

Progress by PQM+ Objective

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

Following a training on the use of the Medicines Risk-based Surveillance (MedRS) tool and subsequent supportive supervision to draft an RB-PMS protocol in Q1, PQM+ worked with the Post-Marketing Surveillance Technical Working Group (PMS-TWG) to finalize the protocol and provide training on sampling strategies and on the final RB-PMS protocol. The training reached 13 samplers (nine men, four women).

PQM+ provided a refresher training on Good Laboratory Practices (GLP) for ANCQ staff to reinforce the importance of applying GLP in routine laboratory analysis. As part of implementing ANCQ's roadmap toward ISO/IEC 17025 accreditation, PQM+ trained 14 technical staff (seven men and seven women) on some advanced requirements of the ISO/IEC 17025 standard on measurement uncertainty.

To build the capacity of the analysts to conduct quality testing per compendial requirements and GLP, PQM+ trained ANCQ staff on the uniformity of dosage units, high-performance liquid chromatography (HPLC), dissolution testing, and ultraviolet visible (UV) spectrophotometry. Nine people (six male, three female) attended. This practical quality control (QC) training has strengthened the capacity of ANCQ's analysts to enable them to test the PMS samples (to be collected in Q3) as well as routine samples, per best laboratory practices and pharmacopeial requirements. In addition, their strengthened capacity will help them better demonstrate their competence during future accreditation audits.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Conduct sampling and screening of samples collected through the RB-PMS protocol.

Burkina Faso

A 2018 decree created the national pharmaceutical regulatory authority, *L'Agence Nationale de Régulation Pharmaceutique* (ANRP), to strengthen the regulatory framework of the pharmaceutical sector in Burkina Faso. The Directorate of Market Surveillance and Quality Control of Health Products at ANRP is the technical body in charge of QA and QC. ANRP collaborated with the Directorate for the Control of Drugs and Non-food Products (DCM/PNA) within the *Laboratoire National de Santé Publique* (LNSP) to conduct sampling of medical products. In 2021, with PQM+ support, LNSP and ANRP established an official collaborative framework.

PQM+ works with ANRP through the PMS-TWG to strengthen its market surveillance function. The program is also improving LNSP's QMS to conform with ISO/IEC 17025 standards and strengthening the capacity of technical analysts to conduct quality testing.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance systems

Throughout Q2, PQM+ supported the development of a five-year strategic plan for LNSP. PQM+ collaborated with facilitators from LNSP and a local firm recruited by the Ministry of Health (MOH) to convene a situational analysis workshop, where three groups consolidated information on managerial, technical, and social aspects for the strategic plan.

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

PQM+ supported ANRP, LNSP, and the national PMS-TWG to disseminate the results of the 2021 RB-PMS. The exercise found no failure among the 320 antimalaria samples (artesunate injection, artemether injection, quinine injection, and sulfadoxine/pyrimethamine tablets) collected from seven regions (Central, Central-East, Central-North, East, Haut-Bassins, North, and Plateau Central). However, 68 percent of the medicines collected were unregistered. ANRP will investigate the source of the unregistered medicines to learn how they reached the market, helping the agency determine the appropriate regulatory actions. Although this PMS round did not find any SF antimalarials, the process includes only samples from targeted regions, not every available product. Therefore, SF drugs could still be on the market.[2] It is important for Burkina Faso to continue surveillance and enforcement activities to deter bad actors. Approximately 40 medicines QA stakeholders from the MOH, health programs, central medical stores, the national order of pharmacists, and other USAID implementing partners (e.g., MTaPs, GHSC-PSM) participated. A USAID/Burkina Faso President's Malaria Initiative (PMI) team also attended and indicated its satisfaction with the work and results.

As PQM+ gears up to support LNSP in its journey toward ISO/IEC 17025 accreditation, PQM+ conducted an assessment to ascertain gaps with regard to the requirements of this standard.

[2] The MedRS tool helps RB-PMS technical working groups assess risks related to medicines, regions, cities, and facilities, which informs the surveillance design.

Due to a coup d'état in January 2022, PQM+ postponed planned February activities until receiving clearance from USP's Global Security to travel again for implementation.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Support LNSP to complete the draft of the strategic plan, which they will present to a wider MOH stakeholder group for validation.
- Provide training and supportive supervision to LNSP for equipment preventive maintenance.
- Train the national PMS-TWG on the online version of the MedRS tool and support them to develop a second RB-PMS protocol for antimalarials.

Democratic Republic of Congo (DRC)

Widespread availability and distribution of non-quality-assured artemisinin combination therapies and non-artemisinin therapies[3] in DRC underscore the need for strong medicines regulatory systems, including PMS. In PY2, PQM+ began working with the Congolese Pharmaceutical Regulatory Authority (*Autorité Congolaise de Réglementation Pharmaceutique,* or ACOREP) and its NQCL – Pharmaceutical Laboratory of Kinshasa (*Laboratoire National de Contrôle de Qualité – Laboratoire Pharmaceutique de Kinshasa,* or LNCQ-LAPHAKI).

Progress by PQM+ Objective

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

PQM+ supervised LNCQ-LAPHAKI to conduct confirmatory testing of 60 samples, including 20 percent of the samples that passed the MiniLab™ screening and all samples that failed the MiniLab™ screening (including artemether injection, artemether/lumefantrine tablets, artesunate suppositories, artesunate injection, quinine sulphate tablets/injection/syrup, and sulfadoxine/piperaquine tablets). All confirmatory testing was completed except for dihydroartemisinin/piperaquine phosphate; it was difficult to source the reference standards for this, as the formulation is not present in any major compendia. PQM+ has identified a vendor who can supply the secondary reference standard, but LNCQ-LAPHAKI may not receive this before the end of June. The vendor's details will be shared with LNCQ-LAPHAKI to enable them to source it successfully for their routine analysis.

As part of the implementation of the roadmap toward ISO/IEC 17025 accreditation, PQM+ trained LNCQ-LAPHAKI staff on measurement uncertainty, an advanced requirement of the standard. The training reached 19 individuals (11 male, eight female). In addition, a training on analytical method verification/validation instructed technical staff on validating noncompendial methods and verifying compendial methods; 20 people (11 male, nine female) attended.

PQM+ provided supportive supervision to develop the second RB-PMS protocol for antimalarial medicines, with 25 PMS-TWG members participating. For the 2022 survey, the PMS-TWG will

[3] https://malariajournal.biomedcentral.com/articles/10.1186/s12936-016-1659-x

collect 319 antimalarial samples from nine USAID-focused provinces (Haut-Katanga, Haut-Lomami, Kasai Central, Kasai-Oriental, Lomami, Lualaba, Sankuru, Sud-Kivu, and Tanganyika).

PQM+ followed up the implementation of the roadmap toward ISO/IEC 17025 accreditation. Action items under the responsibility of PQM+ are on track: training, technical assistance, and support for equipment calibration. However, some action items under the responsibility of LNCQ-LAPHAKI/ Directorate of Pharmacy and Medicines (DPM) were lagging: equipment qualification, replacement of two new defunct UV and visible spectrophotometers, and procurement of Laboratory Information Management Systems software – these were discussed extensively, with solutions proposed for the LNCQ-LAPHAKI team to execute.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Support the PMS-TWG to disseminate the 2021 RB-PMS results.
- Help the PMS-TWG coordinate the sampling, per the second RB-PMS protocol.
- Continue to build the technical capacity of LNCQ-LAPHAKI in equipment preventive maintenance, data integrity, and handling out-of-specification results.

Ethiopia

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, 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+ works 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. 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.

Progress by PQM+ Objective

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

Effective regulation of medical products and the use of appropriate regulatory tools and norms promote and protect public health by ensuring medicines quality, safety, and efficacy; promoting the adequate manufacture, storage, and distribution of medicines; and strengthening the fight against SF products.

In PY2, PQM+ developed a branch-specific road map toward ISO17025:2017 accreditation for each of the branch EFDA laboratories. As part of implementing this map PQM+ trained 17 (14 male, three female) laboratory staff from the four laboratories on ISO/IEC17025:2017-based QMS.

As part of building capacity of the branch EFDA laboratories, PQM+ also procured and supplied five ultrasonic baths to enhance the testing ability of the branch EFDA laboratories. In PY2, PQM+ trained the branch laboratory staff on testing medicines using compendial techniques like the HPLC. The HPLC technique needs use of the ultrasonic bath for sample preparation, but the ultrasonic baths were not in place at the time of training. Hence, procuring this equipment was essential to capacitate the laboratory in this regard.

The RB-PMS sample collection exercise took place during the last quarter of PY2. For this survey, the MedRS tool was used to identify medicines, regions, cities, and facilities to be sampled based on risk scoring. Even though the plan was to collect about 250 samples, per the RB-PMS protocol, enough samples could not be collected from the country because of serious security issues and a shortage of medicines at the time of sample collection. As a result, the team collected only 69 samples. This quarter, the PMS-TWG incorporated the findings into the PMS report, which they then reviewed and finalized. The final PMS report has been submitted to the EFDA Medicine Inspection Directorate for further action. The report notes that one of 16 oxytocin samples was substandard, while all 53 antimalarial samples complied with requirements. Although this round found no SF antimalarials, noncompliant products may still be circulating in the country. While it is encouraging that few failures were reported, the small sample size means this surveillance may not have been able to detect failures effectively. The exercise also showed the presence of unregistered products in the market. EFDA will take relevant regulatory/administrative measures based on the PMS report/findings.

This quarter, PQM+ provided technical assistance to the Medicine Registration and Licensing Directorate in development of one directive and the revision of two directives:

- Developed a medicines authorization directive for registering medicine;
- Revised the medical donations control directive; and
- Revised the special conditions import permission directive.

PQM + also participated and provided technical support on a consultative workshop organized by EFDA to enrich participants' knowledge about the GMP guideline for traditional medicine.

The audit inspection of retail outlets conducted in PY2 showed nonconforming activities related to GDP and Good Storage Practices (GSP).To address this gap, PQM+ reached a consensus agreement with Ethiopian Pharmaceutical Association to develop continuous professional development materials .Based on the agreement with the EPA, PQM+ developed a detailed action plan and received approval on course content to provide training for 250 retail outlet professionals on GSP and GDP from the regulatory perspective. PQM+ is providing technical support in developing the training materials.

In Q2, PQM+ continued supporting the Medicine Inspection Directorate of EFDA to finalize the process of accreditation of the function for ISO/IEC 17020: 2012.The corrective and preventive actions (CAPAs) submitted to the Ethiopian National Accreditation Body were reviewed by the accreditation body and accepted. Finally, the EFDA secured the accreditation certificate during a half-day ceremony in the presence of all relevant stakeholders, including PQM+.

PQM+ received recognition from the EFDA for the program's contribution throughout the accreditation journey. This is the first regulatory authority's pharmaceutical inspectorate supported by PQM+ to achieve ISO 17020.

Figure 3: Recognition for PQM+'s role in ISO/IEC 17020 accreditation of EFDA.

Objective 4: Increase the supply of quality assured essential medical products of health importance

PQM+ provided technical assistance in Q2 to develop an Excel template to enter data about GMP inspection findings for performing trend analyses on historical GMP inspections by EFDA. The agency can use that evidence to identify major areas of risk and develop strategies to implement more efficient risk-based inspections in the future. In addition, it will fulfill the WHO Maturity Level 3 requirement for regularly publishing inspection findings and making them publicly available.

Also in Q2, PQM+ assisted and supervised data entry of 80 (of 300) GMP reports into the Excel database for further analysis.

PQM+ provided technical assistance to develop an EOI for local manufacturers to apply for support toward WHO prequalification. The final EOI is ready to be submitted to the MOH for posting.

Priority Activities for Next Quarter

Next quarter, PQM-Ethiopia plans to:

- Re-establish the RB-PMS-TWG and train its members on the RB-PMS approach and use of the online MedRS tool.
- Disseminate the RB-PMS findings to relevant stakeholders.
- Train health professionals on GDP/GSP, as part of the continuous professional development requirement, in collaboration with the Ethiopian Pharmaceutical Association.
- Collection of PMS samples as per the RB-PMS protocol to be developed in the quarter.
- Finalize the data entry and analysis of GMP audit reports.
- Advertise the EOI for local manufacturers and identify a potential manufacturer for future technical support.
- Provide training on EUA.

Ghana

The Food and Drugs of Authority of Ghana (GFDA) is the national regulatory body responsible for the regulation of food, drugs, clinical trial protocols, and other products. GFDA carries out key regulatory functions through its divisions, Drug Registration and Inspections; Safety Monitoring and Clinical Trials; Medical Devices and Cosmetics; Monitoring and Evaluation (M&E); and Household Chemicals Substances. GFDA is ISO 9001-certified and, in 2020, attained WHO Maturity Level 3. Its Center for Laboratory Services and Research is also ISO/IEC 17025 accredited. At the time of its June 2021 audit by the American National Accreditation Board, it had the largest accreditation scope in Africa.

PQM+ is helping Ghana improve the supply of quality assured medicines by providing technical assistance to select local manufacturers of artemisinin-based combination therapies and maternal and child health (MCH) commodities such as oxytocin.

Progress by PQM+ Objective

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

This quarter, PQM+ worked with GFDA to finalize a report on and disseminate the country's first RB-PMS conducted in 2021. The surveillance activity sampled 201 antimalarials and 177 MCH medicines from 370 facilities (which is a representative sample size) out of approximately 29,000 facilities in the country. Based on stratified random sampling, the selected facilities comprising all risk levels were located in five regions (Ashanti, the former Brong-Ahafo, Central, Eastern and Greater-Accra regions). Forty-five (45) percent of the oxytocin samples assessed failed, as did 6 percent of the misoprostol samples, and 0.6 percent of antimalarial samples. These results indicate that challenges still exist in the quality of MCH medicines in Ghana.. More than 40 medicines QA stakeholders, including the MOH (procurement), health programs, pharmacy council, National Health Insurance Authority, WHO, and the USAID/Ghana Mission, as well as some of implementing partners, (GHSC-PSM and Total Family Health Organisation) attended the dissemination workshop in Accra.

In preparation for the second RB-PMS, PQM+ and the national PMS-TWG convened a workshop to develop the second RB-PMS protocol for antimalarials and MCH medicines and monitored the confirmatory testing of the antimalarial and MCH samples. This year's testing is sampling the following products: oxytocin injection, misoprostol tablets, ergometrine injection, mifepristone + misoprostol tablets, ferrous sulphate syrup, and artesunate powder for injection. The sampling, which will meet the criteria for national geographic representativeness, will be from seven regions in Ghana – Ashanti, Central, Volta, Greater Accra, Western, Upper East, and Upper West regions – as selected using the MedRS tool.

Objective 4: Increase the supply of quality-assured essential medical products of health importance

From the request for EOIs published in the Daily Graphic newspaper for importing and local packaging of iron and folic acid tablets, as agreed between USAID, PSM, Total Family Health Organisation, and PQM+, and for the local manufacturing of amoxicillin dispersible tablets (amox-DT) and chlorhexidine gel, the team received two EOIs for both local manufacture of amox-DT and local packaging of iron and folic acid tablets. However, no EOIs were submitted for local manufacture of chlorhexidine gel. A GMP gap assessment was conducted for a

company interested in manufacturing amox-DT, but they need facility design work to properly absorb technical assistance.

PQM+ visited Atlantic Life Sciences to follow up on the implementation of the roadmap toward the manufacture of quality-assured oxytocin injection. The team learned that the second phase of construction of the small volume parenteral for manufacturing oxytocin injection has been postponed due to competing priorities with production of COVID-19 vaccines, as well as anti-snake and anti-rabies vaccines production.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Provide technical assistance to three local artemisinin-based combination therapy manufacturers, including training and QMS building, per the roadmaps developed in PY2.
- Work with new manufacturers interested in the local manufacture of amox-DT to develop a roadmap for the WHO prequalification of that medicine.
- Support the national PMS-TWG to conduct sampling of antimalarials and MCH medicines for the 2022 RB-PMS.
- Continue to follow up with local manufacturers to respond to the Global Standards 1 (GS1) survey.

Guinea

Guinea's National Directorate of Pharmacy and Medicines (DNPM) is implementing regulatory provisions related to its mandate while strengthening its technical capacity to carry out regulatory functions. The NQCL, *Laboratoire national de contrôle qualité des medicaments* (LNCQM), conducts quality testing of medical products to facilitate decision-making by DNPM. PQM+ works with DNPM to strengthen its market surveillance function by operationalizing a PMS-TWG to implement RB-PMS. Additionally, PQM+ has assisted LNCQM in improving its QMS to conform with ISO/IEC 17025 standards and is strengthening its technical analysts' capacity to conduct quality testing per the ISO accreditation roadmap developed in PY2.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance systems

To assist the DNPM and LNCQM in the development of a framework that delineates agreed upon areas of collaboration and their individual responsibilities, PQM+ conducted a situational analysis on the state of collaboration between the institutions. Through this analysis, we discovered a lack of systematic collaboration for regulating medical products. In addition, LNCQM does not test samples being evaluated for issuance of marketing authorizations.

1. Based on the findings of the situational analysis, PQM+ facilitated a workshop with DNPM and LNCQM (and MEDICRIME Brigade) to draft a collaborative framework between the institutions. This document outlines several ways for the institutions to collaborate on efficient regulation of medicines (e.g., how/when samples will be sent from DNPM to LNCQM to add some efficiencies to the process as well as timelines for sending the test results back to DNPM. Ten people (eight male, two female) participated.

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

Per the implementation of the roadmap toward ISO/IEC 17025 accreditation, PQM+ provided a refresher training on the ISO/IEC 17025 standard on quality risk management and effective standard operating procedure (SOP) writing. The training reached 11 people (nine male, two female). These trainings will help LNCQM as they work toward implementing an effective QMS, which includes writing of SOPs and managing risks within the laboratory.

Procurement of lab supplies required for testing PMS samples—including clearing of MiniLabs™—experienced significant delays, and the vendor has still not shipped the consumables. As a result, sample testing has not yet started.

PQM+ initiated the internal procurement process for key analytical equipment required by LNCQM (dissolution tester, microbalance, Fourier transform infrared spectrometer, precision balance and standard weight set) to conduct key tests to ascertain the quality of medicines.

Objective 3: Increase financial resources for medical product QA optimization

PQM+ conducted a workshop to train LNCQM staff (technical and finance) on how to calculate cost for tests conducted in the laboratory to ensure key considerations are taken and that costing is realistic. PQM+ introduced LNCQM to an Excel tool that will facilitate this process. The tool considers key cost drivers to arrive at realistic testing fees that could sustain LNCQM's operations. Ten people (eight male, two female) attended the workshop, most from LNCQM, with one representative from DNPM in attendance.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Ship PMS samples to the USP-Ghana laboratory for confirmatory testing.
- Provide supportive supervision to LNCQM to implement its roadmap toward accreditation.
- Support the PMS-TWG to develop the second RB-PMS protocol for antimalarials and MCH medicines.

Kenya

PQM+ aims to strengthen the quality of medical products in Kenya by improving governance structures and regulatory systems for medical product QA. 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, and the counties to strengthen in-country stakeholders' capacity in ensuring access to quality-assured medical products in the country.

In Q2, PQM+ focused on improving governance for medical product QA systems, increasing the 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: Improve governance for medical product quality assurance systems

On supporting the national pharmacovigilance (PV)/PMS-TWG to play a more strategic role in coordinating its activities in Kenya, PQM+:

- Offered technical assistance to develop the PV/PMS-TWG's costed work plan and two reports on RB-PMS activities. PPB fully financed one of the PMS activities.
- Is converting the PMS activity reports into manuscripts for publication.

On supporting national and county-level implementation of QA strategies of the MOH Division of Health Products and Technologies and the Division of National Malaria Program:

- At the national level, PQM+ helped develop a training curriculum to manage malaria commodities in Kenyan health care facilities.
- At the county level, PQM+ visited Kisumu and Busia counties to conduct rapid assessments of county and health care facility level systems, processes, and tools to assure the quality of antimalarial medicines. After completing the data analysis, PQM+ will disseminate results of the assessments, recommendations, and proposed interventions to the county and health care facility management teams. Subsequently, in collaboration with county health product and technologies (HPT) units, Busia County Referral Hospital, Jaramogi Oginga Odinga Teaching and Referral Hospital, and Kisumu County Referral Hospital, PQM+ will implement the prioritized interventions.

PQM+ also designed the approach to finalize the NQCL's strategic plan for 2021–2026.

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

On providing technical assistance to PPB to establish an organizational capacity development platform for self-directed learning, PQM+:

- Is supporting PPB to set up an online platform for self-directed learning called the Ustadi Self-Directed Learning Management System (LMS). In Q2, PQM+ completed development and uploaded content to the system. The platform can be accessed at https://ustadi.pharmacyboardkenya.org/login/index.php. PPB staff are piloting the LMS and sharing feedback with the development team.
- Shared the Kenyan experience developing the LMS platform with other PQM+ teams through a learning café.

On facilitating PPB in the adoption, domestication, and implementation of regional guidelines and protocols on regulatory harmonization:

- To support PPB's domestication of the agreed East African Community and Intergovernmental Authority on Development and other regional guidelines on regulatory harmonization, PQM+ met with PPB representatives and helped craft the approach and scope of work for a guideline that includes a monitoring mechanism on finalizing the

registration of antimalarials and reproductive, maternal, newborn, child, and adolescent health products that have been evaluated through harmonization and reliance initiatives.

On supporting workforce capacity improvements at the NQCL by implementing prioritized findings of the human resource (HR) assessment, PQM+:

- Designed the methodology and scope of work for developing the guidance document on required skills for NQCL staffing and met with NQCL representatives to discuss the activity's approach.

Objective 3: Optimize and increase financial resources for medical product quality assurance

To work with the NQCL to rationalize fees for QC testing services for sustainable testing of quality of antimalarial and reproductive/maternal and child health (MCH) products:

- PQM+ supported NQCL to analyze costs and fees of its medicines quality testing services and identify ways to make the lab financially sustainable. The activity compared the current NQCL fees with the costs of its peers both in and outside the country and identified opportunities that support NQCL's sustainability.
- The report identified opportunities to strengthen the financial sustainability of NQCL, such as implementing competitive pricing to attract and retain customers, lowering unit cost per analysis, increasing revenue from a higher volume of samples, and digitalizing its processes. The final report is ready for dissemination to relevant stakeholders.

Objective 4: Increase the supply of quality assured essential medical products of health importance

On strengthening the technical capacity of PPB and local pharmaceutical manufacturers in GMP to increase the local supply of quality-assured antimalarial and reproductive and MCH commodities:

- PQM+ collaborated with PPB to strengthen the board's capacity for regulatory oversight of GMP and to promote GMP compliance by local manufacturers of antimalarials and MCH and reproductive health/family planning medicines, among others. This occurred through a comprehensive study to identify the challenges, risks, and threats facing Kenya's pharmaceutical manufacturing industry and outlining the opportunities therein.
- PQM+ identified some of the challenges encountered including: lack of implementation of the GMP roadmap due to insufficient follow-up by local manufacturers and PPB, insufficient GMP enforcement due to inadequate GMP inspectors, high turnover of experienced staff in the PPB inspectorate department, insufficient technical know-how to ensure satisfactory completion of dossiers, and lack of shared information management system linking regional NMRAs.
- The opportunities identified included: collaboration between academia, industry, and regulators in designing and developing an appropriate syllabus for training skilled professionals to work in the local pharmaceutical manufacturing industry; establishment of a niche production hub for antimalarial, reproductive, maternal, neonatal, and child health and other select products for local, regional, and global markets; dedicated local production of pharmaceuticals for donor-funded programs; and establishment of regional and international bilateral and multilateral agreements for technology transfer. The assignment identified challenges and opportunities in supporting the Kenyan production

of quality-assured medicines in these categories. The findings and recommendations were shared in separate sessions with local manufacturers and PPB. The final assessment report is ready to share with stakeholders.

On strengthening the Federation of Kenya Pharmaceuticals Manufacturers (FKPM) in coordinating and disseminating materials on manufacturing antimalarial and reproductive/MCH products via the FKPM website:

- PQM+ developed the methodology and scope of work for developing QA resources on the manufacture of antimalarials, reproductive, maternal, neonatal, child, and adolescent health products, and other essential HPTs.
- The resources will be posted on FKPM's website for pharmaceutical human resource departments to use in continuing professional development.

Objective 5: Advance global medical product quality assurance learning agenda and operational agenda

In working with the Pharmaceutical Society of Kenya (PSK) to develop or adapt a course on pharmaceutical QA and regulation, PQM+:

- Is collaborating with the PSK to develop an in-service course on pharmaceutical QA, manufacturing, and regulation. Recent assessments in Kenya to identify challenges facing local manufacturers found a mismatch between practical skills the industry requires and what colleges and universities are teaching.
- Has initiated discussions with PSK on developing an in-service course on manufacturing quality-assured pharmaceuticals and regulation that PSK will host. The course will target manufacturers, distributors, PPB personnel, pharmaceutical policy experts, and other relevant professionals.

Priority Activities for Next Quarter

Next quarter, PQM+ in Kenya plans to:

- Validate the PMS strategy and M&E framework of the PV/PMS-TWG costed work plan.
- Participate in the PV/PMS-TWG quarterly meeting.
- Support development of county and health care facility level action plans to improve QA of antimalarials and other HPTs and implement interventions.
- Continue disseminating the QA framework for malaria commodities to remaining counties.
- Disseminate the NQCL costing study to relevant stakeholders.
- Complete the analysis and synthesis of local data from eight rounds of previous PMS activities, reflective of differences in protocols across the rounds, to inform policy direction for QA of antimalarial and reproductive/MCH products. This analysis will take into consideration that all rounds of the prior PMS activities may not have been based on the same sampling methods or protocols.
- Support NQCL to develop its strategic plan.
- Launch the PPB capacity development platform for staff self-directed learning on pharmaceutical regulation.

- Develop guidelines, including a monitoring mechanism, on finalizing the registration of antimalarial and reproductive/MCH products that have undergone evaluation through harmonization and reliance initiatives.
- Develop a guidance document on required skills for NQCL staffing.
- Develop QA resources on the manufacture of antimalarials, reproductive/MCH medicines, and other essential HPTs and upload them to the FKPM website.

