Promoting the
QUALITY OF MEDICINES Plus

PQM+ Annual Report – Program Year 4

USP PHOTO/TIM WOLFER

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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 medical products for HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and other infectious diseases as well as for reproductive, maternal, newborn, and child health.

USP establishes quality standards for medicines the United States Food and Drug Administration (U.S. FDA) is legally mandated to enforce. USP is an independent, scientific nonprofit public health organization and is not a part of the U.S. FDA or any other U.S. Government agency. PQM+ is unaffiliated with, and has not been evaluated by, FDA. References to FDA or to FDA publications do not constitute FDA endorsement of the PQM+ program or of the information provided by it.

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Cover Photo

An associate works in the packaging operations unit of a Bangladeshi gabapentin manufacturer.

Contents

Acronyms

2FDC	two drug, fixed-dose combination
4FDC	four-drug, fixed-dose combination
ADR	adverse drug reaction
AEFI	adverse events following immunization
AMA	African Medicines Agency
AMQF	African Medicines Quality Forum
AMR	antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization
AMV	analytical method verification
ANAB	American National Standards Society National Accreditation Board
API	active pharmaceutical ingredient
ARV	antiretroviral drugs
AUDA-NEPAD	African Union Development Agency- New Partnership for Africa's Development
CAPA	corrective and preventive action
cGMP	current good manufacturing practices
CIP	Coalition of Interested Parties
COVID-19	novel coronavirus of 2019
CPD	continuing professional development
CRO	contract research organization
CRP	collaborative registration procedure
CSV	computerized systems validation
CTD / eCTD	common technical document / electronic common technical document
DAPSC	Diversifying the Asia Pharmaceutical Supply Chain
DMF	drug master file
DT	dispersible tablets (amoxicillin)
EAC	East African Community
EPI	Expanded Program on Immunization
EUA	emergency use authorization
FP	family planning
FPP	finished pharmaceutical product
FTIR	Fourier-transform infrared spectroscopy
GBT	WHO Global Benchmarking Tool to evaluate national regulatory systems

GCP	good clinical practices
GDSP	good storage and distribution practices
Global VAX	U.S. Government's Initiative for Global Vaccine Access
GLP	good laboratory practices
GMP	good manufacturing practices
GSDP	good storage and distribution practices
HPHC	High-Performing Health Care tool
HPLC	high-performance liquid chromatography
HPT	health product technology
HR	human resources
IDP	institutional development plan
IGAD	Intergovernmental Authority on Development (Africa)
IQC	internal quality control
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission
KPI	key performance indicator
LIF	laboratory information file
LMIC	low- and middle-income countries
MedRS	Medicines Risk-based Surveillance
MNCH	maternal, newborn, and child health
mRDT	malaria rapid diagnostic test
MOH	ministry of health
MQCL	medicines quality control laboratory
MRA	medicines regulatory authority
MTaPS	Medicines, Technologies, and Pharmaceutical Systems program
NCL	National Control Laboratory
NGO	nongovernmental organization
NTD	neglected tropical disease
OHS	Office of Health Systems (USAID)
OpERA	Optimizing Efficiencies in Regulatory Agencies
PCR	polymerase chain reaction
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIR	product information report
PIRIMS	Pakistan Integrated Regulatory Information Management System

PMI	(U.S.) President's Malaria Initiative
PMS	post-marketing surveillance
POC	point of contact
PPE	personal protective equipment
PQM+	Promoting the Quality of Medicines Plus
PSS101	Pharmaceutical Systems Strengthening course
PV	pharmacovigilance
QA	quality assurance
QC	quality control
QMS	quality management system
RBI	risk-based inspection
RB-PMS	risk-based post-marketing surveillance
RIMS	regulatory information management system
RRB	regional regulatory body
RSS	regulatory system strengthening
RUTF	ready-to-use therapeutic food
SADC	Southern African Development Community
SATTA	Stepwise Assessment Tool Towards Accreditation
SBCC	social and behavior change communication
SF	substandard or falsified
SOP	standard operating procedure
T2T	test-to-treat
TB	tuberculosis
TOR	terms of reference
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWG	technical working group
TXA	tranexamic acid
UDU	uniformity of dosage units
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeia
UV-vis	ultraviolet-visible spectrophotometry or spectroscopy
WHO	World Health Organization
WHO PQ	World Health Organization prequalification

Letter from the Director

In addition to passion about quality assurance systems, another topic that greatly animates my PQM+ colleagues at U.S. Pharmacopeia (USP) is how our work contributes to sustainable systems. The goal of the PQM+ Program is to sustainably strengthen medical product quality assurance systems in low- and middle-income countries. As we mark the end of Program Year 4, almost two years to the end of the period of performance, it seems right timing to further explore the topic of sustainability.

Sustainable regulatory and quality assurance systems are those that ensure reliable access and safety of essential medical products to the local population over time. PQM+ provides systems strengthening support to multiple institutions that are part of the quality assurance system, enabling them to meet the needs of their population. Sustainability is achieved when those institutions consistently and resiliently provide access to quality-assured medical products and contribute to improvement in health outcomes.

Over the past four years, PQM+ has supported hundreds of institutions and organizations in the pharmaceutical sector, ranging from regulatory authorities to laboratories, public health programs responsible for HIV/AIDS, tuberculosis, malaria, neglected tropical diseases (NTD), maternal and child health (MCH), vaccines, and others, ministry of health department of pharmaceutical services and agencies of ministries of science, industry and trade, national committees and technical working groups, academic institutions, professional associations, and hundreds of pharmaceutical manufacturing companies. Focusing on technical assistance to national regulatory authorities in fiscal year 2023 alone, PQM+ provided regulatory function support for marketing authorization (15 countries), market control (17), regulatory inspections (13), laboratory testing (23), and lot release capacity development (nine). Our support has enabled those regulatory authorities to progress in their WHO Global Benchmarking Tool Maturity Level and in their journey toward sustainable quality assurance systems.

In this work, PQM+ identified regional support as an efficient way to scale our technical assistance and ensure local ownership. Our assistance toward the operationalization of the African Medicines Agency (AMA) best demonstrates the value and reward that can occur from regional support. In 2009, the PQM program—in addition to regular support to individual laboratories—helped establish the Network of National Official Medicines Quality Control Laboratories (NOMCoL) with seed investment from USAID. Over time, this early USAID investment in a small laboratory network evolved into a locally led continental network called the African Medicines Quality Forum (AMQF). More than a decade later, PQM+ began supporting AMRH in 2022 to develop a vaccine laboratory network for Africa. That work was completed this year with submission of the final package of deliverables for the African National Control Laboratories – Reliance Network (ANCL-RN) to the African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD).

A prerequisite for the development of a sustainable system is the local governments' readiness to invest their own resources. We have seen increasing positive signs of government investments in procuring lab equipment, contributing to post-marketing surveillance activities, and absorbing staff training costs. This has provided the platform for sustainability and institutionalization of best practices. An example is in the capacity building PQM+ provides, with the aim of supporting the implementation of recently developed systems and tools. PQM+ monitors the implementation of those tools after training and facilitates future use of the training materials by the institution independently to continue updating their staff skills.

Discrete contributions like strengthening regulatory functions, the development of the ANCL-RN, training programs, and several other interventions you will be reading about in this annual report showcase our effort to support the emergence of sustainable systems in low- and middle-income countries. I hope you enjoy this report, and I sincerely thank my PQM+ colleagues for their passion to strengthen quality assurance systems.

Jude I. Nwokike
Director, Promoting the Quality of Medicines Plus (PQM+)

Executive Summary

Funded by the U.S. Agency for International Development (USAID), the Promoting the Quality of Medicines Plus (PQM+) program provides technical assistance to regulatory authorities (MRAs) and local manufacturers of priority medical products to expand the supply and improve the quality of essential medical products. PQM+ helps expand and ensure access to quality-assured medical products, including those for HIV/AIDS, tuberculosis (TB), malaria, neglected tropical diseases (NTDs), COVID-19, other infectious diseases, reproductive health, and maternal, newborn, and child health (MNCH).

In Program Year 4 (PY4), PQM+ worked with 25 countries[1] and with three regional portfolios[2] to sustainably strengthen medical product quality assurance (QA) systems.[3] The program implemented almost 50 work plans, including:

- 23 Mission buy-ins,[4]
- Three core-funded activities supporting the USAID Bureau for Global Health's Office of Infectious Disease for NTDs and TB and the Office of Maternal and Child Health and Nutrition;
- Four regional buy-ins from USAID's Africa, Asia, Latin America and Caribbean (LAC) bureaus, and East Africa regions;
- One "cross-bureau" funding stream supporting the Office of Health Systems;
- Six funded by the U.S. Government's Initiative for Global Vaccine Access (Global VAX);
- Six other COVID-19 buy-ins;
- One buy-in funded by USAID's COVID-19 test-to-treat initiative to promote access to safe and effective oral COVID-19 therapeutics in low- and middle-income countries (LMICs).

This annual report summarizes activities conducted during PY4 (October 1, 2022, to September 30, 2023) with an emphasis on developments in Quarter 4 (July 1 to September 30, 2023). As the program matures, PQM+'s activities continue to prioritize building sustainability, strengthening medical product QA systems, and furthering the Office of Health Systems' goals of promoting quality, equity, and resource optimization. This report delineates activities by objective and funding source (USAID country Missions and USAID/Washington). All activities align with at least one of PQM+'s five program objectives, as detailed in the Results Framework (Figure 1).

[1] Bangladesh, Benin, Burkina Faso, Burma, DRC, Ethiopia, Ghana, Guinea, Kazakhstan, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Nigeria, Pakistan, Panama, Rwanda, Senegal, South Africa, Tajikistan, Uzbekistan

[2] Africa, Asia, and East Africa.

[3] A few countries are implementing more than one work plan, such as a Global VAX country work plan.

[4] The 24 countries include the list of buy-ins in footnote 1 minus South Africa, which is a Global VAX buy-in and Panama, which is funded regionally. Note that numerous countries have multiple buy-ins. Most of these (I.e., Ethiopia, Mozambique, Nigeria, Rwanda, Senegal, Uzbekistan) include buy-ins related to COVID-19. Several countries (Mozambique, Kenya) have multiple buy-ins funded by non-COVID health areas.

Figure 1. PQM+ Results Framework

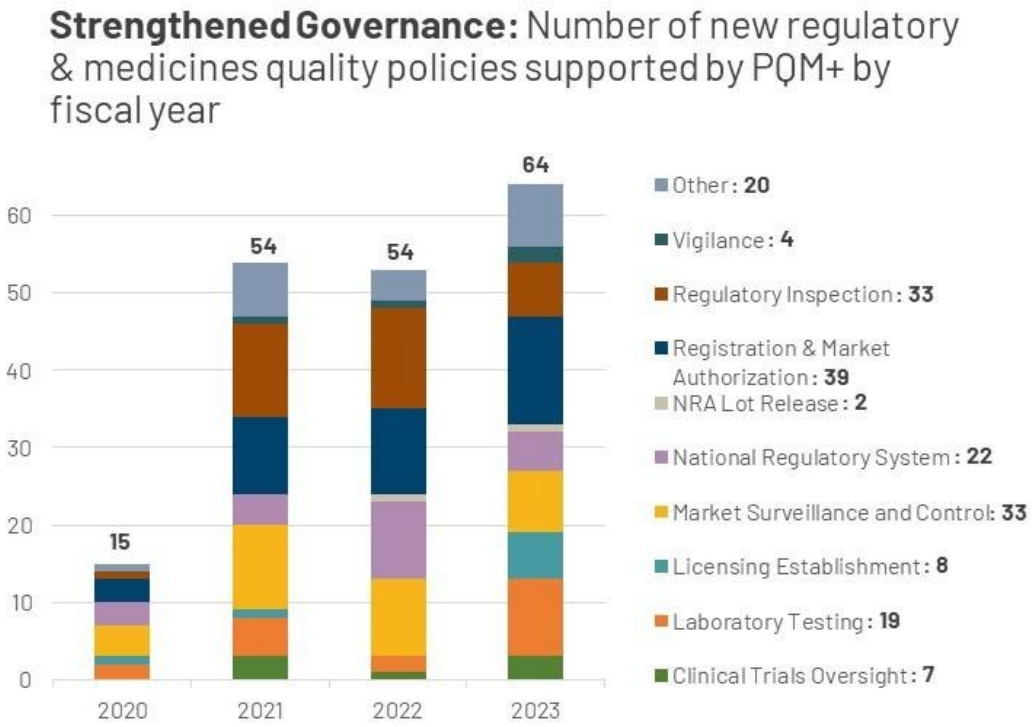
GOAL: SUSTAINABLY STRENGTHEN MEDICAL PRODUCT QUALITY ASSURANCE SYSTEMS IN LMICs				
Objective 1: Governance for medical product quality assurance systems improved	**Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved**	**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

Objective 1: Governance for Medical Product QA Systems Improved

Improving regulatory governance requires the effective and efficient establishment and implementation of QA systems for medical products. PQM+ supports national pharmaceutical QA systems by facilitating the adoption of sound policies and aiding in the development of strategic plans. The program aims to help establish adequate coordination mechanisms that promote sound governance as well as efficiency, accountability, transparency, and alignment of partners. Through the support of PQM+, the program's beneficiaries become more effective in ensuring the quality and safety of medical products, increasing public trust, and freeing up valuable resources that can expand health service coverage to their populations.

PQM+ provides broad support to strengthen key regulatory functions, including market authorization, market control, and regulatory inspect and laboratories. To date, the program has supported 64 policies to strengthen medical product quality assurance system governance (see Figure 2).

Figure 2. Regulatory Policies



Over the past four years, PQM+ has made significant contributions to the development and revision of regulatory policies in Africa and Asia that strengthen medicines quality and health systems globally.

Guidelines and Strategic Plans. During the fourth quarter of PY4, PQM+ supported the development of 19 regulatory guidelines and policies, bringing to a total of 64 developed in PY4, and 187 in the life of the program. These guidelines played a crucial role in establishing sustainable QA systems. For example, PQM+ reviewed **Nepal's** Guidelines on Safe Disposal of Unwanted Pharmaceuticals in response to a WHO Global Benchmarking Tool (GBT) assessment highlighting the need for these guidelines. The review identified gaps relating to regulatory authority requirements, and PQM+ is collaborating with Nepal's Department of Drug Administration (DDA) to address the gaps (e.g., manufacturing waste management and procedures to manage the return of unwanted product to manufacturers). In addition, PQM+ started supporting the DDA in creating the Nepal Pharmaceutical Manufacturing Strategy, which establishes a 10-year roadmap to develop the local pharmaceutical industry to meet national needs and support the export of essential medicines. PQM+ will continue to provide technical support for this strategy in close consultation with stakeholders.

Transparency and accountability are key focus areas within medical regulation. These efforts promoted sound governance, efficiency, accountability, and alignment of partners. Strategic plans developed in countries such as **Bangladesh**, **Malawi**, and **Mali** empowered public organizations to ensure timely access to quality-assured essential medical products and protection from substandard and falsified (SF) products, advancing quality and equity.

Localization. This year, PQM+ began implementation of a new project in support of the "Diversifying the Asia Pharmaceutical Supply Chain (DAPSC)" initiative. PQM+ completed an analysis of two countries—**Uzbekistan** and **Kazakhstan**—as centers for the two-year project to

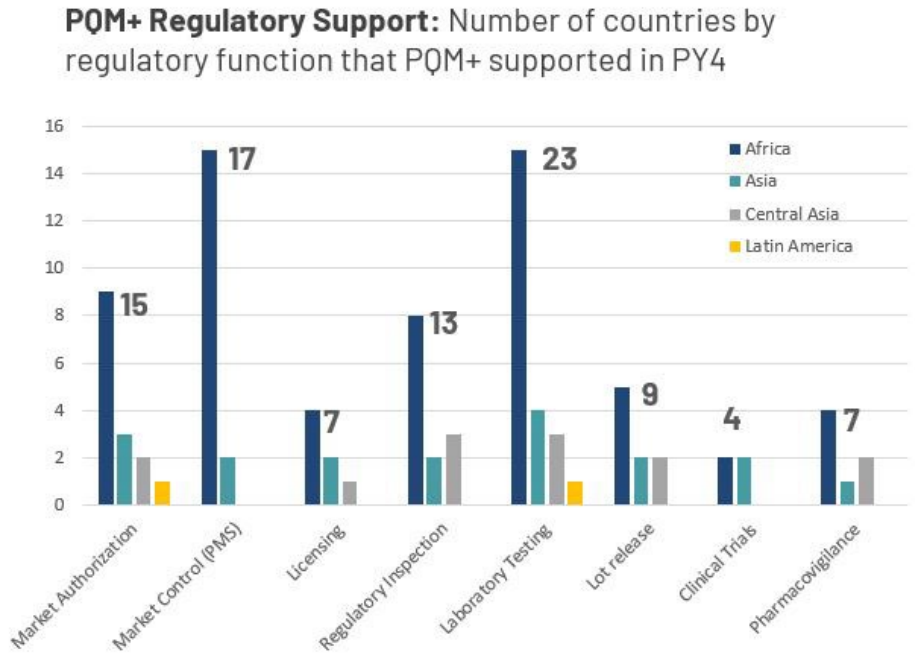
strengthen local capacities in competitive manufacturing, procurement, regulatory systems, technology development and investment, and workforce development. Additionally, this effort will help improve business readiness and the commercial viability of the local pharmaceutical industry to attract investment. One goal of this endeavor is to develop or strengthen the local production of key starting materials (KSMs) and active pharmaceutical ingredients (APIs) to reduce the occurrence of supply chain disruptions, minimize overdependence on one supplying country, and support diversification of the supply chain.

Bangladesh. During the fourth quarter, PQM+ and the Directorate General of Drug Administration (DGDA) committee updated and finalized the regulatory framework document and aligned the document with the new Drugs and Cosmetics Act 2023 (passed September 2023). The regulatory framework document will assist DGDA in mapping all activities within the existing/upcoming required legal and regulatory systems. This regulatory framework document will ensure the necessary oversight of DGDA's regulatory functions and promote good governance. In addition, PQM+ supported DGDA to finalize and disseminate the five-year strategic plan (2023 – 2028) for the National Drug Control Laboratory (NDCL). The strategic plan focuses on: 1) adequately resourcing the NDCL; 2) modernizing lab operations; and 3) expanding lab offerings. This plan will enable NDCL to sustain achievements in operational capabilities and compliance with international standards. PQM+ continues to support DGDA toward achieving World Health Organization (WHO) Maturity Level 3 through implementation of an effective quality management system (QMS) and institutional development plan (IDP).

Objective 2: Strengthening Regulatory Systems

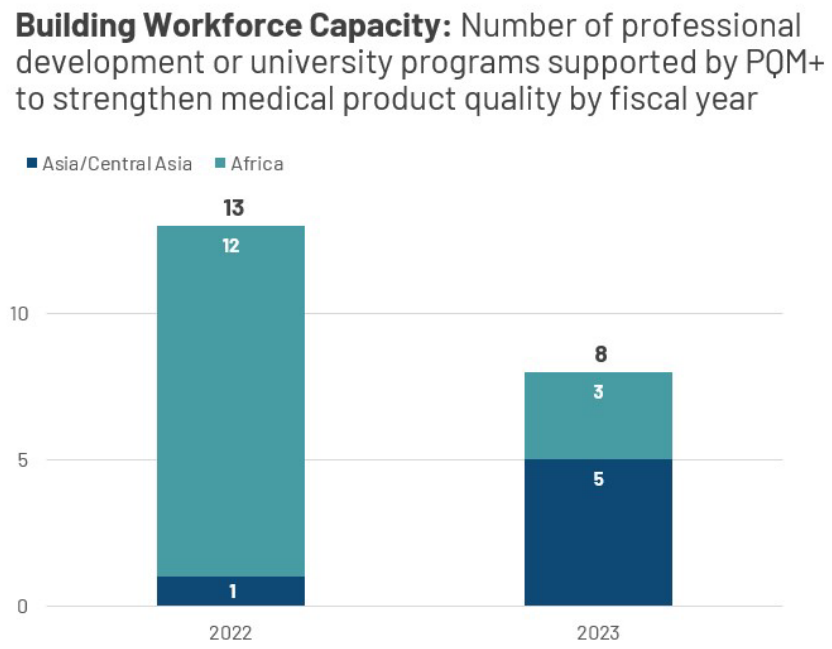
A strong regulatory system facilitates access to safe, effective, and quality-assured medical products and protects public health by preventing the production, supply, and distribution of SF medical products. SF medical products can cause serious health problems, waste scarce resources, and undermine trust in a health system. Figure 3 shows the number of countries and specific regulatory functions that PQM+ supported during PY4.

Figure 3. PQM+ Regulatory Support During PY4



PQM+ is also helping build capacity of the regulatory, laboratory, and manufacturing workforce. The program is helping local organizations (e.g., universities, associations) develop training programs that will be sustainable sources of workforce capacity strengthening (see Figure 4).

Figure 4. Counterpart Training Programs



PQM+ provides support in various areas of regulatory system strengthening (RSS). Highlights include the following activities.

GBT. WHO shared a list of countries that will undergo GBT evaluation this year and invited PQM+ to observe the self- or formal benchmarking of specific countries. PQM+ chose to observe the GBT process for **South Africa** and **Ghana**. By participating in these benchmarking exercises, PQM+ staff gains firsthand insights into any potential deficiencies. This information equips PQM+ to provide technical assistance to recipients addressing corrective and preventive actions (CAPAs), facilitating progress toward their targeted maturity level (ML). During PY4, PQM+ supported two regional portfolios and 17 countries in RSS activities linked to GBT sub-indicators.

Test-to-Treat. The USAID test-to-treat programming focuses on 10 priority countries: **Bangladesh, Botswana, Cote D'Ivoire, El Salvador, Ghana, Lesotho, Malawi, Mozambique, Rwanda,** and **Senegal**. In support of this program, this quarter, PQM+ published a new Test-to-Treat Resource: Scientific and Technical Information on COVID-19 Therapeutics. This 3,000-page package contains public review documents, committee meeting materials, and other technical resources to assist MRAs in LMICs in to make informed regulatory decisions on market authorization of the COVID-19 antivirals nirmatrelvir (co-packaged with ritonavir) and molnupiravir. Additional MRAs may also use the Test-to-Treat resource as needed. The information is also useful for manufacturers/applicants, procurement agencies, donor communities, and health care providers.

Regional Harmonization. In support of the African Medicines Regulatory Harmonization (AMRH) Initiative, PQM+ completed a concept note and terms of reference (TOR) to harmonize requirements for bioavailability and bioequivalence (BA/BE) studies to support approvals of

generic products by the technical working group (TWG). The Evaluation of Medicinal Products Technical Committee (EMP-TC) leadership formally adopted the TOR in August 2023, which was subsequently disseminated to partners and stakeholders to advocate for additional funding and support of activities.

During Q3, PQM+ supported a five-day induction training for 25 newly recruited Pharmacy and Poisons Board (PPB) regulatory staff members. Partnership among PQM+, the Government of **Kenya**, the Bill and Melinda Gates Foundation, Management Sciences for Health, Chemonics, and the World Bank made hiring, equipment, and training efforts possible. The recruits have been deployed in their respective functions and are working on backlogged regulatory tasks (e.g., dossier assessments, GMP inspections, post-marketing surveillance, development of licensing guidelines and SOPs). In addition, PQM+ continued working with the Pharmaceutical Society of Kenya to validate a QA and regulation course that will be linked to the previously developed PPB self-directed learning platform known as Ustadi.

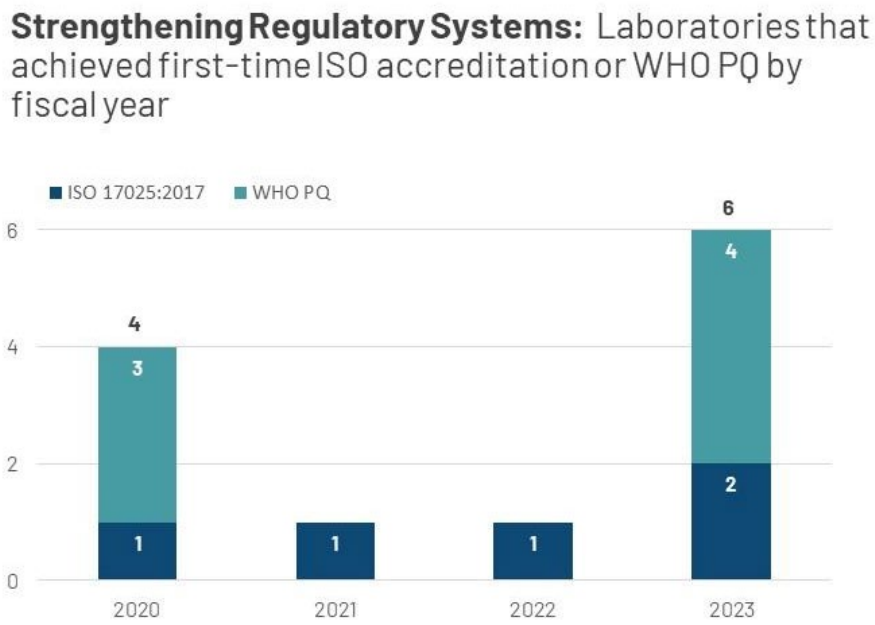
Bangladesh. During the fourth quarter, PQM+ supported DGDA in formulating a draft regulatory framework guidance document, draft registration guidelines, and a draft standard operating procedure (SOP) for registration of medical devices. Additionally, PQM+ supported DGDA to develop training materials and the yearly training plan for medical devices. These initiatives will empower DGDA to implement effective regulations to ensure high standards of quality, safety, and efficacy. PQM+ is also supporting DGDA in risk-based post-marketing surveillance (RB-PMS) system development. In July 2023, DGDA inspectors initiated the first round of surveillance, which will help the National Tuberculosis Control Programme (NTP) and DGDA take steps against substandard and falsified TB medicines.

South Africa. In August 2023, executive team delegates from the South African Health Products Regulatory Authority (SAHPRA) visited USP headquarters in Rockville, where PQM+ staff welcomed them. Subject matter experts presented on several topics during the visit, with accompanying robust discussion. The SAHPRA team highlighted PQM+ implementation and areas of potential future collaboration. A tour of the USP laboratory concluded the visit.

Laboratory System Strengthening (LSS)

PQM+ improves medicines regulatory systems through optimizing the capabilities of national quality control laboratories (NQCLs) to consistently provide reliable and accurate medicines quality data to support regulatory decisions. The NQCL's role in confirming and investigating product quality through testing and analysis against regulatory standards is a key component in ensuring quality assured medicines are available to public and private health institutions. Optimization is accomplished through the development and maintenance of laboratory quality management systems, enhancing analyst technical skills and knowledge, ensuring the availability of functional equipment and instrumentation, as well as the availability of needed reagents and consumables. In PY4, the program's laboratory systems strengthening team provided 59 QA and technical skills trainings, contributed to the maintenance of six NQCL accreditations and four WHO prequalifications (PQs), and sponsored four laboratory exchanges (study tours) to assist countries in improving the availability of quality-assured medicines in beneficiary countries. Since 2019, approximately 50 labs worldwide have been supported by PQM+, with lab accreditations, reaccreditations, or WHO PQ achievement. New accreditations since 2020 are shown in Figure 5.

Figure 5. Laboratories Receiving Accreditation/Prequalification with PQM+ Support



African Laboratory Network. PQM+ executed the Vaccine Regulatory Reliance Laboratory Network consultancy for the AMRH program. The consultancy resulted in the development of a proposed continental reliance framework to establish and manage an African national quality control laboratory network to support vaccine production on the continent. In Q4, PQM+ finalized the proposed reliance network framework, validated its key components in South Africa with the African Union's New Partnership for Africa's Development (AUDA-NEPAD) and AMRH stakeholders, incorporated the feedback that it received, and submitted a final package of documents. These documents include an editable Excel sheet for the five-year costed strategy to operationalize the framework, the use of which will conserve resources by avoiding duplication, increasing efficiency, and distributing or sharing responsibilities.

Panama. In support of the Instituto Especializado de Analisis (IEA), Panama's NQCL, PQM+ initiated the revision of the laboratory's QMS manual, which is the guiding document that defines the laboratory's quality system and provides the framework for its design and implementation. PQM+ conducted a training on good laboratory practices for pharmaceutical quality control laboratories and general requirements for certification of the competence of testing and calibration laboratories (ISO 17025:2017). PQM+ also conducted 10 QMS training sessions to assist the development of 10 SOPs, five of which IEA prioritized to receive PQM+ support for finalization. By prioritizing these documents, the laboratory is ensuring that they have a solid foundation for their quality control process.

Burma. In PY4, PQM+ conducted a series of in-person trainings to enhance the technical capabilities of several laboratories and improve the quality control processes for medicines production. The first, held in collaboration with the Malaria Unit from the WHO Country Office, focused on high-performance liquid chromatography (HPLC), dissolution, and potentiometric titration at the Department of Food and Drug Administration (DFDA) Pharmaceutical Chemistry Laboratory. A QMS workshop further enhanced staff technical skills. At the Burma Manufacturer

1[5] QC laboratory, the second training focused on analytical method validation and verification and laboratory safety. Additionally, PQM+ provided technical assistance to this manufacturer to achieve ISO 17025:2017 reaccreditation. The laboratory currently holds accreditation in 10 scopes of testing by the ANSI National Accreditation Board. At Burma Manufacturer 2, PQM+ organized two in-person training sessions that covered topics such as data integrity, analytical method validation, analytical workflow for ultraviolet-visible (UV-Vis) spectrophotometer, pH, FTIR, and dissolution. These sessions strengthened both the QMS and the technical expertise of analysts as they prepare for ISO 17025:2017 accreditation.