Stakeholders attend a workshop to develop the PV/PMS TWG costed work plan. (PQM+ Kenya photo.)

PQM+ visits a warehouse at Kisumu County Referral Hospital. (PQM+ Kenya photo.)

Liberia

In Liberia, PQM+ is strengthening the country's regulatory system, specifically focusing on supporting the Liberia Medicines and Health Products Regulatory Authority (LMHRA) and its QC laboratory.

PQM+ supported the LMHRA to complete one round of RB-PMS of antimalarial samples in five counties. The LMHRA released the PMS results to the public on January 25. PQM+ also supported the LMHRA to clear its dossier backlog and facilitated the establishment of a technical advisory committee on medical products registration. PQM+ coordinated with the LMHRA to inspect a Liberian manufacturing site.

Also this quarter, PQM+ opened an office in Monrovia. The office has four staff members, including two technical professionals.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance systems

This quarter, PQM+ began a staffing needs assessment at the LMHRA as part of interventions recommended during an HR assessment that PQM+ conducted in PY2. On March 4, PQM+ coordinated with the LMHRA to establish a steering committee, technical task force, and expert working group to facilitate the staffing needs assessment. Also in March, PQM+ trained four LMHRA staff on the theme "LMHRA Staffing Needs Assessment – Applying Workload Indicators of Staffing Need (WISN)."

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

PQM+ coordinated with the regulatory authority in January to release findings from an RB-PMS exercise with samples collected from 272 facilities of all risk levels. These facilities had been randomly selected from 925 facilities across the country using the MedRS tool. The LMHRA found that, of 303 MCH and antimalarial sampled, 87 (29 percent) failed visual inspection, MiniLab™, or compendial testing. These results show high levels of medicines failure in general, though results for individual medicine classes in the surveillance cannot be inferred. LMHRA presented the findings during a dissemination meeting in Monrovia. Representatives from the MOH, USAID, WHO, Liberia Marketing Association, and others attended the dissemination meeting.

Results dissemination workshop participants gather under the meeting banner. (PQM+ photo.)

On January 24, PQM+ and the LMHRA met with the Minister of Health and provided an update on PQM+ activities in Liberia. At the meeting, the minister pledged her commitment to championing medicines quality in Liberia.

LMHRA Managing Director Keturah C. Smith; Liberia Minister of Health Wilhelmina Jallah; and PQM+ West Africa Director Kwasi Boateng.

This quarter, PQM+ coordinated with the LMHRA and the National Standard Lab to train five LMHRA QCL staff and seven National Standard Laboratory staff on the QMS using the Stepwise Assessment Tool Towards Accreditation (SATTA). Immediately after the training, PQM+ assessed the metrological capacity of the National Standards Laboratory. Findings from this assessment will inform PQM+ strategy for strengthening the National Standard Laboratory's metrology capacity. In January, PQM+ also supported the LMHRA to train 13 analysts in compendia methods of sample analysis. The training was conducted at the LMHRA QC lab by laboratory staff.

In February, PQM+ supported the LMHRA to clear its dossiers backlog. LMHRA evaluated 52 dossiers, of which 37 percent (19) were antimalarial medicines. PQM+ is working with the LMHRA to create a system that prevents the dossier backlog, including developing appropriate regulations and SOPs and supporting the LMHRA to set up a technical advisory committee for medical products registration. PQM+ delivered a presentation on the committee's role and responsibility at its February 23 meeting. PQM+ is also coordinating with the Centre for Innovation in Regulatory Science to complete an ongoing assessment of the LMHRA registration process to identify and make recommendations for improving operations efficiency.

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

In March, PQM+ coordinated with LMHRA to conduct a GMP gap assessment of the Global Pharmaceuticals Manufacturing Ltd. site on Bushrod Island. Findings from the gap assessment will allow PQM+ to support Global Pharmaceuticals on implementing GMP. Prior to the inspection, PQM+ provided GMP capacity building for nine LMHRA inspectors.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Conduct a donors meeting for the LMHRA strategic plan.
- Present the LMHRA Act gap assessment report to stakeholders.
- Draft priority regulations.
- Train PMS samplers.
- Start PMS sampling.
- Start and complete MiniLab™ screening.
- Conduct a feasibility assessment of the LMHRA to adopt an integrated regulatory information management system.

Madagascar

PQM+ collaborates with Madagascar's Medicines Regulatory Authority ("the Agency," *Agence du Médicament de Madagascar).* As the sole medicines regulatory authority in the country, it performs all regulatory functions through four technical departments: pharmaceutical inspection, registration, pharmacovigilance, and QC. The National Pharmaceutical Quality Control Laboratory (LNCQM*, Laboratoire National de Contrôle de Qualité des Médicaments)* is part of the Agency's QC department. PQM+ is helping the Agency strengthen the LNCQM's capacity to prepare for ISO/IEC 17025 accreditation and WHO prequalification.

In PY3, in addition to laboratory capacity strengthening, PQM+ is focused on implementing the PMS system on the quality of medicines in the country.

Progress by PQM+ Objective

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

PQM+ worked to strengthen the capacity of Madagascar's LNQCM through the following achievements, with timeframes noted at the end of each:

LNCQM master plan: PQM+ assisted LNCQM to commence drafting its master plan that will align with Madagascar's national pharmaceutical policy. The activity began with a situation analysis involving key informant interviews with various audiences, including *Direction de l'Agence du Médicament de Madagascar* (DAMM) staff and external stakeholders (local experts and laboratory clients). Strengths, weaknesses, opportunities, and threats and political, economic, social, and technological analyses of LNCQM will be conducted to conclude the situation analysis phase. The LNCQM master plan outlines the overall strategy for the lab over the next two years. The master plan includes infrastructural improvements, accreditation, and WHO prequalification concerns and workforce development, among others. Timeframe for completion: July 31, 2022.

LNCQM development plan: PQM+ intends to strengthen the capacity of LNCQM by developing a laboratory development plan. This is a component of the master plan. The first step in this process is conducting a baseline capacity assessment of LNCQM using the Stepwise Assessment Tool Towards Accreditation (SATTA) to identify gaps that will inform the development plan. During Q2, PQM+ reviewed LNCQM's quality documents and commenced developing SATTA training resources. The training material will be used to train LNCQM staff on SATTA to enable them to conduct internal audits and put in place corrective and preventive action (CAPA) plans in preparation for WHO prequalification, ISO/IEC 17025:2017 accreditation, and development of the LNCQM development plan. The SATTA assessment results will reveal laboratory gaps that need to be addressed to achieve ISO 17025:2017 accreditation and WHO prequalification. SATTA results will also inform the laboratory development plan. Timeframe for completion: July 31, 2022.

LNCQM policy, quality manual, and standard operating procedures: PQM+ commenced reviewing LNCQM's documents including policies and standard operating procedures (SOPs). These are expected to be completed in Q3. Timeframe for completion: July 31, 2022.

Staff competency development plan: PQM+ interviewed with the DAMM director, departmental heads, and general staff to collect information on HR capacity needs. PQM+ also developed a questionnaire to use for interviewing external stakeholders and gathering information on perceptions and expectations of DAMM's workforce by its customers. Results of the HR capacity needs assessment will be used to develop the staff competency development plan. This is a component of the master plan. Timeframe for completion: August 31, 2022.

Risk management plan: Development of the LNCQM risk management plan began in Q2. PQM+ developed training resources on risk management to develop the capacity of LNCQM staff to draft their laboratory's risk management plan. This is a component of the laboratory development plan. Timeframe for completion: July 31, 2022.

Procurement of critical laboratory equipment: PQM+ participated in discussions with LNCQM and DAMM staff to identify and prioritize critical laboratory equipment to be procured. A final decision is pending. This is a component of the master plan. Timeframe for completion: September 30, 2022.

PQM+ also worked to strengthen the PMS of medicines quality in Madagascar using a risk-based approach, with the following achievements:

National PMS guidelines: PQM+ offered technical assistance in the review and validation of the national PMS guidelines.

National multi-stakeholder PMS technical working group: Progress included:

- PQM+ offered technical assistance to DAMM to establish a national multi-stakeholder PMS-TWG during a workshop held from February 1-4, 2022 in Antananarivo. The workshop was attended by 21 participants (12 female, 10 male).
- PQM+ participated in the official inauguration of the national PMS-TWG comprising members from DAMM-LNCQM, the General Secretariat, MOH, General Directorate of Care Providing, MOH; Directorate of Pharmacy, Laboratories and Traditional Medicine, MOH; National Malaria, Tuberculosis Control Programs; The Association of Wholesalers; The Purchasing Center for Essential Medicines and Medical Equipment; The National Orders of Physicians and Pharmacists; United Nations Fund for Population Activities, and the USAID Market Partnership and Access to Commodities Together.
- The PMS-TWG elected its officials: president; director of DAMM; vice president, National Order of Pharmacists; and secretary, Directorate of Pharmacy, Laboratories and Traditional Medicine and DAMM.
- The PMS-TWG members reviewed and validated the TWG terms of reference.
- PQM+ presented the RB-PMS concept to the TWG and introduced the MedRS tool for subsequent development of the first RB-PMS protocol for the QC of medicines.

SOP on quality standards and regulatory actions on RB-PMS results: The team began developing the SOP defining quality standards and reliable regulatory actions to be taken by DAMM based on RB-PMS results, to prevent poor quality medical products from reaching national consumers.

Procurement of field-based product quality screening technologies: PQM+ participated in deliberations with DAMM staff exploring the need to procure Raman spectrometers vis-à-vis procuring reagents for MiniLab™ kits that are already in 23 regions of Madagascar. The kits' reagents and consumables are almost expired, and users need refresher trainings. A final decision is pending.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to support DAMM to:

- Conduct a second workshop for the development of the PMS protocol and to do sample collection.
- Finalize the SATTA assessment and the laboratory development plan.
- Finalize the human resource assessment and the staff competency development plan.

- Finalize the situation analysis and the laboratory master plan.
- Finalize the laboratory risk management plan.
- Procure critical laboratory equipment and field-based product quality screening technologies.

TOP: Capacity development of Madagascar's national PMS-TWG on risk-based PMS. (PQM+ photo.)
LEFT: National Pharmaceutical Quality Control Laboratory. (PQM+ photo.)

Mali

In Mali, the DPM and the National Health Laboratory (*Laboratoire National de la Santé,* LNS) oversee medicines regulation. The DPM is a Maturity Level I agency according to WHO's GBT. The LNS tests the quality of medical products, food, beverages, or any substance imported or produced in the country that is intended for therapeutic or dietary purposes, but it lacks both ISO/IEC 17025 accreditation and WHO prequalification.

PQM+ works with the DPM to strengthen its market surveillance function through establishing and operationalizing a PMS-TWG to implement RB-PMS and improve the capacity for medicine registration. In addition, PQM+ has been providing tailored technical assistance to the Medicines Quality Control Laboratory within LNS to attain ISO/IEC 17025 accreditation. This would assure the reliability of testing, increase the public's confidence in ANCQ test results, and help DPM take sound regulatory actions.

Progress by PQM+ Objective

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

PQM+ supervised the testing of antimalarials and MCH medicines for the second round of RB-PMS. LNS completed the testing in Q2 and finalized the report. Of 320 samples collected (225 antimalarials and 95 MNCH) from 320 facilities out of 2,464 stratified and randomized facilities located throughout the country, 74 percent were unregistered, and 1 percent of antimalarials and 4 percent of MCH medicines (diazepam injection) failed QC tests. Although the samples were collected from a nationally representative distribution of facilities, national representativeness of the results for individual medicine classes cannot be inferred because the full sample size was not collected for any individual medicine class. However, the results do indicate quality issues due to the nigh number of unregistered products available in the supply chain in the country. Approximately 40 key medicines QA stakeholders (from entities including USAID/Mali, GHSC-PSM, MTaPs, health programs, *Centrale d'Achats de Médicaments Essentiels Génériques*, *Institut National de Santé Publique*, regional health directorates, and *Odres des Pharmaciens*) convened for the PMS results dissemination in Bamako on February 23.

PQM+ conducted a baseline assessment of the microbiology laboratory using the SATTA tool. The lab scored 37 percent, and PQM+ worked with the laboratory to develop a CAPA to close the gaps identified during this assessment. Progress in implementing this CAPA is routinely monitored by the in-country consultant. In addition, PQM+ conducted a training on the ISO/IEC 17025 standard for the microbiology laboratory for eight staff (five female, three male) to sensitize them on the requirements of the ISO/IEC 17025 accreditation

PQM+ helped LNS' Medicines Quality Control Laboratory prepare for its pre-assessment by the accreditation body, *le Système Ouest Africain d'Accréditation*. The pre-assessment took place on March 31, and PQM+ is working with the laboratory to address identified gaps before the official accreditation assessment.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Conduct a stakeholder workshop to develop a proposed five-year strategic plan for Mali.
- Support the national PMS-TWG to conduct sampling of antimalarials and MCH medicines for the 2022 RB-PMS.
- Continue work with the Medicines Quality Control Laboratory to prepare for the official accreditation assessment.

Mozambique

Mozambique recently established an autonomous medicines regulatory authority, ANARME (*Autoridade Nacional Reguladora de Medicamentos, Instituto Publico)*, which encompasses the Department of Quality Check (*Departamento de Comprovação da Qualidade*). PQM+ has been providing technical assistance in the transition to an autonomous NMRA and assistance moving ANARME toward attaining WHO GBT Maturity Level 3 and achieving ISO 9001:2015 certification. Additionally, PQM+ has been assisting the Department of Quality Check to identify

and bridge gaps toward attaining ISO 17025:2007 accreditation for the lab, including developing the necessary QMS documents, manuals, and processes.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product QA systems

PQM+ provided support to ANARME toward ISO 9001:2015 certification through:

- Facilitating publication of the ANARME statutes in the official government of Mozambique bulletin to finalize the establishment of ANARME: The process was completed, and the statutes/regulations were published in the official government of Mozambique bulletin '*Imprensa Nacional de Moçambique'* on February 9, 2022.
- Supported ANARME to identify an organization to undertake the audit and certification. The organization was identified, and the procurement process is ongoing.

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

In the last quarter of PY2, PQM+ supported the LNCQ to conduct a mock audit to identify gaps that need to be addressed for the laboratory to attain good laboratory practices and ISO 17025:2017 accreditation. During this quarter, PQM+ supported LNCQ to address some of the nonconformities observed during the mock audit.

- PQM+ facilitated the development and review of the following key QMS documents: a) waste management, b) access control, c) customer complaints and feedback, d) training, e) impartiality policy, f) quality policy g) testing and reporting results, h) QC or results, and i) impartiality, confidentiality and nondisclosure agreement.

Other support provided by PQM+ to LNCQ to implement actions in the updated accreditation roadmap and their operations includes:

- Supported root cause analysis and development of the corrective action, risks, and opportunities SOP for the failed Proficiency Tests (PT):
    - Closed the corrective action, risks, and opportunities for loss on drying and ultraviolet and visible spectrometry.
    - Cetirizine corrective action, risks, and opportunities developed but not yet closed because corrective action needs additional cetirizine sample, replacement of expired reagents, and ultrapure water to repeat the test.
- Trained laboratory staff on:
    - Quality risk management, corrective action, risks, and opportunities; impartiality, confidentiality, and nondisclosure agreement.
    - Laboratory solution calculations: preparing stock solutions, dilutions, unity concentrations.
- Identified the service provider to repair water purification systems and repair works.

- Received and cleared one of the TruScan Analyzers procured to support PMS activities; it is now in the custody of ANARME. The second unit of TruScan Analyzer was delivered and is undergoing customs clearance.
- Conducted an audit of progress toward ISO 17025:2017 accreditation using the SATTA tool, which indicated good progress (from 12 percent in September 2021 to 26 percent at the end of January and 47 percent at the end of February). We project a score of 60 percent at the end of March.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Continue to provide technical support to the LNCQ to correct the gaps identified in the previous mock audit and finalize preparation for accreditation including finalization of key documents.
- Facilitate the ISO 9001:2015 initial audit and certification for ANARME.
- Work with the LNCQ to reschedule the incomplete activities and training disrupted by the COVID-19 Omicron virus threat, and any additional training as may be requested by ANARME or LNCQ.

Nigeria

PQM+ is focused on helping ensure the quality of medicines and other medical products in Nigeria, with an emphasis on 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 sustainably strengthen regulatory systems at the national and state levels. PQM+ also strengthens QMS and builds laboratory capacity in QC testing in compliance with international standards.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance systems

Continuing development of the national strategic plan for the pharmaceutical manufacturing sector in Nigeria, PQM+ Nigeria liaised with the Federal MOH in Q2 to:

- Obtain the minister's approval for rollout of the proposed TWG to anchor development of a plan detailed in an earlier concept note.
- Finish recruiting a technical consultant to manage and drive the TWG toward the development of the plan.

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

Following continued technical support from PQM+ through PY2 and PY3 Q1, the Pharmacists Council of Nigeria (PCN) received ISO 9001:2015 QMS certification in January. This followed

the program's support of PCN in conducting the final assessment for certification in December 2021.

PQM+ is supporting finalization of the first round of RB-PMS with the National Agency for Food and Drug Administration and Control (NAFDAC) and started preparing for the second round, scheduled for Q3. Notable developments are:

- Trained 21 NAFDAC staff on RB-PMS, including the use of the online MedRS tool.
- Developed the draft protocol for the next round of PY3 RB-PMS. This protocol was prepared to guide the risk-based post-marketing surveillance of antimalaria and anti-infective medicines circulating in the Nigerian market for the year 2022. In this round, the results for the artemether lumefantrine will be nationally representative, drawn from facilities across the country, as identified from the online MedRS tool using the Cochran formula.
- PQM+ continued working in Ebonyi, Sokoto, and Bauchi states to strengthen the regulatory and QA system by sensitizing the state pharmaceutical inspection committees and operators of retail medical product outlets on topics to enhance the quality of medical products sold.
- This quarter, PQM+ contributed to the update of the patent and proprietary medicines vendor training manual on two topics, Good Visual Inspections of medicines and consumables and GSP to aid proprietary patent medicine vendors in recognizing poor-quality medicines and consumables.

PQM+ convened a 5-day meeting in March for 31 pharmaceutical inspectors from the PCN and state pharmaceutical inspection committees to update their inspector's manual.

- PQM+ Nigeria's deputy chief of party and PCN personnel facilitated several sessions during the meetings and led participants in group work to develop a revised draft inspector's manual for PCN.

PQM+ delivered a 3-day monitoring, evaluation, and learning workshop for 15 members of the M&E TWG at the National Institute for Pharmaceutical Research and Development in March.

- The workshop reviewed basic monitoring, evaluation, and learning concepts and included practical sessions to help participants review and update key components of National Institute for Pharmaceutical Research and Development's M&E system, including indicator definitions and review, design of data collection tools, and review of their monitoring, evaluation, and learning plan.

Objective 4: Increase the supply of quality assured essential medical products of health importance

PQM+ received the following updates from supported manufacturers in Nigeria for the period under review.

- Juhel Nigeria Ltd., a PQM+ supported manufacturer, produced 205,700 ampoules of oxytocin 10 IU from a new active pharmaceutical ingredient source.

- Juhel received positive feedback from the WHO PQ team on an analytical report about the risk of packaging ink and adhesive migration into its magnesium sulfate 50%w/v injection.
- Swipha received initial positive feedback from the WHO PQ team on its zinc sulfate dossier. The WHO PQ team has indicated that it will come to conduct a review of and verification of data for the palatability study conducted by Swipha in June.
- Emzor has received analytical equipment for the QCL of its ready-to-use therapeutic food plant. Emzor is getting port clearance for raw materials to produce full batches.

Priority Activities for Next Quarter

Next quarter, PQM+ Nigeria plans to:

- Conduct the second round of RB-PMS with NAFDAC.
- Present the ISO 9001:2015 QMS certificate to the registrar of PCN.
- Provide technical assistance to PCN for setting up an M&E system, including an M&E training for staff from all departments.
- Commence the regulatory and QA system assessment with PCN in Benue and Kebbi states and the Federal Capital Territory.
- Conduct capacity building for selected NAFDAC staff across the agency about QMS and medical devices regulation and QMS compliance.
- Conduct a gap assessment of NAFDAC's medical devices laboratories toward a scope expansion under ISO 17025 for medical devices tests.
- Facilitate a capacity building exchange program for National Institute for Pharmaceutical Research and Development microbiology staff to NAFDAC's microbiology laboratories.
- Conduct a training for NAFDAC and pharmaceutical industry representatives on quality risk management and its application to regulatory functions such as inspection.
- Provide technical guidance to PQM+ supported manufacturers to respond to queries from the WHO PQ team on dossiers for zinc sulfate, sulfadoxine pyrimethamine, and magnesium sulfate undergoing review; support Emzor as it compiles a sulfadoxine pyrimethamine dossier.
- Follow up with Emzor management on the delivery status of its ready-to-use therapeutic food raw materials from the ports and the status of production of scale-up batches.
- Conduct capacity building on key quality management system topics – Quality Risk Management, Product Quality Review from the industry

Rwanda

As the medical products regulatory field changes, the WHO GBT requires NMRAs to have institutional plans for workforce capacity development in place. One indicator of organizational development and the institutionalization of best practices is an established system for tracking trainings offered to and used by regulatory authorities. The 2018 WHO GBT assessment of Rwanda's FDA recommended developing an institutional competency framework to guide workforce capacity development. The Rwanda FDA sought support from PQM+ to undertake a

training needs assessment in alignment with the WHO global regulatory competency framework.

Progress by PQM+ Objective

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

In Q2, PQM+ supported the development of an RB-PMS protocol, establishment and inauguration of the RB-PMS TWG and compilation of its terms of reference. Notable accomplishments were:

- PQM+ developed and validated the PMS-TWG's terms of reference and national protocol for RB-PMS.
- PQM+ inaugurated and oriented the RB-PMS TWG on the MedRS tool, which will be used in PY4 for RB-PMS of family planning, reproductive health, and MCH medicines. The TWG will use MedRS to select a sample of facilities. Samples of the specified medicines will be collected from the selected facilities for assessment.

In Q2, PQM+ supported the Rwanda FDA QC laboratory to strengthen the testing of medicines and related medical products to assure their quality and play a critical role in protecting public health. Notable developments were:

- Initiated introduction of the SATTA tool in preparation for an internal audit in Q3.
- Initiated implementation of a CAPA plan for the laboratory to address identified performance gaps in line with IDP.
- Initiated the establishment of a roadmap to ISO 17025 accreditation and WHO prequalification of the QC laboratory.

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

In Q2, PQM+ started identifying local manufacturers to work with while conducting a rapid assessment of the QA system and GMP capacity, and supported Rwanda's FDA to train and build capacity of its staff on important topics on QA and GMP. Notable developments are:

- Began identifying local manufacturers for QA systems/GMP capacity assessment.
- Initiated plans to train Rwanda FDA GMP inspectors.

In Q2, PQM+ reviewed procedures that Rwanda Medical Supply Limited (RMS LTD) uses to assure the quality of medicines and other medical products along its procurement and supply chain operations. The review will include policies, guidelines, and practices for supplier selection and prequalification, as well as procedures to assure quality of medical products stored in warehouses and during distribution to all health facilities in Rwanda. Notable developments are:

- Reviewed the RMS LTD standard operating procedures and QA manual.
- Developed an RMS LTD QA framework for procuring and supplying medicines and related medical products in Rwanda.

The University of Rwanda is Rwanda's largest publicly funded higher education institution. PQM+ supports the University of Rwanda in Kigali through the East African Community Regional Centre of Excellence for Vaccines, Immunizations, and Health Supply Chain to design and deliver short- and long-term courses to increase competencies related to QA and QC of medical products in the country.

In Q2, PQM+ collaborated with the Centre to prepare for a rapid training needs assessment (TNA) to identify gaps and to map critical competency needs that will inform curriculum design and content development for the proposed pre- and in-service training modules. Notable developments were:

- Developed and validated TNA approaches.
- Developed tools to be used in TNA.
- Identify stakeholders to engage in TNA.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Support Rwanda FDA
    - To prepare for and continue supporting its QC laboratory toward ISO 17025:2017 accreditation and/or WHO prequalification.
    - To continue building the workforce capacity of the Rwanda FDA in QC and QA by incorporating a RB-PMS approach in current PMS activities.
- Build the capacity of Rwanda's FDA and local manufacturers in GMP to support local manufacturing of quality-assured essential health commodities and ensure inspection of local and external plants to ensure compliance with best practices.
- Develop a QA procurement framework, SOPs, a QA manual, and guidelines in collaboration with RMS LTD.
- Develop QA/QC short- and long-term courses and put in place a clear roadmap for sustainably producing a competent workforce in collaboration with the Regional Centre of Excellence for Vaccines, Immunizations, and Health Supply Chain.

Senegal

The Government of Senegal recently developed a five-year (2019–2023) Integrated Strategic Plan for the DPM and the National Medicines Control Laboratory. The plan recognizes progress made over the past decade, in part due to the support provided through USAID's Promoting the Quality of Medicines (PQM) program, but much work remains to be done. PQM+ works primarily with the DPM to strengthen its market surveillance function through the establishment and operationalization of a PMS-TWG to implement RB-PMS and to improve their capacity for medicine registration. In addition, PQM+ provides support to the National Medicines Control Laboratory to improve its capacity to test medicines.

Progress by PQM+ Objective

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

PQM+ supported the PMS Unit to convene a training for 17 of its members (seven men, 10 women) on the online version of the MedRS tool since the previous PMS was implemented using the offline excel version of the MedRS tool. During this workshop, PQM+ also provided supportive supervision to the PMS Unit members to use the MedRS tool to conduct risk analysis to help develop the second RB-PMS protocol for antimalarial medicines. This year, Senegal plans to collect samples from a nationally representative sample of facilities (334 out of 2,500 facilities located across the country). The antimalarial samples will artesunate injection, artemether injection, artemether/lumefantrine powder for injection, sulfadoxine/pyrimethamine/ trimethoprim tablets, artesunate/sulfamethoxypyrazine/ pyrimethamine tablets, artesunate/ mefloquine oral liquid, and artesunate/mefloquine tablet). After randomization of the 2,560 facilities, the medicines will be collected from facilities located in six regions in Senegal (Dakar, Saint Louis, Djourbel, Kaolack, Kedougou, and Kolda).