Strategic Plans for NQCLs. In PY4, PQM+ supported the Laboratoire Nationale de Santé (LNS) in **Mali** and the National Drug Control Laboratory (NDCL) in **Bangladesh** to develop and finalize strategic plans. In August, LNS held a resource mobilization workshop, and PQM+ provided technical assistance to LNS in the developing a resource mobilization plan to support the implementation of laboratory's strategic plan. The NDCL plan launch was delayed to accommodate the new drug law, which expands the mandate to include cosmetics.

Objective 3: Optimizing Financial Resources

Democratic Republic of Congo. PQM+ prioritized the optimization and increase of financial resources for medical product QA. Initiatives included formulating draft regulatory framework guidance documents and resource mobilization plans. To build on the Q3 training on the use of a new tool to cost the testing services in the **Democratic Republic of Congo** (DRC), PQM+ worked with the *Direction de Contrôle Qualité* (DCQ, the quality control department) to draft an SOP for the use of the tool to cost its testing services. This tool will help the lab to generate sufficient funding from testing medicines to sustain its QMS.

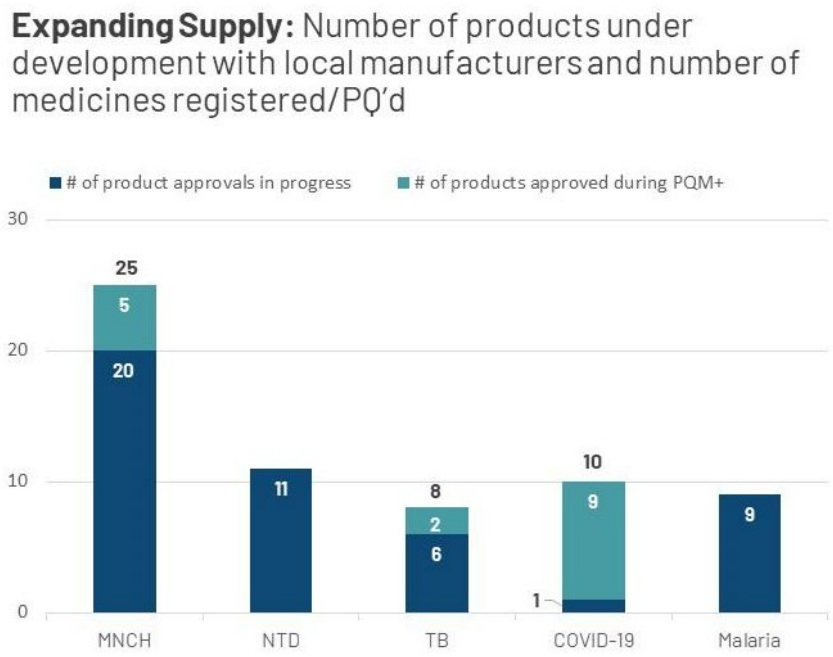
Nepal. After approval by **Nepal's** Ministry of Health and Population (MoHP) to develop the National Medicines Laboratory's (NML's) five-year optimization strategy, NML formed committees to oversee and approve the strategy document and provide direction in the strategy development process. PQM+ facilitated three working committee meetings to develop the strategy, receive feedback, and review the draft.

Objective 4: Expanding the Supply of Quality Assured Essential Medical Products

Chemistry, Manufacturing, and Control (CMC) involves the development, production, and quality control of medicines, vaccines, and medical devices that meet current good manufacturing practices (GMP) and international quality standards. The CMC process plays a crucial role in ensuring that these products are safe, effective, and of consistent quality. CMC processes are important because they help ensure that medical products are of consistent quality and meet required regulatory standards. PQM+ has supported manufacturers throughout the approval process to produce vital medicines and medical products locally (see Figure 6).

[5] For public reporting, PQM+ uses aliases for manufacturers to protect the confidentiality of their data and this program's work with them.

Figure 6. Approval Status of Key Health Products Supported by PQM+



The PQM+ CMC team's work during PY4 focused on technical assistance to 37 pharmaceutical manufacturers in 12 countries (**Bangladesh**, **Burkina Faso**, **Burma**, **Ethiopia**, **Ghana**, **India**, **Kenya**, **Nepal**, **Nigeria**, **Pakistan**, **South Africa**, and **Uzbekistan**) working on 47 product applications for medications, vaccines, and medical devices.

WHO PQ represents an initial stride toward self-reliance, as it signifies a manufacturer's capability to develop a product that adheres to globally acknowledged quality standards and secures market authorization. This achievement can reduce a manufacturer's dependence on external technical assistance. With PQM+ support, Swiss Pharma **Nigeria** (SWIPHA) achieved WHO PQ in May for zinc sulfate DT, a medicine to treat diarrhea in children. SWIPHA Nigeria is the first WHO-prequalified manufacturer in West Africa. On July 12, zinc sulfate DT and syrup from PharmEvo in **Pakistan** achieved WHO PQ, thanks in part to cost- and time-saving technical discussions between PQM+ and WHO.

Global VAX. Earlier this year, PQM+ held a workshop in **South Africa**, in collaboration with AUDA-NEPAD, SAHPRA, Afrigen Biologics and Vaccines, and the WHO-supported COVID mRNA Technology Transfer Hub. The hybrid workshop, aimed at developing the vaccine manufacturing competency of stakeholders including regulators, academia, and private industry and providing a forum for advocacy. PQM+ supported the in-person participation of attendees from **Ghana, Kenya, Nigeria, Senegal,** and **South Africa**, as well as virtual participation from **Rwanda**.

Core TB. After three years of PQM+ collaboration with the Medicines for All Institute (M4All) of Virginia Commonwealth University (VCU) to develop a more efficient manufacturing process for rifapentine API, an important medicine for treatment of latent TB infection and TB, USAID is planning the transfer of this technology to a pharmaceutical manufacturer in Africa. USAID announced this significant milestone recently (https://www.usaid.gov/global-health/health-areas/tuberculosis/global-accelerator-end-tb-plus). This initiative will signify the first step toward Africa achieving self-reliance in API manufacturing and adopting advanced, efficient manufacturing technology to achieve this goal.

Nepal. In seeking WHO PQ for medicines such as azithromycin and zinc sulfate, PQM+ played a pivotal role in guiding three private manufacturers in tasks such as product development, bioequivalence studies, mock audits, and dossier submissions. This included follow-up on CAPAs and assistance in product development. Through the involvement of PQM+, these manufacturers obtained innovator samples of Zithromax by Pfizer to support their WHO PQ endeavors. As a result of PQM+ engagement, these manufacturers made substantial investments in facility upgrades, sourcing APIs from WHO-qualified suppliers, and acquiring essential equipment to ensure compliance with product development and stability study requirements. PQM+ successfully inked roadmap agreements with these manufacturers to facilitate the WHO PQ process. Additionally, PQM+ dispatched a regional expert to Nepal, where 126 technical personnel received training in advanced GMP.

Local Production Strategy Guidance. PQM+ finished a final draft of a Guidance for Developing a Strategy for Local Production of Essential Medical Products and provided one round of revisions in PY4. This document will play a central role in local manufacturing projects in **Kazakhstan**, **Nepal**, **Nigeria**, **the Philippines**, and **Uzbekistan** in PY5.

During PY4, PQM+ conducted a landscape analysis of 17 LMICs across Asia to assess their readiness to expand the local production of priority essential health products (e.g., injectable antimicrobials, multidrug resistance products, and noncommunicable disease products such as insulin and biosimilar cancer drugs). The analysis aimed to understand the market size and demand, share of local production vs. imports, local industry's capability and maturity to expand production, and various other policy and regulatory dimensions. Based on findings from the analysis, the team identified five priority countries (**Indonesia, Kazakhstan, the Philippines, Uzbekistan,** and **Vietnam**) based on high unmet need and high potential for expanding local pharmaceutical manufacturing. In discussion with USAID's Asia Bureau, PQM+ selected the Philippines for an in-depth study to help identify contextual challenges and develop tailored recommendations for growing the domestic pharmaceutical industry of the Philippines.

Objective 5: Advancing the Global Medical Product Quality Assurance Agenda

Learning, Thought Leadership, and Awareness

During PY4, PQM+ continued to develop evidence around medical product quality assurance topics by providing technical contributions to help shape international guidelines from WHO, ICH, and other standards-setting organizations, advancing the development and use of new tools and approaches, providing thought leadership, and raising awareness of the importance of medical products quality assurance.

Thought Leadership/Contributions to International Guidelines, and Global Collaboration. Examples of PQM+'s participation in global discussions and knowledge sharing related to medicines quality in PY4 include:

- Providing technical input for the creation of working groups that will develop technical and operational documents to strengthen South-East Asia Regulatory Network (SEARN) member states' regulatory capacity.
- Continuing to contribute to global MNCH initiatives around medical product quality, including by providing input to a strategic refresh of the Reproductive Health Supply Coalition and collaborating with other USAID partners (the Medicines, Technologies, and

Pharmaceutical Services [MTaPS] program and the Global Health Supply Chain – Procurement and Supply Management program) on efforts to ensure the quality of medical devices.

Research and Analysis. This year, PQM+ made important progress with numerous activities to increase the evidence base related to medical product quality assurance, including:

- Supported two Pakistani clinical research organizations in developing their first bioequivalence study protocols, including reviewing the protocols prior to their submission for regulatory approval.
- Prepared a technical report on demand generation for quality-assured medical products that highlights the evidence gap in this space.
- Collected data for the USAID Office of Health Systems High Performing Healthcare System survey in Kenya and Mozambique.
- Supported a situational analysis on anti-microbial resistance (AMR) in four Department of Livestock Services laboratories in Bangladesh and helped develop a final report on "AMR in Veterinary Public Health Laboratories: Situational Analysis on Strengthening the Lab Infrastructure and Capability."
- Collected data, analyzed findings, and drafted reports on regulation and supply of MNCH medical devices and of tranexamic acid.

New Approaches, Tools, and Resources. Achievements in developing and adapting tools and approaches to improve medical product quality this year included:

- Developing a model local production strategy, which will assist countries and regions with the goal of strengthening sustainable local production to improve access to safe, effective, quality-assured, and affordable medical products by providing key stages and steps that form the "how" of the strategy guide.
- Finalizing a product information report (PIR) on gentamicin and job aids to support registration and inspection of gentamicin.
- Launching the global NTD Medicines Information Dashboard (MID). Using the dashboard, MRAs can efficiently identify sources of quality-assured NTD medicines to leverage reliance relationships and WHO prequalification avenues to facilitate registration; procurement agents can identify potential suppliers and current prices; and manufacturers can identify market gaps, competitors, and sources of quality APIs.
- Developing and releasing a guidance document for MRAs on granting emergency use authorization (EUA) for therapeutics and, specific to COVID-19, a technical information package on COVID-19 therapeutics.
- With South African Global VAX funding, developing a regional competency framework with a focus on vaccines and biologics that details regulatory job functions to support continental workforce development activities.
- Helping the DGDA and the Ministry of Fisheries and Livestock in Bangladesh complete the Bangladesh National Veterinary Formulary.
- Developing a web-based interface to share regulatory information among DRAP and provincial quality control laboratories for post-marketing surveillance in Pakistan.

- Helping introduce use of the electronic Common Technical Document (eCTD) for dossiers in Ghana, including preparing Ghanian vaccine manufacturers to select an electronic regulatory submission software system and training manufacturers and Ghana FDA on eCTD requirements and processes.

Advocacy and Awareness: PQM+ posted the call-to-action paper "Expanding access to quality medicines for babies [and] children" on the PQM+ website and disseminated the paper via social media posts on Twitter and LinkedIn. Other efforts include the following:

- Helped ACOREP in DRC develop a concept note and presentation to be used to sensitize its stakeholders about laboratory costs and the need to increase laboratory funding.
- Supported Bangladesh DGDA in completing a rapid assessment of SF anti-TB medicines in the private sector and in disseminating findings to stakeholders. As a result of this effort to raise awareness of problems, the DGDA and NTP agreed to conduct an assessment of market regulation of anti-TB medicines.
- Also in Bangladesh, PQM+ helped DGDA organize several seminars on the National Quality Assurance Guidelines for Medical Products and RB-PMS in several divisions. These seminars promoted awareness of medical product quality among healthcare professionals, policymakers, administrators, law enforcement agencies, local government officials, and academics.
- In several countries, PQM+ helped raise awareness of medical product quality topics among the public. In Nepal, PQM+ supported the DDA in airing public service messages on SF medicines through national radio stations and on Koshi Province radio stations. In Ethiopia, PQM+ worked to increase community awareness of the safety of COVID-19 vaccines to increase their comfort with getting vaccines. A message on vaccine safety was broadcast for 10 days, reaching an estimated 2 million people.
- Working with FDA Ghana, PQM+ helped develop and disseminate advocacy tools including flyers, posters, banners, branded pens, and audio-visual advertisements on the importance of spontaneous reporting of adverse events following immunization (AEFIs). These were disseminated on buses and at schools, lorry stations, markets, roadsides, pharmacies, and public intercity transportation, as well as through community radio interviews, online news portals, and social media platforms. FDA Ghana estimates these messages on medicine safety reached about 120,000 people in eight priority regions.
- At a global level, PQM+ joined with MTaPS and GHSC-PSM in disseminating the Call-to-Action paper via two webinars for USAID missions, USAID/W, and members of the Child Health Task Force. This paper advocates a series of actions to improve uptake of amoxicillin and gentamicin for children and newborns.

Cross-Bureau Activities and Progress

PQM+'s Cross-Bureau activities focus primarily on thought leadership and innovative and new approaches, which can then be piloted, adapted, or scaled to fit the country context. This buy-in especially aims to advance the global medical product quality assurance operational agenda and learning, with specific attention to developing or applying evidence-based approaches and tools; conducting research and analysis to support medical product quality assurance systems strengthening; and supporting advocacy on the importance of medical product quality assurance for public health.

Highlights of Progress During Program Year 4

- As part of its assistance to AMRH in conducting the Vaccine Regulatory Reliance Laboratory Network consultancy, PQM+ developed a proposed reliance network framework identifying 10 coordination mechanisms across strategic, scientific, and operational elements. PQM+ presented the strategic vision for the reliance network at the AMQF/AMRH Vaccines Subcommittee meetings in Rwanda in May and developed and compiled a package of deliverables for submission to stakeholders in early October. The proposed reliance network will conserve resources by avoiding duplication, increasing efficiency, and distributing or sharing responsibilities, and ultimately help build national control laboratory (NCL) capacity to meet Africa's emerging vaccine manufacturing ambitions.
- PQM+ and technical resource partner, University of Washington, developed a guidance document for MRAs on EUA to expedite marketing authorization decisions and fast-track approval processes for emergency therapeutics. PQM+ oriented 19 of its program country offices in Africa and Asia to the activity and disseminated a survey to collect information on countries' emergency regulatory processes and procedures for approving medicines and non-vaccine biological products.
- Utilizing USAID's HPHC tool which assesses health system performance, PQM+ worked with respective missions and MOH representatives in Kenya and Mozambique to disseminate a survey, collect, and upload data. Data collection and analysis is complete in Kenya and PQM+ is planning a dissemination meeting to share the results with Kenya country stakeholders. In Mozambique, PQM+ has disseminated the survey and is following up with respondents to encourage additional responses. PQM+ anticipates finalizing data collection and sharing the results in Q1, PY5. Both countries will participate in a broader USAID webinar to disseminate findings in early PY5.

Office of Health Systems (OHS)

These activities, funded by OHS, fall under program objectives 2, 4, and 5.

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

AMR module of PSS101 Course. PQM+ provided storyboard review and feedback to MTaPS to develop the new antimicrobial resistance (AMR) Module 11 of the Pharmaceutical Systems Strengthening 101 (PSS101) course. PQM+ delivered a training on Module 9: Medical Product Quality Assurance of the PSS101 in June. Following story board finalization, PQM+ reviewed the Alpha version review of the new antimicrobial resistance (AMR) Module 11 of the Pharmaceutical Systems Strengthening 101 (PSS101) course. The Beta version can be found at the link in the footnote below.[6]. The regulatory section is embedded under "International Approaches to Containing AMR" in the course labeled "Strong Regulatory Systems and AMR."

[6] https://360.articulate.com/review/content/08119775-4dbb-436d-a923-39b2e3d73d87/review

The version of the course at the link below is now with USAID's Global Health eLearning Center (GHeL), undergoing an accessibility review.

EUA guidance document for MRAs. To facilitate rapid access to safe, effective, and quality medical products, PQM+ and technical resource partner, University of Washington, developed a guidance document and one-page overview for MRAs on EUA to expedite marketing authorization decisions and fast-track approval processes for emergency therapeutics, including drugs and non-vaccine biological products.[7] PQM+ shared both documents with WHO for review and will incorporate feedback into a final draft to disseminate broadly via two webinars, one for Africa and one for Asia. PQM+ will continue to partner with the University of Washington to deliver these webinars.

Key achievements include:

- Drafted the EUA Guidance Document and one-page overview for therapeutics (drugs and non-vaccine biological products).

African Lab Network. PQM+ collaborated with AUDA-NEPAD's AMRH program to conduct the Vaccine Regulatory Reliance Laboratory Network consultancy. In previous quarters, PQM+ assessed the capacity of NQCLs in conducting quality control testing for biological products as part of the continental lot release lab network and began drafting the framework with its various components: strategic, scientific, and operational. In Q4, PQM+ finalized development of the proposed reliance network framework, validated its key components in South Africa with AUDA-NEPAD and AMRH stakeholders, incorporated feedback, and submitted a final package of documents that include an editable Excel spreadsheet for the five-year costed strategy to operationalize the framework. The framework seeks to conserve resources by avoiding duplication, increasing efficiency, and distributing or sharing responsibilities.

Key accomplishments include:

- Finalized and delivered to AUDA-NEPAD the package of 10 deliverables comprising the ANCL-RN consultancy.

Increase technical capacity of national MRAs in the Intergovernmental Authority on Development (IGAD) region and/or other regional economic communities. PQM+ worked with MTaPS to develop a roadmap for adoption of digital standards of minimum common standards to support the digitalization of a regulatory information management system (RIMS). PQM+ reviewed and provided comments on multiple rounds of development. PQM+ technical assistance includes data standards identified in the minimum common standards that support interoperable regulatory information-sharing on the key functions that digitalized systems are designed for, e.g., the Zanzibar system for registration of products at the continental level and the OpenRIMS for registration, market control, licensing, and inspection.

Specifically, PQM+ will complement the efforts of MTaPS in meeting the objectives of the information management systems technical committee (IMS TC) for the AMA and support

[7] PQM+ has published two additional EUA guidance documents for diagnostics and vaccines: 1) Promoting the Quality of Medicines Plus (PQM+) 2021. A proposed model to build capacity for emergency use authorization for diagnostics: Guidance for national regulatory authorities. Submitted to the U.S. Agency for International Development by the PQM+ Program. Rockville, MD: U.S. Pharmacopeial Convention. 2) Promoting the Quality of Medicines Plus (PQM+) 2021. A proposed model to build capacity for emergency use authorization for vaccines: Guidance for national regulatory authorities. Submitted to the U.S. Agency for International Development by the PQM+ Program. Rockville, MD: U.S. Pharmacopeial Convention.

preparation for adopting relevant data standards that have not been incorporated in the existing digitalized systems. In particular, this includes modules 2 and 3 of the common technical document (CTD); Identification of Medicinal Products (IDMP)'s five ISOs (substance identification, ISO 11238; pharmaceutical dose forms, units of presentation, routes of administration and packaging, ISO 11239; units of measurement, ISO 11240; regulated pharmaceutical product information, ISO 11616; and regulated medicinal product information, ISO 11615); and structured product labeling (SPL). PQM+ has participated in MTaPS-organized meetings to develop the roadmap and will participate in a call with the IMS TC to socialize the roadmap and discuss the importance and benefits of adopting key priority data standards of specified minimum common standards.

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

Following several rounds of review and discussions with external stakeholders, PQM+ incorporated feedback into a revised draft of the Guidance for Developing a Strategy for Local Production of Essential Medicines and will continue to discuss options for including tools that may be helpful to countries as they use the guidance. Concurrently, the PQM+ strategy team will continue working on local manufacturing strategies in the field (e.g., in Uzbekistan, Nepal, Nigeria, Philippines, etc.); the model can then be enhanced for future iterations with findings from this work. This guidance is intended for countries and regions to use when developing strategies for local production of essential medical products, including how to decide whether to invest in expanding local production.

Following the discussion with USAID, PQM+ plans to share the final document with WHO at the World Local Production Forum in November.

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

Social and Behavior Change Communication (SBCC). PQM+ submitted a draft paper on demand generation for quality-assured medical products and will improve the graphics and visuals in the final version. The paper identifies stakeholders at each level of the quality management system (QMS), but focuses on community-level actors to formalize their role in identifying and reporting substandard and falsified medicines. The paper identifies interventions as well as evidence gaps for further study.

High-performing health care system tool. PQM+ expanded and finalized organization lists for national and subnational levels across the public, private, and nongovernmental organization (NGO) sectors in both Kenya and Mozambique to ensure the lists were representative. PQM+ oriented the Ministry of Health (MOH) points of contact (POCs) to the activity, shared the introduction and information letters with MOH POCs for signatories, and administered the survey in both countries. PQM+ collected responses in Kenya and will share the results in two meetings with stakeholders in mid- and late-October: the first with the MOH and the second with a broader participant list that includes national responding organizations. In Mozambique, PQM+ is continuing to follow up with survey respondents to elicit a higher response rate and will follow the same sequence of activity steps as Kenya. Finally, PQM+ will work with the respective country MOH POCs to share both country experiences and results in a webinar.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Incorporate USAID and WHO comments into the final EUA Guidance Document and one-page overview and conduct two dissemination webinars (one for Africa and one for Asia). PQM+ will translate the documents from English to French and disseminate both versions on PQM+ and Core partner websites, Listservs, social media, and partner forums.
- Share the final Model Local Production Guidance at the World Local Production Forum in November and disseminate in PQM+ supported countries.
- Finish collecting responses to the High-Performing Health Care (HPHC) tool for Mozambique and hold half-day stakeholder meetings for each country to present the findings. PQM+ will develop a summary report to document the process of applying the tool and the key findings and recommendations from the HPHC assessment in each country, as well as participate in an HPHC webinar to share findings from each country.

Africa Bureau to Support the African Medicines Agency (AMA)

With funding from USAID's Africa Bureau, PQM+ is supporting the establishment of AMA as a continental regulatory agency to help develop the pharmaceutical sector in Africa. This funding complements USAID's OHS investments for PY4 to support the AMA.

Progress by PQM+ Objective

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

Bioavailability (BA)/bioequivalence (BE) subcommittee. A priority area for AMRH is harmonizing requirements for registering generic[8] products, as they are the most efficient way to increase access to quality-assured, safe, and efficacious medicines. Generic medicines rely on establishing BE with the originator product to support the safety and efficacy of the generic product. PQM+ developed a concept note for a BA/BE subcommittee under the Evaluation of Medicinal Products technical committee (EMP-TC), discussed it at an EMP-TC meeting, obtained concurrence, and drafted a BA/BE TWG terms of reference that the EMP-TC validated and accepted.

API database. API regulation, including coordination of joint inspection of API manufacturing sites, is one of the AMA's critical functions once operational. In the first phase of this work, PQM+ collaborated with the Bill and Melinda Gates Foundation and the IMS-TC on the design and development of an API database. PQM+ reviewed and provided technical comments on a use case, user requirements, and costing options report. In preparation for the next phase, PQM+ will progress the user specifications, design work, and develop the API database.

Medicines Risk-based Surveillance (MedRS) tool training workshop. Support to Africa's Intergovernmental Authority on Development (IGAD) on regional RB-PMS paused pending approval of the PQM+ East Africa Community (EAC) work plan, with the intent to leverage the

[8] A generic product, as defined by the WHO, is a pharmaceutical equivalent or pharmaceutical alternative product that may or may not be therapeutically equivalent to a comparator product. Products that are therapeutically equivalent are interchangeable.

MedRS tool training workshop activity also planned in that project's work plan. PQM+ plans to piggyback on the EAC-planned and -funded MedRS training and, via the Africa Bureau, sponsor IGAD MRAs and Secretariat members to participate in this workshop. PQM+ will provide training on the MedRS tool utilizing MUHAS as a core flex partner (per the East Africa work plan). An expected outcome of the workshop is the development of a harmonized sampling and testing protocol and implementation plan that can be used by interested IGAD for a future PMS activity. PQM+ will support facilitation of the workshop, participation of IGAD, and a French interpreter for Djibouti. PQM+ will continue to work with colleagues in Kenya to plan and conduct the workshop, now planned for late Q1 or early Q2 of PY5.

RB-PMS testing. PQM+ recruited and onboarded a consultant to work on a report of IGAD's second round of RB-PMS and help coordinate IGAD NMRA participation in the MedRS training workshop. This activity has been on pause pending approval of the EAC work plan and is anticipated to begin in mid-Q1 of PY5.

Priority Activities for PY5, Q1

Next quarter, the Africa Bureau plans to:

- Complete the MedRS workshop for participants from the IGAD REC.
- Report on the second round of RB-PMS.
- Continue support to the EMP-TC to support the BE TWG.
- Support Phase II of the API Database.

Activities and Progress by Country and Regional Buy-Ins

Africa Region

Benin

PQM+ works with the Beninese Agency for Medicines and Other Health Products, *Agence Béninoise du Médicament et des Autres Produits de Santé* (ABMed, formerly *l'Agence Béninoise de Régulation Pharmaceutique*, or ABRP) and the National Agency for the Quality Control of Health Products and Water, *l'Agence Nationale de Contrôle de la Qualité des Produits de Santé et de l'Eau* (ANCQ), to improve the country's medicines regulatory systems and assure the quality of medical products in circulation within the country.

ABMed is responsible for the registration, authorization, and quality control of medicines, medical devices, and other health products. ABMed develops and implements national pharmaceutical policies and regulations, approves licenses, inspects pharmaceutical establishments, and controls the advertisement and promotion of medicines, including herbal and traditional medicines. ANCQ collects and tests medicines at points of entry into the country (land, sea, and air) or at the request of any national institution.

PQM+ is helping ANCQ strengthen its QMS to achieve international recognition (ISO/IEC 17025). Obtaining this accreditation improves the availability of quality-assured medicines by ensuring reliable test results are generated and communicated to the regulatory authority and combating substandard and falsified medicines.

Highlights of Progress During Program Year 4

- Supported dissemination for the first RB-PMS results for antimalarials in Benin and coached the PMS-TWG to implement the second RB-PMS of antimalarials. For the second RB-PMS survey the PMS-TWG, under supervision of PQM+, wrote their protocol, trained their samplers, collected their samples, and started testing them independently.
- 133 technical personnel trained on regulatory, QA and QC topics.
- Made notable progress in implementing the roadmap toward ISO/IEC 17025 accreditation of ANCQ:
  - Built capacity of technical personnel on QA and QC topics.
  - Stepwise Assessment Tool Towards Accreditation (SATTA) score improved by 11% to 61%.
- Strengthened the inspectorate regulatory function as well as import control, including support on developing SOPs and checklists and the procurement of three handheld Raman spectrometers.
- Capacitated inspectorate to conduct inspections with a risk-based approach using the risk-based inspection (RBI) tool.
- Strengthened systems for pharmaceutical waste destruction.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

Collaborative framework. PQM+ supported ABMed and ANCQ to convene a workshop to review the draft collaborative framework[9] that PQM+ proposed, subsequently validating this framework. The framework has now been submitted for adoption by the boards of both agencies. This framework outlines how both parties will collaborate in the discharge of their responsibilities in the medicines registration, marketing authorization, and market control and surveillance regulatory functions.

Waste management. PQM+ supported ABMed to revise and update its waste management procedures and guidelines. These guidelines and procedures will ensure ABRP oversees the destruction of pharmaceutical waste in the country in timely and environmentally safe manner, applying best international practices. Working with ABRP to revise these documents will also help the agency to advance the following WHO GBT sub-indicator, MC04.08: Documented and implemented procedures exist to ensure safe storage and disposal of detected SF medical products.

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

ISO/IEC 17025 accreditation. As part of the implementation of its roadmap toward ISO/IEC 17025 accreditation, PQM+ trained eight analysts (six men, two women) from ANCQ on a quality control test to ensure that medicines do not contain unsafe levels of impurities.

In September, PQM+ conducted a midterm assessment to measure improvement in the QMS of ANCQ following PQM+ intervention, as well as to identify unaddressed gaps. The assessment, conducted using the SATTA, revealed an improvement from 11 percent to 61 percent.

Technical assistance to ANM to expand ISO/IEC 17025 accreditation scope. To enable ANCQ access to metrology services with a wider scope—a key requirement for ISO/IEC 17025 accreditation—PQM+ sought to provide technical assistance to Benin's standards authority (ANM – *Agence Nationale de Métrologie*) to expand its scope and prepare for accreditation. Therefore, following training on measurement uncertainty, internal auditing, and internal quality checks provided to ANM in Q3 by PQM+, ANM revised procedures for these processes that have now been adopted.

Regulatory inspections capacity building. To continue its support to improve the capacity of ABMed's inspectorate, PQM+ assisted the agency to review and revise several inspection checklists and its SOP for regulatory inspections. To facilitate the deployment of the screening devices, PQM+ trained inspectors from ABMed and some analysts from ANCQ on operating the Raman screening devices it procured, which ABMed received in July.