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Conduct a training-of-trainers session on the ISO 17025 standard and internal auditing.
- Support the national PMS Unit to conduct sampling of antimalarial medicines for the 2022 RB-PMS.

Asia Region

Asia Bureau

PQM+'s technical assistance funded by USAID's Asia Bureau aims to promote regional regulatory convergence and reliance. PQM+ will work with 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 regulatory and quality assurance systems. This work leverages the current PQM+ work in Southeast and Central Asia.

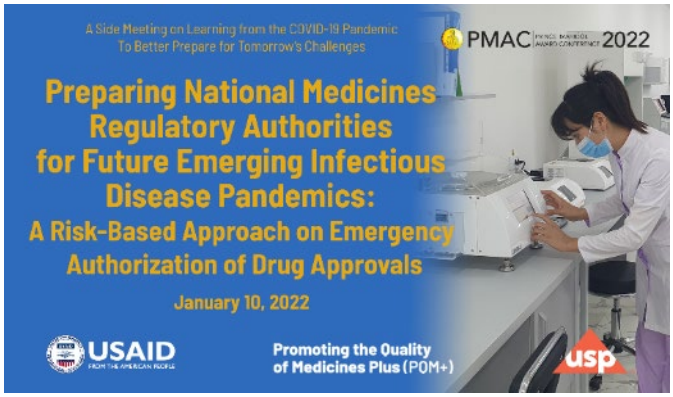
Progress by PQM+ Objective

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

Last quarter, PQM+ presented the Asia Bureau's PY3 planned activities to the ASEAN's PPWG. This reporting quarter, the PQM+ team is drafting a detailed proposal to get ASEAN's consent before activities commence. The team expects to start full implementation of the five ASEAN-related activities next quarter; four of these will kick off at a regional workshop. The five planned activities address the technical areas of marketing authorization, post-marketing surveillance (PMS), GMP inspection, and lot release.

Objective 5: Advance global medical product quality assurance learning agenda and operational agenda

On January 10, the Promoting the Quality of Medicines Plus (PQM+) program held a virtual side session during the 2022 Prince Mahidol Award Conference (PMAC) titled "Preparing National Medicines Regulatory Authorities for Future Emerging Infectious Disease Pandemics: A Risk-Based Approach on Emergency Authorization of Drug Approvals." The session's objective was to highlight critical considerations for equipping and preparing national medical regulatory authorities (NMRAs) regarding the current and future infectious disease pandemics and outbreaks by establishing fast-track and agile medical products approval processes, including emergency use authorization (EUA).



Promotional banner for the PQM+ session at PMAC

- During this session, the PQM+ team shared its experience in building NMRAs' regulatory preparedness, primarily through assistance to develop an EUA pathway and process.

- Seven panelists from NMRAs, donors, academia, and implementing partners reflected on their experiences in adopting or supporting the adoption of national expedited regulatory approval procedures that use regional and global reliance to speed up the availability of and access to life-saving vaccines, therapeutics, and medical devices.
- Of the 197 people who registered for the session, 89 people from 25 countries attended.

Priority Activities for Next Quarter

Next quarter, Asia Bureau plans to:

- Conduct a regional workshop to disseminate findings of the regional landscape analysis and introduce topics and tools on risk-based PMS and GMP inspection.
- Start data collection for a rapid assessment to understand NMRAs' existing capabilities in the lot release function. PQM+ plans to analyze a subset of the 13 countries from those previously assessed under the regional landscape analysis. The PQM+ team is finalizing the selection criteria.
- Kick off data collection on the pharmaceutical market from selected countries across the Asia region. Data will inform an analysis of countries' readiness to expand the local production and supply chain of identified priority essential health products.

Bangladesh

In Bangladesh, PQM+ works with the Directorate General of Drug Administration (DGDA), which oversees medical product quality in Bangladesh and 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. One of DGDA's key functions is PMS of medical products, including vaccines and medical devices.

PQM+ is helping the DGDA toward achieving WHO Maturity Level 3 (ML3) in terms of vaccine regulation; 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 TB medicines and Good Manufacturing Practices.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance systems

PQM+ is supporting DGDA to develop a five-year strategic plan for the National Control Laboratory (NCL) to ensure the sustainability of standard services. Notable developments are:

- On January 15, DGDA formed a 15-member working committee to develop a five-year strategic plan for NCL, with a kickoff meeting on January 17 chaired by the deputy chief of the NCL. Thirteen people (six female and seven male) attended, including six from NCL management, six from PQM+, and one from WHO.
- Subsequently, NCL conducted two more meetings in February on developing the strategic plan. The committee will draft the five-year strategic plan during Q3.

Participants meet in February on drafting the five-year strategic plan.

PQM+ provided technical assistance to the Plasma Plus Application and Research Laboratory (PPL) to achieve international standards for medical product testing (WHO-PQ, ISO/IEC 17025:2017)

- To initiate the technical assistance and get DGDA's buy-in to a new concept, PQM+ held a consultative meeting with DGDA, NCL, and PPL in February. PQM+ program will provide onsite and online training and technical assistance to help PPL to achieve international accreditation.

PQM+ meets with DGDA, NCL, and PPL to initiate technical assistance and get DGDA's buy-in to a new concept.

PQM+ is supporting DGDA to prepare draft ethical marketing and promotion guidelines for pharmaceutical products for submission to a Ministry of Health and Family Welfare (MoHFW) working committee.

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

DGDA received several observations from the WHO formal assessment in July 2021. Based on those observations, PQM+ developed a CAPA plan for nine DGDA functions:

- Supported NCL/DGDA to prepare a “Vaccines Lot Release Guideline in Bangladesh.” It was uploaded to the DGDA website for public opinion and disseminated to relevant stakeholders requesting feedback in February and March.

PQM+ supports NCL/DGDA to prepare lot release guidelines for Bangladesh.

- Assisted the DGDA Market Control (MC) and Quality Management System (QMS) team to prepare new SOPs on the RB-PMS system and implementation of drug policy.
- Supported creation of the SOP for development, implementation, and monitoring and evaluation of the DGDA’s roadmap, plan, and policy.
- Developed two new SOPs and submitted them to DGDA for approval on “Implementation of Quality Policy and Strategic Plan” and “Risk-Based Post-Marketing Surveillance of Medicinal Products.”

PQM+ supported DGDA to implement appropriate mechanisms for using the WHO Collaborative Procedure for Accelerated Registration (CPAR), with these notable developments:

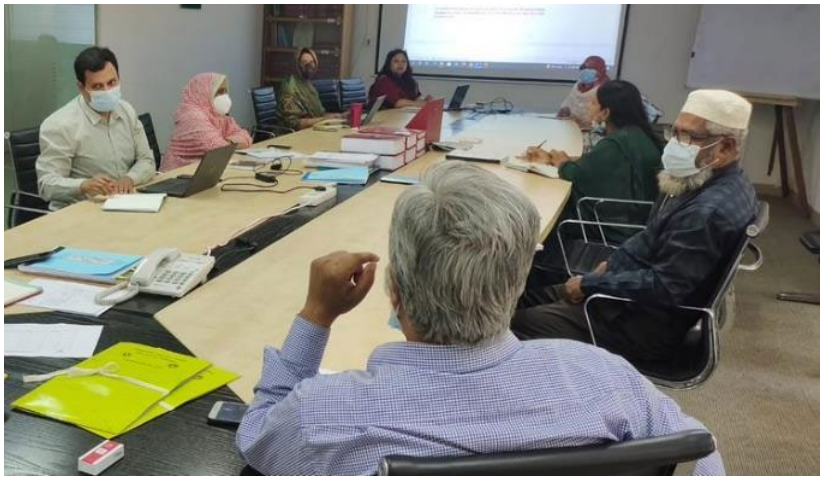
- DGDA has submitted a signed CPAR agreement to WHO HQ to review and sign. After their signature, the bilateral agreement will be completed.
- WHO’s Medicine and Health Products Department (MHP) organized meetings on DGDA’s reliance-related CAPAs and reliance-related IDPs in February.
- PQM+ supported DGDA to introduce the Optimizing Efficiencies in Regulatory Agencies (OpERA) process mapping to integrate tracking and measuring regulatory performance and continuous improvements. This included an orientation session with two DGDA staff in February. PQM+ submitted a draft consent letter to DGDA to nominate a focal person for the OpERA assessment at the end of February.

PQM+ provides technical support to DGDA’s market surveillance and control department to adopt the MedRS tool for efficient implementation of RB-PMS.

- PQM+ is providing technical support to DGDA to prepare the MedRS database for medicines outlets (pharmacies, model medicines shop, model pharmacies, depots, etc.). The program team also prepared a list of required chemicals and consumables for compendial testing of TB medicines and gave a training on MedRS at the end of March.

PQM+ provided technical support to DGDA to implement RB-PMS of anti-TB medicines. Notably, PQM+:

- Provided technical support to DGDA to prepare the sampling and testing protocol of first-line anti-TB medicines – the single and fixed-dose combination of rifampicin, isoniazid, ethambutol, and pyrazinamide. The sample will be nationally representative, with the randomly selected facilities selected from all of the distribution outlets of the National TB Program (NTP) in the country. DGDA will use the MedRS tool for sampling.



PQM+ supports DGDA to prepare a sampling and testing protocol.

- Prepared a list of RB-PMS TB medicines' validity status and the production status of DGDA-enlisted pharmaceuticals.
- Supported DGDA to draft a letter stating that directorate inspectors will collect samples of medical products for testing and other regulatory purposes from all public and private depots, outlets, and national proprietary programs.

PQM+ has been collaborating with DGDA on a rapid assessment of substandard and falsified TB medicines in the private sector. In March, PQM+ organized a consultative meeting on the topic at USP's Bangladesh Office. Prof. Saidur Rahman, chairman of the pharmacology department at Sheikh Mujib Medical University Hospital, and Md. Salahuddin, director of DGDA, attended the meeting with the PQM+ team.

Prof. Saidur Rahman, chair of the pharmacology department at Sheikh Mujib Medical University Hospital, and Md. Salah Uddin, director of DGDA, meet with the PQM+ team. (PQM+ photo.)

PQM+ provided technical support to DGDA to enhance the capacity of the NCL to support the RB-PMS system for priority medicine (i.e., TB, MCH, FP, and animal health products). Notable developments are:

- Finalized and received approval on the SOP for “Freezer -20°C” in January.
- Prepared the draft SOP for “General Procedure for Gas Chromatography Analysis.”
- Prepared and submitted the list of consumables to NCL for TB medicine analysis in February.

PQM+ continued technical assistance to NCL to increase the capacity of vaccine testing, including:

- Assisted with method validation protocol preparation for oral cholera, hepatitis A, measles-rubella, rabies, and tetanus vaccines.
- Assisted in the method validation and report preparation for identification of hepatitis B, meningococcal, and thiomersal content determination.
- Completed proficiency test for two microbiological parameters, sterility test and microbial enumeration, through USP’s Proficiency Testing Program at NSI Lab Solutions.
- Helped prepare the SOP for “Autoclave of the Animal Lab” in January.
- Assisted with QA department’s internal audit of the microbiology laboratory in February.
- Prepared the specification for the size-exclusion chromatography column for use in the analysis of biological products.
- Prepared the chemical, reagent, and standards list for NCL, procuring materials through WHO.

Objective 4: Increase the supply of quality-assured essential medical products of health importance

PQM+ continued technical support to ACI Healthcare Ltd. toward prequalification of first-line TB medicines. Notably, PQM+ is or has:

- Conducted a technical review meeting in January with ACI's TB Project technical team, focused on discussion of the contract agreement milestones 1 and 2 under subaward FAA-21-09 on the progress of four-drug, fixed-dose combination (4FDC) product development. The PQM+ core TB project funds this subaward.
- Conducting a stability study and product development report in the Common Technical Document format for both the active pharmaceutical ingredient and finished pharmaceutical product sections.
- Reviewing the revised batch manufacturing record prepared by ACI.
- Reviewed the dissolution profile study protocol.

PQM+ supported capacity building of the public manufacturer Essential Drugs Company Ltd. (EDCL) to implement GMP in first-line TB medicine manufacturing. PQM+:

- Collaborated with IntraHealth International to conduct a training needs assessment for EDCL staff.
- Submitted the inception report along with detailed methodology, an overview of tools, data collection, and analysis methods prepared for conducting the TNA.

PQM+ initiated collaboration with the Bangladesh Association of Pharmaceutical Industries (BAPI) to raise awareness of GMP for medical products.

- In January, PQM+ met with BAPI management about a collaborative training program targeting pharmaceutical industry officials and their technical staff. At a follow-up meeting in February, participants planned a training program on API manufacturing in Bangladesh.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Continue assisting DGDA in addressing CAPAs based on WHO's July 2021 formal assessment observation.
- Provide continued technical assistance to ACI Pharma in dossier review and submission of the BA/BE study.
- Deliver technical assistance on conducting a gap assessment audit of the PPL lab by Angela N. Oliver, PQM+ senior technical advisor.
- Offer a workshop on the draft regulatory framework for medical devices.
- Conduct a rapid assessment of SF TB medicine.
- Conduct a training needs assessment of EDCL staff.
- Organize training on API for technical staff of manufacturers in Bangladesh.

Burma

PQM+ 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. At the same time, PQM+ is working with private manufacturers to achieve WHO PQ for locally manufactured antimalarials. PQM+ aims to assure the quality of medicines in the country, with a

focus on antimalarials, and thereby contribute to the National Malaria Control Program's effort to eliminate malaria by 2030.

Progress by PQM+ Objective

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

PQM+ delivered the second week of virtual metrology training for 14 staff at DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory. PQM+:

- Used instructional videos, created in collaboration with USP Ghana, for preventive maintenance (PM) and post-PM verification of laboratory equipment to facilitate the hands-on part of the training.

PQM+ conducted an initial gap assessment against ISO 17025:2017 standards at a private lab, YSI Pharmaceuticals Quality Control Laboratory.

The PQM+ team performs a QMS assessment at YSI Pharmaceuticals QC Laboratory. (PQM+ photo.)

During the assessment, the program team:

- Used a hybrid assessment format, with a senior QA/QC laboratory manager joining virtually and an in-country consultant joining on-site.
- Assessed QMS at YSI and witnessed method demonstration by lab analysts.
- Will use findings from this assessment to develop a roadmap toward ISO 17025:2017 accreditation for YSI.

Objective 4: Increase the supply of quality-assured essential medical products of health importance

PQM+ conducted document review on GMP at YSI Pharmaceuticals Manufacturing Facility. PQM+:

- Communicated with four private manufacturers to gauge interest and suitability to receive PQM+ technical assistance on GMP.
- Selected YSI Pharmaceuticals (the only manufacturer producing antimalarials in Burma).

- Began technical assistance with a document review of the YSI Pharmaceuticals site master file and provided recommendations for improvement.

Priority Activities for Next Quarter

Next quarter, PQM+ Burma plans to:

- Deliver Week 3 of metrology training to DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory.
- Deliver measurement uncertainty and data integrity trainings to DFDA laboratories.
- Establish a roadmap toward ISO 17025:2017 accreditation at the YSI Pharmaceuticals QC Laboratory and conduct a QMS workshop.
- Conduct an on-site GMP assessment at YSI Pharmaceuticals.

Nepal

PQM+ provides technical assistance to Nepal's Department of Drug Administration (DDA) to strengthen medical product quality assurance (QA) and quality control (QC) systems and is enhancing the testing capacity of National Medicines Laboratory (NML) to complement the regulatory activities of DDA. PQM+ is also working with local public and private manufacturers to increase the domestic supply of quality-assured medicines.

Reaching its third year of implementation, many activities continued as an extension of the previous year, while new activities include public manufacturer strengthening and introducing quality procurement guidelines for the national health insurance system.

Objective 1: Improve governance for medical product quality assurance systems

PQM+ is collaborating with DDA, the Ministry of Health and Population, and MTaPS to improve medicine-related legislation, policies, and regulations and promote collaboration among stakeholders.

Revision of national GMP and Good Storage and Distribution Practices (GSDP) codes: DDA has put the revised GMP code in the approval process after an internal committee reviewed the revised code. PQM+ supported revision of the current GMP code and has supported drafting four supplemental guides to the GMP code, covering biologicals; heating, ventilation, air conditioning (HVAC); hazardous substances; and the water treatment system. PQM+ and MTaPS are working with DDA to update the national code on sales and distribution of drugs to align with WHO's GSDP code. PQM+ shared a gap assessment of the current code.

High-level consultative forum: Previously, PQM+ supported DDA to organize a high-level meeting of all stakeholders to discuss policy challenges in the pharmaceutical sector. Following the meeting, PQM+ is providing technical support to DDA to develop a policy paper on pharmaceutical reform in Nepal. DDA is reviewing the policy paper draft.

Objective 2: Improve country and regional regulatory system to assure the quality of medical products in the public and private sectors

Strengthen risk-based inspection (RBI) of DDA: PQM+ facilitated a meeting of the TWG on inspection, where the group endorsed the RBI framework and recall guideline. DDA finalized a

list of 24 manufacturers to be ranked using the RBI framework. DDA will inspect selected high-risk manufacturers. In the meantime, PQM+ is supporting DDA to assess information related to those 24 manufacturers. PQM+ also supported DDA to finalize two inspection related SOPs on complaint handling and recall. PQM+ worked with technology firm, Avatour, to demonstrate remote inspection technology to DDA staff on two occasions.

Strengthen RB-PMS of DDA: PQM+ worked with DDA's Management Division and the RB-PMS TWG to institutionalize a risk-based approach in DDA's functions:

- PQM+ facilitated two workshops: one presenting hands-on techniques for the MedRS tool and a second on scoring risks related to medicines using the tool and then developing a protocol for RB-PMS piloting. The TWG finalized the protocol and is reviewing the RB-PMS guidelines.
- Based on the RB-PMS protocol, PQM+ planned to support DDA to collect sample medicines for the RB-PMS pilot in Province 1. The field sample collection took place during the last week of March. The PMS results are representative of the quality of sampled medicines in Province 1 only and not nationally representative.

Regulatory workforce development: PQM+ is engaging consortium partner IntraHealth to conduct three tasks related to workforce development:

- Training needs assessment and training plan for NML: PQM+ facilitated information collection for the training needs assessment. The draft assessment report and training plan are completed and are being reviewed.
- Training needs assessment and training plan for DDA: PQM+ and IntraHealth jointly designed the data collection tools for DDA's training needs assessment. The primary data collection (such as interviews) is underway.
- Staffing needs analysis: IntraHealth identified consultants to conduct staffing needs analysis for NML and initial preparatory work for the analysis (such as the inception report and tools) is underway.

Support NML toward ISO 17025 accreditation: Based on the institutional development plan for NML, PQM+ is supporting NML to strengthen its quality management system, testing capacities, and staff technical skills.

- *Training to NML on various topics in February and March:* USP expert Yenny Francisca facilitated hands-on and in-person training sessions to 20 technical staff on good weighing practices, HPLC and dissolution calibration, and performance validation. Other training sessions covered good documentation practices and internal audits.
- *Equipment upgrades to enhance testing capacity:* After finalizing vendors, PQM+ ordered three essential pieces of equipment: Fourier-transform infrared spectroscopy (FTIR), water purification system, and pH and conductivity meter.

Physical supplies and electronic data warehousing: PQM+ performed a warehouse assessment of lab chemicals, standards, and samples at NML and is now reviewing the assessment report. PQM+ is also planning with NML to strengthen its information management system, especially on inventory management and analytical data storage. PQM+ is implementing an inventory management system for the lab. NML and PQM+ together are studying requirements for the laboratory's data server system. **Objective 4: Increase the supply of quality-assured essential medical products of health importance**

To improve the local supply of quality-assured essential medicines, PQM+ is working with private and public pharmaceutical manufacturers.

Private manufacturers: In the previous quarter, PQM+ collaborated with DDA to conduct a detailed assessment of manufacturers, selected on the basis of their level of GMP compliance and manufactured product, with the help of an external expert. PQM+ is finalizing assessment reports and CAPA plans for those manufacturers to design a roadmap to support them in obtaining WHO prequalification.

Public manufacturer: PQM+ is supporting the only public pharmaceutical company, Nepal Ausadhi Limited (NAL), to achieve compliance toward national GMP. Specifically, two areas were targeted. First is the water treatment facility and for this a service provider is currently working to upgrade the water treatment system to meet industry requirements. Secondly, PQM+ and NAL are working to physically redesign their microbiology section by improving the air handling unit and clean room in accordance with the regulatory standards.

Nepal pharmaceutical manufacturing strategy: PQM+ is collaborating with DDA and other national stakeholders to develop Nepal pharmaceutical manufacturing strategy. PQM+ engaged consortium partner IQVIA to conduct a landscape analysis of the Nepali medicines market. The draft report is completed and is in the process of revision after initial reviews.

Quality procurement guidelines: To assure quality in the procurement process for medicines, PQM+ is assessing the medical product procurement process and developing guidelines for quality assurance at the National Health Insurance Board and a local government unit. Specifically, PQM+:

- Completed an assessment of the medical product procurement process of a local government unit. The assessment report is complete and PQM+ is developing a standard procurement guideline in their jurisdiction.
- Met with the Health Insurance Board to discuss quality medicines procurement at health facilities. Participants set an action plan for the assessment process and selected representative health facilities to assess.

Objective 5: Advance global medical product quality assurance learning and operational agenda

PQM+ worked with DDA to develop public service announcements (PSAs) on SF medicines, and sent the PSAs to the USAID Mission for their approval.

PQM+ has also developed a research proposal for pre- and post-intervention assessments of community pharmacists' awareness and behaviors on the identification of SF medicines. The team will submit the proposal to PQM+ HQ and the Nepal Health Research Council for ethical approval. Similarly, PQM+ is developing a plan to train community pharmacists on identification of SF medicines.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Support the DDA on the approval of the GMP code and finalize the four supplementary guidelines for the code.

- Work with MTaPS and DDA to review and finalize the revised draft code on sales and distribution of codes.
- Support DDA to organize a high-level meeting to discuss a roadmap that will guide development of a Nepal pharmaceutical manufacturing strategy (to be drafted in PY4). To support development of the strategy, PQM+ will finalize a landscape analysis report to share with stakeholders.
- Complete the assessments of health facilities enlisted with the National Health Insurance Board and finalize guidelines for the board and a local government unit.
- Finalize CAPA plans for the six private manufacturers and begin reviewing progress against the CAPA plans. PQM+ and NAL will jointly upgrade the water treatment system and microbiology sections.
- Complete the pre-post assessment on community pharmacists' knowledge and behavior in relation to SF medicines and finalize preparations to train them on the topic.

Pakistan

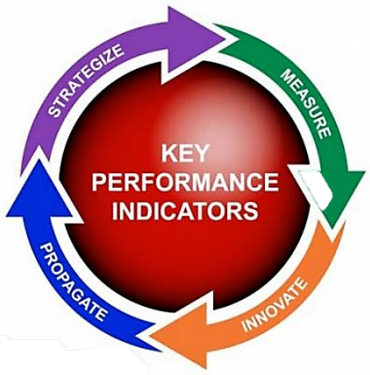
Pakistan's regulatory system has limited capacity for medicines quality surveillance, contributing to the proliferation of SF medical products. Lack of regulatory enforcement and availability of centers to conduct reliable bioequivalence studies reduces confidence in the efficacy of generic medical products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

The PQM+ Pakistan 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 outcomes and contributing to economic development.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance systems

Technical assistance for organizational restructuring and strengthening performance improvement functions at DRAP: In Q2, PQM+ continued supporting DRAP to implement newly developed performance objectives and periodic review of indicators. Earlier, PQM+ developed draft outlines of key performance indicators (KPIs) as part of the overview of performance management, compliance management, and KPIs to measure the efficiency and effectiveness of various regulatory functions at DRAP.



Moving forward, the PQM+ team has developed a comprehensive training program for DRAP staff called "Key Performance Indicators Development and Global Competency Framework." Training workshops for DRAP are planned for the end of March and/or April. These workshops will aid DRAP's

organizational restructuring for better reporting compliance and standardization of practices among DRAP divisions. Key achievements include:

- KPI development orientation meeting with DRAP management.
- Development of training materials (methodology, agenda, relevant forms, etc.) for DRAP's KPIs capacity building program (developed by PQM+) with training of DRAP assistant directors.

Support implementation of a regulatory framework for the National Access, Watch, and Reserve (AWaRe) list: Given the high prevalence of antimicrobial resistance (AMR) in the country, it is especially important that the regulatory framework address priorities identified in the National Action Plan on AMR, which covers May 2017 through June 2022.

A meeting with key stakeholders (including DRAP, provincial regulators, and NIH officials) gave participants an opportunity to share progress and strategies for implementing the National Action Plan on AMR. DRAP shared the following key contributions of PQM+:

- Information about manufacturing licensing is activated in the Pakistan Integrated Regulatory Information Management System (PIRIMS) for antimicrobial consumption (AMC) monitoring. Activation of the AMC Dashboard requires data inputs from the licensing and registration divisions of PIRIMS. The licensing division module is now fully active for data inputs, but registration data is still being incorporated into the registration module. Once the data importation is complete, that data will be reflected in the AMC Dashboard.
- Antimicrobial registration of all products has been developed and will be activated soon.
- Manufacturers are entering batch manufacturing data into the AMC dashboard.
- E-Office (DRAP's in-house data portal) data input is available to monitor raw material import and will be linked with the dashboard when the registration module is activated.

PQM+ has drafted key steps for discussion and proposed implementation of the AMR activity. Progress includes:

- Logging distributors and retailers in the AMC dashboard.
- Training DRAP staff, distributors, retailers, and manufacturers on AMC monitoring, under the umbrella of the AMR regulatory framework.
- Securing the involvement of provincial governments.
- Product registration decision-making (risk-based)

National Medicines Policy (NMP) implementation plan and quality assurance guidelines: The USAID-funded Integrated Health Systems Strengthening and Service Delivery (IHSS-SD) Program revised the NMP of Pakistan after 27 years in 2017, but the country has not yet developed an implementation plan. The final approved NMP could not be launched due to the COVID-19 pandemic. PQM+ has continued to follow up with the Ministry of National Health Services Regulations and Coordination (MoNHSRC) regarding NMP approval.

PQM+ is developing an implementation plan using a matrix of six elements, and has developed a detailed action plan and timeline for these activities.

Support DRAP to develop IDPs: PQM+ continued technical support to DRAP to develop IDPs based on self-assessment gaps. PQM+ assisted DRAP to complete IDPs in the following areas:

- CTD dossier evaluation, with special emphasis on certificates of suitability and bio waiver stability data evaluation.
- Good Pharmacovigilance Practices.
- Risk management on regulatory processes.

During Q2, PQM+ organized a series of trainings, including one on risk assessment and management with the aim of incorporating tools and methods in the DRAP system for risk-based system development. This will help DRAP staff conduct risk-based inspections and dossier evaluations.

Another training addressed the evaluation of CTD dossiers to enhance the DRAP staff's capacity to evaluate medical product dossiers according to international best practices, as well as work to ensure the safety of medical products being manufactured. The 24 participants (eight females, 16 males) shared their appreciation regarding the training contents and facilitators.

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

Improve the laboratory quality system: PQM+ completed a gap assessment of the Public Health Laboratory (PHL) at the Institute of Public Health (IPH) in Lahore for the achievement of ISO 15189 accreditation (an international standard for QMS at medical diagnostic laboratories). PQM+ assistance helped the Pakistan National Accreditation Council (PNAC) complete a pre-audit for ISO 15189 in September 2021. This accreditation would enable PHL to improve its lab testing reliability going forward. PQM+ achievements include:

- Provided technical assistance on preparation of CAPA against PNAC pre-assessment observations. PQM+ supported proper implementation of the CAPA to obtain ISO 15189:2012 Laboratory Quality Management System accreditation for IPH Medical Lab.
- The CAPA report has been submitted to PNAC for review and final audit.

PQM+ has assisted with work in several Pakistan labs, detailed below.

Drug Testing Laboratory (DTL) Lahore: National quality control laboratories in Pakistan use calibration services from accredited external sources, only a few of which operate in the country. For these reasons, Pakistan seeks to build in-country capacity to provide these services. PQM+ is helping DTL Lahore achieve ISO 17025 accreditation for calibration services.

Currently, the lab provides analytical services only and is responsible for the analysis of drug samples. The main scope is physical tests, chemical analysis, identification tests, assays, and impurities tests. However, calibration competence needs to be established to meet the ISO 17025:2017 standard. PQM+ completed a gap assessment of DTL Lahore and provided trainings to its staff, reviewed the SOPs for the calibration of equipment, and shared observations related to the calibration procedures. The key updates are:

- Conducted two days of trainings on "Calibration of Equipment and Advanced Uncertainty of Measurements (ISO/IEC 17025)" for DTL Lahore staff in January.
- Reviewed the SOPs for the calibration of lab equipment.

- Applied for a scope extension to include the calibration laboratory in accordance with ISO/IEC 17025:2017.

PQM+ and the WHO prequalification team established a partnership for peer audits, with PQM+ carrying out a three-day peer audit of DTL Lahore for WHO prequalification of quality control laboratories, monitored online by the WHO PQ team. PQM+ led the peer audit and assisted in preparing a CAPA against the WHO's peer audit observations. DTL Lahore submitted its CAPA to WHO for comments and further actions.

DTL Multan (WHO-PQ peer audit): PQM+ and the WHO-PQ team partnered for peer audits to strengthen the quality control lab system in Pakistan. PQM+ visited DTL Multan to prepare for the peer audit. In Q2, PQM+ supported DTL Multan to prepare the CAPA report in the WHO-PQ required format.

DTL Bahawalpur (WHO-PQ peer audit): PQM+ assisted the lab to review and submit the laboratory information file (LIF) for WHO prequalification, which WHO accepted and approved. The lab prepared the CAPA report and submitted it for WHO-PQ review.

DTL Rawalpindi (WHO-PQ audit): PQM+ provided technical assistance to DTL Rawalpindi during the WHO-PQ audit. As a follow-up activity, PQM+ assisted the DTL for CAPA preparation and submission to WHO. Key achievements by PQM+ during the quarter are:

- Review of the CAPA report.
- Provision of guidance to prepare the lab for a follow-up within six months.

Central Drug Laboratory (CDL) Karachi (WHO-PQ peer audit): PQM+ supported CDL to move toward international accreditation to become a WHO-Listed Authority. During the initial phases, CDL has been assessed for quality management system certification and is continuously engaged with WHO for prequalification as a quality control laboratories. PQM+ has collaborated with the WHO-PQ team to conduct a peer audit. Last quarter, PQM+ helped review and submit the CAPA for the WHO Peer Audit Report of CDL Karachi to WHO HQ for further communication with CDL Karachi. With PQM+ support, CDL Karachi will be positioned to offer sample testing services to other quality control laboratories nationally and internationally.

Table 1: – Status of Labs Accreditation

Laboratory	Accreditation sought	Initial Gap Assessment	CAPA (Corrective and Preventive Action)	(QMS) Quality Management System	Proficiency Testing (PT) /Laboratory Testing (LT)	Official Inspection/ Pre-assessment
IPH Lab	ISO 15189	Completed	Completed	Completed	Completed	Completed Final assessment by PNAC is awaited.
Appellate lab	ISO 17025	Completed	On-going	Developed, under implementation and PT pending	One PT sample is performed and reported. Other sample awaited.	Lab is currently under renovation phase

Laboratory	Accreditation Sought	(QMS) Quality Management System	Initial Gap Assessment	CAPA (Corrective and Preventive Action)	Laboratory Information File (LIF)	Official Inspection/ Pre-assessment
DTL, Rawalpindi	WHO Pre-Qualification	Completed	Completed	CAPA plan is currently under review		CAPA is submitted and reviewed by Inspector, WHO. Follow-up visit for verification of CAPA will be carried out within 6 months.
DTL Multan	WHO Pre-Qualification	Completed	Completed	Completed	Submitted and approved	Completed. Peer audit CAPA submitted to WHO for review.
DTL, Lahore	WHO Pre-Qualification	Completed	Completed	Completed and submitted	Submitted and approved	Completed Peer audit CAP submitted to WHO for review.
	(ISO 17025:2017 (Calibration)	Completed	Initial Gap Assessment by PQM+ completed	Completed	N/A	Application for scope extension to include calibration laboratory in accordance with ISO/IEC 17025:2017 is submitted to PNAC.
CDL, Karachi	WHO Pre-Qualification	Completed	Completed	Completed and submitted	Submitted and approved	CAPA plan against Peer audit submitted to WHO PQ for review.
DTL, Bahawalpur	WHO Pre-Qualification	Completed	Completed	CAPA plan is currently under review	Submitted and approved	Peer audit CAPA is developed and submitted to WHO PQ for review.

Short course on quality assurance and regulatory affairs: Currently, no academic institution in Pakistan offers courses or degree programs in pharmaceutical regulatory affairs. It is essential to include these topics in the academic syllabus (pre-service) and design structured programs for post-service continuous professional development.

For this purpose, PQM+ began developing a short course on regulatory sciences to cover regulatory affairs, including the application of regulatory principles worldwide. Regulatory affairs is a mix of science, management, legislation, and commercialization and encompasses developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated products. PQM+ organized a two-day meeting in March to review the draft course and shared draft course content with key stakeholders (representing the regulatory authority, academia, and the pharmaceutical industry) to get their input.

Roadmap for stepwise implementation of bioequivalence (BE) studies: Pakistan is one of only a few countries where BE studies are not mandatory for marketing authorizations, despite it being a key requirement for PIC/S membership, WHO-PQ, and WHO's Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. PQM+ met with DRAP officials to discuss development of a roadmap for stepwise implementation of BE studies in Pakistan. Mr. Asim Rauf, the CEO of DRAP, said the agency is ready to collaborate, diluting the associated risk and resistance to change from the industry. PQM+ presented a way to develop the roadmap and highlighted that data integrity is the key to the success of any framework. Considering the dynamics of Pakistan, PQM+ proposed several steps for smooth implementation.

At the end of the meeting, participants agreed on the following action points:

- DRAP will send proposed guidelines to the relevant authorities for deliberation and implementation.
- PQM+ will share lists of high-risk priority molecules and products for DRAP to maintain on its website and update periodically.
- In consultation with DRAP, PQM+ will draft a national BE policy and design a roadmap for stepwise implementation for further discussion with regional and international experts in view of best practices.

Objective 3: Increase the supply of quality-assured essential medical products of health importance

Quality-assured priority medical products: PQM+ continued to support development of the pharmaceutical manufacturing industry, monitoring manufacturers' progress in implementing CAPA plans for amoxicillin DT in response to findings from their GMP gap assessments in relation to QMS, current GMP practices on the production floor, and good quality control lab and product dossier practices.

PQM+ visited two manufacturers of amoxicillin DT and zinc DT/oral liquid in Lahore and provided technical assistance toward WHO-PQ. PQM+ also visited a newly selected manufacturer of zinc DT/oral liquid for an inception meeting and provided a detailed orientation on the WHO-PQ process. The manufacturer noted management's commitment to the process.

PQM+ also visited another amoxicillin-DT manufacturer to discuss their challenges and potential solutions. The program conducted a gap assessment and shared the report, requesting a CAPA response to the inspection report detailing the root cause analysis.

National Pharmaceutical Strategy: A key focus of PQM+ is to help foster a business-enabling environment that encourages private sector investment in pharmaceutical manufacturing. Pakistan currently exports approximately $230 million in pharmaceutical products, a small percentage of the global market for pharmaceuticals, valued at more than $1 trillion.

Key achievements during the quarter are:

- As a result of PQM+'s advocacy and engagement, key government stakeholders, representatives of the Board of Investment (BOI) in the Prime Minister's Office, and the chief economist from the Planning Commission within the Ministry of Planning, Development, and Special Initiatives have agreed to highlight the pharmaceutical sector as a key priority sector for focusing government efforts to attract investment and resolve regulatory and business environment challenges.
- PQM+ joined a working group created by the Ministry of Planning, Development, and Special Initiatives on "Enhancing Efficiency-Seeking Investments" (EESI). The group will prepare a three-year rolling growth strategy for economic diversification, transformation, and jobs-led growth. PQM+ participated in a series of meetings and shared short- and medium-term reform/policy proposals resulting from the ongoing strategy building exercise. A key priority area was API manufacturing, and PQM+ prepared and submitted a comprehensive note on API policy formulation.
- In January, PQM+ met with the Pakistan Regulatory Modernization Initiative (PRMI) led by the World Bank Group and shared the rationale and progress of the strategy-building exercise. They agreed to coordinate during monthly meetings, and designated focal points. To document the learning and support the implementation of similar strategy-

building exercises in other places where PQM+ works, the Pakistan team developed a step-by step guide that guides the design, planning, and implementation of the strategy development exercise.

Private sector engagement (PSE): PQM+ continued developing relationships with industry associations and conducted meetings with the Pakistan Pharmaceutical Manufacturers Association (PPMA), the Pharma Bureau, and Healthcare Devices Association of Pakistan to identify regulatory challenges and bottlenecks to industry growth domestically and in export markets.

PQM+ worked to expand partnerships with knowledge leaders in the global pharmaceutical industry, aiming to develop strong relationships and leverage partners' technical expertise to offer training and capacity-building opportunities for DRAP. Using a training needs assessment that DRAP recently completed, PQM+ identified potential private sector partners with knowledge and expertise in DRAP's areas of interest.

During the reporting quarter, PQM+ also shared feedback on the recently issued Reliance Guidance document with DRAP after extensive consultations with private sector stakeholders and global experts.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Work with multiple pharmaceutical sector partners to identify appropriate partners and design a training curriculum for DRAP staff on development of KPIs. Trainings are tentatively planned for Q3.
- Follow up with PNAC for a final assessment of the Institute of Public Health in Lahore for ISO 15189 accreditation.
- Review DRAP's preparation materials regarding IDPs for WHO's final audit.
- Support adoption of two data standards, ISO 11615 and ISO 11238.
- Develop two case studies documenting best practices from countries that have successfully promoted their pharmaceutical sectors to the government/regulator.

Europe and Eurasia Region

Central 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 PIC/S accession.

Progress by PQM+ Objective

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

In Q2, PQM+ continued technical assistance to the Almaty and Karaganda MQCLs to help them achieve and maintain WHO-PQ, with the following developments:

- PQM+ continued technical assistance to Almaty MQCL in implementing a CAPA plan prepared by the lab after PQM+ conducted a peer audit. In accordance with recommendations from the WHO-PQ team, PQM+ assisted Almaty MQCL in preparing additional information requested by the WHO-PQ team. PQM+ reviewed and improved several additional Almaty MQCL SOPs that WHO requested. The CAPA plan and additional documents are ready for submission to WHO.
- The WHO-PQ team confirmed plans for an inspection of the Almaty laboratory in July 2022.
- PQM+ began assisting the Karaganda and Almaty labs to develop their capacity in computerized systems validation (CSV). WHO and PQM+ have identified this area as one that needs further support. In Q2, development of the validation protocols and reports for the laboratory equipment was initiated.
- The Karaganda laboratory received equipment (pH-meter, conductometer, and Karl Fischer titrator) that PQM+ funded; the items are essential for conducting some analyses. The vendor installed the instruments and provided training to the laboratory staff on how to operate the equipment.
- PQM+ assisted the Karaganda laboratory in preparation of the annual report to the WHO-PQ team. PQM+ reviewed the report prior to submission to WHO and the lab submitted it at the end of March.

PQM+ is supporting Kazakhstan in strengthening the pharmaceutical inspectorate and preparing for ascension to PIC/S membership, which will facilitate reliance and open access to the Good Manufacturing Practices (GMP) inspection mechanism with other PIC/S member countries; resources for capacity development; and access to quality-assured medicines.

- PQM+ met with the deputy chairman of the Committee for Medical and Pharmaceutical Control (the Committee), management of the GMP Inspectorate, and NCEM management. PQM+ updated the counterparts on the preparation for accession to PIC/S.

- PQM+ continued technical assistance toward advancing on the roadmap to PIC/S ascension. In Q2, PQM+ helped the GMP Inspectorate prepare their newly developed quality management system for launch.
- PQM+ provided a three-day virtual training for 34 people on the inspection of engineering systems for the staff of the GMP Inspectorate, including approaches for inspecting engineering systems for water for injections, purified water, pure steam, compressed air, and process gases. PQM+ will provide further training on heating, ventilation, and air-conditioning systems and emergency power.

PQM+ continued technical assistance to NCEM in strengthening its PMS system and built on the work conducted in previous quarters.

- As a follow-up to the initial introduction of MedRS, PQM+ rescheduled an onsite in-depth training for the NCEM staff on the tool for April 2022 due to political instability in Kazakhstan. PQM+ is preparing for the training.

PQM+ continued work with NCEM's scientific-educational center (SEC), an important entity in ensuring the sustainability of PQM+'s efforts to build the capacity of the medicines regulatory workforce in Kazakhstan.

- PQM+ and the SEC discussed training topics for the next course. In Q3, PQM+ will develop and deliver a training on how to prepare and administer tests in the courses developed by the SEC.
- The SEC requested assistance from PQM+ with initial procurement of a learning management system (LMS), which the SEC will use for virtual courses and e-learning. PQM+ discussed options of LMS procurement and management and is waiting for SEC's decision. Based on the decision, PQM+ will provide further support to the SEC.

PQM+ continues assistance to NCEM in improving the Medical Devices (MD) Inspectorate. PQM+ identified four areas of technical assistance: development of an MD inspectors' group, development of QMS, training of inspectors, and evaluation of dossier applications.

- PQM+ continued discussion of the QMS developed by the MD Inspectorate. PQM+ reviewed several SOPs and discussed changes in NCEM's relevant QMS documents. The MD Inspectorate is preparing a list of procedures they need to develop.
- The MD inspectors proposed future discussions and trainings. PQM+ will identify the topics to be delivered to the MD Inspectorate.

NCEM started developing the five-year (2021–2025) strategy, which should address key areas of the regulatory system development toward achieving WHO GBT Maturity Level 3 and harmonization with Eurasian Economic Union (EAEU) regulatory requirements.

- NCEM reviewed comments and recommendations from PQM+ on its strategic plan and developed a revised plan based on these recommendations. PQM+ started review of the strategy and will provide feedback.

PQM+ and NCEM discussed providing technical assistance to address the gaps in the registration system and work toward WHO GBT Maturity Level 3. The WHO GBT audit identified four registration sub-indicators that require additional improvement. NCEM believes they can work on these gaps independently.

One gap identified during the WHO GBT assessment was that the Committee for Medical and Pharmaceutical Control (the Committee) needs to establish QMS, due to its involvement in regulatory function. In Q2, PQM+ initiated technical assistance to the Committee in establishing QMS according to ISO 9001. The program identified key areas for discussion and decision-making with top management of the Committee, including the vision of the project, schedule of implementation, top management's role, scope of the QMS, processes and process owners, planning of the Committee development, and coordination of next steps. Discussion and decisions on these topics will define further work, but PQM+ has started addressing some immediate needs, including developing the capacity of responsible staff of the Committee to develop a QMS.

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

Kazakhstan has two associations of local pharmaceutical manufacturers. PQM+ initiated engagement with them to understand the needs of the manufacturers specifically in terms of improving their GMP compliance.

- PQM+ developed a questionnaire to assess the training needs of the local manufacturers and provided it to the SEC for review. After the questionnaire is finalized, PQM+ and the SEC will arrange a meeting with the manufacturers' associations and present it to them. It is expected that the associations will distribute the questionnaire between the manufacturers and collect the results. The SEC will analyze the results and prepare their report on the training needs assessment.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Assist the Almaty MQCL in preparation for WHO-PQ inspection.
- Assist the Karaganda MQCL in maintaining WHO-PQ status.
- Continue technical assistance to the PIC/S working group in the areas outlined in the accession roadmap.
- Continue technical assistance to NCEM on developing approaches and procedures for RB-PMS.
- Continue technical assistance to the SEC to build capacity on workforce development.
- Provide technical assistance to the MD inspection group to become operational and compliant with international standards.
- Provide technical assistance to NCEM in preparation of a five-year strategy.
- Assist the Committee in establishing an ISO 9001 compliant QMS.
- Assess local manufacturers with their training needs.

Tajikistan

PQM+ is strengthening the medicines regulatory system in Tajikistan by providing technical assistance to the State Surveillance Service over Healthcare and Social Protection of the Population (SSSHS). The main objectives are to improve the medicines registration system and to support the medicines quality control laboratory (MQCL) to be able to test the quality of medicines reliably and accurately in accordance with the international standards.

Progress by PQM+ Objective

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

In Q2, PQM+ guided the TWG established by the SSSHS to complete the registration/ market authorization questionnaire based on the WHO GBT for assessing the medicines registration system. PQM+ reviewed responses to the questionnaire and identified gaps and areas of support needed. Based on the responses provided, PQM+ identified legal provisions, rules, and guidelines to support registration/ market authorization as well as organization and management structure to support registration activities. The assessment found a need to improve the regulatory process and communication to enhance efficiency in the registration system. This includes developing SOPs and guidance for good review practices, special registration requirements, and procedures for medical products for national emergencies, epidemics, and pandemics, as well as the dissemination of product information. PQM+ shared the feedback with the TWG and next will work with the TWG to address these gaps.

An important priority for PQM+ in Tajikistan is supporting registration of WHO-prequalified TB medicines. Registration will help in advocating for procuring these WHO-PQ medicines with domestic funding (first-line TB medicines) and in avoiding delays during the importation of WHO-PQ medicines (second-line TB medicines) procured by Global Fund from the Global Drug Facility (GDF). While PQM+ works on strengthening the registration system, as well as advocates for accelerated registration of WHO-prequalified medicines, the program is also working with stakeholders on encouraging manufacturers that have achieved WHO-PQ to apply for registration of their products in Tajikistan. PQM+ will select a local company that can work with the WHO-prequalified manufacturers and, on their behalf, compile and submit dossiers for registration in Tajikistan.

This quarter, PQM+ learned of a new Law on Pharmaceuticals developed in 2021 that Parliament is set to approve this year. The updated draft law has a provision that may allow a simplified registration of some medicines. PQM+ will follow up with the MoH and the SSSHS to provide technical assistance in updating the regulation procedure according to the new law, as well as developing a new regulation on simplified accelerated registration of WHO-prequalified medicines.

PQM+ presented the WHO Good Laboratory Practices (GLP) checklist to the MQCL and guided them in conducting a self-assessment according to the checklist. It helped PQM+ to get an overall understanding of the status of the laboratory and, as a next step, a virtual assessment of the laboratory took place in February. PQM+ assessed the management and infrastructure, equipment, personnel, and SOPs, and the MQCL demonstrated its physiochemical and microbiology methods. PQM+ then developed general findings from the assessment to share with the MQCL.

The MQCL has implemented a QMS and has ISO 17025 accreditation in the old version, from 2005. The MQCL has equipment, infrastructure, personnel, and resources to perform tests, but these need to be operationalized and improved. MQCL has a documentation system that needs review and improvement, and development of new documents and records should follow ISO 17025:2017 and WHO requirements. There is also a need to develop MQCL staff's capacity on physiochemical and microbiological methods and QMS. PQM+ agreed to start technical assistance by improving the QMS, documents, and records management.

PQM+ is planning a study on the treatment results and the incidence of adverse drug reactions for patients treated with the first-line drugs procured domestically and used for treatment of drug-susceptible TB. They will compare these with cohorts from previous years, including when GDF still supplied those drugs. PQM+ developed a scope of work to recruit a technical expert for the study, just as the head of National TB Program (NTP) left that position. The study will start after the new NTP head has become oriented and better informed about the situation.

PQM+ joined the Development Coordination Council (DCC), which seeks to strengthen aid effectiveness in Tajikistan by facilitating information exchange and collaboration within the development community, as well as fostering dialogue on shared priorities with the Government of Tajikistan (GoT). The DCC functions as development partners' coordination mechanism with the GoT in support of the National Development Strategy 2016–2030 and the Mid-Term Development Strategy 2021–2025.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Develop an assessment report and an action plan for addressing identified gaps at the MQCL.
- Present the findings of the assessment of the medicines registration system and identify the priorities for technical assistance to strengthen the system.
- Select and contract a company that can help manufacturers of WHO-prequalified medicines prepare and submit dossiers for approval in Tajikistan.
- Initiate technical assistance to develop a new regulation for simplified registration of WHO-prequalified medicines according to the new draft Law on Pharmaceuticals (approval pending).

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. PQM+ assists the Agency on Development of the Pharmaceutical Industry ("the Agency") around medicines regulatory systems strengthening, including improving the medicines review and registration system, supporting MQCLs to test the quality of medicines reliably and accurately, preparing the GMP inspectorate for PIC/S accession, and introducing RB-PMS to detect substandard and falsified medicine. The program also focuses on increasing the supply of locally manufactured, quality-assured TB medicines by providing technical assistance to pharmaceutical manufacturers.

Progress by PQM+ Objective

Objective 1: Improve governance for medical product quality assurance system

PQM+ is providing technical assistance to the Ministry of Health (MoH) in developing the "pharmaceuticals and medical devices" strategic block of the MoH's Health Strategy 2030. In Q2, PQM+ advisors took part in 23 meetings on strategy development in Tashkent. The

advisors met with various public and private sector stakeholders to gather information for a pharmaceutical and medical devices situational analysis. The meetings were with entities including the Minister of Health and his team, the chamber of innovative health care management, the Uzbek Pharmaceutical Development Agency, the association of local manufacturers, a distributor, hospital directors, and a medical device association. The team also launched the working group for the pharmaceutical and medical devices strategy block by organizing the first working group meeting, attended by about 40 people. Many of these groups have since shared written recommendations for the strategy, which the team is now incorporating into the situational analysis. PQM+ is using the information obtained during the meetings and the results of a desk review to develop the situation analysis, which will inform recommendations for pharmaceutical strategy development as part of the Health Strategy 2030.

In Q2, PQM+ team members discussed several approaches for conducting the landscape analysis of local manufacturers of essential medicines to identify the main players and the policies that support or undercut the local production. They developed a draft questionnaire for data collection. In addition, a corresponding SOW for external consultants (or a vendor) who would help collect the data was developed. PQM+ will organize a working group in collaboration with the Agency to initiate the landscape analyses.

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

In Q2, PQM+ continued to provide technical assistance to strengthen the medicines registration system. Through the COVID funding, PQM+ had initiated the concept of emergency use authorization (EUA), which the updated draft version of Cabinet Resolution #213 included. PQM+ reviewed the EUA provisions in Resolution #213 and provided feedback for improvement. After the EUA provision's approval, PQM+ will work with the registration working group on developing SOPs, guidelines, and processes related to EUA. PQM+ is simultaneously working with the registration working group to develop appropriate SOPs that will meet international standards. PQM+ is providing guidance to develop 47 relevant SOPs; in Q2, PQM+ reviewed two SOPs related to the pharmacopeial center and the pharmacopeia committee. To date, PQM+ has reviewed and provided feedback on 12 SOPs.

In Q1, PQM+ hit an important milestone in advocating and providing technical assistance for using the collaborative registration procedure (CRP) for accelerated registration of WHO-prequalified medicines in Uzbekistan. Two TB medicines, cycloserine and protionamide, were registered through the WHO CRP. In Q2, four additional dossiers were submitted to the Agency for WHO-prequalified TB medicines. The Agency accepted the dossiers for review through WHO CRP and issued invoices to the manufacturers of these products. Payment for registration is anticipated from the manufacturers this quarter, allowing the Agency to review the dossiers.

This quarter, PQM+ continued to work with the newly established Good Practices (GxP) Center, which is responsible for the GMP inspection. PQM+ continued to engage with the working group on developing an updated version of the GMP guideline, training programs for inspectors, and the SOP on QMS and the inspection process. The draft work plan for PIC/S ascension is under review, with PQM+ guiding responsible parties in preparing the updated version with proposals for relevant areas. Based on a training on "Recent Changes in the PIC/S GMP Guide" during Q1, the participants are updating the GMP Guide. With assistance, the list of SOPs has been developed and PQM+ is reviewing it to ensure that all areas are being covered. PQM+ is also reviewing six SOPs on QMS. With PQM+ technical assistance, the working group developed a draft inspection program on sterile and tablet production and PQM+ is reviewing it. Based on

the guidance provided by PQM+, the center is preparing training plans for individual inspectors for 2022. PQM+ continues to provide recommendations concerning cooperation between the inspectorate and the licensing unit (located outside the inspectorate) and the development of a proper system to handle quality defects.