[9] The objectives of the framework are: Coordinate the roles of the two agencies related to applications for marketing authorizations, approval of other health products, and market surveillance and control, as well as for any operation intended to ensure the quality of medicines and other health products; Fix the commitments and responsibilities of each partner; Ensure harmony and synergy in the interventions of both agencies to ensure the quality of drugs and other health products marketed in Benin, and Strengthen the fight against the illicit market and substandard and falsified medicines and other health products in Benin.

Priority Activities in PY5, Q1

Next quarter, PQM+ plans to:

- Supervise the testing of antimalarials for the second round of RB-PMS (2023).
- Provide training to ABMed on using the importation control screening devices to pilot the process PQM+ proposed.
- Support ABMed to host the training module developed for good storage and distribution practices (GSDP) on the Ministry of Health's online platform.

Burkina Faso

A 2018 decree created the national pharmaceutical regulatory authority, *L'Agence Nationale de Régulation Pharmaceutique* (ANRP), to strengthen the regulatory framework of Burkina Faso's pharmaceutical sector. The Directorate of Market Surveillance and Quality Control of Health Products at ANRP is the technical body in charge of quality assurance and quality control. ANRP collaborated with the Directorate for the Control of Drugs and Non-food Products (DCM/PNA) within *l'Agence Nationale pour la Sécurité Sanitaire de l'Environnement, de l'Alimentation, du Travail et des Produits de Santé* (ANSSEAT), formerly the *Laboratoire National de Santé Publique* (LNSP), to conduct medical products sampling. In 2021, PQM+ supported LNSP and ANRP to establish an official collaborative framework.

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

Highlights of Progress During Program Year 4

- Supported ANSSEAT to convene a resource mobilization workshop to sensitize stakeholders and other partners on the need for funds to operationalize its new strategic plan. ANSSEAT designed four projects, for which it has directly solicited funds from partners and the government.
- 78 technical personnel trained on regulatory, GMP, QA and QC topics.
- Made notable progress in the implementation of the roadmap toward ISO/IEC 17025 accreditation of LNSP.
  - Built capacity of technical personnel on QA and QC topics.
  - SATTA score improved by 11% to (from 76% to 85%).
  - Successfully completed ILT/PT for HPLC and dissolution techniques.
- Supported the qualification of analytical equipment linked to proposed ISO/IEC accreditation scope techniques, a key requirement of the standard for which ANSSEAT did not have the resources.
- Completed a GMP and ISO 9001 baseline assessment for Manufacturer #1 and worked with them to develop a roadmap toward local production of antimalarials (short-term) and WHO pre-qualification (long-term) as well as for ISO 9001 certification.
- Built the capacity of the manufacturer's staff on good manufacturing practices (GMP), good laboratory practices (GLP), good distribution practices (GDP), equipment preventive maintenance, and analytical method validation.
- Supported two manufacturer staff on a study visit to two local antimalaria medicines manufacturers in Ghana.

Progress in Quarter 4

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

DCM/PNA Implementation of ISO/IEC accreditation roadmap. Through Q4, PQM+ supported DCM/PNS to qualify and calibrate its devices in preparation for accreditation. PQM+ conducted an end-term evaluation to measure the improvement in the QMS of DCM/PNA following PQM+ intervention and to identify gaps that are still not addressed. The end-term evaluation, conducted with the SATTA, revealed progress from 76 percent to 85 percent, indicating the lab's readiness for an accreditation assessment. PQM+ then guided DCM/PNA to formally express interest for the assessment to *Le Système Ouest Africain d'Accréditation* (SOAC, the West African Accreditation System), while PQM+ works with DCM/PNA to close the remaining gaps identified during the evaluation.

RB-PMS samples. In August, PQM+ worked with ANRP to disseminate the results of its 2022 RB-PMS results at a workshop in Ouagadougou. Of the 283 samples (artesunate injection, artemether injection, quinine injection, and sulfadoxine/pyrimethamine tablets) tested from six regions, four which are border regions —Boucle du Mouhoun, Cascades, Centre, Centre-Nord, Hauts-Bassins, and Nord—281 (99 percent) met quality specifications. While this may not fully reflect the situation of the other regions in Burkina Faso, it is an indicator of good quality antimalarial medicines in circulation. Thirty-three participants across Burkina Faso's health sector attended the workshop to discuss the results.

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

Technical assistance to Manufacturer #1 on manufacturing antimalarials. This is a new manufacturing company that started operating in 2022 and prior to PQM+ technical assistance that started in Q2 of PY4, it had not received any capacity building support. Therefore, as part of the implementation of its GMP roadmap co-created with PQM+, PQM+ trained technical staff of Manufacturer #1 on equipment preventive maintenance, which provided nine designated lab staff (six men, three women) with guidance on maintenance of lab equipment, prioritized by equipment level of use and the WHO prequalification being sought. This is the first effort to build the manufacturer's capacity on equipment preventive maintenance. Through this training, PQM+ also supported and assisted the designated lab staff to be able to optimally carry out basic maintenance of key laboratory equipment; and be able to perform replacement of routine parts. During this training, PQM+ observed that the company's analytical equipment were mostly out-moded and recommended that the management procure more modern and durable analytical equipment.

After the training, Manufacturer #1 staff were able to apply the skills gained from the training to draft protocols to internally conduct basic preventive maintenance of their analytical equipment. Through the life of the program, PQM+ will monitor the application of these protocols, when finalized, to ensure they are being utilized for routine preventive maintenance of the company's lab equipment and continue to encourage management to invest in newer analytical equipment to minimize equipment downtime and enhance reliability of its test data.

As part of the roadmap, to ensure Manufacturer #1's proficiency in testing the products it manufactures (paracetamol) and plans to manufacture (artemether/lumefantrine tablets), PQM+ provided practical training on the application and validation of the analytical methods for these

products, adhering to international best practices within their laboratory environment. PQM+ also trained eight analysts (six men, two women) on how to validate analytical methods.

In August, PQM+ facilitated a visit by two company QA/QC staff members to visit two local antimalaria manufacturers in Ghana (Entrance Pharmaceuticals and Amponsah Efah Ltd.) where they learned from the manufacturers' technical staff about key areas such as production, quality control, and quality assurance. This will help prepare the company to manufacture antimalarials in 2024.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Supervise the sampling and testing of 2023 RB-PMS of antimalarials and antibiotics.

Democratic Republic of Congo (DRC)

The widespread availability and distribution of non-quality-assured artemisinin combination therapies and non-artemisinin therapies[10] 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).

Highlights of Progress During Program Year 4

- Supervised ACOREP's PMS-TWG in the implementation of the third 2023 RB-PMS for antimalarials, as they:
  - Developed their 2023 RB-PMS protocol.
  - Trained samplers and collected samples from six provinces.
- 175 technical personnel trained on regulatory, QA and QC topics.
- Made progress in implementing the roadmap toward ISO/IEC 17025 accreditation of DCQ, including:
  - Built capacity of technical personnel on QA and QC topics.
  - Successfully implemented analytical method verification (AMV) for four products.
  - Successfully implemented measurement uncertainty for four analytical techniques.
- Completed an ISO 9001 baseline assessment for ACOREP, helped develop a roadmap toward ISO 9001 certification, and sensitized staff on the requirements of the standard.
- Trained ACOREP on using a costing model to revise its testing fees structure to improve the lab's sustainability. Developed an SOP for using the costing model, a concept note, and advocacy slides.

[10] ACTwatch Group., Mpanya, G., Tshefu, A. et al. The malaria testing and treatment market in Kinshasa, Democratic Republic of the Congo, 2013. Malar J 16, 94 (2017). https://doi.org/10.1186/s12936-016-1659-x.

Progress in Quarter 4

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

RB-PMS. In Q4, PQM+ supervised ACOREP's PMS-TWG as it completed the sampling of 272 antimalarials[11] for its 2023 RB-PMS exercise from six provinces: Goma (Nord-Kivu), Mbandaka (Equateur), Kalemie (Tanganyika), Kikwit (Kwilu), Tshikapa (Kasaï), and Matadi (Kongo Central). This is a decrease from the nine sample collection provinces in 2022 due to the high travel costs of sampling in DRC.

The confirmatory testing of the 2022 RB-PMS samples is ongoing at DCQ and is delayed due to unstable power supply.

ISO/IEC 17025 accreditation. PQM+ supervised ACOREP's DCQ to complete the implementation of its AMV plan for 2023. The DCQ verified the compendial methods for three antimalarials (artemether/lumefantrine tablets, artesunate injection, sulfadoxine-pyrimethamine tablets) and one antibiotic. PQM+ also guided DCQ's QA team and lab analysts to implement measurement uncertainty for four analytical techniques that are part of their accreditation scope: loss on drying (LOD), pH, dissolution, and UV-visible spectrophotometry. The implementation was completed in Q4.

ISO 9001 certification. To start implementation of the ISO 9001 roadmap for ACOREP that was developed in Q3, PQM+ worked with ACOREP to create three QMS documents: a quality policy, quality objectives, and the scope for its new QMS.

Objective 3: Increase financial resources for medical product QA optimization

To build on the training PQM+ conducted in Q3 for 16 ACOREP staff on the use of a new tool to cost its testing services, PQM+ worked with DCQ to draft an SOP on the tool, which will help the lab generate sufficient funding from testing medicines to sustain its QMS. Further, to help ACOREP advocate for a revision in the QC testing fees, PQM+ helped the agency develop a concept note and PowerPoint presentation to use when sensitizing stakeholders.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Supervise the screening and testing of the 2023 RB-PMS samples.

East African Community

EAC and IGAD are regional economic communities (RECs) established to improve their citizens' health, economic, and social prosperity. The EAC, headquartered in Arusha, Tanzania, aims to enhance political, economic, and social cooperation among its partner states, which include Burundi, DRC, Kenya, Rwanda, South Sudan,[12] Uganda, and Tanzania. Building on

[11] Artemether injection, artesunate injection, quinine injection, sulfadoxine/pyrimethamine tablets, dihydroartemisinin/piperaquine tablets, artesunate/amodiaquine tablets, artemether/lumefantrine tablets, and quinine tablets.

[12] USAID currently has funding restrictions to Sudan and South Sudan that could preclude PQM+ from implementing this work in those two countries.

previous EAC and IGAD achievements, PQM+ will continue to strengthen systems to assure the quality of medical products in the regions by improving the general governance structures and regulatory systems for product QA.

Progress by PQM+ Objective

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

To ensure sustainability of the technical assistance to the EAC region, PQM+ is working with Muhimbili University of Health and Allied Sciences (MUHAS) a partner in the PQM+ program, to build its technical capacity to be able to support the region on PMS activities. This work will orient MUHAS on PQM+ tools and resources and facilitate the university's capacity development with the goal of MUHAS eventually being able to provide related technical assistance. PQM+ undertook a baseline assessment and comparative analysis of MUHAS current tools, technical approaches, and technical capacity for RB-PMS for regional support. The assessment will ensure alignment with PQM+ tools and processes, as well as establish baseline indicators of MUHAS's applicable technical competency. This data will enable tracking MUHAS's progressive proficiency in relevant areas.

Based on that assessment, PQM+ conducted an intensive five-day training of trainers (TOT) of the MUHAS and Tanzania Medicines and Medical Devices Authority (TMDA) technical staff on RB-PMS and the online MedRS tool.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Support the EAC PMS EWG to develop an EAC PMS strategy and PMS guidelines.
- Train members of the MRAs and NQCLs from EAC member states on RB-PMS and the MedRS tool.
- Support the EAC to finalize and disseminate the PMS report on medicines circulating in the EAC region.
- Support the development of digital systems and establishment of a central regional repository of data on the quality of medicines.

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 not mandated to EFDA fall under the jurisdiction of regional government and city administration regulatory bodies. However, the lack of clarity in the mandates of 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 in Ethiopia.

PQM+ works with EFDA and the regional regulatory bodies to build capacity to monitor medical product quality across the supply chain and to strengthen their collaborative working relationship. PQM+ also helps build local manufacturers' capacity to meet international

standards, thereby ensuring that locally produced medical products are of good quality and not harmful to end users.

Highlights of Progress During Program Year 4

- Assisted EFDA in preparing for WHO's ML3 for all regulatory functions except lot release. The official WHO assessment was conducted in PY3 and PQM+ provided technical support to EFDA in developing and implementing the IDP based on feedback collected from WHO's assessment.
- Supported EFDA laboratory in maintaining ISO 17025 accreditation for the 11 physicochemical and five condom testing methods and expansion of the scope of accreditation to glove testing, resulting in the glove testing laboratory being accredited for four key test parameters. Assisted the Diredawa branch toward ISO 17025 accreditation.
- Helped EFDA maintain ISO 17020:2012 accreditation for its medicine inspection function through technical support to addressing the corrective and preventive actions plan based on an external surveillance assessment by the Ethiopian Accreditation Service (EAS).
- Collaborated with Ethiopian Pharmaceutical Association (EPA) to develop and accredit a continuing professional development (CPD) course on detection, reporting, and communication of SF medical products.
- Helped train 350+ health professionals at immunization facilities on cold chain equipment calibration/verification and supported calibration of 300+ pieces of cold chain equipment at immunization facilities.
- Supported the AEFI reporting system in Ethiopia through training to data collectors at the federal and regional levels. Built the technical capacity of the national product safety advisory committee through training on causality assessment techniques, and supported causality assessment of more than 44 SAEs .Technical support from PQM+ has helped Ethiopia achieve Africa's third-highest AEFI case reporting rate, up from lowest on the continent.
- Supported the EPHI calibration laboratory toward ISO 17025 accreditation by conducting a gap assessment, developing a roadmap, and providing training on four identified technical areas.
- Supported implementation of RB-PMS sampling and dissemination of findings to stakeholders.
- Aided the national Expanded Programme on Immunization to draft a national immunization policy and no-fault compensation guidelines.
- Supported the regulatory harmonization annual meeting between EFAD and regional regulatory authorities and EFAD in creating awareness on the new EFDA regulation to selected members of the Parliament.
- Supported the quality assurance of local Giemsa stain manufacturers through a gap assessment, development of a roadmap, and training of staff on GMP and related topics.

Progress by PQM+ Objective

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

Regulation of medical products is central to any functioning health system and plays a critical role in improving public health. Effective regulation of medical products promotes and protects public health by ensuring medicines quality, safety, and efficacy; promoting adequate manufacture, storage, and distribution of medicines; and strengthening the fight against SF products. Regulatory authorities are responsible for monitoring the quality of medical products circulating in the market through the application of various regulatory procedures, including market authorization and PMS.

Activity 2.1 Support EFDA in addressing WHO's GBT assessment findings and prepare it for WHO ML3. This quarter, PQM+ provided supported the following activities related to WHO's ML:

- Supported preparation of a corrective and preventive actions (CAPA) plan and development and implementation of an institutional development plan (IDP), per the recommendation for WHO ML3.
- Provided training on creating awareness on guidelines for advertising and promoting medicines for medical representatives and company representatives.
- Trained the medicines licensing and registration department on available directives, guidelines, and SOPs to assist with preparing for WHO ML3.
- Developed risk-based inspection guidelines for medicines, medical devices, and food at ports of entry for the Central Branch office.
- Participated in the revision of guidelines on reliance and recognition to use as evidence for WHO ML3.
- Assisted EFDA with an awareness creation workshop for PMS findings and assisted with a ceremony for the glove testing laboratory's ISO 17025:2017 accreditation.
- Revised the current EFDA good manufacturing practices guideline (third version).
- Assisted with developing SOPs on GMP Task Force Report Review, a recommendation from WHO GBT assessors.
- Provided technical assistance to EFDA to prepare a project proposal to attain ML3, establish a lot vaccine release system to strengthen local manufacturing, and operationalize the Center for Excellence.
- Assisted with the minimum standard development workshop for higher- and medium-level pharmacies in Adama.
- Provided technical support, including with developing a CAPA plan, for identified gaps during WHO's official benchmarking audit of EFDA.
    - Following approval of the CAPA plan, supported EFDA staff to work on addressing nonconformances. At a workshop in Adama, 25 participants (11 women, 14 men) developed and revised SOPs, work processes, and guidelines related to regulatory functions.
- Delivered a training on developing communication processes and procedures related to clinical trials for six EFDA clinical trials team members (two women, four men). WHO recommended revision of the clinical trial communication SOPs following its EFDA audit. Trainees discussed identification of clinical trial stakeholders and appropriate ways to communicate with internal and external stakeholders related to clinical trials. Following the training, the team prepared a comprehensive SOP on the subject.

In addition to these activities, PQM+ supported EFDA's medicine facility inspection function to maintain ISO 17020 accreditation by supporting an external surveillance assessment of the regulatory function by the EAS. PQM+ also supported the annual conference of the Joint Steering Committee of Regulatory Authorities in Ethiopia.

Activity 2.2 Build capacity of branch EFDA laboratories toward ISO/IEC 17025:2017 accreditation and for the main lab to maintain its accreditation. In 2011, the PQM+ predecessor program, PQM, supported EFDA's main laboratory in becoming accredited for seven test methods, and the scope of accreditation gradually expanded to 20 methods. In PY4, PQM+ planned to support EFDA's medical device laboratory and expand its scope of accreditation. One area of support was the quality assurance of gloves, an especially challenging area since COVID-19.

EFDA has five branch laboratories strategically positioned based on the risk level for the infiltration of SF products in the country. These laboratories are closer to the end users, and their role is to assess the quality of medical products circulating in their catchment areas. They are also actively involved in the PMS programs. Their geographical locations make them ideal to the fight the circulation of SF products, thereby protecting public safety. Currently, none of these laboratories has ISO/IEC 17025:2017 accreditation or WHO prequalification, meaning they may generate questionable test results that may not withstand legal scrutiny. During PY4, PQM+ supported implementation of the branch-specific roadmap toward ISO/IEC 17025:2017 accreditation along with EFDA's central lab experts.

In Q4, PQM+:

- Provided a second round of technical assistance in the form of follow-up supervision to EFDA's Diredawa Branch Lab to enable its ISO/IEC 17025:2017 accreditation.
- Reviewed five EFDA Main Lab SOPs to address deficiencies observed during the WHO GBT audit.
- Supported dissemination of the glove testing laboratory accreditation to relevant stakeholders in the presence of Ethiopian Minister of Health Dr. Lia Tadese.

Table 1. Status of Lab Accreditation in Ethiopia

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	PT	Official Inspection/ Pre-assessment
DMQCD (EFDA)	ISO 17025:2017 (Testing)	Ongoing	Completed	Ongoing	Performed	Planned for PY5
Medical Device Testing Lab (EFDA)	ISO 17025:2017 (glove testing)	Completed	Completed	NA	Performed	Accredited

Activity 2.3: Support EFDA to conduct a national RB-PMS of selected malaria and MNCH medicines.

In Q4, PQM+ supported dissemination of PMS results to stakeholders. One main achievement noted during the dissemination was that EFDA detected SF gloves after accreditation of its glove testing laboratory, and about 42.6 percent of gloves collected during RB-PMS were found to be substandard; EFDA took measures to protect the public health through recalls of poor-quality products. This is a huge impact of the laboratory's accreditation.

Reported malaria cases so far in 2023 have increased by 150 percent over the same period in 2021 and 120 percent over this period in 2022, pointing to a strong need to conduct targeted PMS of antimalarial medicines. Based on this need from EFDA, PQM+ helped develop a protocol for RB-PMS of antimalarial medicines; product collection took place in Q4. Sample collection occurred in targeted areas, so the results will not be nationally representative. EFDA has taken on the majority of RB-PMS activities, including testing and collection of samples, and training of sample collectors. The agency also revised its regulations so manufacturers and importers will contribute to the costs of surveillance.

Left: Health Minister Lia Tadese (center, in white) attends the glove lab accreditation ceremony and PMS results dissemination. Right: Health Minister Tadese recognizes PQM+ for its support to EFDA.

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

Ethiopia considers building capacity for local pharmaceutical production to be a critical strategy to ensure timely access to quality-assured essential medicines at an affordable price. In the past 15 years, the Growth and Transformation Plan II, the National Strategy and Plan of Action for the Development of Pharmaceutical Manufacturing in Ethiopia, and various other government policies and strategies underwent redesigns to promote local production of pharmaceuticals. Despite the remarkable efforts and commitment from the government in creating an enabling policy environment for developing local pharmaceutical production, little progress has resulted in terms of actual capacity to cover national needs for essential medicines from local sources. Moreover, available evidence indicates that existing local manufacturers are facing formidable challenges to continue their operations and remain in business, let alone invest in quality improvements and capacity expansions.

Activity 4.2: Build capacity of selected local pharmaceutical industries for achieving WHO PQ and local GMP certification. In Ethiopia, few Giemsa stain manufacturers supply their products to the public procurement agency. In PY4, PQM+ planned to identify those manufacturers, conduct a rapid gas assessment, and provide relevant technical support for some of the identified once so that they will be able to manufacture quality assured stains to be used for testing of malaria.

In Q4, PQM+:

- Provided technical assistance on developing a roadmap for establishing bioequivalence centers in Ethiopia, initiated by MOH/Arman Hanson Research Institute (AHRI).
- Provided a five-day training for local Giemsa stain manufacturers on good manufacturing practices in collaboration with the malaria elimination program of the MOH and AHRI.
- Follow-up and technical assistance on the implementation of CAPA proposed for local Giemsa manufacturers.
- Supported local pharmaceutical manufacturing organizations toward WHO PQ.
- Evaluated and recommended local Giemsa manufacturers that can attain the expected level of EFDA GMP requirements to supply quality-assured Giemsa stain for the Ethiopian Pharmaceutical Supply Service.

Local Giemsa stain manufacturers took part in GMP training.

Challenges: Ethiopia's security situation has been deteriorating because of the current conflict and may continue to affect progress toward some activities that require travel. PQM+ will endeavor to address issues through virtual communication and continuous engagement with relevant government counterparts.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Administer the accredited CPD course on SF medicines to health professionals throughout the supply chain system.
- Conduct the second-round national assessment of the cold chain system against GDSP regulatory requirements.
- Finalize testing of the RB-PMS samples.

Ghana

The Food and Drugs Authority of Ghana (FDA Ghana) is the national body responsible for the regulation of food, drugs, clinical trial protocols, and other products. FDA Ghana 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 Chemical Substances. FDA Ghana is ISO 9001-certified and, in 2020, attained WHO ML3 status. Its Center for Laboratory Services and Research (CLSR) holds ISO/IEC 17025 certification and WHO prequalification. 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 MCH commodities such as oxytocin.

Implementation of PY4 activities for PQM+ Ghana paused for most of April and May as PQM+ waited for its PY4 funds to be obligated. The funds were obligated in late May 2023.

Highlights of Progress During Program Year 4

- Supported FDA Ghana to complete testing for its second RB-PMS of antimalarials and MCH products. Out of 75 MCH samples collected from 7 regions in Ghana (prioritized by the PMS-TWG by a risk assessment using the MedRS tool), 22 failed to meet quality specification. Out of the 67 antimalaria samples collected, 3 failed to meet their quality specifications. These results are not nationally representative.
- 139 technical personnel trained on regulatory and GMP topics. This includes participants from 10 manufacturers on five key topics (method validation, impurities testing, comparative dissolution studies, stability studies, and eCTD dossier compilation).
- Provided support to FDA Ghana's PMS-TWG to start the implementation of the third RB-PMS on:
  - Developing the 2023 RB-PMS protocol (under PQM+ supervision),
  - Procuring Minilab™ and laboratory reagents for testing, and
  - Supervising training of samplers conducted by select members of the PMS-TWG.
- Supported FDA Ghana to finalize its guidelines of pharmaceutical traceability.
- Finalized the report and disseminated the results of a study to gather information and understand the storage conditions, use, and management of selected MCH commodities in four regions in the north of Ghana known as the zone of influence (ZOI).
- Supported one manufacturer for local production of amoxicillin dispersible tablets and iron and folic acid tablets up to stability studies.

Progress by PQM+ Objective

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

RB-PMS. PQM+ supervised the confirmatory testing of antimalarial and MCH samples collected from samples from seven regions (Central, Ashanti, Greater Accra, Volta Region, Upper West, Upper East, and Western Region) in Ghana, which was completed in August 2023. Seventy-five (75) MCH samples were collected (oxytocin injection, misoprostol tablets, and ergometrine injections). Forty-three (43) of these samples were oxytocin injection and 22 of these samples failed to meet quality specifications. Of the 67 antimalarial samples collected (artesunate for injection), three (3) failed to meet quality specifications.

To start implementing the 2023 RB-PMS protocol for antimalaria and MCH medicines, FDA Ghana trained its samplers under the supervision of PQM+. For the second consecutive year, the training was designed, delivered, and reported on by FDA Ghana staff. Thirty-two (32) people [21 men: 9 women] received training at the five-day workshop.

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

In Q4, PQM+ trained local manufacturers on the Common Technical Dossier (CTD) format, which the FDA Ghana requires for regulatory submissions. This format is also required for the WHO prequalification process. PQM+ organized this training in collaboration with the UK-Ghana Partnership for Jobs and Economic Transformation (JET), implemented by Palladium, to ensure

more manufacturers could benefit, and not only those supported by PQM+ Ghana. The 21 participants included 15 men and six women from 10 antimalaria and MCH local manufacturers.

At the end of Q4, PQM+ had supported its antimalaria manufacturers to finalize their stability studies, AMV, and process validation protocols.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Supervise the sampling of antimalaria and MCH products for the 2023 RB-PMS.
- Support the dissemination of the 2022 RB-PMS results.

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 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.

Highlights of Progress During Program Year 4

- Supported DNPM to convene a dossier evaluation workshop and supervised the assessment of 10 CTD dossiers.
- Trained 63 technical personnel on advanced requirements of the ISO/IEC 17025 standard "Quality Risk Management and Uniformity of Dosage Units."
- Supported the dissemination of Guinea's 2021 and 2022 RB-PMS results for antimalarials and MCH products.
- Provided support to DNPM's PMS-TWG to start implementing the third RB-PMS, including support in:
  - Developing the 2023 RB-PMS protocol and
  - Procuring Minilab™ and laboratory reagents for testing.
- Supported LNCQM to develop a three-year plan for capacity building for maintenance, calibration, qualification, and proper use of equipment at LNCQM.
- Completed a mapping of family planning importers in Guinea.
- Completed sampling of 70 FP medicines from six regions.

Progress by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

In Q4, LNCQM finalized its three-year plan, including developing and costing capacity building activities in the roadmap toward ISO/IEC 17025 accreditation related to metrology

(maintenance, calibration, qualification, and proper use of equipment at LNCQM). This plan also includes capacity building of selected staff in these areas.

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

RB-PMS for antimalaria and MCH medicines: In Q4, DNPM disseminated the results of its 2022 risk-based PMS at a workshop in Conakry, attended by 33 medicines quality assurance stakeholders from USAID and its implementing partners, WHO and different agencies within the Ministry of Health. Of the 167 samples (95 antimalaria and 72 MCH) collected and tested from seven regions in Guinea, seven (7) antimalaria samples (quinine and sulfadoxine/pyrimethamine tablets) and 30 MCH samples (dexamethasone, amoxicillin, oxytocin injection, and iodated polyvidone) failed to meet their quality specifications. At the workshop, the following recommendations were noted: take immediate regulatory actions on the failed batches, train wholesalers on GSDP, and update the list of facilities in Guinea.

To prepare for the 2023 RB-PMS, PQM+ supported the PMS-TWG to develop its protocol for antimalaria and MCH medicines.[13] Samples will be collected from all seven geographical axis, covering the entire country .

Family planning RB-PMS. PQM+ completed the sampling of 70 family planning products (medroxyprogesterone acetate 150 mg/ml, ethynylestradiol/levonorgestrel 0.05 mg/0.25 mg, and ethinyestradiol/norethisterone 0.05 mg/1 mg) from six regions in Guinea. PQM+ also contracted an ISO 17025 accredited laboratory to test the samples.

Training for FP wholesalers. PQM+ invited the private wholesalers it mapped to a GSDP training. However, most of the wholesalers did not respond to the invitation, feeling that they have adequate GSDP capacity.

Dossier support: In August, PQM+ supported DNPM's Dossier Evaluation Committee of Experts, which is made of full time DNPM staff and other medicines experts in the country, to convene one dossier evaluation session to review ten market authorization dossiers submitted for registration. The session built on the dossier evaluation training conducted in 2022 by PQM+ and further strengthens the capacities of the members of DNPM's Committee of Experts responsible for the evaluation and approval of pharmaceutical products for human use.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Supervise the training of samplers for the 2023 RB-PMS
- Finalize the OpERA assessment.

[13] The TWG plans to sample the following antimalarials: artemether 80mg/ml injection, artesunate 60mg powder for injection, artemether-lumefantrine 20/120 dispersible, artemether-lumefantrine 108/1080 syrup, quinine injection, quinine sulfate tablets, and sulfadoxine/pyrimethamine tablets, and the following MCH medicines: oxytocin injection, amoxicillin syrup, amoxicillin capsule, magnesium sulfate, dexamethasone injection, paracetamol tablets, polyvidone, gentamycin eye drops, and ampicillin.

Kenya

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

Highlights of Progress During Program Year 4

- Supported NQCL to develop a strategic plan for 2023-2027.
- Worked with the Pharmaceutical Society of Kenya (PSK) to develop a curriculum and content for a competency-based course on pharmaceutical regulation and QA for pharmacists practicing in Kenya
- Worked with PPB to review the guidelines for licensing and inspection of pharmaceutical manufacturing facilities including for vaccine manufacturers.
- Helped PPB and NQCL develop a draft PPB Act amendment toward legal reforms to strengthen Kenya`s pharmaceutical regulatory system. The reforms will strengthen quality assurance of medicines and other health products and address recommendations by WHO on achievement of ML3 status.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

PQM+ is working with the DNMP and PPB to support the monitoring of quality of malaria Rapid Diagnostics Kits (mRDTs) in the country. PQM+ supported a five-day residential workshop of the pharmacovigilance and post marketing surveillance technical working group (PV/PMS TWG), DNMP, the National Malaria Reference Laboratory (NMARL) and representatives of county governments to develop a protocol for the PMS of mRDTs. The DNMP, PPB and NMARL will use the developed protocol to undertake a PMS of the mRDTs.

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

PQM+ helped PPB and NQCL develop a draft PPB Act amendment toward legal reforms to strengthen Kenya`s pharmaceutical regulatory system. The reforms will strengthen quality assurance of medicines and other health products and address recommendations by WHO on achievement of ML3 status. The draft amendment is under review by the MOH before entering the parliamentary process toward enactment. When enacted, the amendment will strengthen the regulation of pharmaceutical products in the country.

PQM+ supported Busia County to review, finalize, and approve 17 QA SOPs. The county-level implementation of QA strategies is part of the broader supply chain strategy of the MOH through the DHPT and DNMP. Once implemented, the procedures will improve the quality management of antimalarial medicines and other health products. The SOPs were developed from national procedures and will be available for adoption by other counties.

PQM+ facilitated a training of select PPB, NQCL, and public health program staff on the updated MedRS tool. This group included new regulatory staff that PQM+ assisted PPB to recruit. The training increased the country's capacity to conduct quality surveillance of antimalarials and other health products and meet the requirements of attaining ML3.

PQM+ started updating the self-paced learning platform (USTADI) with additional technical materials.

The program assisted PPB with a three-day workshop to strengthen the board's capacity to implement its performance management system. Participants were managers and staff with supervisory roles and accountability for staff performance. The team developed an implementation plan to operationalize the system, which will reinforce PPB's human resource optimization and therefore enhanced regulatory oversight of health products.

Priority Activities for PY5, Q1

Next quarter, PQM+ in Kenya plans to:

- Support PPB through the parliamentary process of amending the PPB laws.
- Continue working with DNMP to support the quality assurance of antimalaria products in the country.
- Assist Busia County to plan for dissemination of the QA SOPs.
- Support and track adoption of recommendations from the performance management workshop.

Lesotho

With USAID funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR), PQM+ is helping Lesotho develop appropriate regulations and support good governance. The national medicines system in Lesotho plays a crucial role in protecting and improving public health by ensuring that essential medical products, such as antiretroviral (ARV) medicines, that are available and used in Lesotho are of good quality, are efficacious, and are safe for human use. Currently, the Ministry of Health (MOH) is performing some basic medical product regulatory functions through its Directorate of Pharmacy, but the country is moving toward an independent regulatory authority as recommended by WHO. and the soon to be enacted Lesotho Medicines and Medical Devices Control Authority (LMMDCA) Bill, 2019.

Highlights of Progress During Program Year 4

- PQM+ conducted a gap assessment workshop using the WHO GBT to identify strengths, areas of improvement, and priorities for the national medicines regulatory authority.
- Provided technical support to the Pharmacy Directorate of the Lesotho Ministry of Health to develop necessary guidelines and procedures for good manufacturing, storage, and distribution practices inspections, and harmonized them with WHO and Southern African Development Community (SADC) guidelines and GMP/GSDP requirements.
- Facilitated a technical workshop in Berea with multiple stakeholders from the Lesotho Ministry of Health and other in-country health systems strengthening implementing partners to support the development of guidelines, SOPs, and tools for licensing of pharmaceutical establishments in Lesotho.
- Supported the draft of a "fit for purpose" organizational chart for the Lesotho MRA that will help the Lesotho team plan for resources required to realize the operationalization of the MRA.

Progress in Quarter 4

Objective 1: Improve governance for medical product quality assurance systems

PQM+ continued to support the Pharmacy Directorate of the Lesotho Ministry of Health to strengthen its regulatory functions by developing appropriate regulations and supporting good governance.

Activity 1.1: Strengthen the national regulatory system in Lesotho by supporting the establishment of the national medicines regulatory authority. The Lesotho Medicines and Medical Devices Control Authority (LMMDCA) Bill, 2019 passed in early September, allowing for the establishment of the Lesotho regulatory authority. PQM+ supported the draft of a "fit for purpose" organizational chart for the Lesotho MRA to support the roadmap developed in Q3. This organizational chart will help the Lesotho team to plan for resources required to realize the operationalization of the MRA.

Activity 1.2: Support implementation of the South African Development Community regional regulatory harmonization strategy and protocols. In September, PQM+ conducted a workshop which included the revision of harmonization guidelines for the Lesotho MRA. Lesotho has adopted the SADC guidelines and made small adaptations to ensure alignment with the Lesotho context.

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

PQM+ continued to support the Pharmacy Directorate of the Lesotho Ministry of Health to strengthen its regulatory functions by developing appropriate regulations and supporting good governance.

Activity 2.1: Improve HIV-related and other medical product registration and marketing authorization processes. PQM+ facilitated a technical workshop in Berea (September 18 – 29, 2023) with multiple stakeholders from the Lesotho Ministry of Health and other in-country health systems strengthening implementing partners to support the development of medical product registration and marketing authorization guidelines and SOPs, for a country-specific approach to manage evaluation and registration of pharmaceutical products in Lesotho. The workshop covered various tools and elements, including:

- Development of 13 reference books.
- Adaptation of the SADC labeling guideline for Lesotho.
- Adapting Module 1 of the CTD guideline to suit the Lesotho context.
- Development of a dossier screening checklist.
- Presentation on the importance of marketing authorization.
- Development of a dossier assessment flow chart.
- Development of registration template for Lesotho.
- Adopting the guide for assessors and orienting assessors to the guide.

- Development of SOPs and guidelines for reliance, donations, and exemptions (Section 60 of the Act). Also created a checklist for donations.
- Development of templates for assessing products under full review (new applications, variations, and responses) and reliance.
- Development of SOPs for review of new applications, responses, and variations.

Activity 2.2: Strengthen vigilance, market surveillance and quality control of antiretrovirals and other medicines. PQM+ facilitated a technical workshop in Berea in August with multiple stakeholders from the Lesotho Ministry of Health and other in-country health systems strengthening implementing partners to support development of regulatory market surveillance and control guidelines and SOPs, for a risk-based approach for monitoring the quality and safety of ARVs and other essential medicines in Lesotho.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Support Lesotho's MOH to develop policies, guidelines, and SOPs for recognition and reliance on other NRAs for regulatory functions. This includes the development and finalization of memoranda of understanding for information sharing between MRAs.
- Continue assisting the Directorate of Pharmacy to develop essential regulations, guidelines, and SOPs for prioritized regulatory functions, specifically guidelines for clinical trials.

Liberia

PQM+ is enhancing Liberia's regulatory framework, supporting the Liberia Medicines and Health Products Regulatory Authority (LMHRA) in six of the eight regulatory functions outlined by the WHO GBT. PQM+ also supports the Liberia School of Pharmacy and Global Pharmaceuticals Manufacturing Limited.

Highlights of Progress During Program Year 4

- In PY4, the LMHRA Board approved regulations to standardize national practices for subcontracting testing services, registration of medical devices, identification of medical items, and quarantine of flawed pharmaceutical products. The addition of these four new regulations brings the total number of regulations operationalized with PQM+ support to 11. The new regulations aid in bridging gaps identified by the LMHRA WHO GBT assessment and facilitate the implementation of the Liberia Drug Act of 2010, which grants LMHRA the responsibility and authority to take action to ensure that safe and quality-assured medicines reach the Liberian people.
- Additionally, PQM+ helped the LMHRA to complete two rounds of PMS and release the findings. The overall sample failure rates for the first and second rounds were 16% and 11%, respectively.
- Although these PMS results were not nationally representative, they offered convincing information that enabled LMHRA to withdraw almost $56,000 worth of SF and unlicensed antimalarial and MCH drugs from circulation. The medicines removed from circulation were mainly the malaria drugs artemether lumefantrine and artemether injections and the MCH drug oxytocin.
- Global Pharmaceutical Manufacturing and Laboratories Limited acquired its license to manufacture medicines in Monrovia with assistance and support from PQM+. In May, the company began commercial manufacturing of artemether-lumefantrine to treat malaria and oral rehydration salts and metronidazole 400mg, priority essential medicines for MCH. Global Pharmaceuticals Ltd. is the first and only pharmaceutical manufacturer in Liberia.

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

Assuring the quality of medical products in circulation within a country requires the regulatory authority to have readily available, accurate information to inform its decisions. In July 2023, PQM+ coordinated with LMHRA to validate the results of a feasibility assessment on the use of the Integrated Regulatory Information Management System (IRIMS). This activity contributed to the fulfillment of strategic plan goal six to develop/review and implement an effective information management system for its regulatory functions. The use of an integrated electronic information management system by the LMHRA contributes to improved decision-making and efficiency through centralization of relevant information and data related to its functional areas.

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

PQM+ supported the University of Liberia's School of Pharmacy to complete development of course material for one of five modules of the medical product short course curriculum. In 2022, PQM+ supported the School of Pharmacy to create a curriculum for QA of medical products. In Q4, the curriculum was validated at a meeting attended by the School of Pharmacy, Ministry of Education, Ministry of Health, and the LMHRA.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Conduct stakeholder mapping activities in coordination with the LMHRA to identify institutions and people who could influence the amendment of the LMHRA Act.
- Facilitate one stakeholder engagement meeting for LMHRA.
- Train QC analysts in testing selected analytical techniques and pharmaceutical products by the standard method.
- Draft additional two regulations for LMHRA.

Madagascar

PQM+ collaborates with the Medicines Agency of Madagascar (AMM, *Agence du Médicament de Madagascar*) to strengthen its capacity to regulate, evaluate, and control medicines' quality in the country. AMM performs its medicines regulatory functions through four technical departments: pharmaceutical inspection, registration, pharmacovigilance, and quality control. The program has provided extensive assistance and support to the quality control technical department through the National Pharmaceutical Quality Control Laboratory (LNCQM, *Laboratoire National de Contrôle de Qualité des Médicaments*),

Highlights of Progress During Program Year 4

- Assisted AMM to implement its first RB-PMS protocol, developed in 2022, with financial support for the sampling logistics, the purchase of reference chemicals for testing, and facilitation of PMS TWG workshops that help advocate on the importance of PMS among TWG members and other partners. AMM took the lead on development of the 2023 RB-PMS protocol and the search for associated funding.
  - Provided technical support in protocol development; AMM managed all logistics for the sampling.
- Supported AMM to put in place risk-based testing by donating consumables to replenish MiniLab™ kits in 2023. These kits allow testing in the field based on the level of risk to the quality of a product. AMM is owning the full process of RB-PMS and associated risk-based testing. This is key for the sustainability of this activity.
- To develop the capacity of LNCQM, PQM+ activities focused on increased compliance to ISO 17025:2017 standards, supporting improvement of human resources, equipment, facilities and environmental conditions, process improvement, and a quality management system.
  - PQM+ contracted an outside expert to assess the new LNCQM premises against international standards and provided tiered recommendations for how AMM must upgrade laboratory premises to reach these standards.
  - PQM+ facilitated the procurement of a dissolution tester, reagents, and chemicals to ensure LNCQM's operations and testing activities. The supplies will help LNCQM to test relevant medicines for MCH, family planning, and malaria, improving the laboratory's ability to provide necessary quality tests to ensure medicines' safety and effectiveness for the Malagasy people.
- With PQM+ support, LNCQM updated 12 SOPs and two new HPLC instructions.
- Provided theoretical and hands-on training on ISO 17025 standards and the key topics of estimation of measurement uncertainty, method validation and verification, equipment preventive maintenance, and HPLC principles and testing to build the capacity of laboratory staff.
- To help AMM increase their capacity in the regulatory inspection function (per the WHO GBT) in PY4, PQM+ trained 19 staff, including AMM staff and pharmacists from other directorates and regions, on good storage and distribution practices as well as on the PQM+-developed Risk-Based Inspection (RBI) tool, including theoretical training and practical field inspections. PQM+ provided AMM with the tools to implement inspection, including the RBI tool, protocols, guidelines, and checklists.

Progress in Quarter 4

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

Activity 2.1: Strengthen post-marketing surveillance of medicines quality in Madagascar using a risk-based approach. PQM+ continued assistance to AMM in implementing its first round of its RB-PMS protocol for reproductive health and antimalarial medicines. AMM completed sampling of 119 medicines in 12 regions and the laboratory tested the samples throughout the quarter.

PQM+ conducted a workshop in the beginning of July with AMM and the PMS TWG to validate the new RB-PMS protocol that will cover 18 regions. After this validation, AMM personnel have started sampling five types of medicines (for TB, MCH/family planning, HIV, malaria, and antibacterial) in August and September. The AMM personnel are also distributing MiniLab™ kits donated through PQM+ and providing refresher training to local samplers. MiniLab™ is a field-based product quality screening technology that is used for selected PMS samples.

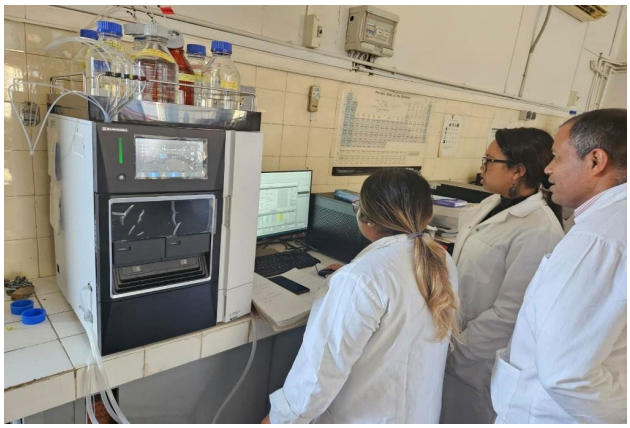
Activity 2.2: Strengthen the capacity of LNCQM. In July, PQM+ conducted a five-day theoretical training for five LNCQM lab analysts on estimation of the measurement uncertainty, methods

validation and verification, and equipment preventive maintenance. These topics are key elements in the ISO 17025 standards. PQM+ also helped LNCQM draft and finalize SOPs associated with measurement uncertainty, methods validation, and methods verification.

PQM+ participated in an official handover ceremony between the Ministry of Health and USAID. Participants included the USAID/Madagascar Country Director, the General Secretary of the Ministry of Health, the AMM Director, the USAID Resident Advisor, and representatives from PQM+ and AMM/LNCQM. Via PQM+, USAID donated a dissolution tester and laboratory chemicals, references, and consumables for MiniLab™ kits. The value of the donation was approximately $150,000 USD. This equipment will help LNCQM test relevant pills, tablets, and capsules for maternal and child health, family planning, and malarial medicines, thereby improving the laboratory's ability to provide necessary quality tests and ensure medicines' safety and effectiveness for the Malagasy people. This improved capacity of the AMM laboratory for testing the quality of medicines will increase AMM's effectiveness in checking the quality of medical products on the market and detecting SF medical products as part of routine market surveillance.

Left: USAID Mission Director Anne N. Williams and MOH General Secretary Dr. Lethicia Lydia Yasmine take part in the equipment and kit official handover ceremony at the Ministry in July. (PQM+ photo) Right: LNCQM's director and a representative of the local health center in Manakara receive MiniLab™ kits during the PMS sampling tour in September. (LNCQM photo)

PQM + conducted a five-day hands-on training on HPLC principles and applications for five LNCQM lab analysts. Participants completed practical exercises using PMS samples collected from the field using the HPLC equipment and interpreted the results.

LNCQM analysts take part in the HPLC training. (PQM+ photos)

Table 2. Status of Labs Accreditation in Madagascar

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-assessment
Laboratoire Nationale de Contrôle Qualité des médicaments (LNCQM)	ISO 17025 : 2017	Review ongoing	Done	Yes	No	Laboratory is waiting to move to another location

Priority Activities for PY5, Q1

Pending USAID approval of the Madagascar PY5 work plan, next quarter PQM+ plans to:

- Finalize the first RB-PMS protocol report.
- Participate in the AMM's strategic planning workshop.
- Work on the LIMS implementation advocacy report.
- Work on the laboratory upgrade advocacy report.
- Continue supporting the laboratory in its QMS implementation.

Mali

In Mali, the Directorate of Pharmacy and Medicines (DPM) and the National Health Laboratory (*Laboratoire National de la Santé,* LNS) oversee medicines regulation. The DPM is an ML1 agency. 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. In January 2023, LNS achieved ISO/IEC 17025 accreditation for four quality control techniques at its medicines quality control laboratory (LCQM) with direct support from PQM+ starting in 2020.

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.

PQM+ also is providing tailored technical assistance to the Medicines Quality Control Laboratory within LNS to attain ISO/IEC 17025 accreditation, expanding their accreditation scope and including pharmaceutical microbiology testing.

Note: A quarter (25 percent) of PQM+ Mali funds was obligated in July and the balance (75 percent) was obligated in September 2023. As a result, Q4 saw minimal implementation.

Highlights of Progress During Program Year 4

- Provided technical assistance to LNS' LCQM to prepare for its ISO/IEC 17025 accreditation scope expansion. Officially expressed interest to SOAC for three additional analytical techniques.
- 37 technical personnel trained on Regulatory, QA and QC topics.
- Supported LNS to start the process of operationalizing its Medical Devices laboratory.
  - Revised five SOPs to integrate medical devices and drafted one new SOP for testing mRDTs.
  - Supported procurement of needed devices and consumables for testing.
- Supported LNS to validate its five-year strategic plan, convene a resource mobilization workshop and develop a resource mobilization plan.
- Supported DPM to convene a workshop to review seven CTD dossiers with technical guidance from PQM+.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

Operationalization of Mali LNS five-year strategic plan. PQM+ supported Mali LNS to convene a workshop to mobilize resources for its newly validated strategic plan 2024–2028 (developed with PQM+ support). In preparation for the workshop, PQM+ supported LNS to cost the strategic plan, ensuring that stakeholders had an estimate of the funds needed for LNS to operationalize the plan. About 35 LNS staff, external partners, and members of LNS' *Conseil d'Administration* (board of directors) attended the workshop and deliberated on how to fund the necessary activities to support the LNS Strategic Plan. Despite not securing immediate funding, participants agreed that the LNS should be able to increase the percentage of its budget supported by lab revenues from around 13 percent to 40 to 50 percent by 2028 through improved coordination with public partners (e.g., DPM, PPM) and private industry.

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

Regulatory inspections capacity building. In July, PQM+ trained 11 inspectors (nine men, two women) from IS and DPM on GSDP and a risk-based approach to inspections applying the RBI tool. As part of this training, PQM+ also coached identified inspectors at DPM and IS to conduct two inspections in the field using the RBI tool. The training familiarizes the inspectors with the inspection processes and adoption of the PQM+ RBI tool, including both GSP and GDP modules. The RBI tool is designed to strengthen the inspection process of national medical regulatory authorities by using a risk-based approach and facilitating the adoption of international standards and best practices in conducting regulatory inspections. The training workshop focused on theoretical and practical training on GSDP module, which included: (1) the implementation of the GSDP module of the risk-based inspection tool (RBI tool), (2) the development of a pharmaceutical GMP inspections plan and inspection checklist; (3) site visits to the pharmaceutical distribution chain/channel (wholesaler and retail pharmacies) for practical

implementation of the RBI tool and GSDP inspection training knowledge through coached inspections.

Dossier evaluation workshop. Building on the evaluation of CTD format training conducted by PQM+ in PY3 to build the capacity of DPM's medicines registration committee, PQM+ supported DPM to convene a workshop to review actual product dossiers in the CTD format. Seven product CTD dossiers were fully evaluated by 17 assessors (12 men, five women). The recommendations from the session include (1) the need for capacity building of DPM on Module 5 of CTD format: bioequivalence, Biopharmaceutical Classification System (BCS), and biowaivers, (2) the need for stability studies for pharmaceutical products, (3) the need to confirm specifications from pharmacopeias and (4) the need for DPM to ensure its administrative office adequately screens the dossiers for compliance with the CTD format before they are assigned to the Committee of Experts. The committee must revise existing templates to ascertain whether the application requires a BE study or is eligible for a biowaiver.

LNS' LCQM ISO/IEC 17025 scope expansion. In Q4, LNS submitted an expression of interest to SOAC to expand its accreditation scope to include three other analytical techniques (HPLC, dissolution, and UV-spectrophotometry). The laboratory is awaiting confirmation from SOAC for the timing for this accreditation assessment.

Priority Activities for PY5, Q1

Next quarter, pending obligation of PY4 funding, PQM+ plans to:

- Supervise Mali's PMS-TWG as it develops its fourth RB-PMS protocol using the MedRS tool.
- Provide hands-on training on mRDT testing.

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 national MRA 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.

Highlights of Progress During Program Year 4

- Engaged LNCQ leadership and technical personnel to review plans for completing training related to ISO 17025:2017 accreditation, including hands-on practical sessions with PQM+ laboratory specialists.
- With the LNCQ, reviewed planned procurements for equipment, reagents, and services required for ISO 17025:2017 accreditation and to support the planned RB-PMS.
- Facilitated the first ISO 9001:2015 audit of ANARME-IP in collaboration with Bureau Veritas®.
- Identified key ARVs used in the national HIV program in preparation for risk assessment and development of the PMS protocol and identification of appropriate quality tests for samples to be collected.
- Worked with the LNCQ to identify and quantify reagents and reference standard needed to support sample quality testing.
- Identified potential suppliers for reagents/reference standards, water purification system, and equipment calibration and maintenance services.
- Supported the division of pharmacovigilance and clinical trials at ANARME-IP to develop a scope of work for the activity as well as the training agenda to support capacity development for ANARME-IP personnel.

Progress in Quarter 4

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

Provide technical assistance to ANARME-IP to conduct risk-based post-marketing surveillance for antiretroviral medicines and long-acting contraceptive implants. There are existing challenges with medicines storage and distribution infrastructure that have led to concerns on the quality of antiretroviral drugs (ARVs) in the supply chain in Mozambique especially at the lower levels of the system. These threaten the benefits of antiretroviral therapy to the patients and may potentially lead to treatment failure. Additionally, poor quality contraceptive implants risk method failure and potentially compromise the reproductive health of women in Mozambique. PQM+ is supporting ANARME,IP to assess the quality of ARVs and contraceptive implants through risk-based post-marketing surveillance (RB-PMS) in order to provide the necessary evidence to support programmatic decisions. PQM+ is utilizing a systems-strengthening approach, using the opportunity to strengthen overall PMS systems for ANARME-IP and contribute toward achievement of WHO GBT ML 3.

In Q4, PQM+:

- Between July 12-14, 2023, provided technical assistance to the ANARME,IP technical staff in identifying gaps related to conducting RB-PMS from the perspective of the WHO's GBT requirements. PQM+ subject matter experts (SMEs) assessed the Market Control (MC) function of ANARME,IP using specific PMS related indicators' and identified missing documents, like SOPs for substandard and falsified (SF) product detection, sampling , taking regulatory measures, conducting RB-PMS, testing, and storage and retention of PMS samples. PQM+ shared related SOP templates with ANARME for customization and PQM+ will review the documents ANARME puts together before finalization.
- Trained the multisectoral PMS-TWG on RB-PMS, use of the online Medicines Risk Scoring (MedRS) tool, and PMS protocol development. The training, conducted between

July 17-21, 2023, involved 26 members (17 female, 9 male) of the PMS-TWG with representation from seven stakeholder organizations (ANARME,IP, MoH health programs [Malaria, TB, EPI, MCH], Central Medical Stores [CMAM], and the private sector [Pharmacists Society of Mozambique]).

- Supported the PMS-TWG in developing a PMS protocol focused on ARVs (dolutegravir 10mg dispersible tablets) and contraceptive implants (Etonogestrel 68mg and Levonorgestrel 150mg). PQM+ also supported the sample collection in eight provinces between September 17 and 22, 2023.

Support LNCQ to strengthen its reliability testing capacity for PMS and prepare for ISO 17025:2015 accreditation. As part of the systems strengthening approach in support of PMS, PQM+ is working with the LNCQ to develop capacity to produce valid and reliable sample testing results. Additionally, ANARME,IP is pursuing WHO GBT ML3 and ISO 17025:2017 accreditation for the LNCQ. PQM+ is providing technical assistance to LNCQ in addressing the gaps identified in the roadmap towards ISO 17025:2017 accreditation.

Table 3. Status of Labs Accreditation in Mozambique

Laboratory	Accreditation Sought	Initial Gap Assessment	CAPA	QMS	PT/LT	Official Inspection/ Pre-assessment
Laboratório Nacional de Comprovação da Qualidade (LNCQ)	ISO/IEC 17025:2017	Initial gap assessment by PQM+ completed/ conducted	In progress	Development and review of most QMS documentation completed	Two PTs conducted. CAR for failed PT conducted; New PT procured and awaiting installation/maintenance and calibration of equipment.	Not done

During Q4, PQM+:

- Conducted a two-week workshop in August and September for the LNCQ technical personnel that involved training and hands-on practical sessions on using pharmacopeias, internal quality control checks and control charts, measurement uncertainty, and compendial testing techniques (dissolution, UDU, and determination of related compounds and impurities by the HPLC method) and an introduction to analytical method validation.
- Procured, delivered, installed, and qualified several pieces of laboratory equipment, including a water purifier and refrigerators with temperature control mechanisms.
- Facilitated equipment calibration and maintenance of two Karl Fischer titrators and pH meters that were previously out of service but have been repaired and are now functional. PQM+ supported the maintenance and qualification of the pH meter and the LNCQ received the required material to maintain the HPLC and dissolution test apparatus. Functional equipment will ensure that LNCQ's premises meet international standards and that the lab has the capacity to perform medicines quality testing.
- Procurement for proficiency testing finalized and the tests have been shipped. This is critical component of ISO 17025:2017 accreditation as it demonstrates the laboratory's competency and validates its measurement process by comparing its results to set standards and other participant laboratories. PQM+ will support the LNCQ in conducting a round of PT after repairs, maintenance, and calibration of all the necessary equipment.

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.

Highlights of Progress During Program Year 4

- Supported Swipha Nigeria Ltd. to obtain WHO prequalification for its zinc sulfate dispersible tablets, the first for this product in Africa.
- Assisted Manufacturer #3 to obtain local market authorization for its ready-to-use therapeutic food (RUTF) product. PQM+ is now working with the manufacturer to start the local production of groundnut paste, a core component of the RUTF, as well as move the product to commercial production.
- Supported NAFDAC and NIPRD to extend the accredited scopes of two NAFDAC and one NIPRD quality control laboratories to cover medical devices and microbiology testing (sterility, microbial limit, and bacterial endotoxin tests).

Progress in Quarter 4

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

PQM+ supported the Pharmacists Council of Nigeria (PCN) to cascade training on QMS and ISO 9001:2015 to the Kano Zonal Office in September. The training started with a one-day awareness session on ISO 9001:2015 and QMS for all cadres of staff (13 women, 28 men) while the remaining three days were used to train lead implementers (12 women, 20 men) and develop SOPs. This is part of its strategy toward the national implementation and sustainability of the QMS across the board in the PCN.

PQM+ conducted a training on internal auditing and SATTA for four NAFDAC laboratories (Kaduna, Maiduguri, Oshodi, and Calabar/Port-Harcourt) in September (nine women, 16 men). During the training, participants developed the SOP on SATTA as audit tool for use in all the seven NAFDAC laboratories. The SATTA tool was used to conduct the audit of NAFDAC Central Laboratory, Oshodi, serving as an end-term assessment for the lab as it prepared for its annual surveillance in October.

PQM+ also supported the interlaboratory comparison (ILC) on bacterial endotoxin tests (BET) between NIPRD and NAFDAC laboratories in July 2023 to fulfill the requirement for the ISO 17025:2017 clause on ensuring the validity of results.

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

The WHO PQ team fully reviewed the sulfadoxine + pyrimethamine (SP) product dossier submitted by Manufacturer #4 without any request for additional information.

- WHO has also completed two rounds of review on the CAPA plan submitted by the manufacturer after their last inspection without any further observations.

- Manufacturer #4 is awaiting the declaration of GMP compliance and prequalification of the SP product soon.

Manufacturer #6 received technical assistance from PQM+ in reviewing the sterilization process for their magnesium sulfate injection. This came in response to concerns by the WHO PQ team about the cycle time due to the sensitivity of the container closure system (CCS) to heat at elevated temperatures.

PQM+ conducted GMP workshops on annual product quality review in two locations:

- In Lagos for pharma industry personnel and the CDDDP in July for 56 participants (26 men, 30 women) from 25 companies in the South-West region.
- In Enugu for pharma industry actors from the South-South and South-Eastern regions in August, drawing 52 participants (35 men, 17 women) from 25 companies.