In Q1, with PQM+ technical assistance, Tashkent and Andijan laboratories received ISO 17025 re-accreditation from the national accreditation body. In Q2, PQM+ conducted trainings on internal audits and CAPAs for four participants from the Andijan MQCL. PQM+ is also working closely with the Andijan MQCL to bring its CAPA and internal audit programs in line with WHO-prequalification requirements. This technical assistance includes developing and updating existing procedures, documents, and forms, and restructuring existing processes. PQM+ is finalizing the hiring of an expert for ISO 90001, which defines standards on QMS. This expert will develop the capacity of the QMS group to help support the Agency. PQM+ is also reviewing floor plans and designs for the Urgench MQCL and will provide feedback and recommendations to comply with best practices for laboratory design.

In January, Uzbek President Shavkat Mirziyoyev issued a decree on developing the pharmaceutical industry, including a provision on introducing PMS to the country's regulatory system. This is an important milestone as the first introduction of a PMS concept and PQM+ providing crucial advocacy efforts and familiarizing the Agency staff with PMS. The decree resulted in the establishment of a working group on PMS; PQM+ guided the group in drafting PMS procedures and rules, then reviewed the document and provided feedback for improvement. PQM+ will draft the SOP with the working group and help build the Agency's capacity on PMS and implementing the PMS approach in the country.

In Q2, PQM+ developed and signed a task order with Purdue University to provide technical assistance to the pharmaceutical technology university at Tashkent Pharma Park. An assessment to determine the exact types of assistance is underway, with a target of curriculum development. .PQM+ held a kickoff meeting with Purdue to initiate the technical assistance. Representatives from the Agency and Purdue's technical advisors planned to meet at USP in the last week of March to discuss needs and planned technical assistance.

Objective 4: Increase the supply of quality-assured essential medical products of health importance

In Q2, PQM+ continued technical assistance to Nobel Pharmsanoat toward prequalification of its TB product levofloxacin. PQM+ reviewed and provided feedback on the dissolution profile protocol for biowaiver study and the dossier batch manufacturing report. PQM+ also provided guidance to Nobel on a small-batch production, which Nobel initiated in March. PQM+ is planning for an onsite technical assistance for Nobel to conduct GMP assessment, product development, and dossier preparation.

The Uzbekistan delegation visited the U.S. during the last week of March, with preparations by PQM+ throughout the quarter. The delegation comprised Agency personnel (including the Agency director) and several manufacturers of medicines and medical products from Uzbekistan. The visit included a day-long summit to connect U.S. pharmaceutical manufacturers with representatives of the Agency to share firsthand information about the pharmaceutical regulatory landscape, new incentives for foreign pharmaceutical companies interested in entering the Uzbekistan market, and opportunities for collaboration with Uzbekistan pharmaceutical companies. PQM+ held the event on behalf of the Agency at USP headquarters in Rockville. Keynote speakers included Daniel Rosenblum, the U.S. ambassador to Uzbekistan, and Sardor Kariev, director of the Agency. PQM+ managed all logistics related to

the summit, including invitations and social media outreach prior to the event, and the agenda, translation, catering, audiovisual support, and more on the day of the event. The Agency also met with USAID during this visit.

In Q2, PQM+ discussed the approach for Uzbekistan's local pharmaceutical industry improving GMP compliance, a requirement before accession to PIC/S. Training will assist the local industry in understanding GMP requirements and facilitate achievement of GMP compliance. To address this need, PQM+ will identify and hire a company to develop and deliver GMP training materials to the local industry. In Q2, PQM+ also developed an SOW for the potential vendor.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Draft and finalize the situational analysis to inform the pharmaceutical and medical devices block of the Health Strategy 2030.
- Identify and hire a company to conduct a pharmaceutical assessment of manufacturers of essential medicines in Uzbekistan and initiate the assessment.
- Review the SOPs to support strengthening the medicines registration system and facilitate the drafting of process steps and guidelines for EUA.
- Continue facilitating registration of the four WHO-prequalified TB medicines through the WHO CRP mechanism as needed.
- 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.
- Continue to work with Andijan MQCL to bring their CAPA and internal audit in line with WHO PQ requirement.
- Initiate technical assistance to the Agency on compliance with the QMS standards in ISO 90001.
- Provide inputs to the Agency on the floor design plan for the Urgench laboratory to align with the best practices on laboratory design.
- Continue technical assistance to the PMS working group to operationalize RB-PMS in Uzbekistan following the approval of the decree.
- Initiate assessment of the Pharmaceutical Technology University in collaboration with Purdue University.
- Provide onsite technical assistance to Nobel Pharmsanoat for mock assessment, product development, and dossier preparation.
- Identify and hire a company to provide GMP training for local Uzbekistan pharmaceutical manufacturers.

COVID-19

Bangladesh

Coordination and Operations: PQM+ is working with the Directorate General for Drug Administration (DGDA) to strengthen regulation for licensing oxygen manufacturing plants and registration of medical oxygen production. Early in the quarter, PQM+ kicked off the activity by hiring an oxygen expert and introducing him to DGDA's director and director general. Subsequently, PQM+ organized a meeting with the DGDA-established medical oxygen regulation working committee in February. Seven representatives from DGDA, PQM+, and WHO attended the meeting and discussed existing in-country and international regulatory practices as well as developing new regulations for medical oxygen gas and containers, oxygen regulators, and the central oxygen supply system.

Based on discussions, the working committee decided to 1) finalize the working group members to ensure representation of departments and issuance of an office order, 2) develop a list of existing legal documents and regulations for medical oxygen, as well as a list of medical oxygen manufacturers/facilities in Bangladesh, 3) review existing oxygen production methods in Bangladesh, and 4) develop a tool for completing a gap analysis of Bangladesh's medical oxygen gas manufacturing facilities.

PQM+ also organized a meeting to discuss existing regulations of medical oxygen in Bangladesh with manufacturers, importers, and retailers in mid-February; 11 people attended from eight organizations (Bangladesh University of Engineering and Technology, Abul Khair Oxygen, Union Oxygen Ltd., Oxyjog medical and industrial oxygen consultancy firm, Essence Industrial Gas Ltd., Linde Bangladesh Ltd., Spectra International Ltd., and Spectra Oxygen Ltd.). During the meeting, PQM+ and stakeholders discussed global standard good practices (GxP), existing GxP in Bangladesh, and problems, challenges, and opportunities with the regulatory system for medical oxygen in Bangladesh. From the discussion, PQM+ learned:

- Two major aspects of medical oxygen can be substandard or falsified: the quality of gas and the quality of the container.
- No regulations or fixed specifications exist for oxygen containers, but stakeholders say it is essential to regulate the type of container and the information tracked on it (e.g., manufacturer name, batch number, expiry date, instruction for storage, and usage instructions).
- Bangladesh does not have any regulations in terms of the life cycle of oxygen used at medical facilities. According to stakeholders, these are critical regulations, and inspections must occur to ensure compliance.
- Bangladesh has the capacity to test medical oxygen only in gaseous forms; no testing facilities are present for oxygen in liquid form. This leaves a major gap that could lead to substandard medical liquid oxygen.
- Liquid medical oxygen is the only form that Bangladesh imports. Of 14 manufacturers that received a no-objection certificate (NOC) for manufacturing medical oxygen during the pandemic, only three have medical oxygen manufacturing licenses for regular production, sale, storage, supply, and marketing.

- Bangladesh medical facilities are using supply lines that are not up to American Society for Testing and Materials (ASTM) standards, potentially compromising patient lives and raising supply costs.

This meeting was important to get stakeholders' feedback on regulatory system harmonization from both the regulator and manufacturing/import stakeholder sides. PQM+ will continue to gather information on the status of medical oxygen regulation and manufacturing in Bangladesh and align current practices to international best practices.

PQM+ finalized a gap assessment questionnaire to inform the development of a medical oxygen regulation assessment in Bangladesh, and disseminated the questionnaire to relevant stakeholders such as regulators, academia, manufacturers, biomedical engineers, and medical doctors. Within the month, PQM+ had drafted the gap assessment report, which it will use to recommend areas for improvement in medical oxygen regulation, as well as develop a medical oxygen regulation guideline. PQM+ also assisted in the formation of a consultation group of key stakeholders for the development of medical oxygen regulation guidelines in Bangladesh on March 14. This group will serve as the expertise in developing guidelines, based on their knowledge and experience in stages along the medical oxygen supply chain. Once finalized, the DGDA will own the guideline and rely on it to strengthen the regulation of medical oxygen in terms of quality, safety, and efficacy.

PQM+ also visited a medical oxygen manufacturer, Linde Bangladesh, on March 15. This visit helped PQM+ understand the manufacturing, compliance, storage, and distribution processes for liquid and gaseous medical oxygen, enabling PQM+ to make recommendations in its gap assessment. The program will plan another visit to a different manufacturer as a next step.

Immunization Readiness and Implementation: PQM+ is supporting the Directorate General for Drug Administration (DGDA) in vaccine testing and risk-based post-marketing surveillance (RB-PMS). In January, PQM+ worked to assess the capacity of potential third-party labs to conduct COVID-19 vaccines testing. As part of the activity, the team reached out to the Institute of Biological Products in the Department of Medical Sciences at Thailand's Ministry of Public Health. However, the lab stated some critical limitations for testing; namely, they do not have the methods for testing, reference standard material, and critical reagents needed for confirmation of the vaccine products based on final product specifications. The lab would have to procure these needed supplies, limiting the ability to complete the activity in the given implementation timeline. Therefore, PQM+ has decided not to work with this lab.

PQM+ also explored the COVID-19 vaccine testing capability of the in-country Institute of Epidemiology, Disease Control, and Research (IEDCR) public health laboratory. On January 20, the PQM+ Bangladesh team visited the laboratory facility at the IEDCR in Dhaka along with the National Control Laboratory (NCL) deputy chief. During the assessment visit, the team had a formal meeting with the director and the principal scientific officer. The team also physically visited the Microbiology and Virology (Serology and Molecular) Laboratory, observing the equipment status and assessing the lab's capability. PQM+ observed that various pieces of lab equipment were not fully calibrated, the lab does not have any accreditation, and it does not have sufficient human resources to perform multiple functions of vaccine testing. Considering the capability and availability of resources, PQM+ determined it is not possible to carry out COVID-19 vaccine testing in IEDCR. The institute's management also did not express interest in conducting testing at this time. As of the end of January, PQM+ had assessed three potential third-party labs and reported its findings to DGDA. No further assessments are planned.

PQM+ organized a workshop on "Risk-Based Post-Marketing Surveillance (RB-PMS) Guidelines for Vaccine" and "Sampling and Testing Protocol for COVID-19 Vaccines" on February 22. Chairing the workshop was Md. Mahbubur Rahman, the DGDA director general, with Dr. Samina Choudhury, USAID's activity manager for PQM+, present as a special guest. Twelve DGDA representatives participated, including DGDA Director Md. Ashraf Hossain and other senior officials from DGDA and the National Control Laboratory (NCL). PQM+ presented an overview of vaccine post-marketing surveillance and concepts around RB-PMS, including risk-based sampling, the risk-based approach to testing, and monitoring and evaluation. The workshop emphasized the importance of coordination between stakeholders, as well as elements crucial to a PMS plan for COVID-19 vaccines, including risk scores in the sampling strategy, mapping of vaccine sites, and plans for recall and disposal of substandard and falsified vaccines. Those who attended will be better able to coordinate with other stakeholders to advocate for risked-based vaccine safety surveillance to safeguard the people of Bangladesh.

Laboratory Systems: PQM+ is working with DGDA's National Control Laboratory (NCL) to establish a personal protective equipment (PPE) testing laboratory to ensure quality-assured PPE. During February, PQM+ onboarded a PPE consultant and worked to understand the status of equipment testing in Bangladesh by visiting Intertek PPE Lab, a private lab at the Beximco Industrial Park. PQM+ spoke with Intertek's PPE lab manager to understand the processes and the facility Intertek has for testing PPE. PQM+ observed that Intertek has an extensive PPE testing facility, which is not receiving samples from any entities to test. Based on this initial assessment, PQM+ considers Intertek to be a valuable partner in terms of training NCL lab staff while DGDA works to establish its own public sector PPE testing lab. PQM+ also observed in-person lab equipment crucial to PPE testing, including the grams per square meter (GSM) cutter, which checks the quality of face mask and gown fabric.

Based on this visit, PQM+ is laying out its strategy to assist DGDA with establishing a PPE testing laboratory, including procuring priority PPE testing equipment, helping DGDA establish a PPE testing guideline (detailing what PPE testing should be done and how frequently), and supporting DGDA with its post-marketing surveillance of PPE. PQM+ received approval from the program's agreement officer in February to procure two pieces of PPE testing equipment: a particulate filtration efficiency (PFE) tester and a mask pressure difference tester, with delivery expected at the end of April. These pieces of equipment are critical to the lab's functioning.

On March 8, PQM+ and the team from Giant Engineers (a supplier selected through a PQM+-managed open bidding process to provide equipment for PPE testing) jointly visited DGDA and the proposed medical device testing lab site where the medical device and PPE testing lab will be established. The visit allowed Giant Engineers and a PQM+ biomedical engineer expert to assess the suitability of the site, room condition and places where equipment will be set, and any renovation requirements, as well as to check the status of things like electricity, water supply, and air conditioning. The visiting team recommended required renovation and changes based on their assessment. Next, the visiting team met with the NCL deputy chief and the DGDA director, who are both members of the site selection committee, to discuss recommendations. During the meeting, NCL and DGDA agreed to meet separately to make the final selection of the designated space for establishing the PPE lab and submit the final report of the selection process for approval.

Burkina Faso

Immunization Readiness and Implementation: PQM+ is working to support the medicines regulatory authority (MRA), *Autorité National de Regulation Pharmaceutique* (ANRP), to

strengthen its AEFI surveillance system, build its capacity to grant regulatory approval for COVID-19 vaccines in alignment with the country's National Vaccine Deployment Plan, and improve its lot release functions. In January, as a result of PQM+ technical assistance in December, the ANRP granted EUA for the Moderna vaccine; by the end of the month, ANRP had imported 370,000 doses of the vaccine into the country.

February activities were impacted by a coup d'état in January, which put travel on hold. During the reporting period, PQM+ continued to implement activities that could occur remotely, including working with MTaPS and ANRP to plan a three-day training on AEFI for vaccination staff from the country's 13 regions. PQM+ developed the terms of reference for the training and assigned modules for each entity to prepare. Vaccination staff who participate will be able to cascade this training in their individual regions.

In March, PQM+ implemented the training of vaccination staff in partnership with MTaPS. Twenty-six vaccination staff from throughout Burkina Faso, representing the national immunization program, learned about AEFI, including the various classifications, common errors committed during immunization, and how AEFI notifications should occur. This training is critical to promote the notification of AEFI with the Med Safety digital application, which has been low and of poor quality. The training also sought to equip potential trainers for the detection and notification of COVID-19 AEFI. These trainers are expected to cascade the training to the district level. In addition to this training, PQM+ started a training needs assessment on EUA that will be developed for ANRP. At the end of March, PQM+ developed a questionnaire and sent it to ANRP staff to gather information on the proposed audience.

PQM+ also worked with ANRP to better understand its existing lot release regulatory function. PQM+ used the GBT lot release indicators to collect some baseline information on this function. It was clear that beyond the decree creating the agency, which gives the ANRP the mandate for lot release, no policies, guidelines, or procedures are in place to manage this function. In addition, technical personnel with responsibility for the lot release function indicated the need to better understand what is required of them. PQM+ worked with ANRP to formulate terms of reference for development of a lot release procedure and for training on the procedure to a wider ANRP audience. In March, following the collection of information on the lot release function using the WHO GBT lot release indicators, PQM+ conducted a virtual orientation for the two designated regulatory staff for vaccine lot release at ANRP. During this orientation, a PQM+ expert presented on the recommended procedures for lot release in producing and importing countries and focused on options to develop the lot release function in phases. PQM+ also discussed the status of lot release development in Burkina Faso. No lot release function is in place in Burkina Faso, including written documentation and guidelines, so ANRP and its staff will need to get acquainted with the necessary documentation for lot release and with the lot summary protocols as a critical tool and develop a strategy for the release of vaccines. PQM+ tasked the ANRP team to decide what strategy the agency would like to adopt. PQM+ suggested points for ANRP to consider in deciding on an appropriate strategy.

Laboratory Systems: PQM+ is working to build the capacity of the national quality control lab, *Laboratoire National de Santé Publique* (LNSP), to test COVID-19 vaccines. In January, PQM+ submitted the French translation of an assessment report of LNSP's microbiological laboratory's capacity to test COVID-19 vaccines. After an initial delay, LNSP received vaccine dossiers from ANRP and started developing a list of specific consumables required for testing as indicated in the vaccine dossiers, with support from PQM+. This list will guide PQM+ in procuring lab supplies and equipment, enabling LNSP to conduct quality testing of the vaccines. In February, PQM+ supported LNSP to finalize the list of specific consumables required for testing, as

indicated in the Pfizer and Moderna vaccine dossiers. PQM+ has initiated procurement of these lab supplies and equipment that will enable LNSP to conduct quality testing of the vaccines. A total of 20 pieces of equipment (including their accessories) and 25 types of consumables are required to test the COVID-19 vaccines registered in Burkina Faso. When the quotations are in, PQM+ will work with LNSP to prioritize this procurement in alignment with the available budget.

Ethiopia

Immunization Readiness and Implementation: PQM+ is supporting the Ethiopia Food and Drug Authority (EFDA) to conduct risk-based inspection of cold chain facilities across the country. In January, PQM+ supported EFDA and regional inspectors to conduct cold chain inspections in Addis Ababa and part of Oromia. Also, PQM+ worked collaboratively with EFDA to develop a database and start entering inspection data. PQM+ in February supported EFDA to enter all cold chain inspection data into the database. By the end of the month, PQM+ and EFDA had completed data entry and analysis and produced a draft report. In March, PQM+ worked with EFDA to finalize the report. The assessment has shown numerous gaps in Ethiopia's cold chain system that could significantly affect the quality of COVID-19 vaccines circulating in the country. Some gaps are related to a lack of calibration/qualification of cold chain equipment, monitoring of refrigerators/ environment, the QMS, and staff competency. Stakeholders will review the report in early April during a workshop in Addis Ababa, and PQM+ will incorporate input from the stakeholders. Finally, under EFDA's leadership, the program will share the report with all stakeholders in Ethiopia's COVID-19 vaccine supply chain system. Based on the crucial work of this cold chain system, the USAID/Ethiopia Mission recognized PQM+ for its outstanding technical leadership in an implementing partner meeting on March 28.

Surveillance, Case Finding, Rapid Response Teams, Case Investigation, and Contact Tracing: PQM+ is working to strengthen product defect reporting through adverse drug reaction (ADR) reports. In February, PQM+ coordinated with EFDA to train select health workers at COVID-19 active surveillance sites and regional regulatory bodies to promote the detection, reporting, and processing of COVID-19 vaccines and related product defects through the passive ADR reporting system. A total of 56 participants (20 female, 36 male) attended the training including those from EFDA (13), regional regulatory bodies (seven), and health facilities (36). This training sought to increase participants' understanding and awareness on monitoring the quality and safety of COVID-19 vaccine products and improve product defect reporting practices. This will contribute to protecting public health through early identification of adverse events associated with defective COVID-19 vaccines and facilitating their recall/removal from distribution networks, increasing public confidence in the vaccines and vaccination program.

As part of this activity, EFDA will deploy inspectors from its Market Surveillance and Relevance Directorate to survey seven high-risk sites in Ethiopia. In March, PQM+ developed the survey proposal and protocol and covered logistical costs, such as travel for the inspectors. The purpose of this survey is to ascertain the status of COVID-19 vaccines in the supply chain system and identify the routes that are responsible for the illegal marketing practice in the country to support evidence-based decision-making. This survey is planned to be complete by middle of April, with a report based on the findings to follow.

PQM+ is also helping EFDA's national safety advisory committee improve its review of AEFI data. In January, PQM+ provided technical assistance to EFDA's national safety advisory committee on the investigations of three new cases of serious adverse events (SAEs) following administration of COVID-19 vaccines. PQM+ joined EFDA in further investigating previously reported cases of SAEs at St Paul's, Menelik, and Zewditu hospitals in Addis Ababa to complete

all the records and relevant information and facilitate timely analysis for causality. PQM+ supported EFDA with thorough data collection, review of records, interviews, and observations.

In February, PQM+ provided technical assistance to EFDA on investigations of two new cases of SAEs following administration of COVID-19 vaccines and further investigation of data for SAE cases in Addis Ababa at Tuludimtu health center, Tirunesh Beijing hospital, Akaki Kaliti health center, Inderasie clinic, and MCM Korea hospital. Technical assistance included clinical records review, interviewing, data collection/analysis, and drafting the causality analysis for the National Safety Advisory Committee.

In Q2, PQM+ provided technical and logistics support to the National Safety Advisory Committee to perform causality analysis for 10 SAE cases and grouped them in the following categories:

- Inconsistent causal association (subcategory coincidental, meaning the vaccine had nothing to do with the SAE): three cases.
- Unclassifiable (meaning there is no clear cause): five cases.
- Consistent with causal association (meaning the vaccine played a role): two cases.

Following completion of the casualty analysis, the National Safety Advisory Committee provided recommendations to the National Immunization Program (EPI) for program improvements. The committee recommended that all vaccination sites conduct a pre-screening of vital signs prior to vaccination as well as facilitate financial support for proper diagnosis and treatment of patients with SAEs, a crucial part of proper causality analysis. The draft recommendations are under review by EFDA for submission to the EPI program.

Ghana

Immunization Readiness and Implementation: PQM+ is supporting the Ghana Food and Drug Authority (Ghana FDA) with its cohort event monitoring (CEM) on COVID-19 vaccine distribution, expected to last eight months. Approximately 10,000 participants are expected to be enrolled and followed on predetermined days after receiving the first and second doses of the COVID-19 vaccine. As of March 22, 13 million doses of the five COVID-19 vaccines (Oxford/AstraZeneca, Pfizer, Moderna, Johnson & Johnson, and Sputnik V) had been administered in Ghana. The cumulative number includes 8,505,664 doses of Oxford/AstraZeneca, 2,264,589 doses of Pfizer, 1,063,160 doses of Moderna, 1,196,431 doses of Johnson & Johnson, and 17,982 doses of Sputnik V. Based on a review of safety reports from the vaccinations, including reports from pregnant women and children aged 15 to 17, no safety concerns have emerged; the safety reports and reporting patterns after these groups were included have not changed. As a result, the Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) concluded that the five vaccines granted EUA by the Ghana FDA and being deployed in Ghana are safe and effective, and recommended their continued use.

In January and February, PQM+ supported the enrollment of CEM study participants during the deployment of Pfizer and Moderna vaccines through its COVID-19 vaccine funding. The team worked toward a minimum of 700 enrollments per site. The number of study participants enrolled at the end of February is below, showing that PQM+ has exceeded the enrollment of 3,000 participants planned under this project.

Region	Number of Participants
Ashanti	466
Central	211
Volta	214
Bono East	596
Northern	850
Greater Accra (Mamprobi)	856
Greater Accra (Tema General Hospital)	732
Total enrolled	6,425 (64.2% of target)
Total enrolled with direct PQM+ support	3,925 (130% of target)

In March, at the end of PQM+ support using COVID-19 Vaccines Technical Assistance funds, PQM+ met with the FDA Ghana and EPI to assess progress in implementing the CEM and to find out if a need existed for training (refresher or new study team members) on AEFI, the CEM protocol, and the use of WHO's Open Data Kit (ODK) software. No new members have joined the study team and FDA Ghana indicated that it did not need refresher training. They did say, however, that some study team members may require a refresher training on the use of the ODK software for data entry.

As part of its COVID-19 American Rescue Plan (ARP) work plan, PQM+ continued to support the enrollment of CEM study participants during the deployment of Pfizer and Moderna vaccines in March and supported the follow-up of enrolled participants to gather information on AEFI. A marked reduction in enrollment of participants occurred in March; no new enrollment was recorded in the Ashanti and Bono East regions and marginal enrollment was seen in the Central and Volta Regions. Three sites have already met or exceeded their enrollment target for this study. Based on discussion with the EPI, the sites that had no new enrollment indicated they did not have the required vaccines. Despite coordination at the national level and follow-up by the EPI lead on the project, when the vaccines are deployed to the regions and then to the districts, they do not always get to the enrollment sites due to other district-level priorities. About 6,659 participants of the target of 10,000 have been enrolled since March 2021. More than 4,000 of these participants were enrolled with support from PQM+ since November 2021. PQM+ will intensify its monitoring in the Central and Volta regions to understand the consistently low enrollment numbers, despite EPI's assurance that vaccines would be available there.

Laboratory Systems: The Ghana FDA microbiology laboratory is currently at Biosafety Level II; however, vaccine testing should be conducted in a Biosafety Level III environment. This quarter, PQM+ worked with Ghana FDA to enable the quality control laboratory to conduct all tests required for COVID-19 vaccines. During the reporting period, PQM+ finalized the technical report for the assessment of the FDA Ghana microbiology laboratory and shared it with Ghana FDA. PQM+ also confirmed delivery of the first shipment of the lab supplies PQM+ procured for Ghana FDA laboratory to conduct the potency testing of COVID-19 vaccines. The second delivery is expected soon.