Priority Activities for PY5, Q1

Next quarter, PQM+ Nigeria plans to:

- Collaborate with the Food and Drug Services (FDS) department of the MOH to collect more data and update zero draft of the NSPP.
- Supplement logistics funding for Pharmaceutical Inspectorate Committees in five states and the FCT to conduct quarterly routine inspections.
- Coordinate resource mobilization advocacy visits to state MOHs.
- Support NAFDAC to conduct training on the RB-PMS tool on antimalarial, MCH, and family planning commodities. The MedRS training activity will take place in PY5 Q1, while the RB-PMS session will be in Q2.
- Complete CAPA plan for Manufacturer #4.
- Conduct capacity building on GMP/QMS and dossier electric Common Technical Document for Manufacturer #2 and Manufacturer #7 (amoxicillin DT) .
- Organize capacity building on CTD/eCTD dossier compilations, review, and assessment for industry and CDDDP.

Table 4. Status of Labs Accreditation in Nigeria

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-assessment
NAFDAC National Control Laboratory for Vaccines and Biologicals, Yaba, Lagos	ISO/IEC 17025	Completed	Completed	N/A	N/A	Accreditation current till December 2023.
NAFDAC Zonal Laboratory Agulu, Anambra State	ISO/IEC 17025	Completed	Completed	N/A	N/A	Accreditation current till December 2023.
NAFDAC Central Drug Control Laboratory	ISO/IEC 17025 WHO prequalification	Completed Completed	Completed Completed	Completed Completed	Completed	Accreditation current till December 2023. WHO prequalified: September 2023.

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-assessment
NAFDAC Kaduna Laboratory Service	ISO/IEC 17025	Completed	Completed	N/A	N/A	Accreditation current till December 2023.
NIPRD Quality Control Laboratory	ISO/IEC 17025	Completed	Completed	In- progress	N/A	Official reassessment completed. Awaiting submission of CAPA.

Rwanda

PQM+ is building the capacity of the Government of Rwanda (GOR) to manage the country's pharmaceutical system (focusing on product quality assurance) to meet its public health needs. The primary focus is strengthening the medicines regulatory system in quality assurance areas, including those outside the mandate of other USAID programs (e.g., risk-based post-marketing surveillance and drug quality control lab strengthening). This will contribute significantly to improving the Rwanda FDA regulatory system as an essential public health function and advancing implementation of the government's National Pharmaceutical Sector Strategic Plan. PQM+ also supports Rwanda Medical Supply Limited and the Regional Center of Excellence for Vaccine Immunization and Health Supply Chain Management.

Highlights of Progress During Program Year 4

- In PY4, PQM+ provided TA to Rwanda FDA to strengthen its post-marketing surveillance system, quality control laboratory system and current good manufacturing practices (cGMP). Interventions included:
  - Trained 26 members of RB-PMS TWG,(14 men, 12 women) on sample collection.
  - Trained 14 Rwanda FDA staff (8 men, 6 women) on prevention, detection, and response to SF medical products.
  - Provided technical support to Rwanda FDA to conduct two RB-PMS TWG meetings.
- Assisted Rwanda FDA to develop a public awareness campaign plan on Rwanda FDA services and conduct a public awareness campaign on prevention, detection, and response to substandard and falsified medical products i.e., quality and safety of medicines.
- Conducted trainings for Rwanda FDA QCL personnel:
  - 26 staff (19 men, seven women) on development, validation, and verification of analytical method (AMV), a requirement for ISO/IEC 17025 accreditation.
  - 20 staff (15 men, five women) on measurement uncertainty, competence-based internal audit, equipment preventive maintenance and calibration of ISO/IEC 17025: 2017 accreditation and/or WHO prequalification selected analytical techniques.
- Supported Rwanda FDA QCL to acquire and install laboratory security enhancing equipment (cameras), occupational health safety tools, and environmental condition monitoring devices (fire alarms/extinguishers, smoke detectors, temperature/humidity monitoring devices).
- Supported GMP inspections in India for Rwanda FDA regulatory inspection function to achieve ML3.

Progress in Quarter 4

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

The medical product QC laboratory is a core component of the medicine regulatory system and needs to be well-equipped, adequately staffed, and properly managed. PQM+ provides technical assistance to Rwanda FDA in its WHO prequalification and ISO/IEC 17025:2017 accreditation pursuits. In Q4, PQM+ supported Rwanda FDA to:

- Train quality control laboratory (QCL) 20 staff (15 men, five women) on measurement uncertainty, competence-based laboratory internal auditing, equipment preventive maintenance, and calibration.
- Conduct a measurement uncertainty evaluation for the selected scope techniques for ISO/IEC 17025:2017 accreditation
- Collect data to develop the laboratory's uncertainty budget for the selected scope techniques for ISO/IEC 17025:2017 accreditation.
- Improve internal audit program planning and performance of internal auditing of their laboratory management system.
- Develop a CAPA plan from audit findings.
- Conduct equipment preventive maintenance and calibration.
- Develop and manage equipment preventive maintenance and calibration plans and schedules.

Table 5. Status of Lab Accreditation in Rwanda

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-assessment
Rwanda FDA (QCLD)	ISO 17025:2017	Completed	Completed	Plan is under review	N/A	Plan for mock audit and work on the CAPA
Rwanda FDA (QCLD)	WHO prequalification	Completed	To be completed	To be completed	Pending submission and approval	Prepare for gap assessment, work on the LIF, and submit for approval.

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

The Rwanda Medical Supply (RMS), a state-owned parastatal company established in 2020 plays a major role in overseeing the central-level procurement of essential medicines and other medical products used within the public sector health system in Rwanda. In view RMS's major role, PQM+ worked with RMS to put in place a robust quality assurance (QA) system for medicines and other medical products. In Q4, PQM+ supported RMS to

- Train 20 participants (14 men, six women) on ISO 9001:2015 based QMS and internal audit

- Train 21 participants (15 men, six women) on use of SOPs and review/development of the quality manual.

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

University of Rwanda (UR) is the country's largest publicly funded higher education institution, formed in 2013 through the merger of previously independent public institutions of higher education, the largest of which was the National UR. To support UR to build the capacity of pharmacy students in quality control laboratory testing, PQM+ provides technical assistance to build the capacity of lab teaching staff. In Q4, PQM+ supported the university to

- Assess gaps in its teaching laboratory
- Train five laboratory teaching staff (four men, one woman) on advanced QMS and internal audit, method validation and verification, equipment calibration, design of experiments, uncertainty calculations, and proficiency testing.
- Support 21 teaching and nonteaching staff members in developing and reviewing five SOPs and the quality manual according to ISO/IEC 17025:2017 standard.

Priority Activities for PY5, Q1

Next quarter, Rwanda plans to finalize all PY4 carryover activities:

- Test, analyze results, compile, and publish the country's first RB-PMS report.
- Finalize the procurement of three selected scientific journals on the quality and safety of medical products.
- Train QCL staff on good laboratory waste management.
- Support QCL staff to conduct a mock audit and initiate the ISO 17025:2017 accreditation and WHO prequalification process.
- Finalize procurement and provide technical assistance to QCL to participate in interlaboratory comparisons of test results for HPLC, UV, dissolution, pH, LOD, FTIR, titration, UDU, or KF with one of three approved proficiency testing providers.
- Finalize the development of the QMS quality manual for approval, provide technical assistance to RMS on a mock audit, and initiate ISO 9001:2015 certification process.

Senegal

PQM+ works with the new *Agence Sénégalaise de Regulation Pharmaceutique du Senegal* (ARP), a fusion of the former *Direction de la Pharmacie et du Médicament* (DPM) and *Laboratoire National de Contrôle des Médicaments* (LNCM), to strengthen its market surveillance function through a PMS unit to implement RB-PMS and to improve the capacity for medicine registration. In addition, PQM+ provides support to ARP's National Medicines Control Laboratory (*Direction de Contrôle Qualité*/DICQ) to improve its capacity to test medicines.

In February 2022, following the GBT assessment of October 2021, Senegal embarked on a process to develop an action plan to attain GBT ML 3 by December 2022, based on direction from the president, Macky Sall. Both institutions, LNCM and DPM, were therefore busy with this process and started putting together the regulatory documents required. As a result, between February – April 2022, both beneficiaries were not available for implementation of PQM+ activities given ARP had prioritized development of regulatory documents (laws, guidelines,

SOPs) over activities such as implementing RB-PMS (sampling and testing) and ISO 9001 support for ARP, which were in the PQM+ workplan. In April 2022, a law was passed establishing a new medicines regulatory authority in Senegal and a new Director General was nominated. This further delayed implementation as ARP also focused on the operationalization of the new agency which included the development and implementation of a new organigram.

Highlights of Progress During Program Year 4

- Supported the dissemination of the 2022 antimalarial RB-PMS results and coached the PMS Unit of Senegal to implement its third RB-PMS for Senegal by supporting training on the new MedRS tool, development of a new RB-PMS protocol, procurement of Minilab and testing reagents, and provision of logistics for the sampling missions.
- Completed an ISO 9001 baseline assessment for ARP and worked with them to develop a roadmap toward ISO 9001 certification.
- Trained 147 technical personnel of ARP (including its lab, DICQ) on QA and QC topics, including:
  - Internal quality control (DICQ)
  - Out of specification (DICQ)
  - Internal audits (ARP)

Progress by PQM+ Objective

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

RB-PMS of antimalarials. In Q4, the RB-PMS samplers completed the antimalarials sampling from six regions per the 2023 RB-PMS protocol. A total of 251 antimalarial samples were collected from eight regions in Senegal (Djourbel. Kaolack, Tambacounda, Kedougou, Dakar, Kolda, Zingunchor and Saint Louise). The samples are now being coded and entered into the laboratory's sample database.

ISO 9001 systems strengthening for ARP. Through the quarter, PQM+ conducted a baseline assessment of ARP as per the requirements of the ISO 9001:2015 standard to ascertain the gaps the agency has with respect to the ISO 9001 standard. The outcome of the baseline assessment (see Annex 1) established the following facts:

- The QMS team of ARP has implemented some aspects of the ISO 9001 QMS as prescribed in the roadmap developed in PY3 to enhance their progress toward ISO 9001:2015 certification.
- QMS documentation (SOPs and forms) some QMS requirements are in place and implemented, some exist as draft documents and others have not been drafted.
- A formal QMS which is compliant to ISO 9001:2015 and effective has not yet been established.

ARP plans to complete implementation of the aspect of the IDP that was generated from their WHO GBT self-assessment that relates to the establishment of an institutional quality management system. This quality management system is based on the ISO 9001:2015 quality management systems requirements and is intended to enhance the chances of ARP maturing into a ML3 Medicines Regulatory Authority

Furthermore, in Q4, to monitor the implementation of the newly established QMS, PQM+ trained 20 regulatory officers (11 men and 9 women) from ARP QA team on internal audits. This training provided instruction on the theory and principles of internal auditing, one of the critical elements of ISO 9001 compliance and WHO GBT. As part of this workshop, ARP staff trained these same trainees on ARP's procedure for internal audits.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Support the PMS unit to test the antimalaria samples for the 2023 RB-PMS.
- Facilitate a visit by DiCQ analysts to Ghana to be coached on advanced QC analytical techniques.

Asia Region

Asia Bureau

PQM+'s technical assistance (TA) 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.

Highlights of Progress by PQM+ During Program Year 4

- This program year, to enhance the knowledge and understanding of the current global regulatory requirements to be considered during product registration and evaluation of biological products, including vaccines, and that are applicable to the evaluation of clinical and analytical aspects of BA/BE studies, PQM+ Asia Bureau conducted two virtual trainings of trainers (ToTs) on product evaluation of biological products and BA/BE studies. A total of 46 regulatory assessors from nine ASEAN member states attended the training.
- In May 2023, the PQM+ Asia Bureau team participated in the SEARN regional workshop, the objective of which was to support the network's member states in using market surveillance, inspection, laboratory testing, and marketing authorization risk-based approaches to ensure quality of medicinal products. The member states requested guidance from invited international organizations, including USP, to address issues related to medicines contamination at the national and regional levels. During the workshop, the PQM+ team assisted the drafting of the SEARN Regional Action Plan 2023-24. The SEARN Secretariat floated an expression of interest to various stakeholders to join the network Coalition of Interested Parties (CIP) and invited PQM+ program to join the coalition. PQM+ joined the SEARN CIP and expressed interest in potential areas for future TA in PY5.
- In PY4, PQM+ also conducted a landscape analysis of 17 LMICs across Asia to assess their readiness to expand the local production of priority essential health products (e.g., injectable antimicrobial, multidrug resistance products, noncommunicable disease products such as insulin and biosimilar cancer drugs). The analysis aimed to understand the market size and demand, share of local production vs. imports, local industry's capability and maturity to expand production, and various other policy and regulatory dimensions. Based on findings from the analysis, the team identified five priority countries (Indonesia, Kazakhstan, Philippines, Uzbekistan, and Vietnam) based on high unmet need and high potential for expanding local pharmaceutical manufacturing. In discussion with USAID Asia Bureau, PQM+ selected the Philippines for an in-depth study to help identify contextual challenges and develop tailored recommendations for growing the domestic pharmaceutical industry of Philippines.

Progress in Quarter 4

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

Following the development of SEARN Regional Action Plan 2023-24, PQM+ team provided technical input for the creation of working groups that will assist the development of technical and operational documents to strengthen SEARN member states' regulatory capacity.

This quarter, PQM+ Asia Bureau received final approval from the PPWG for the implementation of all ASEAN-related activities that were initially proposed for PY4. These are:

- Dissemination of the regulatory landscape analysis' findings in relation to ASEAN member states
- A ToT course on product evaluation of complex APIs
- Regulatory system strengthening, harmonization, and reliance workshop with a focus on risk-based approaches on RB-PMS and risk-based inspection (RBI) tools
- Training on vaccine lot release program implementation and maintenance

The team has moved forward with the planning of the approved activities for implementation in PY5.

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

Following the selection of the Philippines for the in-depth study to help identify challenges and develop tailored recommendations for growing the country's domestic pharmaceutical industry, PQM+ is moving forward with arrangements for a scoping visit the first quarter of PY5. During the visit, PQM+ team aims to:

- Orient the in-country stakeholders on PQM+ proposed approach to enhance access to priority essential health products through optimization of local manufacturing capability and resilience.
- Identify relevant information sources and acquisition mechanisms to identify priority essential health products for the market segmentation, policy, and regulatory analysis.
- Engage with key stakeholders to define the activity implementation plan.

Priority Activities for PY5, Q1

Next quarter, Asia Bureau plans to:

- Conduct training on vaccine lot release program implementation and maintenance.
- Conduct scoping visit to the Philippines.

Bangladesh

In Bangladesh, PQM+ works with the Directorate General of Drug Administration (DGDA), which oversees medical product quality in the country 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 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 in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

PQM+ supported DGDA to finalize the regulatory framework document.

- In this reporting quarter, in collaboration with DGDA committee, PQM+ updated and finalized the regulatory framework document and aligned the document with the new Drugs and Cosmetics Act 2023 (passed September 7, 2023, and gazette published September 18, 2023). The regulatory framework document will assist DGDA in mapping out all activities within the existing/upcoming required legal and regulatory systems. This regulatory framework document will ensure the necessary oversight of DGDA's regulatory functions and promote good governance.
- In September, PQM+ conducted training on the regulatory framework to raise awareness among 32 DGDA officials (20 men, 12 women) to help them understand the context and correlate legal provisions, policies, and standards with the regulatory functions.

PQM+ supported DGDA to finalize and disseminate the five-year strategic plan for the National Drug Control Laboratory (NDCL).

- PQM+ assisted DGDA in finalizing the NDCL's five-year strategic plan (2023 – 2028). The strategic plan focused on three key response areas: adequately resourcing the NDCL, modernizing lab operations, and expanding lab offerings, and the activities related to these. The plan has been aligned with DGDA's five-year strategic plan (2022. –.2026). This strategic plan will enable NDCL to sustain achievements in operational capabilities and compliance with international standards.

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

Sub-Objective 2.1. Support DGDA to make improvements across seven regulatory functions toward sustainable systems development for DGDA. PQM+ Supported DGDA toward the eventual achievement of WHO ML3 through the implementation of an effective QMS and IDP.

- PQM+ actively supports DGDA and NDCL in achieving WHO ML3. PQM+ supported DGDA and NDCL in conducting a self-assessment (September 15 to 27, 2023), of DGDA's regulatory functions according to WHO GBT indicators. WHO regional experts, in collaboration with PQM+ staff, reviewed the progress. Following the self-assessment, PQM+ updated the IDP and CAPA plan. DGDA organized a Coalition of Interested Parties (CIP) meeting on October 02, 2023, to share progress and identify the way forward.
- During this quarter, PQM+ supported DGDA and NDCL in developing two new SOPs[14] and reviewing and updating 10 other SOPs.[15]

PQM+ assisted DGDA to prepare the draft regulatory framework document for medical devices.

- In this quarter, PQM+ supported DGDA in formulating draft regulatory framework guidance document for medical devices, revising the draft registration guidelines for medical devices 2015, and developing the draft SOP for registration of medical devices. Additionally, PQM+ supported DGDA to develop training materials and the yearly

[14] 1) SOP for public health emergency, crisis, and risk management; and 2) SOP for regulatory system harmonization and benchmarking.

[15] 1) SOP for Procedure for Communication & Decision Making Channel of DGDA_V3; 2) SOP for Qualification, Selection and Listing of Vendor_V2; 3) SOP for Procedure for Management Review_V-4; 4) SOP for Complaint handling and measuring customer satisfaction_V-2; 5) SOP for Procedure for Internal Audit_V-3; 6) SOP for Confidentiality Management_V-3; 7) SOP Procedure for handling conflict of interest_V-2; 8) SOP for development and adaptation of Guidelines_V-3; 9) SOP for selection of external experts for different expert advisory technical committee_V-3; and 10) SOP for development of legal provision_V-2.

training plan for medical devices. These initiatives will empower DGDA to implement effective regulations to ensure high standards of quality, safety, and efficacy.

PQM+ provided TA to DGDA to build capacity based on Optimizing Efficiencies in Regulatory Agencies (OpERA) recommendations.

- On August 15, 2023, PQM+ collaborated with the DGDA focal point to complete the responses on OpERA country questionnaire. On September 04-05, 2023, PQM+ conducted working sessions with the relevant DGDA staff to finalize the questionnaire. This questionnaire will be sent to the Centre for Innovation in Regulatory Science (CIRS) for the preparation of a country report that will provide information and recommendations to DGDA. These recommendations will help DGDA enhance its good review practices for dossier review and approval, ensuring an evidence-based approval process for medical products.

PQM+ has been supporting DGDA in RB-PMS system development.

- In June 2023, the DGDA RB-PMS committee finalized the RB-PMS sampling and testing protocol of first-line anti-TB medicines using the MedRS tool. On July 15, 2023, DGDA inspectors initiated the first round of surveillance. The surveillance will help NTP and DGDA to take any necessary steps to guard against SF TB medicines.

PQM+ provided technical support to DGDA and NDCL to review and implement standard vaccine lot release guidelines.

- PQM+, in collaboration with NDCL, revised and updated the vaccine lot release guidelines. These national guidelines comprehensively outlined the necessary procedures for the release of vaccine lots, spanning from the lot submission process to the issuance of lot release certificates. The adoption of standard vaccine lot release guidelines will strengthen regulation of vaccines and toward WHO ML3.

PQM+ supported DGDA to assess the current practices followed by DGDA in providing registration for manufacturing API in the country.

- PQM+ supported DGDA to assess the existing processes of registration of API for manufacturing and approvals of facilities. The assessment report has been submitted to DGDA including the standard drug master filing (DMF) procedure. Adoption of the standard DMF procedure strengthens the DGDA's existing API registration process, ultimately helping to ensure the quality of API.

PQM+ supported DGDA to conduct the rapid assessment of SF anti-TB medicines in the private sector.

- During this reporting quarter, PQM+ supported DGDA to complete the rapid assessment of SF anti-TB medicines in the private sector. DGDA finalized the report and disseminated it to the relevant stakeholders. Based on the findings of the assessment, DGDA and NTP agreed to conduct an assessment of market regulation for anti-TB medicines.

Sub-Objective 2.2. Medical product QCL capacity strengthening to support sustainable PMS program. PQM+ is providing TA to enhance the capacity of NCL's vaccine laboratory to achieve and sustain WHO ML3.

- In July, WHO SEARO scientists conducted a follow-up audit at the NCL vaccine laboratory wing to assess the CAPA progress for laboratory access and testing & lot

release functions. The PQM+ assisted NCL in providing responses for the indicators and sub-indicators.

- In July, PQM+ assisted NDCL staff to prepare the method validation report of potency test of adsorbed tetanus vaccine, which was ultimately approved by the QA Head.
- In July, PQM+ facilitated a training session for 20 NDCL technical staff (14 men, six women) on the SOP "Operation and Cleaning of High-Performance Size Exclusion Chromatography." During the session, the NDCL technical staff actively learned the efficient operation and maintenance of the machine.
- In July, PQM+ conducted a training session for 22 NDCL staff (16 men, six women) on "Identifying Adenoviral Vector Backbone in Covishield Vaccine Samples through Real-time PCR (Identification Test)." The training equipped NDCL analysts with both theoretical understanding and practical skills, enabling them to proficiently perform the identification test on Covishield Vaccines and other similar vaccines. Additionally, all necessary reagents and standard methods are now accessible to them.
- In July, PQM+ conducted a training session on the "Standard Operating Procedure of ELISA Reader" for 20 NCL staff (15 men, five women). This training focused on the operational procedure of the newly introduced ELISA Reader, designed for conducting the LPS Inhibition test of the Oral Cholera Vaccine. The knowledge gained from this session is crucial for testing the Oral Cholera vaccine, specifically addressing the critical lot release parameter.
- In August, with the assistance from PQM+, NDCL staff prepared and obtained approval from the QA Head for version 01 of the standard testing procedure for "Determination of Molecular Size distribution of Meningococcal Polysaccharide vaccine by High-Performance Size Exclusion Chromatography."
- In August, PQM+ supported NDCL staff in performing an endotoxin kinetic test on rabies vaccine (Human) using a kinetic chromogenic method. This marked the inaugural test of locally produced vaccines utilizing a newly introduced Endotoxin Kinetic Analyzer machine.
- In July and August, PQM+ provided technical support to NDCL to prepare and approve of three new SOPs.[16]
- In August, with assistance from PQM+, NDCL staff prepared and obtained approval from the QA Head on the standard testing procedure for "Potency Test of Rabies Vaccine (Human)."
- In September, with assistance from PQM+, NDCL staff prepared and obtained approval from the QA Head on Analytical Method Verification of Protocol of determination of endotoxin content by Kinetic Chromogenic Method.
- In September, PQM+ assisted NDCL staff in conducting method verification (endotoxin kinetic chromogenic method) testing parameter linearity (assurance of criteria for the standard curve) that determined the correlation coefficient value of samples.

[16] 1) Operation and Cleaning of High-Performance Size Exclusion Chromatography (Model:AKTA pure 25m; 2) Operating prodedure of ELISA Reader, Model: SpectraMax(R) ABS Plus; and 3) Operation, Cleaning and Maintenance of Endotoxin Detection Analyzer and WinKQC(R) Software 6.3.0 version (Model No. ELx808LBS, Lonza, USA).

- In September, PQM+ assisted NDCL staff in conducting method verification testing parameter that determined interfering factors (measure the product positive control recovery percentage between 50-200%) of test solution.
- In September, PQM+ assisted NDCL staff in conducting the method verification testing parameter precision between two analysts by kinetic chromogenic method of rabies vaccine (human).
- In September, PQM+ conducted a theoretical training for 17 NDCL staff (11 men, six women) on the "Analytical Method Verification of determination of Endotoxin content by Kinetic Chromogenic Method," after completing all the verification parameters for determining endotoxin content through the kinetic chromogenic test. The training equipped NDCL personnel with the knowledge to routinely and more accurately determine the endotoxin content of vaccines and biologics using the newly introduced kinetic chromogenic method. Additionally, they gained the ability to verify the endotoxin content of any other vaccines or biological products through the kinetic chromogenic method in the long run.
- In September, with assistance from PQM+, NDCL staff prepared and obtained approval from the QA Head on the standard testing procedure for "Potency Test of Tetanus Toxoid Vaccine (Absorbed)."
- In September, PQM+ assisted NDCL staff in conducting the identification test of Covishield vaccines by Real-time PCR (RT-PCR).
- In September, PQM+ complied with all test reports and approved “Analytical Method Verification of Report of Determination of Endotoxin content in Rabies Vaccine (Human) by Kinetic Chromogenic Method.“

PQM+ is helping DGDA to build the capacity of the Central Drug Testing Laboratory (CDTL), Chattogram to test medicines’ quality and continue technical assistance to the NCL physicochemical lab.

- In July, the American National Standards Society National Accreditation Board (ANAB) performed a surveillance audit on ISO 17025 in NDCL's Physicochemical lab. NDCL staff, supported by PQM+, successfully navigated the audit. The audit observation revealed no major or critical findings; instead, the auditor provided two minor findings.
- In July, PMQ+ supported NDCL staff in performing two PT (UV-Vis and low-level enumeration and identification) in NCL.
- In August, PQM+ provided training to two (one man, one woman) CDTL staff on Good Laboratory Practices (GLP), uniformity of dosage unit, and daily performance checks of the balance to enhance their functional skills.
- In August, PQM+ provided training to eight (six men, two women) physicochemical staff of NDCL on Measurement Uncertainty of titration and Hardness, closing the ANAB CAPA and enhancing their skills.
- In August, PQM+ visited CDTL and assisted the staff to maintain proper labeling of the equipment with equipment ID, to perform daily check of balance and complete equipment database.
- In August, PQM+ conducted hands-on training for eight CDTL staff (seven men, one woman) on using, cleaning, and maintaining the UV-VIS spectrophotometer.

- In August, NDCL's physicochemical lab obtained the ISO/IEC 17025:2017 certificate following the ANAB surveillance audit conducted on July 9-10, 2023.

PQM+ is providing TA to Plasma Plus Research and Testing Laboratory (PPRTL) to address CAPA to achieve international standards on medical product testing (WHO-PQ, ISO/IEC 17025:2017).

- In July, PQM+ delivered theoretical training on QMS: Internal audit and analyst qualification to three (male) PPRTL staff.
- In July, PQM+ actively supported PPRTL staff in revising and obtaining approval for the SOP on environmental monitoring.
- In August, PQM+ actively supported PPRTL in completing the CAPA progress report based on gap assessment.
- PQM+ provided the procedure for calibration of gas chromatography to the PPRTL analyst to conduct the GC calibration.

PQM+ is providing technical support to the Institute of Epidemiology Disease Control and Research (IEDCR) toward accreditation (ISO 15189 & 15190)

- On September 25, 2023, the senior management team, in the presence of Prof. Dr. Tahmina Shirin, the Director of IEDCR, approved the CAPA plan. The plan, in strict adherence to ISO 15189 standards, outlines identified non-conformities, corresponding action steps, and a well-defined timeline for task completion. Furthermore, IEDCR has announced the establishment of a dedicated QA Unit, with an approved functional organogram. These strategic measures, developed in collaboration with the PQM+ team, aim to ensure IEDCR's compliance with ISO 15189 standards.

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

PQM+ is continuing technical support to ACI Healthcare Ltd. (AHL) toward the prequalification of first-line TB medicines.

- In August 2023, contract research organization (CRO) ACDIMA, Jordan successfully cleared the BE study of first-line anti-TB medicines (fixed dose combination-4FDC). AHL and PQM+ experts are collaboratively preparing the dossier for submission to WHO.

PQM+ provided technical support to Essential Drugs Company Limited (EDCL) to conduct good practices (GxP) training for technical staff based on TNA.

- On August 05-10, 2023, the PQM+ team conducted advanced training sessions on GxP in pharmaceuticals at the Dhaka plant. The team organized two separate batches, catering to a total of 57 EDCL technical staff (46 men, 11 women). The primary goal was to enhance the knowledge and understanding of the current global regulatory requirements related to basic GMP, QMS, and data integrity for the technical staff.
- September 24-26, 2023, Continuing Education Center (CEC), a renowned training facilitation organization hired by PQM+, conducted a three-day training program on GxP. The training aimed to enhance the training facilitation skills of 25 (18 men, seven women) technical staff members from EDCL to prepare as master trainers. The selected master trainers represented four plants.

PQM+ provided TA to build the capacity of a selected local CRO to support BE studies in the country.

- In an ongoing effort, PQM+ supports the technical capacity building of Bangladesh CROs to meet international standards in Good Clinical Practices (GCP) and GLP for the conduct of BE studies. .In February 2023, three selected CROs formulated their CAPA plans. Throughout this quarter, PQM+ meticulously reviewed and finalized these plans in September 2023

PQM+ supported Bangladesh Association of Pharmaceutical Industries (BAPI) to develop trainers pool to provide pharmaceutical training toward building a training unit at BAPI.

- From September 3 to 5, 2023, PQM+ collaborated with BAPI to organize a ToT course titled "Evaluation of Complex API and its finished dosage form." The course aimed to enhance the skills of master trainers in the pool. A total of 29 trainees (26 men, three women) underwent the ToT, which PQM+ staff facilitated. The training comprised two phases: 1) an industry visit to a local API manufacturing facility by the trainers' pool, and 2) the ToT course on the evaluation of complex API and its finished dosage form.

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

PQM+ supported DGDA to organize divisional workshops to build awareness about quality-assured medical products in line with National Quality Assurance Guidelines (NQAG)

- On August 28, in collaboration with PQM+, DGDA organized a divisional-level seminar on the NQAG for Medical Products and RB-PMS in Khulna Division to promote awareness about medical product quality among health care professionals, policymakers, administration, law enforcement agencies, local government officials, and academics. DGDA Director Md. Salahuddin presided over the meeting. A total of 70 participants attended the seminar.
- On September 19, the DGDA, in collaboration with PQM+, organized a divisional-level seminar on the NQAG for Medical Products and RB-PMS in Rangpur Division. The seminar aimed to promote awareness about medical product quality among health care professionals, policymakers, administration, law enforcement agencies, local government officials, and academics. Major General Mohammad Yousuf, the Director General of DGDA, presided over the seminar. The PQM+ Regional Director attended the meeting. A total of 60 participants attended the seminar.

PQM+ provided TA to DGDA for situational analysis and planning of strengthening regulation capacity, marketing surveillance, control, and quality testing of anti-microbial veterinary medicines at national and sub-national levels.

- In July, PQM+ provided technical support to Department of Livestock Services (DLS) to conduct situational analysis on antimicrobial resistance (AMR) in four DLS laboratories: Central Disease Investigation Laboratory, Veterinary Public Health Laboratory, Quality Control Laboratory, and Field Disease Investigation Laboratory.
- In July, DLS high officials and PQM+ engaged in a fact and finding sharing meeting to assess four laboratories. Additionally, PQM+ visited Renata Limited to evaluate the GMP status of veterinary products.

- In September, PQM+ disseminated the final report on "AMR on Veterinary Public Health Laboratories: Situational Analysis on Strengthening the Lab Infrastructure and Capability" to DLS and shared the conclusive findings and recommendations.

PQM+ provided technical support to DGDA and the Ministry of Fisheries and Livestock and DLS in developing Bangladesh National Veterinary Formulary. During this quarter, PQM+ completed development of Bangladesh National Veterinary Formulary, and the document is in the printing stage.

Priority Activities for PY5, Q1

- Continue support to DGDA in achieving WHO ML3.
- Support AHL in submitting the 4FDC dossier to WHO for PQ.
- Assist DGDA in implementing RB-PMS for TB-medicines.

Table 6. Status of Labs Accreditation in Bangladesh

Laboratory	Accreditation Sought	Initial Gap Assessment	CAPA	QMS	PT/LT	LIF	Official Inspection/ Pre-assessment
National Control Lab (Physicochemical Lab)	ISO: IEC 17025/2017 (reaccreditation) By ANAB	Completed	Completed	Completed	Completed	Submitted and approved	In July 10-11, 2023, ANAB surveillance audit was conducted.
National Control Lab (Microbiology Lab)	ISO: IEC 17025/2017 (reaccreditation) by Bangladesh Accreditation Board (BAB)	Completed	Completed	Completed	Completed	Submitted and approved	Achieved BAB accreditation in 2017

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-assessment
National Control Lab (Physicochemical Lab)	WHO PQ	Completed	Completed	CAPA closed	Submitted and approved	Achieved WHO PQ in March 2020.
National Control Lab (Microbiology Lab)	WHO PQ	Completed	Completed	CAPA closed	Submitted and approved	Achieved WHO PQ in March 2020.
National Control Lab (Microbiology Lab +Vaccine Chemical lab)	WHO ML3	Completed	Completed	CAPA closed	-	Reassessment by WHO is pending; ML3 not yet been achieved

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.

Highlights of Progress During Program Year 4

- In PY4, PQM+ provided TA to DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory to achieve ISO 17025:2017 reaccreditation. The laboratory is currently accredited in 10 scopes of testing by ANAB.
- In PY4, PQM+ organized two in-person training at DFDA on data integrity, analytical method validation, HPLC, dissolution, and potentiometric titration to 63 participants (six men, 57 women). PQM+ also organized one in-person QMS workshop at DFDA attended by 30 participants (two man, 27 women). These events enabled DFDA Nay Pyi Taw lab to improve their technical skills especially on method validation, which is part of the quality control process of locally manufactured medicines. Due to U.S. Government restrictions, it is becoming increasingly difficult to provide direct compensation to DFDA personnel during these trainings. Hence, PQM+ collaborated with WHO Country Office – Malaria Unit, which covered expenses for travel, lodging, meals, and per diems for DFDA participants. In PY4, WHO supported direct expenses for 93 participants (nine men, 84 women) across three in-person PQM+ trainings.
- At YSI QC Laboratory, PQM+ organized two in-person trainings covering data integrity, analytical method validation, analytical workflow for UV-Vis spectrophotometer, pH, FTIR, and dissolution. Across the two trainings, PQM+ trained 30 participants (two men, 28 women) from YSI. These trainings strengthened both QMS and technical expertise of YSI analysts as they prepare for ISO 17025:2017 accreditation.
- In PY4, PQM+ organized three technical webinars to provide learning opportunities for DFDA personnel. However, some participants faced language barriers exacerbated by the virtual delivery format. To overcome this issue, PQM+ collaborated with USP Education to provide e-learning alternatives, which DFDA personnel could access independently. As a result, USP Education offered free access to on-demand courses to registered DFDA personnel – making it easier for them to learn at their own pace and comfort. In PY4, DFDA personnel attended 55 on-demand courses. PQM+ also leveraged USP Education resources to complement planned webinars and in-person trainings.

Progress in Quarter 4

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

In Quarter 4, PQM+ planned to organize in-person training on interlaboratory testing and measurement uncertainty at DFDA Nay Pyi Taw Laboratory and YSI QC Laboratory. These trainings were moved to the Quarter 2 of PY 5 due to delays in obligation of funds from U.S. President's Malaria Initiative (PMI).

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

In Quarter 4, PQM+ planned to organize an on-site cGMP assessment at YSI manufacturing facility. However, due to the delays in obligation of funds from PMI, PQM+ moved the activity to the Quarter 1 of PY5.

Priority Activities for PY5, Q1

Next quarter, PQM+ Burma plans to:

- Conduct on-site cGMP assessment at YSI manufacturing facility.
- Facilitate a QMS workshop at DFDA Mandalay Pharmaceutical Chemistry Laboratory.
- Continue to assist YSI QC Laboratory in document revision and document preparation for ISO 17025 accreditation.


Left: DFDA analysts prepare a sample for HPLC analysis during the analytical method validation training in Nay Pyi Taw. Right: PQM+ staff demonstrate pipetting skills during the analytical method validation training at YSI QC Laboratory.

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.

Highlights of Progress During Program Year 4

- With DDA, successfully advocated with the Ministry of Health and Population (MoHP) to revise the GMP code to ensure quality assurance in local medicines manufacturing.
- Worked with DDA worked to scale up RB-PMS to the national level, but resource constraints led to more limited sample collection than planned.
- Facilitated DDA's development of draft PMS-related regulations and waste management guidelines, and PQM+ and DDA are contemplating an effective way to accommodate additions to the current formal documents.
- Oversaw a follow-up SATTA that revealed an increase in NML's compliance with ISO 17025 requirements and NML proactively fulfilling QMS-related requirements.
- Successfully installed and tested a laboratory data management system at NML. However, a technical issue regarding the RBI tool is impeding operationalization of the RBI approach at DDA.
- Engaged with private manufacturers, resulting in them leveraging their resources to ensure quality in manufacturing and facility optimization.
- Successfully advocated with local governments to form committees to ensure quality in medicines procurement.
- Nepal Pharmacy Council has decided to develop a CPD course for its professional members.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

Revision to the GMP code and development of technical guidelines: In PY3, PQM+ supported DDA to revise the national GMP code in line with WHO's guidelines on good manufacturing

practices. In October, the MoHP approved the revised GMP code. To complement the revised GMP code, PQM+ assisted DDA to develop five technical guidelines, which are now in the review and approval process.

DDA and Nepali manufacturers discussed a wide range of topics, including updates on the GMP code.

PQM+ supported DDA to organize an interactive program with manufacturers, at which amended provisions of the GMP code were disseminated and technical guidelines to the code were discussed and shared. Discussion topics included common findings from GMP and GLP inspections, adoption of CTD, the process and timeframe for the approval of analytical method validation, comparative dissolution studies, and product registration and dossier filing issues.

Guidelines on safe disposal of unwanted pharmaceuticals: PQM+ supported DDA to organize an extensive discussion on this topic to review current government guidelines as well as explore the inadequacies around safe disposal of unwanted pharmaceuticals. PQM+ assisted DDA to produce a draft to address the gaps in current government guidelines, focusing more on pharmaceutical waste at government health facilities and covering the disposal of unwanted pharmaceuticals generated through regulatory activities such as recall, testing, seizures, etc.

Assist the regulatory authorities to draft PMS regulations: Nepal's current Drug Act does not have adequate provisions to facilitate implementation of risk-based approaches in DDA's PMS function, so PQM+ has assisted DDA to develop a draft on PMS regulations. PQM+ and DDA are discussing the best approach to incorporate PMS provisions in DDA's legal instruments, which is also a GBT recommendation.

Left: A DDA official collects samples during risk-based post-marketing surveillance.
Right: A policy dialog meeting addresses ways to boost the national production of essential medicines.

Assist the development of the Nepal Pharmaceutical Manufacturing Strategy: DDA agreed to start the manufacturing strategy formulation process with internal and external consultations. PQM+ developed a background paper for strategy development and engaged a PQM+ regional expert to support the strategy development process. PQM+ developed questionnaires and a list of experts for gathering information on the manufacturing strategy. Based on the ongoing landscape analysis of Nepal's medicines market, the strategy aims to show a roadmap to strengthen domestic production for self-sufficiency and increase essential medicines quality.

High-level policy dialogue: In December 2022, PQM+ supported DDA in organizing a policy dialogue focusing on the domestic production of essential medicines among a high-level drug advisory group that included representatives of national-level health agencies, professional bodies and councils, academia, and private sector entities. The group discussed implementation of existing policies and government directives to strengthen domestic production. PQM+ Director Jude Nwokike delivered a keynote speech on the importance of medicines quality and timely access to improve public health, as well as emphasized the need for protection of pharmaceutical manufacturers. Since PY2, PQM+ has been supporting DDA to hold policy dialogues on wide-ranging pharmaceutical issues.

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

Strengthen risk-based inspection of DDA: After PQM+ introduced the RBI approach and helped DDA develop an RBI framework and plan, DDA inspected 13 of 19 manufacturers found to be high risk. PQM+ supported DDA to create databases for 67 of 80 local allopathic manufacturers that have received marketing authorization for products in Nepal. DDA's Inspection TWG discussed finalizing RBI-related guidelines, SOPs, and further steps.

Strengthen product registration and market authorization function of DDA: PQM+ conducted a gap assessment of the registration and marketing authorization function based on the existing legal procedures, resources, and GBT recommendations. Subsequently, PQM+ collaborated with DDA's drug evaluation and registration division to draft and finalize five SOPs related to the registration and marketing authorization function, as well as required provisions for adopting the CTD format that will support streamlining the documents submissions process for product licensing. PQM+ Nepal called in a regional expert to facilitate a training on the RBI and CTD evaluation approaches to 30 DDA and NML staff.

Strengthen RB-PMS of DDA: During the year, PQM+ supported DDA's Management Division to roll out RB-PMS nationally through its branch offices. This followed a preparatory workshop to develop the RB-PMS protocol and provide training on sample collection. PQM+ worked with DDA's central office and three branch offices to provide technical and logistic support for the collection of 282 samples from 78 brands of eight types of medicines. Further, PQM+ is assisting DDA to finalize the RB-PMS guidelines. DDA has approved four SOPs related to RB-PMS, which PQM+ helped develop, laying the foundation for RB-PMS institutionalization. PQM+ is continuing to develop training materials on RB-PMS that will aid regulatory authorities to implement RB-PMS moving forward. In addition, PQM+ supported one of the DDA branch offices to enhance documentation by installing a file storage optimizer/ document repository.

Support NML toward ISO 17025 accreditation: Based on an IDP created in PY3 to assist the National Medicines Laboratory in achieving ISO 17025 accreditation, PQM+ supported the following areas:

- Collaborated with NML to improve its warehousing capacity by upgrading its storage and handling systems of chemicals, reference standards, and medicine samples as well as reorganization of their inventories. The aim was to create an efficient, safe workspace.
- Worked with NML to finalize a corrective and preventive action (CAPA) plan based on the January 2023 five-day follow-up assessment on NML's ISO accreditation process. With PQM+ assistance, NML successfully conducted its first-ever internal audit and management review. Additionally, PQM+ facilitated SOP development and implementation. The program also supported installation of the repository system for proper document handling.

NML personnel take part in hands-on training.

- Facilitated training to NML technical personnel on six priority QA and analytical topics as well as on the ISO 17025:2017 lead assessor. PQM+ also actively helped develop a training curriculum focused on QA topics to build an effective training program at NML.
- Supported the enhancement of testing capabilities by acquiring essential testing equipment and accessories, namely a semi-micro balance with antivibration table, digital refractometer, F1 class weights, and a dissolution calibration tool kit. PQM+ also facilitated the procurement of pharmacopeias and assisted in proficiency test program participation.

Assist NML in the selection of private laboratories for outsourcing testing activities: To expand quality testing of medicines in Nepal, PQM+ completed baseline assessments of two private medicines testing laboratories using SATTA to comply with ISO 17025 requirements. PQM+ finalized assessment reports and CAPA plan after technical reviews with the laboratories.

Assessment of a private medicines testing lab.

Strengthen management information system of regulatory bodies: PQM+ is supporting DDA and NML to strengthen their information management system on the following areas:

- **Risk-based inspection tool:** PQM+ recently developed an RBI tool for regulatory bodies to conduct risk-based inspections. The home office has chosen DDA Nepal for user testing of the RBI tool. Presently, the home office is finalizing the RBI tool software after the initial user testing in three countries.
- **Making MedRS tool interoperable with DDA's information system:** PQM+ is coordinating the acquisition of source code to install the MedRS tool on DDA's local server to ensure interoperability with DDA's existing system. PQM+ is drafting an agreement with DDA to ensure integrity and sustainability for the supported tool.
- **Electronic data integrity management system at NML:** PQM+ has supported NML in installing and upgrading its server to host the laboratory information management system for ensuring laboratory analytical data integrity. PQM+ has completed the software installation process and user training.

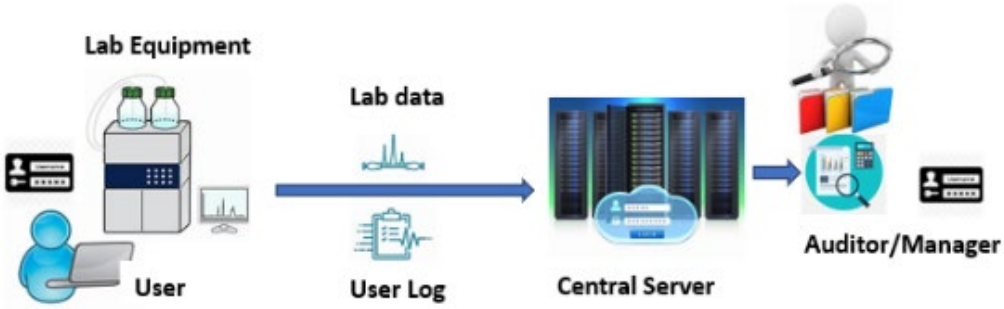


Illustration of the laboratory data management system at NML through a centralized server.

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

Develop five-year laboratory optimization strategy: After MoHP approval to develop NML's five-year strategy, the laboratory formed a steering committee to oversee and approve the strategy document and a working committee to provide direction in the strategy development process. PQM+ supported this process by helping draft the strategy through consultative meetings and interviews. Furthermore, PQM+ facilitated three working committee meetings to work on the strategy to receive feedback and review the draft. PQM+ collaborated with the working committee to draft a strategy that is now in review.

Participants discuss the laboratory optimization strategy.

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

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

Private manufacturers: In a bid to attain WHO prequalification for medicines such as azithromycin and zinc sulfate, PQM+ conducted CAPA follow-up of three manufacturers and supported them in product development. PQM+ facilitated acquisition of innovator samples of azithromycin (Zithromax by Pfizer) for the WHO prequalification process. With PQM+ engagement, the manufacturers have invested significant resources in upgrading their facilities and procuring active pharmaceutical ingredients (APIs) from WHO-qualified vendors and the necessary equipment to ensure compliant product development and stability studies. PQM+ signed a roadmap agreement with three manufacturers to attain WHO prequalification. PQM+'s regional expert visited Nepal to train manufacturers' personnel on advanced GMP topics, with 126 technical staff attending.

A trainer instructs private manufacturers on advanced GMP.

Public manufacturer: PQM+ is working with the country's only public pharmaceutical company, Nepal Ausadhi Limited (NAL), to achieve compliance toward national GMP certification. PQM+ conducted a reassessment of NAL to review its progress toward national GMP compliance. Additionally, PQM+ is supporting calibration, qualification, and validation of manufacturing equipment and facilities for GMP compliance and training of NAL personnel on validation.

Strengthening of local HTP manufacturers: PQM+ is assisting a health technology product (HTP) manufacturer of disposable syringes and blood collection tubes to attain ISO 13485 accreditation. PQM+ conducted a baseline assessment and CAPA follow-up reviews, after which the manufacturer addressed major nonconformities. Now the manufacturer is prepared to submit its document for accreditation application.

Left: BE center assessment at Kathmandu University.
Right: Local government health staff participate in a medicines quantity estimation exercise.

Support establishment and upgrading of the bioequivalence laboratory: PQM+ supported an assessment of two potential BE laboratories (Tribhuwan University and Kathmandu University) and made recommendations to function as a contract research organization (CRO) during a one-day finding-sharing and orientation session. PQM+ shared the assessment reports with the BE laboratories for development of IDPs.

Improve quality assurance in the supply chain of medicines in local government units: PQM+ is working with two local government units (LGUs) in Bagmati Province to ensure quality assurance in their annual procurement of medicines. PQM+ conducted an assessment on QA practices in procuring medical products for the two LGUs and facilitated workshops on medicines forecasting and quantification. With PQM+ advocacy, the local governments have formed quality assurance committees to ensure procurement of quality medicines and are incorporating additional QA clauses in their procurement tender. PQM+ is helping them develop SOPs for medicines procurement, receiving, storage, and distribution.

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

Increase awareness of SF medicines among public and health professionals: PQM+ supported DDA to air public service messages on SF medicines awareness through national radio stations and local stations in Koshi Province. In coordination with DDA, PQM+ is developing two infographic stickers targeting pharmacies and the customers with information on medicines quality assurance as well as awareness of SF medicines.

PQM+ partnered with the National Health Research Council to facilitate a session on "Promoting the Quality of Medicines in Nepal" at the annual summit of Nepal's health and population scientists. PQM+ presented on two topics—quality assurances in procurement and regulatory provision—to ensure the quality of medicines in Nepal as well as facilitated a panel discussion and Q&A sessions.

Left: A DDA branch officer facilitates a training on visually identifying SF medicines.
Right: Health professional council representatives meet with PQM+.

Training health professionals on visual identification of SF medicines: PQM+ completed the second phase of training with a post-training assessment to 48 community pharmacists on visually identifying SF medicines to assess changes in community pharmacists' knowledge and behaviors. This followed last year's first phase of training, which included a pre-training assessment. PQM+ has developed a training curriculum on visual identification of SF medicines. The curriculum is aimed at strengthening the capacity of health professionals (e.g., pharmacists, medical doctors, nurses, and paramedics) through their respective councils. Prior

to this, PQM+ facilitated a discussion with representatives of health professional councils on the course development.

Support the Nepal Pharmacy Council on establishing a CPD course: In a move to initiate CPD courses for its members, Nepal Pharmacy Council and PQM+ held few formal and informal discussions on the development of CPD course requirements. The Council requested PQM+ for the development of the course, which could be taken online through their website. Similarly, the Council formed a three-member committee to collaborate with PQM+ on the development of CPD courses. PQM+ will be employing the visual identification of SF medicines training curriculum to develop the first CPD course.

Strengthen stakeholders' coordination through DDA to combat the circulation of SF medicines: PQM+ supported DDA's Birgunj branch office to organize a workshop to strengthen stakeholders' coordination and collaboration to combat the circulation and proliferation of SF medicines in its custom border areas. AT the DDA-facilitated workshop, representatives from customs, local government, district administration, and civil society shared experiences in controlling SF medicines. PQM+ is assisting DDA to implement a border coordination framework agreement to ensure coordination among government agencies.

Participants at a stakeholder coordination meeting in Birgunj address the proliferation of SF medicines.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Support the DDA and MoHP to develop or revise official documents, such as revising the national guidelines on safe disposal of unwanted pharmaceuticals, drafting a Nepal Pharmaceutical Manufacturing Strategy, and finalizing the National Medicines Laboratory Five-Year Strategy and Action Plan.
- Support DDA to organize a policy dialog meeting among broad stakeholders on reforming the pharmaceutical sector, as well as assist DDA to strengthen stakeholders' coordination mechanism to combat the proliferation of SF medicines at vulnerable border points.
- Assist private manufacturers in the product development phase for WHO prequalification of azithromycin and zinc sulfate and assist the public manufacturer to address GMP nonconformities.
- Continue to assist DDA to implement and institutionalize risk-based approaches in post-marketing surveillance and inspection of manufacturers.
- Support and prepare NML to apply for ISO 17025 audit.

- Strengthen quality-assurance mechanisms in local governments' procurement cycle in purchasing essential medicines.

Pakistan

In Pakistan, provision and access to quality health services is a major concern. Health regulations (particularly drug regulations), strengthening the drug testing labs network (at the federal and provincial levels), availability of centers to conduct reliable bioequivalence studies reduced confidence in the efficacy of generic medical products manufactured in the country, are some key technical areas to address for achieving long-term health targets and sustainable economic development. Inconsistent government policies for the pharmaceutical sector have undermined the private sector's potential role in improving health outcomes.

PQM+ Pakistan 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.

Highlights of Progress During Program Year 4

- Supported DRAP in developing and implementing 50 IDPs and assisted during the WHO observation audit, followed by a full GBT assessment.
- Supported drug testing laboratories (DTLs) in Multan, Lahore, and Rawalpindi on the WHO prequalification process, providing technical assistance on their preparation for WHO's assessment. PQM+ assisted during WHO's final assessment and development of a CAPA plan afterward. As a result of PQM+ support, DTL Rawalpindi, DTL Multan, and DTL Lahore have achieved WHO prequalification status.
- Continued supporting manufacturers for the WHO prequalification process. As a result of extensive PQM+ support, Manufacturer #5 achieved WHO prequalification status for its zinc dispersible tablet and zinc oral suspension, the first product globally that received WHO PQ for oral suspension. PQM+ supported other manufacturers in the implementation of CAPA plans to address gaps and assisted them in identifying potential sources of APIs and reference products for developmental studies.
- Conducted training for the National Quality Control Laboratory for Biologicals and for provincial DTLs in collaboration with the Biopharmaceutical Analytical Testing Laboratory at Northeastern University (BATL). PQM+ collaborated with the Pakistan Pharmaceutical Manufacturers Association (PPMA) for capacity building of the pharmaceutical industry on the quality risk management approach in regulatory inspections based on WHO and PIC/S guidelines.

Objective 1: Governance for medical product quality assurance systems improved

Activity 1.1: Develop a national medicine implementation plan. In August, a technical working group meeting on National Medicine Policy convened in Islamabad. The TWG comprises representative from all stakeholders and included high-ranking health managers and decision-makers from federal and provincial governments, including Gilgit-Balistan (GB) and Azad Jammu and Kashmir (AJK), as well as industry leaders, medical and pharmacy experts, and educators. The TWG deliberated on a comprehensive action plan for implementation of

interventions on all six technical aspects[17] of the national medicine policy. The final national medicine policy implementation plan has been handed over to the Ministry of National Health Services, Regulation, and Coordination (MoNHSRC). Activities included:

- A consultative workshop on the draft national medicine policy implementation plan.
- Finalization of the national medicine policy implementation plan.

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

Activity 2.1: Continue technical assistance to DRAP to address gaps identified in its GBT assessment through the implementation of the IDP. PQM+ and DRAP organized a meeting with the senior leadership of health departments in Sindh and Punjab to discuss the draft letter of understanding between DRAP and the Sindh health department to increase collaboration, coordination, and communication on the crosscutting regulatory functions identified in the GBT for compliance with indicators. Both health departments appreciated the efforts by PQM+ and DRAP to enhance coordination and communication between federal and provincial regulatory bodies. Activities included:

- DRAP meetings with provinces on the implementation of IDPs.
- List of IDPs.
- Review of guidelines.

Activity 2.2: Continue support to DRAP for its accession to PIC/S. During the reporting quarter, PQM+ collaborated with the Pakistan Pharmaceutical Manufacturers Association to conduct a training session to build the pharmaceutical industry's capacity on PIC/S GMP standards. It also covered implementation of a quality risk management approach in preparing manufacturing facilities for regulatory inspections based on PIC/S and WHO GMP standards. PQM+ trained industry representatives to prepare for and undergo the WHO GMP audits for prequalification of products. The 125 participants included 41 women and 84 men representing the 32 pharmaceutical industry entities. DRAP has submitted an application to the PIC/S secretariate and its PQM+ trained inspectorate division is working to implement the CAPA guidance.

Participants gather at the end of a training session on the quality risk management approach in regulatory inspections based on PIC/S and WHO guidance.

[17] Access to essential medicines; regulations, safety, and quality of medicine; manufacturing and supply chain; rational use of medicine; research, development, and innovation; and human resource development.

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

Activity 3.1: Continue supporting NQCLs to streamline information sharing and reporting mechanisms for SF medical products. PQM+ developed a web-based interface to share regulatory information between DRAP and provincial quality control laboratories for PMS testing of medicines. PQM+ trained DTL staff on using the interface for data sharing. This tool has enabled DRAP to strengthen the market surveillance and control function of the national regulatory system through real-time sharing of regulatory information and decision-making, in accordance with WHO GBT. Activities include:

- Development of the PIRIMS interface.
- Development of an SOP for use of the interface.
- Training DTL staff on using the interface.

Activity 3.2: Continue to support NQCL to develop a lot release system for vaccines. PQM+ conducted a gap assessment of the National Control Laboratory for Biologicals (NCLB) on ISO 17025. PQM+ identified six very serious and 18 essential-level deficiencies related to gaps in the laboratory quality management system, calibrations and qualification, infrastructure of the microbiology lab, measurement of uncertainty, internal audits, equipment management, good documentation practices, and trainings of staff. In the event of closeout, PQM+ will conduct trainings of NCLB staff to build their capacity for sustainability. Activities include:

- Training NCLB staff on lot release of biologicals.
- Mock assessment of NCLB on ISO 17025 QMS standards.
- Development of a CAPA plan.

Activity 3.3: Provide TA to selected labs to acquire ISO 17025 accreditation/WHO PQ for testing methods of antimicrobial and maternal and child health products. PQM+ provided guidance and technical support to the CDL DRAP Karachi during the implementation of a CAPA plan to address all observations/deficiencies as identified in the WHO PQ inspection report. Of the WHO-identified observations, 95 percent have been addressed. Corrective and preventive action on one observation regarding the recruitment of technical staff is in the implementation process. The CAPA implementation report has been submitted to WHO, which scheduled a follow-up visit for onsite verification of the CAPA implementation.

PQM+ provided technical support to DTL Bahawalpur staff on developing and implementing a CAPA plan against deficiencies observed during a mock inspection, per WHO PQ lab guidelines. The lab has submitted the corrective action plan to PQM+, which trained staff on implementing CAPAs and undergoing an expected WHO inspection in November.

PQM+ provided guidance and technical support to the NIH-appellate lab on the ISO 17025 standard, development and implementation of the laboratory quality management system, development and implementation of a CAPA plan against the gap assessment report, and selection of testing parameters for the accreditation scope. PQM+ experts provided guidance to NIH lab technical staff on the complete accreditation process by the Pakistan National Accreditation Council (PNAC) and the development of quality system documentation. Activities included:

- Implementation of CAPA at CDL and DTL Bahawalpur.
- Conducted mock audit for DTL Bahawalpur.

- Developed a quality management system at the NIH lab.
- Submitted an application to PNAC.

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

Activity 4.1: Provide TA to four selected manufacturers to achieve WHO PQ for quality-assured manufacturing of zinc and amoxicillin dispersible tablets (key MCH priority products). The PQM+ technical team supported Manufacturer #2 (a local manufacturer of amoxicillin DT) in the implementation of a corrective action plan against deficiencies mentioned in its gap assessment report, along with guidance about conducting a comparative dissolution profile of the target product. PQM+ also supported the manufacturer in facing the challenge regarding the failure of stability studies of the target product and provided a solution to move forward. Currently, Manufacturer #2 is working to manufacture a new bio-batch by using a different amoxicillin API source. In the event of closeout, PQM+ will train selected manufacturers on the WHO prequalification process, CAPA development, and other critical aspects including QMS, good documentation practices, and investigation of out-of-specification requests. Activities include:

- CAPA implementation.
- Preparation of CTD dossier for WHO submission.
- Training of industry on WHO PQ.

Activity 4.3: Continue to develop national capacity to conduct BE studies to assess the safety and efficacy of priority medical products. PQM+ reviewed the draft bioequivalence study protocol shared by the Institute of Biological, Biochemical, and Pharmaceutical Sciences (IBBPS)-Dow University of Health Sciences. Another selected BE center, the Center for Biological Studies and Clinical Research (CBSCR), has shared its protocol with PQM+ for review. PQM+ shared observations and suggested modifications in the draft protocol before sending it to DRAP for regulatory approvals to conduct a real-time BE study at IBBPS. This study will serve as a hands-on training of the IBBPS team on BE studies in accordance with international best practices. PQM+ has reviewed protocols from both BE centers and submitted them for the necessary regulatory approvals. Activities included:

- Training BE centers on BE protocol development.
- Development and review of protocols.