Kazakhstan

Immunization Readiness and Implementation: PQM+ is supporting the National Center for Expertise for Medicines, Medical Devices, and Medical Equipment (NCEM) in strengthening the vaccine surveillance system to ensure its ability to detect, investigate, and analyze AEFI and adverse events of special interest (AESI) and enable an appropriate and rapid response. Under

this activity, PQM+ has been tasked with conducting a situational analysis of the pharmacovigilance (PV) system in Kazakhstan in alignment with the WHO's recent GBT assessment and providing related technical assistance in support of Kazakhstan's effort to reach Maturity Level 3 (ML3), specifically in its vigilance functions. This quarter, PQM+ finalized its situational analysis of the PV system in Kazakhstan in alignment with the WHO GBT and in support of Kazakhstan's efforts to reach ML3 in the vigilance function and discussed findings with NCEM. The report highlights Kazakhstan's internal strengths within its current PV system as well as areas of improvement, specifically the need to organize PV processes between two existing PV entities, trainings for staff within the PV department, and SOPs to be developed. After PQM+ translates the report into Russian, it will be shared more widely with the PV department at NCEM. PQM+ also worked with the WHO Collaborating Center for Pharmacovigilance based in Morocco to set up PV workshops on the development of a three-year PV roadmap and trainings. In February, PQM+ prepared training materials and discussed participants. PQM+ hosted this virtual training on the PV process at the end of March into the start of Q3 for 14 (one male, 13 female) staff from NCEM's PV department to familiarize them on proper implementation and management of a PV system. After this training, PQM+ plans to work with the WHO Collaborating Center to plan other trainings involving all PV stakeholders (including the Committee for Medical and Pharmaceutical Control, NCEM's PV department, and representatives from the immunization program and Ministry of Health) in April to enable a collaborative discussion on the development of a PV system in Kazakhstan.

PQM+ is also providing technical assistance to NCEM in strengthening its lot release systems, which allow for the continuous quality and safety monitoring of biological products through a regulatory release system on a lot-by-lot basis. This is a relatively new area for NCEM, as it has not been assessed by the WHO team as part of the WHO GBT process. In January, PQM+ completed the review of NCEM's draft self-assessment of its lot release function based on the WHO GBT and shared feedback with NCEM. PQM+ also reviewed regulatory documents related to lot release that NCEM provided. In February, PQM+ and NCEM discussed some gaps identified during the lot release self-assessment review, including those related to legal provisions, regulations, and guidelines. Based on the discussion, PQM+ identified a lack of legislation specific to vaccine lot release. NCEM needs to develop a revised strategy for the release of batches of imported vaccines as well as domestically produced vaccines. PQM+ suggested action items such as reviewing the WHO guidance document on vaccines lot release, developing a detailed lot release procedure, developing criteria for recognizing results from external testing laboratories and others. PQM+ will discuss the other five lot release indicators during the next call. Based on PQM+'s recommendations, NCEM is working on the revision of Kazakhstan's Order 282 on quality assessment of medicines and medical devices. The revised order will include detailed information on the quality assessment of vaccines, which is directly related to WHO's GBT Function 9 (lot release). PQM+ reviewed the section related to vaccines and provided comments. In March, PQM+ continued to work with NCEM to revise Order 282. This work resulted in the identification of specific gaps, including the lack of a strategy for the release of batches of imported vaccines as well as domestically produced vaccines. PQM+ is working with NCEM on addressing those gaps.

In March, PQM+ finalized the recruitment of a vaccine testing expert who, starting in April, will assist the MRA in lot release and assist the quality control laboratory in testing vaccines for lot release in compliance with international requirements.

Pakistan

Coordination and Operations: PQM+ is supporting the Drug Regulatory Authority of Pakistan (DRAP) to strengthen its COVID-19 vaccine vigilance. In January, PQM+ drafted guidance documents for COVID-19 vaccine EUA holders on AEFI and submitted them to DRAP for review and comments. The finalized guidance document for EUA holders will enable DRAP to effectively monitor COVID-19 vaccine EUA holders and ensure vaccine vigilance in terms of AEFI reporting. PQM+ also worked to develop guidance on risk management planning for COVID-19 vaccines for DRAP. Per best international practices, vaccine manufacturers and importers have legal and moral responsibilities to highlight and report any risks associated with vaccines and submit their risk management plan to the regulatory authorities (including vaccine safety data) to protect at-risk/vulnerable individuals. The finalized guidance document on risk management plans and how to develop them will ultimately equip DRAP with appropriate vaccine safety data to control/mitigate any potential risks to individuals during the government's COVID-19 vaccination drive. DRAP sent its feedback on the draft guidance documents, which PQM+ will incorporate before seeking final approval from DRAP's Policy Board.

Related to this work, PQM+ is working with DRAP to establish a Pharmacovigilance Risk Assessment Expert Committee to strengthen the agency's AEFI reporting for COVID-19 vaccines and vaccine vigilance. In March, PQM+ submitted a letter containing proposed committee composition, roles, and responsibilities. This committee will play a critical role in keeping EUA products safe by evaluating the safety signals and quality issues on a priority basis. The committee will be a comprehensive AEFI surveillance system at the national level.

To strengthen AEFI and other vaccine surveillance while ensuring quality assurance of the COVID-19 vaccine during storage and distribution in Pakistan, PQM+ collaborated with DRAP in updating the guidance document on RB-PMS to include COVID-19 vaccines. To implement this guidance, PQM+ plans to host training workshops for DRAP staff and federal/provincial drug inspectors on RB-PMS of COVID-19 vaccines. In February, the PQM+ team finalized arrangements for these upcoming trainings, including development of training material and agenda, while PQM+ AEFI provincial coordinators also coordinated with government counterparts and stakeholders to ensure relevant nominations were provided for the upcoming training. PQM+ conducted these two four-day workshops in March for DRAP, provincial drug controllers, provincial quality control boards representatives, and other government stakeholders. The 83 participants at the two trainings included 77 males and six females. Training topics included: an overview of regulatory oversight process through drug life cycles, risk-based approaches in regulatory management of drug life cycles, procedures for conducting audits for current GMP per PIC/S, procedures for conducting regulatory inspections of pharmaceutical supply chains, regulatory oversight procedures for suspect medicinal products (including substandard, unregistered/unlicensed, and falsified medicines), an overview of DRAP guidelines on RB-PMS of drugs and vaccines, as well as practical approaches in designing a PMS assignment, among other topics. These training workshops will assist the Government of Pakistan to implement a unified quality management system in the entire country, based on DRAP's guidance document for RB-PMS for COVID-19 vaccines, and will help the government ensure the quality of drugs and COVID-19 vaccines throughout the supply chain. The workshops also equipped DRAP and local/federal drug inspectors with tools of risk assessment for COVID-19 vaccines, at various points of storage and distribution, to maintain effective quality assurance of COVID-19 vaccines and ultimately contribute toward saving lives during the COVID-19 pandemic.

Immunization Readiness and Implementation: In collaboration with national stakeholders, PQM+ is developing a National Action Plan for AEFI Surveillance for COVID-19 Vaccines. In January, the PQM+ team met with the Director General (DG) of Health at the Ministry of National Health Services Regulations & Coordination (MoNHSR&C) to update them on progress and held a coordination meeting with the Federal Expanded Program on Immunization (EPI) the following day to brief them on the discussion with the DG Health. Following this meeting and throughout the quarter, PQM+ worked with both entities to ensure the AEFI guidelines and National Action Plan went through proper review channels, including gathering feedback from provincial stakeholders. By the end of March, PQM+ had included the ministry's feedback as well as obtained feedback from the provinces. Once the guidelines and action plan are approved, PQM+ will partner with the Federal EPI to conduct trainings on AEFI reporting to provincial health care commissions and private sector hospital staff. Implementation of these AEFI guidelines would help formally establish the roles and responsibilities for key AEFI stakeholders, such as the DRAP, FDI, Provincial Healthcare Commissions, and other relevant stakeholders, which would improve AEFI surveillance of COVID-19 vaccines and contribute towards enhancing COVID-19 vaccination in Pakistan, ultimately saving lives.

PQM+ is also working with stakeholders in Pakistani provinces to ensure private sector health care facilities are engaged in vaccine vigilance and AEFI surveillance, including establishing or revitalizing AEFI committees. In January, the Sindh provincial coordinator visited seven hospitals that had received trained on AEFI reporting in December to facilitate hands-on entry of AEFI data in the National Immunization Management System (NIMS) vaccine immunization portal. In addition, PQM+'s discussions with the Sindh Healthcare Commission indicated that private sector health providers are eager to report on AEFI cases and are requesting additional support in terms of hands-on trainings/on-site assistance. The other PQM+ AEFI provincial coordinators continued to regularly coordinate and communicate with provincial stakeholders, including the CEO of the Sindh Healthcare Commission, co-chairperson of the AEFI Committee-Sindh, chief of the Health Sector Reforms Unit (HSRU) at the Department of Health (DOH) in Khyber Pakhtunkhwa (KP), and Government of Balochistan for coordination on PQM+ AEFI activities. The PQM+ AEFI provincial coordinators also engaged with provincial EPI, WHO, and health care commissions for coordinating the revitalization of provincial AEFI committees.

In February, the PQM+ AEFI provincial coordinators continued to regularly communicate with provincial stakeholders, including provincial health care commissions, provincial EPI, provincial WHO focal persons, and other government stakeholders. The AEFI provincial coordinator in Sindh met with Dr. Asad Ali at Agha Khan University Hospital, a focal person for the National AEFI Review Committee for COVID-19 vaccines and a member of the National Command and Operation Centre COVID-19 Vaccination Task Force, to discuss AEFI reporting and PQM+ AEFI activities. The Sindh coordinator also met with Dr. Khalid Shafi, co-chairman of Sindh's Provincial AEFI Committee, to discuss AEFI reporting in the province. During the meeting, Dr. Shafi committed to requesting that EPI finalize the draft national AEFI guidelines to expand AEFI reporting trainings for private sector hospitals in Sindh, and ultimately enhance AEFI reporting and data use for vaccine vigilance.

As of February, the provincial EPIs for Punjab and Balochistan have included respective PQM+ AEFI provincial coordinators as members of AEFI provincial committees. This is considered an initial step for the investigation and reporting of AEFI and will help activate and strengthen these committees to ensure effective vaccine vigilance of COVID-19 vaccines in Pakistan going forward. PQM+ and EPI in Punjab agreed to hold monthly meetings to analyze both routine and supplementary immunization activities. This will help improve AEFI reporting and data monitoring and analysis in Punjab.

On March 3, PQM+ met with the Director General (DG) of Health in Sindh, Dr. Rukhsana, who is also the AEFI committee chairperson and Dr. Sohail Bin Saeed, the WHO AEFI focal person in Sindh, Karachi, and discussed revitalization of the provincial AEFI committee and inclusion of the PQM+ AEFI Provincial Coordinator in Sindh, a pathologist, and a pulmonologist into the committee, in addition to revision of the committee's terms . Inclusion of the proposed new members in the Provincial AEFI Committee for Sindh will help to activate and strengthen it to ensure effective vaccine vigilance of COVID-19 vaccines in Pakistan. Revitalization of the AEFI provincial committee in Sindh will work to ensure regular review of AEFI data and reporting by the committee members and key AEFI stakeholders and improve the overall AEFI reporting rate in Sindh going forward.

Meanwhile, the PQM+ AEFI Coordinator-Sindh coordinated with Dr. Ahmad Raza Kazmi, Director Clinical Governance & Training, and Dr. Altaf Hussain Khawaja, Director Licensing and Accreditation, Sindh Healthcare Commission (SHCC) for the inclusion of AEFI cases in SHCC's checklist for private hospitals. This will help to increase and improve AEFI reporting for COVID-19 vaccines by the private sector in Sindh and help to ensure improved vaccine vigilance in the province. Similarly, the PQM+ AEFI Coordinator-Baluchistan coordinated with the Baluchistan Healthcare Commission, Department of Health, FDI, and WHO to request the committee to nominate a pulmonologist/general physician (who is already working on COVID-19 AEFI cases) to be included in the Baluchistan Provincial AEFI Committee.

Moreover, while AEFI committees exist in Pakistani provinces, most are dormant; there is a need to revitalize them to cover COVID-19 vaccine data review (including conducting causality assessments of serious AEFI) so the government can establish an effective vaccine vigilance system for COVID-19 vaccines. PQM+ is collaborating with WHO to strengthen provincial AEFI committees for COVID-19 vaccination by revising their terms of reference and including clinical experts on the committees, in addition to working with key AEFI stakeholders to revise procedures for the investigation of serious AEFI cases and train committees on revised procedures. In March, PQM+ held an internal, virtual training session for provincial AEFI coordinators on the development of SOPs for coordination mechanisms among key stakeholders of AEFI surveillance systems at the provincial level. This training equipped the provincial coordinators with the skills to craft appropriate SOPs to establish coordination mechanisms with defined information flow, roles, and responsibilities for their assigned provinces. Provincial coordinators will now work with provincial stakeholders to develop the SOPs, which AEFI committees will maintain and implement going forward. Implementation of these SOPs will help establish and reinforce vaccine safety surveillance systems at the provincial level and will help improve coordination with provincial AEFI committees to improve COVID-19 vaccine safety and surveillance around Pakistan.

In addition to advocating for revitalization of AEFI committees, PQM+ conducted three training sessions on AEFI reporting for COVID-19 vaccine for health care commissions and private health care providers in Baluchistan, Punjab, and KP. About 40 people participated in each training session, with 123 participants (72 men, 51 women) across the three. For these training sessions, PQM+ developed a draft desk guide for AEFI reporting (in line with the National AEFI Guidelines) for private health care providers, in addition to developing the training agenda and materials. EPI and WHO joined PQM+ in facilitating these trainings. To assess the impact of the training, PQM+ distributed pre- and post-training assessment forms to training participants. On average, the three regions showed a 57 percent increase in AEFI surveillance knowledge between the pre- and post-testing (56 percent in Baluchistan, 55 percent in Punjab, and 61 percent in KP). Topics in the training sessions included AEFI classification, surveillance cycle, role of private health care providers, and hands-on training for reporting. These trainings

will help build the capacity of provincial health care commissions, private sector hospital staff, and other stakeholders to effectively report on AEFI cases, while also contributing toward the expansion and improvement of AEFI reporting in Pakistan.

Uzbekistan

Surveillance, Case Finding, Rapid Response Teams, Case Investigation, and Contact Tracing: PQM+ is supporting the Agency in strengthening pharmacovigilance (PV) and vaccine surveillance systems. PQM+ is working with the Services for Sanitary and Epidemiological Well-being (SSEW), which is in charge of the NIP, the Agency, and its State Center of Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment (the State Center) and other national and international stakeholders. PQM+ will use findings from the assessment of the current vaccine safety surveillance and pharmacovigilance systems (completed during the first tranche of USAID COVID-19 vaccines funding) to design the interventions in its current American Rescue Plan (ARP) work plan.

This quarter, PQM+ completed the review of the national standard of the Good Pharmacovigilance Practice (GVP) developed by the Agency in 2021. PQM+ provided written feedback with recommendations to the Agency on improving the GVP standard. This national standard will guide pharmacovigilance in Uzbekistan. PQM+ also prepared for a workshop on developing coordination mechanisms between the PV and the national immunization program. The workshop will establish the main lines of coordination and collaboration between the PV department and immunization program to anticipate and minimize potential risks of COVID-19 vaccines and to assure that AEFI are reported, analyzed, and shared in the international database (Vigibase). The workshop is planned for April 2022. Anticipated deliverables to follow this workshop are roles and responsibilities for each party; understanding international standards on integrating PV into the immunization program; channels of communication between the two departments; and documenting mechanisms that need to be in place between the two programs for efficient coordination. In March, PQM+ prepared for another training, planned for the end of April for NIP immunization specialists. The training will focus on WHO's COVID-19 Vaccines Safety Surveillance Manual, and best practices in this area. Additionally, PQM+ finalized a contractual agreement with the WHO Collaborating Center for Pharmacovigilance based in Morocco. The center will work closely with PQM+ to provide technical assistance to Uzbekistan on PV and AEFI strengthening.

Progress by Health Elements

Maternal and Child Health (MCH)

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

Progress This Quarter

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

This quarter, PQM+ met with USAID and Newborn Essential Solutions and Technologies 360, a program developing and delivering a bundle of high-quality products and services for hospital-based newborn care at scale to reduce preventable neonatal death in sub-Saharan Africa, to discuss the proposed development of a guidance document on quality testing methods for priority medical devices targeting regulators and manufacturers to increase the knowledge and practices for testing priority MNCH medical devices circulating in the LMIC markets. PQM+ also reviewed the draft list of MNCH priority medical devices shared by the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) program and followed up with the PQM+ countries on the current landscape around how medical devices are regulated and tested. PQM+ is currently reconsidering this activity given the limited information available on the current landscape of how medical devices are regulated and tested in LMICs. PQM+ plans to suggest an alternate activity in the next quarter.

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

PQM+ proposed to develop a technical brief describing the impurities in chlorhexidine and how manufacturers can address them during chlorhexidine production. The goal of this brief is to share information with local manufacturers to increase the supply of quality-assured sources for the product. This quarter, PQM+ began researching available background information e.g., technology transfer report, compendia, GSK Digluconate (7%) Gel Technology Transfer Report, and developed an outline for the technical brief on the importance of 4 chloroaniline (4CA) impurities in chlorhexidine.

Objective 5: Advance a global medical products QA learning and operational agenda

PQM+ is collaborating with two USAID partner programs – MTaPS and GHSC- PSM – to organize a series of consultative meetings to identify actions to increase access to and use of quality-assured medicines for newborns and child health. The consultative meetings will be convened by the Commodities Sub-Group of the Child Health Task Force, co-chaired by UNICEF and USAID. Specifically, this quarter:

- PQM+ continued participating in weekly meetings with MTaPS and PSM to coordinate progress on preparations for the consultative meetings.

- PQM+ participated in three separate meetings with other organizations supporting newborn and child health: Save the Children, R4D, and PATH
- PQM+ reviewed the evidence shared by members of the Child Health Task Force and collected additional information to prepare the evidence brief for the consultative meeting, scheduled for quarter three (on three consecutive Tuesdays in May)

Priority Activities for Next Quarter

In Q2, PQM+ plans to:

- Continue planning with the two USAID partner programs to execute the first of three planned consultative meetings on access to and use of quality-assured medicines for newborns.
- Finish developing the technical brief on the importance of 4 chloroaniline (4CA) impurities in chlorhexidine.
- Begin developing the online course on quality assurance of medical devices focusing on MNCH.

Neglected Tropical Diseases (NTDs)

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.

Progress This Quarter

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

The overall goal of the Core NTD program is to improve the availability of affordable, safe, effective, quality-assured NTD medical products for patients in need. PQM+ uses a system strengthening approach; to build the capacity of manufacture, advocate the WHO PQ program, and represent PQM+ globally to identify, meet, and network with new manufacturers interested in investing in producing quality-assured NTD medical products.

In pursuit of its goal to increase the availability of quality NTD medicines, PQM+ continues to support manufacturers with direct technical assistance and to raise awareness of the WHO prequalification (PQ) program. In terms of support to manufacturers, PQM+ continues to support two manufacturers towards WHO PQ for two NTD products- albendazole 400mg tablets and praziquantel 600mg tablets. For albendazole 400mg tablets, the product dossier has undergone full assessment by WHO. WHO is currently reviewing the additional data submitted in Q1.

For praziquantel 600mg film-coated tablets, WHO issued a conditional PQ approval in April 2021 for the product pending onsite inspection and repeat BE Study. The onsite inspection was

conducted in November 2021 and Medopharm was found to be GMP compliant for the manufacture of praziquantel tablets 600 mg. This quarter PQM+ completed the procurement and contractual process for the BE consultant that will provide ongoing support to the manufacturer. With USAID's approval for partial financial support to the manufacturer to cover the cost of the BE study, PQM+ began the sub-award contractual process. PQM+ also reviewed and provided feedback on the draft BE study protocol.

PQM+ began planning for participation in the annual West Africa Pharma Healthcare Show, an international Medical Pharmaceutical & Healthcare Industry trade fair in Ghana. PQM+ will utilize this opportunity to update manufacturers on PQM+ technical support towards WHO PQ, promote applications for the expression of interest of the eight NTD products of interest, disseminate some of the findings from Africa and Asia NTD market landscape analysis, and engage stakeholders on the supply gaps revealed by the survey. PQM+ began coordinating the event logistics with the USP Ghana office and the procurement process for the event registration.

To increase awareness among African manufacturers about the WHO PQ program, PQM+ began planning for the three-day workshop tentatively planned to be in Mombasa, Kenya. The workshop concept note and agenda were drafted and shared with WHO for their review. PQM+ received positive feedback from WHO.

PQM+ continued the development and enhancement efforts of the publicly available NTD database and dashboard 'NTD|MID' for regulators, manufacturers, procurement agencies, suppliers, donor communities, and other interested parties in planning for procurement, supply, and use of NTD medical products. This quarter, PQM+ shared an updated version of the tool with USAID for their review and feedback. The data on approved NTD finished pharmaceutical products (FPPs) from Tanzania and the US Food and Drug Administration was added to the tool while efforts were made to add NTD data from other stringent regulatory authorities. Efforts to include third-party data such as API sources, manufacturing locations, and production capacity as well as other discussions to establish application programming interfaces with subscribed users such as UNICEF, WHO and manufacturers were not successful and can be re-evaluated during future iterations of the tool. Besides these challenges, PQM+ made progress towards the finalization of the tool by utilizing only the publicly available data. The process for transfer of hosting and maintenance of the tool to USP from the program developer was also initiated. PQM+ also began planning for the tool's soft launch webinar targeting a wide stakeholder audience, tentatively planned for early Q3.

PQM+ continued efforts to promote and disseminate the repackaged GMP e-learning course. During this quarter, PQM+ promoted the course at the relevant GMP activities from other PQM+ buy-ins e.g., Nepal, Myanmar, Regional GMP Training Webinar for Nigeria, Ghana, Liberia, and others. PQM+ also sent reminders to 4,072 individuals registered for the GMP course to complete the course.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Continue ongoing technical assistance to supported manufacturers until full WHO PQ is attained.
    - For albendazole, PQM+ expects to receive feedback on the submitted additional data to the WHO PQ team by the end of March 2022. PQM+ has commenced

discussions on the GMP mock audit planning and execution with the manufacturer and expects to finalize plans by next quarter.

    - For praziquantel, PQM+ plans to conduct a remote or an in-person audit of the CRO site based on travel restrictions and feasibility.

- Begin to review the EOI applications.
- Finalize report for the NTD landscape market analysis.
- Finalize and launch the NTD dashboard for public users and collect feedback for improvement.
- Continue to promote uptake and module completion for the GMP eLearning course.

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.

Progress This Quarter

Objective 2. Improve country and regional regulatory systems to assure the quality of medical products in the public and private sectors

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 pipeline of new TB medicines and regimens are in varying stages of clinical research. In this evolving situation, it is important for national medicines regulatory agencies (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 a virtual workshop for representatives of MRAs and manufacturers from high-burden TB countries, at which the Agency will share experiences on the regulatory review of new TB medicines. Previously, PQM+ identified and submitted topics of interest and a draft agenda for the workshop to U.S FDA. In Q2, PQM+ continued to meet with U.S FDA to prepare for the webinar, which is planned for August 16-18, 2022. PQM+ is broadening the agenda to include regulatory experience and learnings beyond TB medicines. U.S FDA and PQM+ are also collaborating to develop and release a promotional video for the webinar before June 2022 to generate wider interest and a larger audience for the webinar. PQM+ submitted a draft agenda of the webinar with preliminary speakers to U.S FDA. PQM+ is working with U.S FDA and USAID to identify keynote speakers for the event.

In Q1, PQM+ continued to support two pharmaceutical manufacturers of first line, fixed-dose combination (4FDC) TB medicines in Pakistan. Previously, PQM+'s technical assistance to one manufacturer enabled the finalized compilation of a dossier, including the report on a completed stability study and bioequivalence 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. As a result, the 4FDC dossier of Schazoo has been submitted to and accepted by WHO for full assessment. In Q1, PQM+ provided technical assistance to Schazoo in responding to the first-round additional data and comments requested from WHO. In Q2, PQM+ continued to work with Schazoo and submitted the pending dossier question to WHO on March 11, 2022. Schazoo is awaiting WHO's feedback on the submitted response. PQM+ is planning an onsite mock assessment for Schazoo during the first week of May 2022 as part of site preparation for WHO inspection. Currently, Schazoo is waiting for a date from WHO on the inspection.

Another Pakistani manufacturer, Pacific Pharmaceutical has submitted an updated dossier along with stability studies of the 4FDC product. PQM+ has reviewed the updated dossier and held a meeting with Pacific. Pacific will work to correct the missing information as per the comment provided by PQM+ and will submit the updated dossier along with the stability data for review by PQM+ prior to submitting to WHO. The PQM+ team will continue to provide technical assistance through full prequalification of the product by Pacific.

During Q2, work progressed in the validation of methods to test for nitrosamines impurities in rifapentine and rifampicin TB medicines. PQM+ completed procurement for several samples of Rifampin active pharmaceutical ingredients (APIs) and finished products (tablet and injections). These API and finished products will be used to validate the methods to test for nitrosamine. The process for validation of methods to test for nitrosamine impurities will continue in the next quarter.

In Q2, PQM+ provided ongoing technical guidance and monitoring of the Virginia Commonwealth University (VCU) subaward for phase 2 on optimization, scale up, and integration of the synthesis process on developing an alternative route to produce APIs for a priority TB product. During the laboratory phase, in PY2 Q4, the team successfully identified a synthesis route and demonstrated each step of the target continuous manufacturing process. In Q2, PQM+ is working on finalizing criteria for identifying a manufacturer for the technology transfer, the next step after Phase 2. PQM+ is also exploring potential manufacturers for technology transfer.

In Q2, PQM+ signed a non-disclosure agreement with one of the manufacturers based in Africa, which currently produces two TB APIs. Based on the initial review, the manufacturer has the potential to implement innovative approaches for manufacturing of TB APIs. Under the current Core TB workplan, PQM+ plans to provide technical assistance to the manufacturer to work towards prequalification of their TB API product, which will be an important step towards diversification of the global supply of TB APIs.

Priority Activities for Next Quarter

Next quarter, PQM+ will:

- Follow up with the manufacturer in Pakistan to review the updated dossier along with the stability data for review by PQM+ prior to submitting to WHO

- Follow up with the manufacturer in Pakistan to respond to WHO questions and queries as needed while WHO reviews the dossier and plan for mock assessment
- Continue joint work with VCU on Phase 2 the manufacturing process optimization for a priority TB product.
- Conduct an assessment visit of the manufacturer in Africa to work toward prequalification of their important TB API product.
- Continue to 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

Social media: We shared a combined 53 posts on Twitter and LinkedIn to spotlight PQM+'s progress and activities around the world. We also began posting tweets in French. Our posts earned 975 engagements, with tweets about our work with the Rwanda FDA topping the list. Engagements are the total number of interactions (retweets, replies, quotes, and likes) received for the tweets published during a specific time frame. LinkedIn content continues to perform especially well, with posts earning up to 77 likes. Collectively, our posts earned more than 58,000 impressions during the second quarter.

Success stories: We submitted three success stories about Pakistan achievements (remdesivir, CDL Karachi, and PIMS lab) to USAID for review. Based on feedback, PQM+ is revising them. We also drafted stories about Ghana's first RB-PMS exercise and Uzbekistan's successful use of WHO's CRP for TB medicines.

Webinars: Jude Nwokike spoke as part of the MarketLinks webinar "When Global Health Supply Chains Go Local: Partnering with Countries to Support Their Manufacturing Goals" and co-authored the blog post "Opportunities in Advanced Manufacturing Technologies for Local Production of Health Commodities." During the Prince Mahidol Award Conference, PQM+ convened an online panel to discuss strategies to help national regulatory authorities prepare for emerging infectious disease pandemics.

Website: PQM+ submitted its new website (www.usp-pqmplus.org) to USAID for approvals on December 14, 2021. In January, at USAID's request, PQM+ resubmitted the privacy and 508 compliance forms for approvals, which are required for governance board review.

Newsletter: PQM+ disseminated its sixth newsletter, which featured Uzbekistan's Quality Club, achievements by NTD manufacturers, and the new Guides to Accelerate EUA. Our open rate continues to be high (45 percent).

Annex 1: Monitoring, Evaluation, and Learning Update

PQM+ reports on its performance monitoring indicators twice a year. The PQM+ Monitoring Results Table (Table A.1) presents results from the first two quarters of FY2022 for PQM+ country and core buy-ins. Results are organized by PQM+ objectives and sub-objectives. Country and 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 indicators the buy-ins are reporting on in PY3). Annex 1B shows the start dates of all PQM+ buy-ins.

How to Read the M&E Results Table

The following provides background information on the M&E Results Table and specific indicators that warrant explanation.

Buy-ins and indicators. Buy-ins listed under indicators in Annex 1A appear under those indicators in the M&E Results Table unless they have no data to report for this reporting period. If an Annex 1A indicator is missing from the Table, it means no buy-ins had data to report.

Policies (1.1a, 4.4a, and CUST 2 [Nepal]). PQM+ supports counterparts in developing new and improved regulatory and medicines policies. Results for indicator 4.4a, which tracks ***medicine*** policies, laws, and regulations, are subsumed under the indicator 1.1a, policies, laws, and regulations related to medical product quality. Also included under indicator 1.1a are Nepal's national policies, guidelines, and regulations; these are collected under its CUST 2 indicator.

Coordination and Cooperation (1.3a and 1.4a). PQM+ promotes collaboration among the various counterparts and sectors involved in medical product quality. Indicator 1.3a tracks coordination among *public* entities with responsibilities for medical product quality, while indicator 1.4a tracks collaboration among *public and private* stakeholders. Under 1.3a, PQM+ tracks whether public agencies have been identified, focal points named, a coordination mechanism defined, and information exchanged. Under 1.4a, the program ensures that multisector groups have (1) a coordination framework (terms of reference or TOR) and (2) chairperson; whether they (3) hold regular meetings per the TOR, and (4) distribute meeting minutes; and whether (5) most members attend most meetings. For both indicators, each of the components is scored 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 scores are 8 (100%) for 1.3a and 10 (100%) for 1.4a. Once these public and multi-sectoral groups are fully functional (i.e., they have scored 100%), PQM+ will continue monitoring their sustainable operation.

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) 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 monitor likelihood of its sustainability.

Milestone indicators. Generally, it takes years for quality control laboratories to achieve ISO accreditation or WHO prequalification (PQ) (**2.2h**) or for manufacturers to achieve local market

authorization or WHO PQ (**4.1c**). Each of these outcomes requires completion of a set of activities, as shown in Table A.2. 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 Table A.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 vary in 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. Scores and weights are used to calculate the overall percentage of milestones achieved. The total possible score for each set of activities is 20 (100%). When a QC laboratory or manufacturer achieves a score of 100%, they have completed all the milestones and should receive accreditation, pre-qualification, or market authorization in the near future.

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
1. Gap assessment / roadmap toward accreditation / prequalification	1. GMP assessment and gap analysis
2. Institute a quality management system (QMS)	2. Product and dossier development
3. Lab equipment and facilities readiness	3. Close out GMP CAPAs
4. Analytical methods readiness	4. Dossier compilation
5. Proficiency testing	5. Dossier acceptance
6. PQM+ mock audit / interim assessment	6. PQM+ mock audit
7. Inspection/audit by the accreditation/inspection body	7. MRA or WHO audit
	8. MRA or WHO dossier review

Training (2.5b). PQM+ buy-ins generally do not maintain databases of each trainee who participates 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.

Errata. Some PY2 data points found to be incorrect have been adjusted in this report. The new data are marked "(adjusted)."

PQM+ PY2022 Monitoring Results

Table Legend

n/a: Not applicable. Buy-in is new to PY3, or results are from PY2.

- (dash): No data as either work has not reached a stage where results can be reported, or activity has not yet begun.

0: No results achieved.

N/A: Data are not available.

Not PY2 (or PY3) indicator: Buy-in did (does) not have the indicator in the year referenced.

No target: Target not set as results cannot be predicted.

TBC: Data will be collected.

New PY3: Counterpart is new to PY3.

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
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					
Liberia LMHRA	0	7	No target	1	2
Nepal DDA	64[1]	57	No target	6	7
Total 1a				**7**	**9**

Government enforcement action in response to regulatory violations is a sign that the government is committed to keeping its citizens safe. PQM+ is tracking the number of MRA enforcement actions to address various SF medical products in eight countries (see Annex 1a). In the first quarter of PY3, Liberia's LMHRA seized 36 cartons[2] and 34 additional boxes of quinine injections (two different batch numbers). In the second quarter, the LMHRA confiscated 750 bottles (150 mg.) of quinine in syrup form and 25 boxes of quinine, as well as 28 boxes of amoxicillin from three pharmacies, including in Monrovia. Nepal's DDA recalled 6 different products (including 2 MNCH drugs in dosage form for pediatric use) in Q1 and 7 in Q2 (1 FP/RH, 1 MNCH, and 5 others).

[1]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 governments are different, there is an overlap or gap in the reporting periods for this baseline.
[2]A carton contains several boxes; the number of boxes in a carton varies by product.

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
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	6	0	2
Legislation for Laboratory Service Sub-Contracting in Bangladesh (PY2)				Drafting	Drafting
Vaccine Lot Release Guideline in Bangladesh (PY3)				-	Drafting
Ethical Marketing and Promotion Guidelines for Pharmaceutical Products (PY3)				-	Drafting
Bangladesh COVID-19	0	3	No target	0	0
Bangladesh Guideline for RB-PMS of COVID Vaccines (PY2)				Adopted	
Bangladesh Protocol for Testing COVID Vaccines (PY2)				Adopted	
Bangladesh EUA/No Objection Certificate (NOC) Guideline for Vaccines (PY2)				Adopted	
Burkina Faso	0	1	1	0	0
Collaborative Framework between ANRP and LNSP (PY2)				Submitted	
Ethiopia	0	9	2	3	4
Medicines and Medical Devices Import, Export, and Wholesale Directive (PY2)				Adopted	
Directive for Medicines GMP Inspection Procedures (PY2)				Adopted	
Guidance for Cold Supply Chain (PY2)					Submitted
Directive—Medicine Packaging, Repackaging, and Labeling (PY2)					Submitted
Directive—Good Clinical Practice (PY2)					Submitted
Directive—Clinical Trial Application, Review, and Authorization (PY2)					Submitted
Guidance on Waiver of GMP Inspection Based on SRA Procedure (PY2)					Submitted
Strategies to Strengthen Local Manufacturers' Performance on EPSA's Award (PY3)				Drafted & Adopted	
Guideline—Reliance of Regulatory Decisions Based on Reports of Regulatory Authorities in Other Countries (PY3)				Drafted & Submitted	
Variation Guideline for Vaccines (PY3)				Drafted & Adopted	
Special Conditions Import Permission Directive (PY3)					Drafted & Submitted
Medical Donations Control Directive (PY3)					Drafted & Submitted
Medicine Authorization Directive for Registration of Medicine (PY3)					Drafted & Submitted

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
GMP Guideline for Traditional Medicines (PY3)					Drafted & Submitted
Kazakhstan	0	0	No target	0	1
On approval of rules of pharmaceutical inspections on good pharmaceutical practices (PY3)					Revising
Kazakhstan COVID-19 ARP	0	0	No target	0	1
Order 282—On approval of Rules of Quality Assessment of Medicines and Medical Devices Registered in Kazakhstan (introduction of requirements for quality assessment of vaccines) (PY3)					Revising
Kenya	0	2	3	0	0
Guideline for Development, Review and Approval of Regulatory Instruments (PY2)				Adopted	
RB-PMS Guideline (PY2)					Adopted
Liberia	0	7	11	10	0
Regulation on LMHRA Consideration of Decisions, Information and Data from Other NCLs (PY3)				Drafting	Drafting
Regulation to Allow Sub-Contracting of Testing Services (PY3)				Drafting	Drafting
Emergency Use Authorization (PY3)				Drafting	Drafting
Regulations for Foreign and Local Inspections (PY3)				Drafting	Drafting
LMHRA Reliance Policy on Inspection (PY3)				Drafting	Drafting
Regulation for Quarantine (PY3)				Drafting	Drafting
Regulations/Policy on Trace and Track (PY3)				Drafting	Drafting
Regulation for the Registration of Medical Devices (PY3)				Drafting	Drafting
LMHRA Reliance Policy on Marketing Authorization (PY3)				Drafting	Drafting
Regulations for Product Variations (PY3)				Drafting	Drafting
Mozambique	0	1	1 (PY2 target)	0	0
Regulations for Medicines and Lab Quality Assurance (PY2)				Drafting	Drafting
Nepal	0	2	7	2	4
GMP Code [revised] (PY2)				Submitted	
Risk-Based PMS Guideline (PY2)				Drafting	Drafting
Guideline—Product Recall (PY3)				Drafted	Submitted
Risk-Based Inspection Framework (PY3)				Drafted	Submitted
Guideline—Biological Product Manufacturing (PY3)					Drafting

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Guideline—Handling & Manufacturing of Hazardous Substances (PY3)					Drafting
Guideline—Heating, Ventilation, and Air Conditioning System (PY3)					Drafting
Guideline—Water for Pharmaceutical Use (PY3)					Drafting
Nigeria	0	0	1	0	1
PCN Inspectors' Manual (PY3)					Drafted & Submitted
Pakistan	0	10 (adjusted)	4	3	0
Contract Manufacturing Amendment to Drug Rules 1976 (PY2)				Adopted	
National Pharmaceutical Sector Growth Strategy (PY2)				Drafting	Drafting
Guidance on Monitoring API and Medicine Shortages (PY2)				Drafting	Drafting
Guidance Document for Pre-Marketing Risk Assessment (PY3)				Drafting	Drafting
AWaRE Regulatory Intervention Guidance Document (PY3)				Drafted	Submitted
Outline of Key Performance Indicators (KPIs) for DRAP (PY3)				Drafted	Submitted
Pakistan COVID-19 Vaccines	0	7	No target	2	3
Guidance Document for Risk Based Post-Licensure Monitoring of Biological Products (PY3)					Drafted & Adopted
Guidance for Reporting of Adverse Event Following Immunization (AEFI) by Emergency Use Authorization (EUA) Holders (PY3)					Drafted & Submitted
Guidance for EUA holders for preparation of Risk Management Plans and Periodic Safety Reports for COVID-19 Vaccines (PY3)					Drafted & Submitted
National Guidelines for Adverse Events Following Immunization (AEFI) Surveillance-COVID-19 Vaccine (PY3)				Revised	Submitted
National Action Plan for AEFI Surveillance For COVID-19 Vaccines (PY3)				Drafted	Submitted
Uzbekistan	0	4	3	1	0
Regulations Related to GMP Inspections (PY1)				Revising	Revising
Resolution of Cabinet Ministers #213 (PY2)				Drafting	Drafting
Regulations related to GxP Activities (PY3)				Drafting	Drafting
Uzbekistan COVID-19 ARP	0	0	No target	0	1
Standard on Good Pharmacovigilance Practice (PY3)					Drafting
Total 1.1a				**21**	**17**
A national policy and regulatory framework is essential to ensuring the quality of medical products in countries. PQM+ is helping 12 countries (see Annex 1a) develop or revise and submit for adoption medical product quality assurance legislation, policies, and guidelines. During the first two quarters of PY3, the program supported a total of 38 new					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
regulations and guidelines. Eleven PY2 and PY3 policies were adopted and 21 submitted in the first two quarters of PY3. Substantial policy work is being done in Ethiopia, Liberia, and Nepal.					
1.2. Systems that facilitate transparency and accountability promoted					
1.2c.2. PQM+-supported MRA disseminated registration results, by quarter					
Uzbekistan Agency	Yes	Yes	Yes	Yes	Yes
1.2c.3. PQM+-supported MRA disseminated licensing results, by quarter					
Uzbekistan Agency	Yes	Yes	Yes	Yes	Yes
1.2c.4. PQM+-supported MRA disseminated post-marketing surveillance results, by quarter					
Burkina Faso	Yes, MRA report w/ PMS results	No	Yes	No	Yes
Ghana	Yes	No	Yes	No	Yes
Liberia	No	No	Yes	No	Yes
Mali	Partial	Yes	Yes	No	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 Uzbekistan, the Agency continues to disseminate registration and licensing results. To complement its extensive PMS support, PQM+ assists 12 other countries (see Annex 1a) in disseminating their PMS results. In the first half of PY3, Burkina Faso, Ghana, Liberia, and Mali reported PMS results. PMS is ongoing in the other countries so they do not yet have results to disseminate this year.					
1.3. Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted					
1.3a. PQM+-supported MRA in coordinating and communicating with other authorities involved in medical product regulatory oversight, by quarter (result captures percent of coordination components in place)					
Guinea DNPM-LNCQM	0%	TBC	87.5%	75%	75%
Uzbekistan WHO CRP	0%	Not PY2 indicator	100%	88%	88%
PQM+ is promoting regular coordination and information-sharing among public sector stakeholders involved in assuring the quality of medicines in some countries. PQM+ tracks whether public agencies have been identified, focal points named, coordination mechanism defined, and information exchanged. The Medicrime Brigade in Guinea is harmonizing with other stakeholders. Agencies and focal points have been named, while the coordination and information exchange systems are not yet fully established. Uzbekistan's Agency has all coordination components in place. Information related to WHO CRP are currently being exchanged with WHO.					
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					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Benin	0%	90%	100%	90%	90%
Burkina Faso	0%	70%	90%	90%	90%
DRC	0%	90%	90%	90%	90%
Ghana	0%	90%	90%	90%	90%
Guinea	0%	90%	90%	90%	90%
Kenya	0%	90%	90%	90%	90%
Liberia	0%	90%	90%	90%	90%
Madagascar	0%	n/a	20%	10%	40%
Mali	0%	90%	90%	90%	90%
Mozambique	0%	10% (adjusted)	No target	10%	10%
Rwanda	0%	n/a	90%	0%	40%
Senegal	0%	90%	90%	90%	90%
Other Multisector Groups					
Burkina Faso ANRP QA/QC workshop	N/A	90%	100%	-	90%
Liberia LMHRA's Technical Advisory Committee (TAC)	TBC	n/a	20%	-	10%
Nigeria Bauchi state QA committee	0%	0%	60%		70%
Nigeria Ebonyi state QA committee	0%	0%	60%		30%
Nigeria Sokoto state QA committee	0%	0%	60%		70%
Nigeria TWG, National Strategy for Pharmaceutical Manufacturing Sector	0%	0%	80%	-	10%
Pakistan Working Group, Ministry of Planning on Healthcare Investments	0%	0%		-	90%
Uzbekistan Quality Club	0%	30%	100%	100%	100%

PQM+ promotes coordination and 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 and functioning of technical working groups (TWGs) to establish priorities for, oversee, and report results of RB-PMS activities. TWGs also make recommendations for enforcement action to the MRA. To determine the extent of multisectoral coordination and 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 most 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%). By the end of PY2, PQM+ had helped form 10 new groups in Benin, Burkina Faso, DRC, Ghana, Guinea, Kenya, Liberia, Mali, Mozambique, and Senegal. All but the TWG in Mozambique score high (2) on four of the five

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
components—i.e., they have established and can document the TOR, elected officials, minutes, and attendance. However, they continue to rely on PQM+ to fund meetings. Once TWGs are funded by governments, they may be considered fully institutionalized (100%). TWGs in the relatively new buy-ins of Madagascar and Rwanda have both established TORs and chairs. PQM+ also assists MRAs in coordinating multisector stakeholders involved in overall medical product QA. 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 such workshop took place in PY3 Q2. In Liberia, PQM+ is reforming the LMHRA's expert committee (originally set up to provide independent medical and scientific advice on the safety, quality, and efficacy of medicines) with a new TAC. Group members are reviewing a new TOR with more detailed roles and responsibilities. In Nigeria, PQM+ is involved in state- and national-level efforts to coordinate multisectoral groups to advance medical product QA. At the national level, the TWG responsible for developing a national strategy for pharmaceutical manufacturing sector has signed and approved the TOR. Substantial work on forming state QA committees has been done in the states of Bauchi and Sokoto, though the TOR, meeting, and minutes are not fully established. The Ebonyi committee has not yet held any meetings. In PY3, PQM+ will assist the formation of three new groups in Benue, FCT, and Kebbi. In Q2, Pakistan's working group on enhancing efficiency-seeking investments held its first meeting. Uzbekistan's Quality Club is fully functional and has held two meetings to date, including an Uzbek-American pharmaceutical summit in Rockville, MD in Q2.					
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, by quarter					
Bangladesh	N/A	3%	No target	0%	
Burkina Faso*	N/A	-	No target		0%
Ethiopia*	2.27% (hand sanitizer)	-	No target		1%
Ghana*	N/A	-	No target		11%
Kazakhstan	0%	n/a	No target	5%	
Liberia*	N/A	-	No target		29%
Mali	5%	3%	No target		4%
Notes: PQM+-supported PMS surveys are designed to support MRAs in their market surveillance and control functions, allowing the MRA to monitor the quality of medical products in the country and to prevent, detect and respond to SF medicines when found. Each PMS quality survey has its own focus. Generally, for USAID-supported PMS quality surveys, MRAs sample numerous medicine classes of interest to the country and to the USAID health program. Generally, this means that the nationally representative sample size is split among multiple medicines classes, so the results for those individual medicine classes are not nationally representative. When desired, nationally representative surveys for individual medicine classes will be designed and results reported appropriately. Even when results are not nationally representative, they can provide signals of medicine quality issues in the market. Unless the medicine classes assessed and the sample sizes are consistent between multiple rounds of PMS in a country, comparison of PMS results between rounds should be done with caution. PY3 PMS results: ● Bangladesh: None of 306 samples (multiple medicines) failed. ● Kazakhstan: 49 of 948 samples failed (types of medicines not specified by NCEM). PMS is a fairly new concept in Kazakhstan.					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
• Mali: 4% of 320 samples collected from 5 regions--1% antimalarials, 4% MNCH medicines [diazepam injection]—failed; 74% of samples were unregistered. This is Mali's second round of RB-PMS. The failure rates for the individual medicine classes are not nationally representative. PY2 PMS results reported in PY3 Q1 and Q2 (results were still unavailable at the end of PY2): • Burkina Faso: None of 315 anti-malarial samples failed; however, 68% of medicines were unregistered. • Ethiopia—The shortage of medicines in the country at the time the PMS was done in PY2 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. Only 1 FP/RH sample failed. These results are not nationally representative. • Ghana: 42 of 378 samples failed. Failure rates for specific medicines were: 45% oxytocin, 6% misoprostol, 0.6% antimalarials. The medicine class-specific results are not nationally representative. • Liberia: 46 malaria and 41 MNCH samples of a total of 303 samples failed. The failure rates for the malaria samples and for the MNCH samples are not nationally representative.					
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					
Pakistan	0	10		3	0
Rwanda	0	n/a	8	3	1
The regulatory functions of many MRAs in LMICs have been benchmarked against global standards per the WHO Global Benchmarking Tool. 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 systematically address these recommendations. In Q1, PQM+ helped Pakistan's DRAP complete 3 recommendations (best practices in clinical trials and adaptation of international guidelines, Good Clinical Practices, and assessment and evaluation of pre-clinical and clinical trial data). Rwanda's FDA completed 4 out of 8 recommendations in Q1 and Q2.					
2.1d.1. Score on institutionalization of use of an inspection checklist by PQM+-supported MRA, by quarter					
Kazakhstan NCEM	0%	Not PY2 indicator	No target	33.3%	50%
2.1d.2. Score on institutionalization of remote inspection by PQM+-supported MRA, by quarter					
Kazakhstan NCEM	0%	Not PY2 indicator	No target	83.3%	83.3%
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 above). In Kazakhstan, PQM+ is helping NCEM develop an inspection checklist, a SOP, training, and a tracker. The NCEM now has a SOP and can train its staff on implementing remote inspection. The MRA is currently putting a system in place to track the outcomes and results of remote inspections.					
2.1k. Number of standard operating procedures and quality assurance manuals developed or updated and adopted by project supported MRA, by quarter					
Bangladesh DGDA (regulatory systems)	0	47	3	15	3
Ethiopia EFDA (inspection)	0	40	15	27	0
Kazakhstan NCEM (inspection)	0	11		0	6
Uzbekistan Agency (registration, laboratory testing)	0	6	27	3	0
Total 2.1k				**45**	**9**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
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 the first half of PY2, helped MRAs in 4 countries with 54 SOPs.					
2.2. Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened					
2.2a. PQM+-supported QC laboratory score on SATTA					
Burkina Faso LNSP	3%	3%	56%	-	29%
Liberia LMHRA QCL	TBC	47%	No target	-	48.7%
Liberia National Standard Laboratory	TBC	New PY3	No target	-	47.9%
Mali LCQM	21%	21%	No target	61% (mock audit)	-
Mali Microbiology Laboratory	TBC	New PY3	60%	37%	-
Mozambique DCQ	14%	14%	No target	14%	55%
Tajikistan MQCL	-	n/a	No target	-	32%
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 the first two quarters of PY3, PQM+ completed SATTAs for three new laboratories—Liberia's National Standard Laboratory, Mali's Microbiology Laboratory, and Tajikistan's MQCL. PQM+ uses these results to develop roadmaps to address gaps. Also, in PY3, national laboratories in Burkina Faso, Liberia, Mali, and Mozambique that PQM+ worked with in PY2 made substantial progress in improving areas of weakness. Against their baselines, Burkina Faso's LNSP improved by 26 percentage points, whereas Mali's LCQM and Mozambique's DCQ both jumped about 40 percentage points.					
2.2b.1. Number of PQM+-supported laboratories that achieved ISO accreditation or WHO prequalification, by quarter and number of methods					
Burma Nay Pyi Taw PCL	ISO 17025:2017 (10 methods)	ISO 17025:2017 re-accredited (10 methods)	ISO 17025:2017 re-accredited (10 methods)	ISO 17025:2017 re-accredited (10 methods)	-
Nigeria NAFDAC Vaccines and Biologics Lab	ISO 17025:2017 (10 methods)	ISO 17025:2017 reaccredited (14 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (23 methods)	-
Nigeria NAFDAC zonal lab, Agulu	ISO 17025:2017 (7 methods)	ISO 17025:2017 reaccredited (16 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (16 methods)	-
Nigeria NAFDAC zonal lab, Kaduna	ISO 17025:2017 (7 methods)	ISO 17025:2017 reaccredited (16 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (16 methods)	-
Nigeria NAFDAC zonal lab, Yaba	ISO 17025:2017 (7 methods)	ISO 17025:2017 reaccredited (17 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (17 methods)	-
Nigeria NIPRID NQCL	ISO 17025:2017 (6 methods)	ISO 17025:2017 (6 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (6 methods)	

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Uzbekistan Tashkent	ISO 17025:2017 (105 methods)	-	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (115 methods)	
PQM+ helps laboratories achieve international (or national) accreditation or WHO prequalification as evidence of their quality and competence. Having to renew accreditation means that laboratories must continue to meet the rigorous standards of the accrediting body. In Q1 of PY3, QC laboratories in Burma and Nigeria[1] were re-accredited for ISO 17025:2017. Uzbekistan's Tashkent laboratory was reaccredited through a national accreditation body in Q1. [1]In Nigeria, PQM+ no longer actively supports these labs to either expand or sustain their accreditation, but the support provided by PQM and PQM+ created the foundation for ongoing re-accreditation and even scope expansion. To the best of our knowledge, only the Vaccines and Biologics Laboratory has expanded its scope (i.e., number of methods).					
2.2d. Number of non-laboratory entities involved in medical product quality assurance that achieved ISO accreditation/certification with PQM+ support, by quarter					
Ethiopia EFDA Medicine Inspection Directorate (ISO 17020:2012)	0	0		0	1
Nigeria Pharmacists' Council of Nigeria (ISO 9001:2015)	0	0	No target	0	1
In addition to helping laboratories achieve ISO accreditation, PQM+ helps other entities meet international standards that demonstrate the consistency and quality of their operations. In Q2, the Ethiopia EFDA Medicine Inspection Directorate achieved ISO 17020:2012 certification, which signifies that it meets requirements for competence in performing inspection and for the impartiality and consistency of its inspection activities. This is the first such accreditation for a regulatory authority that was supported by PQM+ or PQM. Also in Q2, the PQM+-supported Pharmacists' Council of Nigeria received certification for meeting ISO 9001:2015 standards for its quality management system.					
2.2h. Percentage of milestones toward accreditation/WHO PQ achieved by a PQM+-supported laboratory, by quarter					
Bangladesh Microbiology Laboratory (WHO PQ)	0%	-	35%	-	55%
Bangladesh Physiochemical Laboratory (WHO PQ)	0%		35%	10%	10%
Bangladesh Vaccine Laboratory (WHO PQ)	0%	55%	70%	35%	35%
Liberia LMHRA QCL (ISO 17025)	0%	35%	40%	40%	40%
Liberia LMHRA National Standards Lab (ISO 17025)	0%	New PY3	10%	-	10%
Madagascar LQCM (ISO 17025)	0%	n/a	10%	5%	20%
Mali LCQM (ISO 17025:2017)	0%	90%	100%	90%	90%
Mozambique (ISO 17025:2017)	30%	30%	No target	45%	45%
Nepal NML (ISO 17025:2017)	0%	45%	80%	45%	90%
Pakistan DTL Lahore (ISO 17025:2017) (calibration)	0%	0%		30%	100%
Pakistan Institute Medical Sciences (ISO 15189)	0%	50%	100%	80%	90%
Rwanda QCL (WHO PQ and ISO 17025)	0%	n/a	40%	0%	5%