Priority Activities for Next Quarter

Next quarter, PQM+ plans to:

- Hold closeout meetings with stakeholders.
- Develop a closeout report.

Europe and Eurasia Region

Central Asia/Kazakhstan

PQM+ is strengthening the medicines regulatory system in Kazakhstan by providing technical assistance to the NCEM. The main objectives are to improve the medicines registration system; support medicines quality control laboratories (MQCLs) so they can test the quality of medicines reliably and accurately according to international standards; strengthen the GMP inspectorate; and prepare the country for accession to PIC/S, as well as to support the NCEM in establishing an RB-PMS system.

Highlights of Progress During Program Year 4

- Assessed the readiness of Almaty and Karaganda MQCLs in preparation for a WHO PQ follow-up audit through conducting internal audits and providing feedback and necessary CAPAs, ensuring the correct implementation of previous recommendations, and updating SOPs.
- Supported the PIC/S working group in Kazakhstan through amending regulatory documents to align them with PIC/S requirements for licensing manufacturers and addressing quality defects, developing the Inspectorate's QMS, inspection coaching, and PIC/S application.
- Supported the NCEM in implementing RB-PMS through discussions with the Ministry of Health on the feedback from a virtual WHO GBT audit in May 2023 and proposing necessary legislative changes.

Progress in Quarter 4

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

PQM+ is providing technical assistance to Almaty and Karaganda MQCLs in preparing for the WHO PQ follow-up audit.

- In July, a PQM+ computerized system validation (CSV) expert visited the Almaty lab to conduct an IT infrastructure and computerized systems audit, verifying the correct implementation of the recommendations given during previous visits in preparation for the computerized systems component of the WHO PQ audit. Similar recommendations were given to the Karaganda lab during a teleconference with PQM+.
- In July, PQM+ experts assisted Almaty and Karaganda labs started implementation of newly developed and updated SOPs. They prepared a letter and notified WHO that they are ready for follow-up for the audit.
- In August, PQM+ held a four-day mock-up audit to assess the quality management and technical operations of the Laboratory for Quality Control and Standardization of Medicinal Products against the requirements of WHO Technical Report Series (TRS). 957, 2010 Annex 1: “WHO Good practices for pharmaceutical quality-control laboratories” (GPPQCL) and associated references to determine the capacity to perform physical chemical quality control testing of finished pharmaceutical products.

The PIC/S working group is amending the Public Health Code and other regulatory documents to calibrate them with PIC/S requirements for licensing manufacturers and handling quality defects.

- In September, two employees of the Inspectorate, one from the Committee and one from NCEM, took part in the Korea-ASEAN GMP Inspectorate Training and Conference in Seoul, South Korea. The invitation to this conference was received with the assistance of PQM+ and the trip was financed by PQM+.
- PQM+ is working with the Inspectorate to prepare for the WHO observing inspection as part of the WHO GBT, scheduled for November.

Following the virtual WHO GBT audit in May, the WHO GBT team provided feedback to NCEM on PMS.

- In August, PQM+ held a meeting with the Committee and NCEM team to discuss legislative changes and next steps on implementation RB-PMS.

PQM+ is helping establish the medical devices inspection unit and build capacity of the group, including training inspectors with a focus on ISO 13485.

- PQM+ reviewed NCEM's procedures for medical devices inspection, such as regulatory documents, SOPs, the inspections plan, and the inspection report and gave recommendations to improve them.
- In September, a PQM+ technical expert met with NCEM to discuss recommendations and is planning a coaching inspection for a local medical devices manufacturer in Q1.

PQM+ has identified a local QMS expert to work with the committee to establish QMS. The expert started working in close collaboration with the Committee.

- In Q4, a "standards-making" process map (algorithm and workbook) was developed. Changes to the licensing SOP and the corresponding order of the MoH were made. The draft is not signed yet.
- Work on the process of issuing registration certificates for medicines and medical devices is in process.
- Qualification requirements for employees of the Committee, to confirm their competence to carry out the function of NCEM control / supervision, is also under development.

While the QazVac site remains in progress, PQM+ worked with the NCEM to develop a lot release protocol for the imported vaccine.

- PQM+ reviewed the lot summary protocol (LSP) at QazVac for compliance with WHO requirements and the development of checklists for its review. PQM+ provided comments on QazVac LSP to NCEM.

In May 2023, the Government of Kazakhstan approved the procedure for the national registration of strategically important medicines that also includes TB medicines. In Q4, PQM+ worked with NCEM staff to start WHO CRP capacity building. Guidelines and SOP templates for the implementation of the WHO CRP were provided to NCEM. PQM+ will continue to support NCEM in implementing the WHO CRP.

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

In Q4, PQM+ continued working with IntraHealth to translate the foundational GMP eLearning modules. The translation of the modules is in process.

Priority Activities for PY5, Q1

Next quarter, PQM+ Kazakhstan plans to:

- Support the Almaty and Karaganda MQCLs toward WHO prequalification.
- Work with the Inspectorate on preparing for the WHO coaching inspection and the PIC/S application.
- Support the Committee and NCEM on implementation of RB-PMS and provide training on RB-PMS.
- Regularly meet with the top management of the Committee and NCEM to discuss progress in joint activities.
- Further support NCEM in preparation for the on-site WHO GBT assessment.
- Support NCEM on implementation of the WHO CRP procedure.

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.

Highlights of Progress During Program Year 4

- Engaged with the State Center in Tajikistan to assess its GMP inspection capacity development progress, conducted training on PIC/S requirements, proposed a roadmap for GMP inspection development, collaborated with the MRA on establishing a new GMP unit, and worked on updating the GMP e-learning modules and translating them to Russian.
- In partnership with Avicenna Tajik State Medical University (ATSMU) and Purdue University, developed a course schedule for ATSMU's pharmacy division to strengthen the faculty's capacity building and curriculum strengthening.
- Facilitated the registration of WHO-prequalified TB medicines in Tajikistan through collaboration with manufacturers and a local registration company, resulting in the successful registration of nine first-line TB medicines in PY4, followed by the engagement of additional manufacturers and submission of dossiers for five more TB medicines. This marked the first registration of WHO-prequalified TB medicines in Tajikistan.
- Continued assisting the State service in enhancing its medicines registration system, including the establishment of a TWG and the development of SOPs for screening applications and evaluating assessments based on a PQM+ assessment, highlighting the need for improvements in the regulatory process and communication within the registration system.
- PQM+ assisted the State service in addressing the vulnerability of hard copy product dossiers by establishing a registration information management system (RIMS) that includes digitization and electronic organization with backups. Progress in PY4 included initiating discussions, adapting the RIMS software, completing adaptation, and internal testing and demonstration of the RIMS module to the MRA.

Progress in Quarter 4

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

PQM+ continued to support the MRA on the registration module of the RIMS, which will include a function of digitization and electronic organization with proper backups of submitted dossiers. Accomplishments included:

- Developed specifications for IT hardware for central servers' system and networking devices procurement and installation.
- Completed internal testing and demonstration of the RIMS to the MRA, which is testing the system's capabilities.

PQM+ increased the number of dossier submissions to support increased registration and availability of quality-assured TB medicines. The MRA finalized revision of the submitted dossiers and issued invoices for payment for five additional TB medicines: isoniazid H100, ethambutol E100, RHZ 75/50/150, isoniazid H300, and linezolid 600mg.

PQM+ supported the Dushanbe MQCL to increase compliance to ISO 17025 standards through trainings, CAPA, and SOP development, in addition to providing equipment to expand medicines testing. Accomplishments included:

- Provided a training comparing the old and new versions of ISO 17025 to laboratory staff.
- Supported the Dushanbe MQCL in developing a CAPA plan. In Q4, the MQCL received ISO 17025:2017 accreditation.
- Received approval from MQCL management on the developed SOP on complaints.
- Delivered a dissolution tester to the MQCL to support increased laboratory testing capabilities.

PQM+ collaborated with the MRA to develop a roadmap highlighting key areas where improvements in GMP are necessary. Accomplishments included:

- Continuing support for the 12-month transitional period to the MRA's newly established GMP unit to transfer all relevant competences to this unit, which the roadmap highlights.
- Provided a Russian version of GMP Guide (published in Kazakhstan) and PIC/S version of GMP Guide based on changes to the latest PIC/S version that were only in English.

Priority Activities for PY5, Q1

- Procurement of IT hardware and networking devices for central servers' system.
- Complete registration of five second-line TB medicines.
- Conduct the training on the correct use of the dissolution tester to the MQCL staff.
- Teach courses at ATSMU according to the approved schedule.
- Update and approve the GMP guide.
- Continue repackaging the Foundations of GMP modules.

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.

Highlights of Progress During Program Year 4

- Restructuring of the Agency for Pharmaceutical Industry Development (the Agency) split into the MRA, now under the Ministry of Health and named the Center for Pharmaceutical Product Safety (CPPS). The Agency, with its mandate to advance pharmaceutical industry development for Uzbekistan, is also undergoing changes.
- Hosted the Minister of Health of Uzbekistan at the USP office in Rockville, Maryland. PQM+ discussed PQM+ technical assistance with the CPPS delegation that traveled with the health minister.
- Finalized the "pharmaceuticals and medical devices" strategic block of the MoH's Health Strategy 2030.
- Completed a literature review and in-depth interviews with stakeholders to inform the Pharmaceutical Manufacturing Strategy for Uzbekistan.
- Organized a training on Preparation of Registration SOPs for the CPPS staff, building their capacity to prepare and review SOPs for registration of medicines.
- Both MQCLs, Tashkent and Andijan, received ISO 17025 reaccreditation confirmation from the national accreditation body, which is now internally recognized given the national accreditation center's International Laboratory Accreditation Cooperation membership. PQM+ provided technical assistance to both MQCLs through this reaccreditation process by guiding their preparation for the inspection visit and reviewing the MQCL's CAPA to the National Accreditation Center. PQM+ facilitated training sessions for both laboratories to strengthen their QMS as part of the CAPA.
- Provided training for the MRA staff on PMS and MedRS in Tashkent, with an overview of the RB-PMS approach and a hands-on training on using the MedRS tool.
- Purdue University designed and launched training for the faculty member of the Pharmaceutical Technology University on regulatory and quality areas.
- Through a local vendor, PQM+ conducted GMP training for manufacturers, with three of eight modules completed.
- Manufacturer #22 completed the protocol for biowaiver lot and batch manufacturing report; manufactured a biowaiver lot, and completed stability investigations. They also finalized a biowaiver report, which will be part of the WHO PQ dossier for levofloxacin.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance system improved

The Medicines Regulatory Authority was named the Center for Pharmaceutical Product Safety (CPPS) and the head and his deputy were replaced again. The Agency for Pharmaceutical Industry development (Agency) also moved back into the Ministry of Health.

PQM+ completed an initial desk review of secondary literature on the pharmaceutical industry in Uzbekistan. The review informed interviews with 24 stakeholders, including pharmaceutical manufacturers, academia/ institutes, the NMRA, and policymakers. PQM+ is consolidating findings from the interviews. Next quarter, PQM+ will develop draft recommendations and share them with the key stakeholders in a validation workshop.

PQM+ participated in the first-ever Uzbek-U.S. Health Forum in Tashkent in September. USAID signed a new memorandum of understanding with the Government of Uzbekistan to expand access to safe and quality TB and other medicines in Uzbekistan. PQM+ Program Director Jude Nwokike delivered a keynote speech at the event. PQM+ also presented at the pharmaceutical sector breakout session on the key considerations for pharmaceutical manufacturing and regulatory sector development.

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

PQM+ completed an in-person assessment of Tashkent MQCL: specifically evaluating its readiness for WHO PQ. Tashkent MQCL aims to achieve WHO PQ by 2025. PQM+ also facilitated two training sessions for the MQCLs to strengthen their QMS on designing and operationalizing processes through the development and revision of SOPs.

PQM+ partner Purdue University continued to provide modules on quality and regulatory areas to the faculty of the Pharmaceutical Technology University. The modules were initiated in Q3. After completion of six modules, there was a two-week pause to reassess how the students are doing. After a short student survey of the students, the modules resumed in Q4 for completion in September.

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

In Q4, PQM+ through local company Vialek, selected after a procurement process, started training manufacturers in Uzbekistan on several GMP topics, including eight modules. PQM+ has completed the first three modules on GMP rules, pharmaceutical quality system, personnel, and outsourcing activities; documents, records, and data integrity; and Infrastructure. The remaining five modules will be completed by December. Representatives of 18 private pharmaceutical manufacturers participated in the trainings. These manufacturers account for more than 70 percent of local market turnover. Moreover, employees from the Agency and teaching staff of the Tashkent Pharmaceutical Institute participated in these trainings.

- PQM+ continues to work closely with Manufacturer #22 to prepare the dossier for levofloxacin for WHO PQ. The manufacturer is working on a biowaiver report denoting that the product does not require bioequivalence study. The biowaiver report will be part of the WHO PQ dossier. The manufacturer and PQM+ hosted several USAID

delegations, including the Deputy Assistant Administration for the Asia Bureau, Anjali Kaur, for a site visit to the manufacturer to showcase PQM+ and the company's collaboration.

- In collaboration with IntraHealth International, PQM+ continues to update and repackage the Foundation of Good Manufacturing Practices e-learning modules into Russian for the Central Asia region. PQM+ is in the process of translation and review of the GMP modules into Russian.

Priority Activities for Next Quarter

Next quarter, PQM+ Uzbekistan plans to:

- Continue to work with Tashkent and Andijan MQCL to bring their CAPA and internal audit in line with WHO PQ requirement.
- Continue technical assistance to the Agency on compliance to QMS 9001:2015.
- Continue technical assistance to Manufacturer #22 for dossier preparation and readiness to submit to WHO PQ.
- Continue registration of WHO prequalified TB medicines.

Uzbekistan – Diversifying the Asia Pharmaceutical Supply Chain (DAPSC)

PQM+ held several meetings with USAID to prepare for the DAPSC assessment visit to Uzbekistan. A team of PQM+ team and USAID traveled to Tashkent in August 2023 and met with several stakeholders such as the government agencies, manufacturers, and others to inform the work planning for DAPSC. PQM+ is preparing an outline for proposed activities for DAPSC for Uzbekistan for submission to USAID.

Latin America and the Caribbean Region

Panama

PQM+ in Panama has been tasked with strengthening the country's laboratory and testing capacity to improve its ability to ensure medical product quality and developing or revising curricula for relevant departments at the University of Panama to institutionalize and standardize information and requirements to sustainably ensure and prepare the regulatory workforce.

To achieve this, PQM+ collaborates with key stakeholders, including the National Secretariat of Science, Technology, and Innovation (SENACYT), the main stakeholder coordinating the implementation of the action plan for local pharmaceutical development and manufacturing; Panama's national medicines regulatory authority (Dirección Nacional de Farmacia y Drogas [DNFyD]); the national quality control laboratory (Instituto Especializado de Analisis [IEA]); the University of Panama's Pharmacy Department; and others.

Highlights of Progress During Program Year 4

- To support the IEA, PQM+ initiated the revision of the laboratory's quality management system (QMS) manual, the overall guiding document that defines the laboratory's quality system and provides the framework for its design and implementation. The manual is expected to be finalized during PY5, Q1.
- Conducted a training on good laboratory practices for pharmaceutical-quality control laboratories and general requirements for certification of the competence of testing and calibration laboratories (ISO 17025:2017). The 48 participants (34 women, 14 men) represented the IEA and other organizations, including DNFyD, scientific research body under SENACYT (referred to by its Spanish acronym INDICASAT), and the University of Panama-Department of Pharmacy.
- Conducted 10 QMS training sessions to assist the development of 10 SOPs, five of which IEA prioritized to receive PQM+ support for finalization. By prioritizing these documents, the laboratory is ensuring a solid foundation for their quality control process.
- Assisted the revision of DNFyD's pharmaceutical product registration and renewal guide, including the requirements from the IEA, allowing DNFyD to align the dossier requirements to Panama's latest legislation and international best practices

Progress by PQM+ Objective

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

From March to April 2023, PQM+ conducted a rapid assessment of DNFyD and IEA to identify areas for improvement under the marketing authorization and laboratory testing regulatory functions. Following the rapid assessment, PQM+ provided recommendations for areas of improvement. It is critical that DNFyD conduct a self-benchmarking of its entire regulatory system to identify its current status, strengths, and areas for improvement to advance to ML 3. In Q4, PQM+ facilitated several separate and combined meetings with the DNFyD and IEA to promote coordination among the institutions and build common understanding around the GBT assessment process and its importance to help the country achieve its goal of strengthening the country's regulatory system. The DNFyD scheduled its GBT self-assessment, to be assisted by

the Pan American Health Organization (PAHO) in November. DNFyD requested PAHO's approval for PQM+'s participation as an observer throughout the assessment.

PQM+ also conducted a 3-day in-person training focused on:

- Good regulatory practices.
- Good review practices.
- Requirements for registration based on the Common Technical Document.

A total of 47 Marketing Authorization Department staff (32 females and 15 males) attended the training.

Priority Activities PY5, Q1

Next quarter, PQM+ plans to:

- Assist IEA in finalizing the laboratory's QMS manual and pending SOPs.
- Assist DNFyD in finalizing two assessment reports with checklists for the marketing authorization and renewals processes.
- Participate as observer during the PAHO-assisted GBT self-assessment, upon final approval.

COVID-19

Bangladesh

Laboratory Systems

In Bangladesh, PQM+ is working with the National Control Laboratory (NCL) to build its capacity to test personal protective equipment (PPE) at its newly established medical device testing laboratory. PQM+ procured four pieces of equipment (mask and respirator breathing resistance tester, universal tensile strength tester, medical gloves hole detector for quality testing of PPE; and paramagnetic oxygen analyzer for oxygen concentration testing to ensure the regulation system of medical oxygen). These will expand the NCL's testing capacities for the medical devices laboratory as a whole. During the previous quarter, the lab received and successfully installed three pieces of equipment (mask and breathing resistance tester, universal tensile strength tester, and medical gloves hole detector) that were procured by PQM+. In July, the NCL received the paramagnetic oxygen analyzer, also procured through PQM+.

In Q4, PQM+ supported the lab to develop SOPs for the three pieces of newly installed equipment. In July, PQM+ conducted a training session for seven NCL technical staff (two women, five men) on the equipment. The training session focused on teaching NCL analysts the scope of testing parameters and the standard methods of medical mask testing. NCL analysts acquired the skills to operate the equipment and gained the capability to train future staff members. Additionally, they learned to prepare samples according to the standard methods before loading them into the machine, ensuring the quality of the analyses conducted on PPE.

In July, PQM+ conducted the identification test of COVISHIELD vaccines using an RT-PCR machine along with four dedicated NCL technical staff and achieved the desired result. The test confirmed the identity of the vaccine sample, which DGDA sought in relation to an AEFI report.

COVID-19 Therapeutics (Test to Treat/T2T)

Policy, Planning, and Coordination

PQM+ is providing technical assistance across several countries to introduce and refine a COVID-19 T2T service delivery model using the currently authorized antiviral medications (nirmatrelvir/ ritonavir [Paxlovid] and molnupiravir). Manufacturing constraints and a complex regulatory pathway from licensing to market authorization/prequalification result in a protracted timeframe for availability of generic medicines, including these oral antivirals. PQM+ has contributed to the USAID-introduced test-to-treat (T2T) program in 10 priority countries[18] by facilitating product authorization or registration of COVID-19 therapeutics (Paxlovid and Lagevrio and their respective WHO-prequalified generic versions, nirmatrelvir/ritonavir co-packaged tablets and molnupiravir capsules). The highlighted cells in the table below indicate progress during Q4.

[18] Bangladesh, Botswana, Cote D'Ivoire, El Salvador, Ghana, Lesotho, Malawi, Mozambique, Rwanda, and Senegal

Country Name	Molnupiravir		Nirmatrelvir/ritonavir	
	Movfor - Hetero	Lagevrio - Merck	Nirmacom - Hetero	Paxlovid - Pfizer
Bangladesh	N/A	-	N/A	-
Botswana	Registered (July 2023)	-	Submitted (May 2023)	-
Cote d'Ivoire	Rejected (August 2023)	Registered (Unknown)	-	-
El Salvador	Submitted (October 2021)	EUA (Unknown)	Submitted (April 2023)	-
Ghana	Registered (November 2022)	Registered (2022)	Submitted (May 2023); Regulatory requests submitted (September 2023)	Registered (December 2022)
Lesotho	Emergency Use (January 2023)	N/A	Emergency Use (May 2023)	Emergency Use (May 2023)
Malawi	Registered (April 2023)	-	Registered (May 2023)	-
Mozambique	Submitted (Unknown)	-	-	-
Rwanda	Submitted (December 2021)	-	-	EUA (no longer active)
Senegal	Approved, Pending Certificate (May 2023)	-	-	-

In Q4, to assist NMRAs in LMICs in making informed regulatory decisions on their market authorization, PQM+ conducted a comprehensive review of regulatory and scientific documents that can be used to support the assessment of the quality, safety, and effectiveness of nirmatrelvir (co-packaged with ritonavir) and molnupiravir. PQM+ then prepared a scientific and technical information package for these medicines, which are used to prevent serious disease and death in high-risk populations when administered early in a COVID-19 infection. The information is also useful for manufacturers/applicants, procurement agencies, donor communities, and health care providers. The information package is organized by categories, namely, General Information on COVID-19 and Treatments (Package 1); followed by specific information related to nirmatrelvir (co-packaged with ritonavir; Packages 2A-C) and molnupiravir (Packages 3A-C). The final information package has been posted on the PQM+ website.

Finally, in Q4, PQM+ continued to work with its two identified manufacturers, India Manufacturer #6 and Pakistan Manufacturer #12, on the development of nirmatrelvir/ritonavir. During Q4, both were being supported by PQM+ to cost-share for the procurement of roller compactor equipment. This equipment is necessary to process nirmatrelvir/ritonavir, due to certain niche and moisture-sensitive manufacturing processes to form granules of the product. Due to loss of market share potential, India Manufacturer #6 decided to halt all development activities indefinitely. PQM+ is no longer working with this manufacturer. In addition to a roller compactor, Pakistan Manufacturer #12 was being supported with cost-sharing of API procurement. In lieu of cost-sharing on both the roller compactor and API for the company, PQM+ determined the most efficient procurement approach to be full procurement of the roller compactor only. PQM+ and Pakistan Manufacturer #12 are working on the roller compactor procurement and logistics for its delivery from China.

Ethiopia

Cold Chain and Supply Logistics

In Ethiopia, PQM+ is supporting EFDA to build capacity in cold chain regulation for vaccines. Under its previous American Rescue Plan project, PQM+ Ethiopia conducted a cold chain regulatory inspection, which highlighted gaps in terms of compliance to international regulatory requirements and best practices. The findings showed non-conformities in staff technical capacity in GDP, GSP, good documentation practice (GDocP), and QMS implementation. One major finding PQM+ identified during the assessment was the poor cold chain equipment calibration/verification/maintenance system at the immunization facilities visited during the assessment. PQM+ started addressing this gap in Q3, and as a continuation of this technical assistance at the immunization facilities, PQM+ collaborated with the Ethiopian Metrology Institute (EMI) and provided calibration support. In Q3, PQM+ and EMI provided support to facilities located in Addis Ababa and Sheger cities. In Q4, PQM+ provided the same support to immunization facilities in the Diredawa and Jimma regions.

No.	Type of equipment	Location	Cold chain Equipment calibrated*
1	Refrigeration equipment	Addis Ababa/Sheger (Q3)	42
2	*Refrigeration equipment*	*Diredawa (Q4)*	*45*
3	*Refrigeration equipment*	*Jimma (Q4)*	*21*
		Total	**108**

This calibration of cold chain equipment work is important as it ensures that readings from cold chain devices, such as refrigeration equipment, are accurate, consistent, and reliable. This ensures that the vaccines and other medicines stored in these devices are high quality and safe for the public to use.

PQM+ is working to build regulatory and manufacturing workforce competency. As part of building the workforce's technical capacity, PQM+ has been supporting EPHI to have an internationally recognized (ISO/IEC 17025:2017) calibration laboratory so it can calibrate cold chain equipment at immunization facilities and contribute to the quality assurance of medical products, including COVID-19 vaccines, throughout the supply chain. In this regard, PQM+ collaborated with the Ethiopian Accreditation Service (a government body mandated to accredit testing, calibration, and inspection facilities) and the Ethiopian Metrology Institute (EMI) and trained eight EPHI staff (one woman, seven men) on the following key QMS topics:
1) requirements of ISO/IEC 17025:2017, 2) estimation of measurement, and 3) internal audit.

Training on these topics will help EPHI establish an ISO 17025 accredited calibration laboratory. Once accredited, it will generate technically valid and competent results consistently. This is important in improving the quality assurance of medical products in Ethiopia in a sustainable manner, as locally sourced, quality calibration is less cost-prohibitive than sourcing calibration from international vendors.

PQM+ collaborated with Ethiopian Pharmaceuticals Association (EPA) to develop and accredit a CPD course on detection, prevention, response, and communication of SF medical products, including COVID-19 vaccines. PQM+ and EPA provided the accredited course training to 47 pharmacists (14 women, 33 men). EPA will be able to deliver this course to pharmacists in the

future. Building the technical capacity of health professionals on detection, prevention, response, and communication is key to improving the regulatory system in the country.

Policy, Planning, and Coordination

PQM+ is working to strengthen coordination and alignment in regulatory practices between federal and regional regulatory bodies so they will be able to share experience, align their legislation/guidelines, and advocate for the quality of medical products. PQM+ is working with EFDA to conduct annual review meetings with regional regulatory authorities to discuss areas of collaboration in quality assurance of medical products. Since EFDA alone cannot meet its mission of protecting the public from the impact of SF products, PQM+ will work with the authority to create public awareness by hosting events using appropriate local media. During Q4, PQM+ provided support for the second biannual joint steering committee meeting between EFDA and regional regulatory authorities. The 123 regulators (28 women, 95 men) from the federal level and the regions met and communicated on challenges, ways forward, and areas for future collaboration. PQM+ presented on findings and interventions of an assessment last year to check compliance of the cold chain system against the national GDSP requirements.

PQM+ also worked with EFDA and the MOH's Expanded Program on Immunization (EPI) program of the Ministry of Health during the COVID-19 vaccination campaign in the Northern region of the country. PQM+ supported the distribution of vaccine data-capturing tools developed by EFDA/MOH, including AEFI reporting tools, to the vaccination sites. PQM+ also supported a community mobilization event to increase the awareness of the community on the safety of COVID-19 vaccines and enhance the public's confidence in vaccination. The radio message on the safety of COVID-19 vaccines was broadcast to the community for 10 days using the local radio station, with an estimated 2 million people reached.

Finally, PQM+ supported the annual conference of the Ethiopian Pharmaceuticals Association in supporting printing of the annual bulletin and delivered a keynote address during the conference related to the role of all stakeholders in the quality assurance of medical products, including COVID-19 vaccines. Coordinating and collaboration with professional associations and the public improves awareness on quality assurance of medical products and helps exchange information and evidence for mutual benefits.

Pharmacovigilance and Safety Monitoring

PQM+ is working to strengthen product quality defect reporting through adverse drug reaction (ADR) reporting. Ethiopia has a passive ADR monitoring system where health care providers voluntarily send ADR data and product defect reports, so medicines/vaccines quality issues (often caused by cold-chain storage problems) can be captured and reported in real time. One major gap PQM+ identified in a recent assessment of the country regarding the rollout of COVID-19 vaccines and the related AEFI reporting systems was that the country does not have a guideline or directive as part of the national immunization policy to compensate people who are affected by quality and/or safety problems from vaccines in general and COVID-19 vaccines in particular. In Q4, PQM+ provided technical support to the EPI at the Ministry of Health and EFDA to establish a technical working group comprising EFDA, EPI, and USAID's Global Health Supply Chain Program-Procurement and Supply Management program for the development of a vaccine injury no-fault compensation guideline. After finalization and MOH approval, the guideline will become law. The TWG has prepared a concept note to be endorsed by officials at the ministry as a preparatory phase for the guideline development. The vaccine injury no-fault

compensation guideline will help EPI provide fair, expedited compensation to those who suffer vaccine injury, further enhancing public confidence in the vaccination program.

In addition, PQM+ facilitated a causality assessment workshop in August in Bishoftu for 29 participants (22 men, seven women) from the national Pharmacovigilance Advisory Committee (PAC) and pharmacovigilance experts at EFDA. At the workshop, the PAC reviewed reports and classified three severe adverse events (SAEs) from COVID-19 vaccines and provided recommendations to the regulatory authority for an effective safety monitoring of vaccines and prevention of unnecessary patient harm. PAC used the WHO online causality assessment tool and categorized two of the three reports as indeterminate. One report was classified as consistent, which indicates a possibility of the adverse event being related to vaccination. Involving stakeholders and building their capacity on pharmacovigilance related activities helps get more accurate data that the regulator authority can use in evidence-based decision-making.

Laboratory Systems

PQM+ is supporting EFDA to increase the capacity of its quality control laboratories. EFDA has a medical devices testing laboratory aimed at testing the quality of medical devices before and after marketing authorization as part of its quality assurance process. Since 2014, the laboratory has been ISO/IEC 17025:2017 accredited for its male condom testing system based on support from PQM+'s predecessor program, PQM. The laboratory is just starting to test other medical devices like gloves, syringes, and rapid diagnostic tests (RDTs), and there is a need to build the quality management system in these areas so the medical device test results will be accurate, traceable, internationally recognized, and better protect the public from diseases like COVID-19 through evidence-based decision-making. PQM+ is supporting this activity both through COVID-19 and field support funding.