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
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 (see Table A2 above). The closer a laboratory is to 100%, the more milestones it has completed. Of note, in PY2, PQM+ is helping Pakistan DTL Lahore pursue ISO 17025:2017 accreditation for calibration services, and Pakistan Institute Medical Sciences laboratory pursue ISO 15189 for diagnostic testing.					
2.2i. Number of standard operating procedures and quality assurance manuals developed or updated and adopted by PQM+-supported laboratory, by quarter					
Bangladesh Vaccine Laboratory	0	34 (3 laboratories)	21 (all labs)	12	11
Guinea	0	0	10	1	0
Kazakhstan	0	24 (2 laboratories)		0	9
Liberia	0	36 (LMHRA CCL)		0	6
Mali LCQM	0	2	10	5	0
Mozambique	0	0	No target	0	10
Nepal NML	0	7	7	0	1
Uzbekistan Tashkent	0	1	12	5	0
Total 2.2i				**23**	**33**
SOPs help ensure that accepted procedures are followed consistently to ensure consistent performance and results. SOPs underpin many efforts to strengthen laboratories and are essential for accreditation. In the first two quarters of PY3, PQM+ supported laboratories in 8 countries with 56 new SOPs.					
2.3. Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported					
2.3a. Regulatory decisions using reliance, by quarter					
Uzbekistan (registration)	0	0	3	2	0
In PY3 Q1, Uzbekistan's Agency registered two products (prothionomid and cycloserine) through the WHO's collaborative procedure for registration. Using CPR substantially reduces the time and cost of registering new medicines, which will increase availability of quality-assured medicines in the Uzbekistan market.					
2.3c.1 Score on institutionalization of use of WHO collaborative procedure for accelerated registration at PQM+ supported MRA, by quarter					
Uzbekistan Agency	25%	83.3%	100%	83.3%	83.3%
PQM+ is helping the MRAs in Tajikistan 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. A score of 100% means the procedure has been fully incorporated into counterpart practices (see scoring convention above). Uzbekistan's Agency has a SOP, can offer training, and is developing an information system to track the use and results of the collaborative procedure for registration.					
2.5a. Number of in-service training programs that address quality assurance/quality control topics delivered with PQM+ support, by quarter					
Bangladesh	0	35	19	4	1
Bangladesh COVID-19 ARP	0	6	No target	1	0
Benin	0	4	6	1	2

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Burkina Faso COVID-19 ARP	0	n/a	No target	1	1
DRC	0	4	4	4	3
Ethiopia	0	6	4	1	1
Ethiopia COVID-19 ARP	0	n/a	No target	1	1
Ghana	0	4	4	2	1
Ghana COVID-19 ARP	0	0	No target	1	0
Guinea	0	6	7	3	2
Kazakhstan	0	9	4	3	1
Kenya	0	1	1	1	1
Liberia	0	11	6	2	5
Madagascar	0	n/a	1	1	2
Mali	0	10 (adjusted)	6	3	1
Mozambique	0	2	No target	1	0
Nepal	0	4		3	5
Nigeria	0	8		4	2
Pakistan	0	18		2	4
Pakistan COVID-19 Vaccines	0	14	No target	2	5
Rwanda	0	n/a	2	0	1
Senegal	0	3	4	2	1
Uzbekistan	0	11	5	1	2
Uzbekistan COVID-19 ARP	0	n/a		1	0
Total 2.5a				**38**	**35**
2.5b. Number of individuals who successfully completed a PQM+-supported in-service training program, by quarter				**F / M**	**F / M**
Bangladesh	0			14 / 30	9 / 17
Benin	0			4 / 10	11 / 16
Burkina Faso	0			3 / 5	10 / 16
DRC	0			19 / 30	19 / 28
Ethiopia	0			10 / 45	23 / 50

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Ghana	0			15 / 36	1 / 7
Guinea	0			2 / 28	2 / 9
Kazakhstan	0			80 / 15	35 / 10
Kenya	0			15 / 15	1 / 9
Liberia	0			7 / 37	15 / 45
Madagascar	0	n/a		7 / 1	6 / 4
Mali	0			7 / 7	4 / 7
Mozambique	0			12 / 8	
Nepal	0			17 / 26	11 / 20
Nigeria	0			66 / 84	11 / 14
Pakistan	0		350	21 / 18	65 / 165
Rwanda	0	n/a			16 / 21
Senegal	0			8 / 9	10 / 5
Uzbekistan	0			15 / 8	1 / 3
Total (disaggregated)	**0**			**F: 325 (43.7%) M: 419 (56.3%)**	**F: 250 (35.9%) M: 446 (64.1%)**
Grand total 2.5b				**744**	**696**
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 percentage of female trainees are as follows: Q1—43.7%; Q2—35.9%.					
2.5c. Number of training programs developed or revised to address quality assurance / quality control topics with PQM+ support, by quarter					
Kenya PPB	0	1	10	0	9
PQM+ is helping counterparts develop short QA/QC courses, modules, and curricula to build workforce capacity. In Q2, PQM+ helped develop content for 9 e-learning courses for Kenya PPB's self-directed learning platform.					
2.5d.1. Score on institutionalization of staffing program adopted by PQM+ supported MRA, by quarter					
Liberia LMHRA	0%	0%	50%	0%	66.7%
2.5d.2. Score on institutionalization of skills program adopted by PQM+ supported MRA, by quarter					
Madagascar Agency	0%	n/a	100%	-	16.7%
Rwanda FDA	0%	n/a	100%	83.3%	83.3%

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
2.5e.2. Score on institutionalization of skills program adopted by PQM+ supported QC laboratory, by quarter					
Madagascar LNCQM	0%	n/a	100%	-	16.7%
Nepal NML	0%	n/a		-	16.7%
Rwanda FDA QCL	0%	n/a	100%	83.3	83.3%
To improve the sustainability of its interventions, PQM+ promotes workforce development approaches that help counterparts (MRAs and laboratories) build, retain, support, and motivate their workforce. PQM+ begins by (1) conducting a comprehensive assessment of counterparts' human resources across four pathways: staffing, skills, working conditions, and staff motivation; then works with counterparts to (2) design interventions to strengthen areas prioritized for support, and (3) develop and utilize a central tracking system to monitor implementation of/or results from the intervention. PQM+ scores each of these components 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 the first half of PY3, PQM+ completed human resources assessments and helped develop a system to manage records for skills programs at Rwanda's MRA and QCL and work on developing a skills intervention is ongoing. In Madagascar (Agency, LNCQM) and Nepal (NML), PQM+ is currently assessing human resources for a skills program. In Liberia, an assessment and development of an intervention for a staffing program for LMHRA continues, while a tracking system is now in place.					
2.5f. Number of membership organizations that were strengthened in advancing members' understanding of medical product quality assurance by PQM+, by quarter					
Nigeria	0	2	2	1	1
PQM+ helped strengthen two membership organizations in PY2: (1) Pharmacist Council of Nigeria (technical assistance in attaining ISO 9001: 2015 accreditation officially attained in Q2, trainings on ISO 9001: 2015 awareness, training of lead implementers and internal auditors on ISO 9001: 2015); and (2) Pharmaceutical Manufacturers' Group of Manufacturers' Association of Nigeria (training on validation to increase GMP knowledge and skills within the industry).					
Uzbekistan	0	1	1	1	0
PQM+ helped strengthen the Association of Domestic Manufacturers (conducted Quality Club meeting with Agency, Agency's staff board, and association)					
Total 2.5f				**2**	**1**
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.3. Score on institutionalization of risk-based approach to post marketing surveillance at PQM+-supported MRA, by quarter					
Kenya PPB	0%	66.7%	100%	66.7%	83.3%
Nepal DDA	0%	33.3%	83.3%	33.3%	50%
Rwanda FDA	0%	n/a	67%	0%	50%
PQM+ is working to institutionalize RB-PMS in 12 countries (see Annex 1A). By Q2, Kenya's PPB had SOPs and a tracker in place and was developing its staff training. Nepal's DDA began developing 2 of 4 SOPs needed and a record system, trained its PMS focal person, and adopted PQM+'s RB-PMS training materials. Rwanda's FDA is also developing the necessary SOPs and training for its staff.					
3.2. Sustainable resources mobilized					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
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					
Kenya PPB (PY2)	No	-	Not PY3 indicator	No	Yes
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 PY3 Q2, PQM+ helped Kenya's PPB analyze its costs (a carry over activity from PY2).					
OBJECTIVE 4: SUPPLY OF QUALITY-ASSURED ESSENTIAL MEDICAL PRODUCTS OF PUBLIC HEALTH IMPORTANCE INCREASED					
4.a. Number of treatments of quality-assured medicine produced by PQM+-supported manufacturer					
Nigeria – Chlorhexidine gel			No target		1.26 million
Nigeria – Amoxicillin DT			No target		600,000
Nigeria – Co-trimoxazole			No target		75,000
PQM+-supported manufacturers produced the following medicines in Q2: ● Enough Chlorhexidine gel to prevent 1.26 million umbilical cord infections in newborns ● Enough Amoxicillin DT to treat 600,000 severe pneumonia infections in children 2 - 12 months ● Enough Co-trimoxazole to treat 75,000 opportunistic infections in children > 5 years living with HIV/AIDS Note that many other PQM and PQM+-supported manufacturers continue to manufacture quality-assured medicines, but PQM+ in many cases is not able to obtain production data, which is considered proprietary, from these manufacturers.					
4.1. Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/dossiers supported					
4.1a.3. Score on institutionalization of new training program and training and tracking system at PQM+-supported manufacturer, by quarter					
Uzbekistan Nobel	0%	Not PY2 indicator	100%	100%	-
4.1c. Percentage of milestones toward market authorization or WHO prequalification achieved by PQM+-supported manufacturer, by quarter					
Bangladesh ACI Ltd., WHO PQ	n/a	37.5%	50%	47.5%	47.5%
Ghana Amponsah Efah Ltd., Alu 20/120 mcg	0%	10%	No target	25%	25%
Ghana Entrance Pharmaceuticals, Alu 20/120 mcg	0%	0%	No target	25%	25%
Ghana M&G Pharmaceuticals Ltd., Amox. DT 125 mg	0%	New PY3	No target	-	10%
Nepal Chemidrug, Amoxicillin DT 125 mg	0%	Not PY2 indicator	No target	-	32.5%
Nepal DJPL, Azithromycin 500 mg	0%	Not PY2 indicator	No target	-	32.5%
Nepal DJPL, Zinc sulphate 20 mg	0%	Not PY2 indicator	No target	-	32.5%
Nepal Magnus, Azithromycin 500 mg	0%	Not PY2 indicator	No target	-	32.5%
Nepal Omnica, Zinc sulphate 20 mg	0%	Not PY2 indicator	No target	-	32.5%
Nepal Quest, Azithromycin 500 mg	0%	Not PY2 indicator	No target	-	32.5%

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Nigeria May & Baker ALu 80/480 mcg	n/a	0%	No target	10%	10%
Uzbekistan Nobel, 2FDC anti-TB	n/a	40%	50%	55%	55%
Achievement of market authorization or WHO prequalification for a new medical product is a long process with many stages (see Table A.2 above). In the first half of PY3, 12 PQM+-supported manufacturers made progress toward market authorization or WHO prequalification. Of note, PQM+ started working with 5 new manufacturers in Nepal (3 new products) and one new manufacturer in Ghana (M&G Pharmaceuticals). PQM+ also provides ongoing support to 6 manufacturers in Nigeria that are pursuing WHO PQ of 6 products.					
4.3. Capacity for market intelligence and analytics of public health pharmaceutical markets increased					
4.3a. Number of market profiles or market analyses for priority medical products developed by PQM+, by quarter					
Core MNCH, *Survey of Manufacturers of Amoxicillin and Beta-Lactam Products in Africa* (PY2)	0	0	Not PY3 indicator	0	1
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					
Ethiopia	0	0	No target	0	3
Nigeria	0	0	No target	2	0
Total 5.1a				**2**	**3**
PQM+ develops new approaches and tools to improve medical product quality, enhance efficiency, or improve sustainability. In the first half of PY3, PQM+ rolled out five new tools. These included job aides for drug quality assurance for Nigerian operators and customers of patent medicines shops and community pharmacies; and cold chain assessment checklists for importers (EPSA)/wholesalers and health facilities as well as an Excel database template for GMP inspection findings in Ethiopia.					
5.1b.1. Number of PQM+-supported entities that adopted SATTA, by quarter					
Mali Microbiology Laboratory	0	0	1	0	1
Mali's Microbiology Laboratory adopted the SATTA tool in the second quarter of PY3. Training in the use of SATTA is part of PQM+'s lab strengthening strategy. Adoption of the tool will help laboratory staff conduct routine internal audits to identify areas for improvement.					
5.1b.2. Number of PQM+-supported entities that adopted MedRS, by quarter					
Madagascar	0	n/a	1	0	1
Nepal DDA	0	0	Not PY3 indicator	0	1
Rwanda FDA	0	n/a	1	0	1
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. In PY3 Q2, three additional countries (shown) adopted the tool. PQM+ offers an online version of the tool (MedRSv2). Thus far, 17 countries have subscribed to the online tool, 14 of which have used it, with PQM+ support, to develop PMS protocols.					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
5.1b.4. Number of PQM+-supported entities that adopted *Guidance Document on RB-PMS of MNCH Products*, by quarter					
Ghana	0	0	1	0	1
Liberia	0	0	1	1	0
The *Guidance Document* (published by the Core MNCH Program in PY2) was used by MRAs in Ghana and Liberia in the first half of PY3.					
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					
Asia Bureau	0	0	10	0	1 pres., 1 pub.
Burma	0	1	No target	1 pres.	0
Ethiopia	0	4	1	2 pres.	0
Kazakhstan	0	3	1	2 pres.	0
Kenya	0	5	3	1 pres.	2 pub.
Liberia	0	2	1	0	1 pres.
Nigeria	0	0	No target	1 pub.	0
Pakistan	0	4	4	1 pres.	1 pres.
Uzbekistan	0	1	2	3 pres.	2 pres.
Total 5.2a				**11**	**8**
PQM+ conducted 15 conference and workshop presentations and produced 4 new technical publications in the first two quarters of PY3. Of note were (1) a journal article (PLOS ONE) on healthcare providers' experiences with oxytocin for prevention of post-partum hemorrhage in Nigeria; and two technical reports on (2) the challenges and growth opportunities for Kenya's pharmaceutical manufacturing sector, and (3) the financial sustainability of Kenya's National Quality Control Laboratory. Asia Bureau's landscape analysis of the medical product QA systems for SEARN and ASEAN member countries was released in Q2.					
5.2e. Number of modules in the Foundations of GMP eLearning course that were completed, by quarter					
Core NTD	4,000	3,469	150	37	590
Users completed a total of 627 Foundations of GMP e-learning modules during quarters 1 and 2. Since April 2021, PQM+ has sent out reminders periodically to users who have not completed their modules. It appears this strategy may be playing a role in boosting completion rates.					
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					
Uzbekistan	0	4	2	3	2
There were numerous awareness raising/advocacy events in Uzbekistan: First Quality Club meeting; hand-over event of HPLC to Andijan MQCL (with USAID participation); USAID visit to Tashkent Pharma Park; Uzbek-American pharmaceutical summit in Rockville, MD; World TB Day.					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
5.3b. Number of instances of media coverage of PQM+-supported medical product quality assurance-related events or topics, by quarter					
Bangladesh	0	13	10	7	0
Burkina Faso	0	9	No target	0	1
Core NTD	0	3	No target	0	1
Ethiopia	0	6	No target	1	0
Ghana	0	2	No target	0	2
Kazakhstan	0	8	2	1	1
Kenya	0	7	2	2	0
Liberia	0	8	No target	0	1
Madagascar	0	n/a	1	0	2
Pakistan	0	31	No target	2	0
Uzbekistan	0	9	6	3	7
Total 5.3b				**16**	**15**
External Partnerships					
CC.PPP.a. Number of external partnerships that PQM+ helped establish in the reporting period					
Bangladesh	0	1	7	5	0
In Q1, PQM+ established the following partnerships: National TB Control Program of DGHS (collaborative work to implement TB activities); Bangladesh Association of Pharmaceutical Industries (potential partner for API); WHO (partnership for collaboration of interested partner meeting); Bangabandhu Sheikh Mujib Medical University and Healthcare Pharmaceuticals (a for-profit business)—both as potential partners for vaccine testing to support NCL, DGDA.					
Core MNCH	0	0	1	0	1
PQM+ established a partnership with Newborn Essential Solutions and Technologies 360 (aPVO developing and delivering a bundle of high-quality products and services for hospital-based newborn care). We are discussing development of a guidance document on quality testing methods for priority MNCH medical devices.					
Ethiopia	0	8		0	1
PQM+ reached an agreement with Ethiopian Pharmaceutical Association to develop Continuous Professional Development (CPD) materials.					
Kazakhstan	0	0	2	0	2
PQM+ began engaging two pharmaceutical manufacturers' associations to understand the needs of manufacturers in terms of improving their GMP compliance.					
Pakistan	0	5	2	1	3
Pharmaceutical manufacturing, marketing and distribution companies in Q1, and three manufacturers' associations (Pakistan Pharmaceutical Manufacturers Association, Pharma Bureau, and Healthcare Devices Association of Pakistan) in Q2					

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3 Q1	PY3 Q2
Rwanda	0	n/a	1	0	1
Collaborating with the University of Rwanda on an MPQA course.					
Total CC.PPP.a				**6**	**6**

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

Mission and Directed Core Buy-Ins by PQM+ Indicator, PY3							
1a Bangladesh Benin Ethiopia Guinea Liberia Mali Nepal Senegal 1.1a Bangladesh Burkina Faso Ethiopia Guinea Kazakhstan Kenya Liberia Mozambique Nigeria Pakistan Rwanda Uzbekistan 1.2c.2 – 1.2c.3 Uzbekistan 1.2c.4 Bangladesh Benin Burkina Faso DRC Ethiopia Ghana	1.2c.4 (cont.) Guinea Kazakhstan Kenya Liberia Mali Senegal 1.3a Bangladesh Guinea Uzbekistan 1.4a Bangladesh Benin Burkina Faso DRC Ethiopia Ghana Guinea Kenya Liberia Madagascar Mali Mozambique Nigeria Rwanda Senegal Uzbekistan	2a Bangladesh Benin Burkina Faso DRC Ethiopia Ghana Guinea Kazakhstan Kenya Liberia Mali Nepal Nigeria Senegal 2b Bangladesh Kazakhstan Rwanda 2c Bangladesh Kazakhstan Mali 2d Ethiopia Nigeria	2.1a Bangladesh Ethiopia Kazakhstan Nepal Rwanda Senegal 2.1b. Bangladesh Tajikistan Uzbekistan 2.1d.1-2.1d.2 Bangladesh Kazakhstan 2.1g Liberia 2.1i Kazakhstan Uzbekistan 2.1j Bangladesh	2.1k Bangladesh Benin Burkina Faso DRC Ethiopia Guinea Kazakhstan Madagascar Nigeria Rwanda Senegal Tajikistan Uzbekistan 2.2a Burkina Faso Ethiopia Guinea Madagascar Mali Mozambique Nepal Rwanda Tajikistan	2.2b.1 - 2.2b.2 Bangladesh Burma DRC Ethiopia Nigeria Mali Mozambique Uzbekistan 2.2c.1 Burma Tajikistan 2.2c.2 Burma Madagascar Mali Senegal Uzbekistan 2.2c.3 Burma Mali Senegal 2.2c.4 Rwanda Uzbekistan	2.2c.5 Benin Guinea Liberia Mali Tajikistan 2.2c.6 Guinea Mali Tajikistan Uzbekistan 2.2f DRC Rwanda 2.2g Bangladesh Ethiopia Mozambique Nepal Rwanda 2.2h Bangladesh Benin Burkina Faso Burma DRC Ethiopia Guinea Kazakhstan Liberia	2.2h (cont.) Madagascar Mali Mozambique Nepal Pakistan Rwanda Tajikistan Uzbekistan 2.2i Bangladesh Benin Burkina Faso Burma Ethiopia Guinea Kazakhstan Liberia Madagascar Mali Nigeria Rwanda Senegal Tajikistan Uzbekistan 2.2m All listed under 1.4a Bangladesh

Mission and Directed Core Buy-Ins by PQM+ Indicator, PY3							
2.3a Kenya Rwanda Uzbekistan 2.3c.1 Tajikistan Uzbekistan 2.3c.2 Tajikistan 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	2.5a, 2.5b (cont.) Senegal Tajikistan Uzbekistan 2.5c Asia Bureau Bangladesh Core TB Core MNCH Kenya Liberia Mali Nepal Pakistan Rwanda Uzbekistan 2.5d.1 Liberia 2.5d.2 Madagascar Rwanda 2.5d.3 Nepal 2.5e.1, 2.5e.3 Kenya	2.5e.2 Burma Madagascar Mozambique Nepal Rwanda 2.5e.4 Mali 2.5f Ethiopia Kazakhstan Kenya Nigeria Uzbekistan 3.1a.2 Kazakhstan Nepal Pakistan Uzbekistan 3.1a.3 Bangladesh Burkina Faso DRC Ethiopia Ghana Guinea Kazakhstan Liberia Mali Nepal	3.1a.3 (cont.) Rwanda Senegal 3.1b.1 Ethiopia Mali 3.1b.3 Burma 3.2b.4 Ethiopia Rwanda 3.2b.5 Ethiopia 4a Nepal Nigeria 4b Nepal Nigeria 4c Bangladesh Core TB Nepal Nigeria Uzbekistan	4.1a Burma Nepal 4.1b Bangladesh Core TB Ghana Nigeria 4.1c Bangladesh Core NTD Core TB Ethiopia Ghana Nepal Nigeria Pakistan Uzbekistan 4.1d Bangladesh Burma Rwanda 4.1e Core NTD Ethiopia 4.2.1a, 4.2.1b Bangladesh	4.3a Asia Bureau Core MNCH Core NTD Nepal Uzbekistan 4.4a Kenya Rwanda 5.1a Asia Bureau Bangladesh Benin Core MNCH Core NTD Core TB Kenya Mozambique Nigeria Rwanda 5.1b.1 Benin Madagascar Mali Mozambique Rwanda Ethiopia Kazakhstan Kenya	5.1b.2 Bangladesh Benin Ethiopia Kazakhstan Liberia Mali Rwanda 5.1b.3 Nigeria 5.1b.4 Benin Mali Nigeria 5.1b.5 Benin Mali 5.2a Asia Bureau Bangladesh Benin Burkina Faso Core MNCH Core NTD Core TB	5.2a (cont.) Liberia Mali Nepal Nigeria Pakistan Rwanda Tajikistan Uzbekistan 5.2e Core NTD 5.3a Asia Bureau Bangladesh Core MNCH Core NTD Ghana Kazakhstan Nepal Uzbekistan 5.3b Asia Bureau Bangladesh Benin Burkina Faso Burma Core MNCH Core NTD DRC Ethiopia Ghana Guinea Kazakhstan

Mission and Directed Core Buy-Ins by PQM+ Indicator, PY3							
5.3b (cont.) Kenya Madagascar Mali Nepal Nigeria Pakistan Rwanda Senegal Tajikistan Uzbekistan 5.3c Asia Bureau Bangladesh STIR-10/11 Nepal CBLD-9 Nepal Nigeria CUST 2 Nepal (see 1.1a, 2.2i, and 2.1k) CC.CF.a Asia Bureau Core MNCH Core NTD Core TB	CC.PPP.a/b Bangladesh Core MNCH Core NTD Core TB Ethiopia Ghana Kazakhstan Kenya Liberia Pakistan Rwanda Uzbekistan PSE-1 / PSE-2 Nigeria Uzbekistan PSE-3 Nigeria SN 42-SN 43 Tajikistan						

Annex 1B. Start Dates of Buy-ins by PQM+ Funding, including for COVID-19

		PY 1 (October 2019-September 2020)				PY 2 (October 2020-September 2021)				PY 3 (October 2021-September 2022)			
Buy-Ins		**Q1**	**Q2**	**Q3**	**Q4**	**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		Ended 1/30							
Mozambique					1-Jul				Ended 9/30	NCE through 9/2022			
Pakistan Covid-19					1-Jul					Ended 12/31			
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							

		PY 1 (October 2019-September 2020)				PY 2 (October 2020-September 2021)				PY 3 (October 2021-September 2022)			
Buy-Ins		**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Serbia Covid-19						1-Oct		Ended 4/30				NCE through 5/2022	
Guinea							1-Jan						
Cross Bureau Covid-19							1-Feb						
DRC							1-Mar						
Madagascar							1-Mar						
Bangladesh COVID-19 Vaccine								1-Apr		Ended 11/30			
Ghana COVID-19 Vaccine								1-Apr			Ended 2/28		
Pakistan COVID-19 Vaccine								1-May					
Uzbekistan COVID-19 Vaccine								1-Apr		Ended 12/31			
Rwanda (PY2/PY3 work plan)								1-May					
Ghana Vaccines								1-May					
Pakistan Vaccines								1-May					
Burkina Faso Covid-19 ARP									1-Aug				
Tajikistan									1-Aug				
Ghana Covid-19 ARP										1-Oct			
Kazakhstan Covid-19 ARP										1-Oct			
Uzbekistan Covid-19 ARP										1-Oct			
Bangladesh Covid-19 ARP										1-Nov			
Ethiopia Covid-19 ARP										1-Nov			