In Q3, the medical device laboratory was assessed by ANAB. After the assessment, ANAB confirmed that there was no nonconformance related to testing gloves and the medical device lab is now accredited for four key glove test parameters: 1) freedom from holes, 2) physical properties, 3) dimension test, and 4) powder residue. Now that EFDA's lab is accredited to perform quality tests of medical gloves, it can ensure that this crucial PPE meets the quality requirement to protect Ethiopians now and in future public health emergencies.

In Q4, inauguration of the glove testing laboratory's accreditation was conducted with all relevant stakeholders present, including Health Minister Dr. Lia Tadese. During the event, EFDA disseminated the impact of the glove lab accreditation. About 42.6 percent of PMS glove samples were found to be substandard and EFDA is now able to take regulatory measures, since the lab has developed confidence in its test results through the accreditation. Previously, EFDA was sending glove samples to overseas accredited laboratories, a more expensive mode of testing. Dr. Tadese recognized PQM+ for its technical and financial support. The quality assurance of laboratories plays a key role in generating accurate, precise, and internationally recognized data. This creates confidence to the regulatory authority to take relevant regulatory measures an protect the public health.

Ghana

Policy, Planning, and Coordination

PQM+ received Global Vaccine Access (Global VAX) funding to support the Ghana Food and Drug Authority (FDA) to acquire and operationalize a complete regulatory management system,

such as the IRIMS, which improves and streamlines regulatory processes. With an operational IRIMS, Ghana FDA can offer electronic services to its clients, increasing the consistency, transparency, and efficiency of its regulatory process and operations with which they manage client requests while also improving their quality management systems. Implementation of IRIMS will help Ghana FDA meet GBT indicator RS09.08 (the national regulatory authority uses computerized systems to process information, manage records, and analyze data). IRIMS will help improve the regulatory oversight for all medical products, including COVID-19 vaccines, by increasing the standardization of regulatory processes. An improved regulatory system will provide the necessary confidence among stakeholders that regulation of COVID-19 vaccines is done effectively. Between Q2 and Q3, PQM+ completed the IRIMS feasibility study for FDA Ghana and worked with the agency to define the specifications for the type of system that will best suit their regulatory operations and existing information communication technology (ICT) infrastructure. In Q4, PQM+ completed the technical and financial evaluation of the bids submitted by potential vendors for the IRIMS, with input from FDA Ghana. In September, PQM+ and FDA Ghana selected a vendor whose proposal best met the project budget and the IRIMS scope of work (SOW) developed in Q3. PQM+ issued a purchase order (PO) for an IRIMS system that covers the following modules:

- Product Registration Module
- Premise Registration Module
- GMP Inspection Module
- Import Export Module
- Controlled Drugs Module
- Post-marketing Surveillance Module
- Pharmacovigilance Module
- Disposal Module
- Clinical Trial Application Module
- Promotion and Advertisement Module

The IRIMS also addresses basic administrative functions such as user management, document management, reports, and dashboards. The selected vendor has designed and developed IRIMS for five national regulatory authorities in Africa (Tanzania, Zambia, Rwanda, Uganda and Botswana). The cost of the IRIMS for FDA Ghana is being supplemented by the COVID-19 supplemental funding. PQM+ has kicked-off the project to install the IRIMS with a proposed implementation plan developed by the vendor.

PQM+ is also working with vaccine manufacturers to build their capacity in local production of vaccines. Ghana's prospective vaccine manufacturer, DEK, broke ground for the construction of its manufacturing facility in April 2023. The workforce recruitment process has begun and is ongoing. DEK requires technical advice and assistance to establish GMP for sterile manufacturing of biologics/vaccines. Atlantic Life Sciences (ALS) is a local manufacturer already supported by PQM+ for the manufacture of the oxytocin injection. Its vaccine fill and finish facility infrastructure is complete, its clean room facilities are ready, electrical installations completed, equipment installed and qualified and heating, ventilation, and air conditioning (HVAC) systems are also installed and functional. While ALS has not prioritized production of COVID-19 vaccines, it is currently Ghana's only biological products manufacturer and PQM+ has offered technical assistance for biomanufacturing capacity building interventions. In Q4,

PQM+ conducted a training for FDA Ghana and the two upcoming vaccine manufacturers on product dossier submission using the eCTD format. As Ghana strives toward adoption of an IRIMS to facilitate its regulatory process for information exchange/ transmission, manufacturers need to be prepared to submit their dossiers in a compatible format. The focus of this training was to help the manufacturers prepare for the selection and acquisition of an electronic regulatory submission (eRS) software system. In the first section of the training, the focus was on the evolution of CTD dossier to the eCTD format. The second part of the training focused on how to select an eRS system, which is an essential component of a modern medical product sponsor's ability to submit product applications to export to markets where eCTD the accepted submission mode. Thirteen technical staff (four women, nine men) from DEK, ALS, and FDA Ghana participated in this five-day training on electronic submission of the CTD dossier. The training ensured that DEK and ALS staff would be able to build a CTD-compliant submission package by understanding the requirements to convert from CTD and non-CTD to the eCTD format and to understand the criteria to be used for evaluating software vendors. In addition, the training will help both manufacturers to build a clear process during submission which will include inputting of the appropriate contents/documents into the respective module, sections, or subsections. FDA Ghana's participation in the training provided an opportunity to build its own capacity in preparation of their adoption and implementation of the IRIMS solution for modernizing regulatory process and e-transmission of information.

Pharmacovigilance and Safety Monitoring

PQM+ is supporting the Ghana FDA to advocate for improved safety reporting at the lower-level facilities – clinics, community-based health planning and services (CHPS) zones, and health centers. FDA Ghana is at WHO ML 4 for vigilance, indicating that it applies existing processes for pharmacovigilance in line with international best practices. During its active surveillance of AEFI from COVID-19 vaccination implemented in 2021/2022 with technical assistance from PQM+, most recorded AEFIs were reported through deliberate follow-up by the study team, which is costly and difficult to sustain. Improving spontaneous reporting will reduce the need for active surveillance to be implemented, saving limited resources. However, this requires advocacy, especially at the lower levels of the public health system where reporting rates continue to be low. In Q4, as part of implementation of the strategy developed in Q2, and to supplement the training delivered to more than 400 health care workers in Q3 on AEFI and ADR reporting for health care workers from eight regions (Eastern, Northeast, Upper East, Upper Western North, Greater Accra, and Savannah), PQM+ worked with FDA Ghana to disseminate the advocacy tools developed in Q3 – Med Safety App flyers, posters, banners, branded pens, and audio-visual advertisements. Between August and September 2023, PQM+ supported FDA Ghana to disseminate these audiovisual social and behavioral change communication tools on buses, schools, lorry stations, markets, roadsides, pharmacies, and public intercity transportation to educate and engage passengers to continue to spread the medicine safety messaging. In addition, PQM+ helped FDA Ghana reach a wider audience through community radio interviews, online news portals, and social media platforms such as YouTube. Through this sensitization and advocacy, FDA Ghana estimates that it reached about 120,000 people in its eight priority regions. In addition to the sensitization of the community health workers in Q2, this round of advocacy helped increase awareness among the targeted audience about medicine/health product safety, improved awareness and advocacy among stakeholders, and further enhanced the capacity of FDA staff in effectively communicating medicine/health products safety information.

Laboratory Systems

PQM+ received Global VAX funding to support Ghana FDA to strengthen the capacity of its laboratory to complete independent lot release of COVID-19 mRNA vaccines. Quality control testing laboratories that meet international requirements for best laboratory practices enable the regulatory authority to assess the quality of medical products. The regulatory authority needs this critical service to review applications for marketing authorization and variations to existing marketing authorizations, post-marketing surveillance, and lot release. Ghana's QC testing laboratory is ISO/IEC 17025 accredited for several parameters. This laboratory also has capacity to test some vaccine quality attributes, such as appearance, pH, sterility, and bacterial endotoxins. In 2021, through COVID-19 technical assistance funds, PQM+ procured laboratory equipment and supplies to enable the Ghana FDA QC laboratory to test the viral vector platform COVID-19 vaccines. However, the QC laboratory requires additional equipment, accessories, and consumables required for the QC testing of mRNA COVID-19 vaccines. Also, additional capacity building is needed to enable the QC analysts to test the COVID-19 vaccines per the manufacturers' methods. This quarter, the capillary gel electrophoresis system and cell-based flow cytometry system used in the testing of biological products, including as COVID-19 vaccines, that PQM+ procured for FDA Ghana, were delivered to FDA Ghana's Center for Laboratory Services and Research (CLSR). PQM+ coordinated with the vendor and FDA Ghana to plan the installation and operation qualification and user training, now scheduled for the second week of October.

Furthermore, in Q4, PQM+ developed the materials for the quality control training it plans to deliver to FDA Ghana's analysts to build their capacity for vaccine testing. The training designed by PQM+ will introduce analysts from the physicochemical, microbiology laboratory, and the proposed molecular biology laboratories to the theory of analytical techniques used for mRNA (and other) vaccines – western blotting, reverse transcriptase RT-PCR, mass spectrometry, HPLC, florescence/ultraviolet spectroscopy, enzyme-linked immunosorbent assay (ELISA), scanning electron microscopy, sterility testing and limulus amebocyte lysate (LAL) endotoxin testing. This will be followed by a hands-on training on selected analytical techniques using the newly procured equipment.

Mozambique

Policy, Planning, and Coordination

PQM+ received American Rescue Plan (ARP) funding to work with ANARME-IP to conduct RB-PMS for COVID-19 vaccines and therapeutics in Mozambique, as well as train ANARME-IP staff on COVID-19 vaccine dossier review, quality control testing, and emergency use authorization. Poor storage and transportation conditions potentially influence the quality of medical products available to patients and clients, compromise outcomes of treatment, and increase the risk of long-term morbidity and mortality from COVID-19. Additionally, the inadequate institutional and laboratory capacity of ANARME limits its capacity to effectively monitor the quality of COVID-19 medical products in the health system. PQM+ will provide technical support to ANARME-IP and its PMS TWG to develop an RB-PMS protocol for COVID-19 vaccines and therapeutic medical products, conduct samples collection, and utilize existing LNCQ capacity for quality control (QC) testing to support quality assurance of COVID-19 medical products. In Q4, PQM+ provided technical support to ANARME-IP on the implementation of RB-PMS and review of key documents related to PMS. Additionally, PQM+ provided training to 26 (17-F, 9-M) members of the multisectoral PMS TWG in the

implementation of RB-PMS and the use of the online Medicines Risk-based Surveillance (MedRS) Tool (that incorporates vaccines risk-scoring). Although there was a de-classification of COVID-19 as a public health emergency, leading to the de-prioritization of COVID-19 related activities, PQM+ employed a holistic systems strengthening approach; building the capacity of the PMS-TWG to conduct PMS activities for the broader medicinal and health products portfolio.

In addition to supporting ANARME-IP's in RB-PMS, as part of the capacity development strategy for ANARME,IP towards achievement World Health Organization Global Benchmarking Tool Maturity Level 3 (WHO GBT ML3) and maintaining ISO 9001:2015 certification, PQM+ continued to engage with the ANARME-IP Division of Evaluation of Medicines, Biologicals and Health Products to develop a training package to improve capacity for vaccines and biologicals dossier review and product registration with a focus on emergency use authorization. Due to competing priorities at ANARME-IP, the training was rescheduled for the month of November 2023.

Laboratory Systems

PQM+ works with the LNCQ to effectively support RB-PMS activities for COVID-19 vaccines and therapeutics. LNCQ requires the necessary testing capacity that ensures generation of valid and reliable results. PQM+ has been supporting the LNCQ to strengthen its capacity for compendial testing and close the gaps identified in the roadmap toward ISO 17025:2017 accreditation as part of the laboratory systems strengthening assistance. In Q4, PQM+ subject matter experts provided a practical, hands-on training to the LNCQ technical personnel in the use of the pharmacopeia and in compendial testing techniques for medicines quality testing. Additionally, PQM+ supported the delivery and installation of a water purification system and refrigerators to support sample testing and storage. PQM+ supported the repair, maintenance and calibration of various equipment including Karl Fisher titrators, automatic titrators, and pH meters. The material necessary for the repair and calibration of the HPLC, dissolution apparatus, UV/Vis Spectrophotometer have been received in-country and are awaiting scheduling of the works by the services provider. In addition to ensuring the capacity of the LNCQ to provide reliable and valid test results, these investments also aim at preparing the laboratory for ISO/IEC 17025:2017 accreditation, a great milestone for ANARME,IP, and supporting ANARME-IP in the progress toward WHO GBT ML3, in turn ensuring that it can perform necessary quality testing on COVID-19 products in the future.

Nigeria

Policy, Planning, and Coordination

PQM+ received Global VAX funding to support Nigeria's NAFDAC to update its existing guidelines for imported COVID-19 vaccine regulation, laboratory testing, vaccine manufacturing site inspections, and post-approval changes of COVID-19 vaccines. In collaboration with NAFDAC, PQM+ conducted the closeout event for Global VAX, Nigeria. This ended the implementation of this project, spanning June 2022 – September 2023. A total of 45 stakeholders (25 males, 21 females) attended the close-out event. The stakeholders included delegates from the four directorates in NAFDAC: Registration and Regulation (R&R), Drug Evaluation and Research (DER), Port Inspection (PID) and Vaccines, Biologics and Medical Devices- Laboratory Service Directorate (VBM-LSD). Stakeholders from the Federal Ministry of Health (Food and Drug Services) were also in attendance. The close-out event provided an opportunity to present the work done and showcase the progress achieved as a result of Global VAX project implementation in Nigeria.

Laboratory Systems

PQM+ is also working to strengthen NAFDAC's laboratory testing function for vaccines. PQM+ is supporting the lab to develop, review, and revise new and existing laboratory procedures focused on vaccines. This quarter, PQM+ conducted two training courses. The first was on general laboratory management for 12 NAFDAC's vaccine laboratory unit staff (10 men, two women) including technicians, clerks, and attendants in August. Topics included an overview of the quality management system; overview of good laboratory practices; GDocP/record management; management of laboratory equipment; handling of laboratory reagents/chemicals; laboratory housekeeping; disinfectants for laboratory use; introduction to laboratory safety manual; handling of test items for analysis; cold chain practices in the laboratory; cleaning and housing of laboratory animals; handling of laboratory animal waste; laboratory personnel health; vaccination for lab staff; and laboratory design and safety measures.

PQM+ also provided theoretical training for 25 NAFDAC staff (18 men, seven women) in September. The trainee group comprised analysts, technicians, biomedical engineer, quality assurance, and support staff. Training topics included methods for flow cytometry, fluorometry, and agarose gel electrophoresis on new equipment NAFDAC procured for its lab (flow cytometer, Agarose Gel Electrophoresis System and Qubit fluorometer 4.0). These instrumental techniques enhance the quality and safety testing of vaccines and other biologicals to determine the quality and concentration of RNA sample isolated from mRNA vaccine sample (e.g. Moderna, Pfizer/BioNTech), determine the concentration/size of DNA in adenovirus vector-based COVID-19 vaccine samples (e.g. Janssen (Johnson & Johnson) & Oxford/AstraZeneca), determine the presence of immunogen in a vaccine sample (E.g. spike protein, spike protein DNA, spike protein mRNA) and assess the integrity of isolated DNA in a vaccine sample. The flow cytometer system in particular offers novel opportunity for quality testing of vector-based vaccines and for pharmacovigilance aimed at assessing safety and cellular immunogenicity of COVID-19 vaccines and related biologics.

Rwanda

Pharmacovigilance and Safety Monitoring

PQM+ received Global VAX funding to provide technical assistance to the Rwanda FDA to strengthen its capacity to provide regulatory oversight of COVID-19 vaccines imported into the country and expected to be manufactured locally in the near future. This will help assure the efficacy, quality, and safety of COVID-19 vaccines and biological products used in Rwanda. RB-PMS plays a key role in the quality assurance of medical products and protection of consumer safety. In Q4, to build human resource capability, PQM+ conducted a workshop in August 2023 with Rwanda FDA to train the RB-PMS technical working group members on how to use the updated version of the MedRS tool for PMS of vaccines and supported them to develop a protocol that will be used for the risk-based PMS of vaccines in the country's market. In the same workshop, 18 members (10 men, eight women) of a multisectoral technical working group from Rwanda FDA, Rwanda Biomedical Center (vaccines unit), Rwanda Central Medical Stores, Rwanda National Pharmacy Council, Private Sector Federation (association of importers and wholesalers of pharmaceutical products and medical devices), Rwanda Referral Hospitals, and PQM+ were engaged in the selection of eight (8) of 61 available vaccines in the national supply chain system for the first vaccines RB-PMS in Rwanda. The eight selected vaccines are DTaP/Hib (diphtheria, tetanus, acellular pertussis, haemophilus influenzae type B), hepatitis B,

MR (measles and rubella), MR (measles and rubella), BCG Culture (bacterial culture - antigen), Rota (rotavirus), PCV7 or PCV13 (pneumococcal conjugate), IPV (polio), and HPV (human papillomavirus).The trained technical working group members are and will continue to be involved in the quality surveillance of medical products, including vaccines, to ensure their quality is not compromised.

Senegal

Human Resources for Health

PQM+ received Global VAX funding to support Senegal's ARP to reach ML 3. Specifically, PQM+ is working to strengthen the systems for registration and marketing authorization, pharmacovigilance, and testing for biologics such as COVID-19 vaccines. In Q4, PQM+ supported ARP's participation in two study visits intended to expose regulatory personnel to the pharmacovigilance (PV) and registration and market authorization (MA) practices as executed by experienced regulatory counterparts.

1. **Study visit to the Moroccan Poison Control Center (MRPC) WHO-collaborating center for pharmacovigilance:** Four (4) regulatory officers (all female) from the pharmacovigilance unit of ARP visited the anti-poison and pharmacovigilance center in Rabat, Morocco in July 2023. During the visit, ARP shared their WHO Global Benchmarking Tool (GBT) journey to improve the maturity level of their vigilance function with MRPC who in turn oriented the regulatory officers on the systems, processes, and operations of the PV center. Furthermore, the staff of MRPC trained the ARP visiting staff on the following areas:
    a. Harmonization of pharmacovigilance analysis methods
    b. Investigating AEFIs in pharmacovigilance
    c. Causality assessment
    d. Material vigilance, with a focus on medical devices
    e. The French method for attributing adverse drug reactions
    f. Risk minimization in pharmacovigilance
2. **Study visit to the Food and Drug Authority (FDA) Ghana for MA:** Four (4) regulatory officers (2-F, 2-M) from the medicines registration and inspections unit of ARP visited FDA Ghana in August 2023. As part of this study visit, ARP shared their WHO GBT journey for their registration and marketing authorization function with the FDA Ghana team. ARP has already implemented 88 percent of the ML3 sub-indicators for MA and sought specific technical advice in addressing the remaining four sub-indicators in their institutional development plan (IDP). FDA Ghana shared their journey to becoming a maturity level 3 authority and provided recommendations on addressing the remaining sub-indicators. Furthermore, FDA Ghana shared with the Senegalese delegation their experiences and processes for granting emergency use authorization (EUA). ARP was able to leverage this visit to start discussions on signing a memorandum of understanding (MoU) for future collaboration with FDA Ghana.
3. **Study Visit to *Centre Humanitaire des Métiers de la Pharmacie* (CHMP) for lot release (LT):** The last study visit planned under this project is a study visit to CHMP in

France. In Q4, CHMP developed and shared a concept note as well as the associated cost for hosting the three analysts from Senegal. The concept has been accepted by ARP and the visit is scheduled for October 2023.

The aim of this visit is to strengthen skills and practices in vaccine quality control. It will focus on training and practical situations relating to the control elements routinely carried out on samples of vaccines placed on the market, but also on locally produced vaccines. The following areas will be covered during the visit: **1)** vaccine identity, i.e. the suitability of the vaccine for the expected specifications (in accordance with the product specifications); **2)** vaccine activity in the laboratory; **3)** vaccine component stability tests; **4)** microbiological safety (absence of contamination by foreign micro-organisms); **5)** validation of vaccine quality control methods; and **6)** qualification of cleanrooms, in compliance with international standards UNI EN ISO14644, Federal Standard in the United States and Good Manufacturing Practice (GMP) for the pharmaceutical sector, as well as European Pharmacopoeia directives.

Laboratory Systems

PQM+ is working to strengthen the laboratory testing function and equip and build capacity for testing of biologics. Senegal's NQCL has some capacity to test biologics in country, specifically the yellow fever vaccines that Institut Pasteur Dakar (IPD) produces. This laboratory, however, requires new equipment, accessories, and consumables to test COVID-19 vaccines. In Q3, the medicines regulatory authority ARP started work on the refurbishment of its laboratory, DICQ, to create more space for vaccine testing and meet international requirements. PQM+ is supporting this work by procuring needed equipment and building the capacity of laboratory analysts. In Q4, two of the four pieces of equipment - UV-Vis spectrophotometer and florescence spectrometer – that PQM+ procured for Senegal ARP to test biological products, such as COVID-19 and other vaccines, were delivered to the laboratory. The other two pieces of equipment, a reverse transcriptase real time polymerase chain reaction system and an osmometer, are expected to arrive in country in October.

Throughout the quarter, PQM+ developed materials for a quality control training it plans to deliver to ARP's DICQ analysts to build their capacity for vaccine testing next quarter. The training designed by PQM+ will introduce analysts from the physicochemical and microbiology laboratories to the theory of analytical techniques used for mRNA (and other) vaccines – western blotting, reverse transcriptase real time polymerase chain reaction (RT-PCR), mass spectrometry, high performance liquid chromatography (HPLC), florescence/ultraviolet spectroscopy, enzyme-linked immunosorbent assay (ELISA), scanning electron microscopy, sterility testing and limulus amebocyte lysate (LAL) endotoxin testing. This will be followed by hands-on training on selected analytical techniques using the newly procured equipment. This training is necessary to capacitate the DICQ to assess the critical quality attributes of vaccines and facilitate lot release and/or post-marketing surveillance.

South Africa

Human Resources for Health

PQM+ received Global VAX funding to strengthen the South African Health Products Regulatory Authority (SAHPRA)'s capacity to provide regulatory oversight to assure the efficacy, quality, and safety of vaccines, including COVID-19 vaccines and biologics, throughout their production, storage, distribution, and use in country. In Q2, PQM+ conducted a rapid strengths,

weaknesses, opportunities, and threats (SWOT) analysis of SAHPRA's current market authorization (MA) processes and procedures. The results from the SWOT analysis were used to formulate key recommendations which included: building internal staff capacity and resources to: 1) address the current and expected workload, 2) limit reliance on external experts, specifically for pharmaceutical evaluation, inspectorate activities, and clinical evaluation. Based on these recommendations, during Q4, PQM+ conducted a training program focused on market authorization and licensing from July 10-12. The training provided technical support to SAHPRA in the areas of marketing authorization of biological and pharmaceutical products and licensing of pharmaceutical establishments with specific focus on 1) market authorization (MA) of biological products, 2) MA of pharmaceutical products, and 3) licensing requirements and regulations for pharmaceutical establishments. A total of 11 participants (6M, 5F) attended the training, representing SAHPRA, the Department of Health, and the South African Pharmacy Council.

PQM+ was also tasked with developing a biomanufacturing competency framework and database for SAHPRA. Vaccine manufacturing is an advanced industry, requiring a workforce with specialized and diverse technical knowledge, skills, and abilities (i.e., competencies) obtained through education, training, and experience. Recognizing the common need for biomanufacturing and regulatory capacity development across the African region, PQM+, in collaboration with Purdue University Biotechnology Innovation and Regulatory Science (BIRS) Center, developed a regional competency framework with focus on vaccines and biologics-specific regulatory job functions to support the broader continental workforce development activities. As of Q4, PQM+ finalized this framework, and will package it to ensure a user-friendly and informative. This concludes PQM+ work in South Africa per the approved work plan.

Laboratory Systems

PQM+ is also working to strengthen SAHPRA's capacity to provide regulatory oversight to assure the efficacy, quality, and safety of vaccines, including COVID-19 vaccines and biologics, including through quality testing. At the moment, SAHPRA outsources its testing of medicines and biological products, but it is imperative that it maintain its governance and authority to receive timely testing results from its identified testing laboratories. SAHPRA currently uses two external laboratories affiliated with academic institutions for quality control (QC) testing: NWU's Research Institute for Industrial Pharmacy (RIIP) incorporating the Centre for Quality Assurance of Medicines (RIIP®/CENQAM®) for small molecules and University of the Free State (UFS) - South African National Control Laboratory for Biological Products (SANCLBP) for biologics. As part of this activity, in May 2023, PQM+ initiated a process with SAHPRA, RIIP®, CENQAM®, and SANCLBP to document the standard operating procedures (SOPs) for information flow within their respective workflows. During Q4, PQM+ consolidated the information flow processes received into a single process flow which can be used in future by SAHPRA to outline the information flow requirements within a LIMS mapping. This concludes PQM+ work in South Africa per the approved work plan.

Uzbekistan

Policy, Planning, and Coordination

While things are still settling at the country's CPPS, the National Immunization Program (NIP) within the MoH has not been impacted, and therefore PQM+ is continuing to provide technical assistance to the NIP to strengthen its vaccine safety surveillance capacity. PQM+ worked with NIP to establish a working group to develop an AEFI surveillance guideline that will provide

complete guidance to staff on how to detect, report, investigate, and respond to AEFI events. NIP developed a draft guideline, which PQM+ technically reviewed. PQM+ also reviewed the training program NIP drafted on epidemiological surveillance of AEFI. In Q4, the AEFI guideline was finalized and approved by NIP.

In Q4, PQM+ also prepared for a training for officials and specialists of MoH, CPPS, and the Committee for Sanitary and Epidemiological Welfare and Public Health. The intensive four-day training, scheduled for the first week of October, will enhance the skills of the National Vaccination Committee in the investigation and causality assessment of AEFIs. The training will also inform the committee members on how to 1) understand the fundamental principles of AEFIs investigation and causality assessment; 2) master appropriate investigation and causality assessment tools and methods; and 3) use WHO guidelines and software.

The restructuring also impacted the lot release activity. However, in PY4 Q4, PQM+ continued to advocate with the CPPS for example, during a scheduled follow-up meeting, PQM+ introduced WHO GBT indicators for lot release.

Progress by Health Elements

Maternal and Child Health (MCH)

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

Progress in Quarter 4

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

PQM+ translated the finalized Product Information Report (PIR) for gentamicin and two related job aides to support inspection and registration of gentamicin for national MRAs. The French translations of the PIR and job aids were completed, reviewed, and disseminated.

PQM+ collaborated with MTaPS and GHSC-PSM and disseminated the Call-to-Action paper via two webinars –one with USAID missions and USAID/W and another with USAID/W and others including members of the CHTF to orient them to the paper.

PQM+ administered the questionnaire for MNCH medical devices and the questionnaire for tranexamic acid – both focused on regulation and supply. PQM+ collected and validated the responses, analyzed the findings, and drafted the paper on MNCH medical devices.

For TXA, PQM+ collected responses to the questionnaire in Ghana and Madagascar and is progressing them in DRC and Mali. PQM+ developed the sampling protocols and budgets and will begin sample collection in Ghana, Madagascar, and DRC for shipment to Mali for testing.

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

- PQM+ provided review and comments on the following:
- Provided technical review and comment on draft oxygen systems QA technical resource document for applying quality assurance practices to health-facility medical oxygen.
- Provided input to the RHSC on a strategic refresh of the Coalition.
- Participated in discussions and information exchange of medical devices with MTaPS and PSM across each of the USAID programs.
- Disseminated the newly published MNCH medical devices 'Special Considerations for Regulations' with PQM+ country colleagues and shared virtual orientation invite offered by AUDA-NEPAD & AMDF.
- Developed abstract for the RHSC General Membership Meeting (GMM) in Accra in October under the following sub-theme: Examining our financial landscape & our future security. Topic: Kenya pilot experience with the SF burden model for oxytocin.

Priority Activities for PY5, Q1

Next quarter, PQM+ Core MCH plans to:

- Finalize data collection, analysis, and draft the report on the regulatory landscape of MNCH medical devices in LMICs.
- Complete the data collection on the survey and the testing, finalize the analysis and draft the report.

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 patients in need.

Progress in Quarter 4

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

PQM+ is continuing to work with existing and newly identified manufacturers of NTD medical products to ensure that enough sources of quality-assured medicines are available on the market.

- Finalized the GMP CAPA response and supporting documents for Indian Manufacturer 1 and submitted to WHO. PQM+ continued to provide technical support on the additional data for the dossier, and the facility was successfully accepted for compliance with GMP. There are no pending questions on product dossier, and the facility is awaiting final listing of the product and publication of WHOPAR and WHOPIR on WHO PQ website.
- Discussion on further production of the company's experimental batches of mebendazole 500 mg tablet is still on hold and pending more details on whether a tech transfer is possible. For praziquantel 600mg, PQM+ received and reviewed the first draft of QOS and shared feedback with Indian Manufacturer 1 who are working on draft dossier preparation.
- For India Manufacturer 2, the product development is still in progress for albendazole 400mg tablets. The exhibit batch production is expected by February 2024. For ivermectin 3mg tablets, the pilot batch production for product development will begin by November.
- For Bangladesh Manufacturer 1, planning for product shipment of azithromycin 500 mg to the US market for WHO PQ submission has been postponed to December 2023.
- Kenya Manufacturer 1 changed their plan to work on albendazole as a priority and not continue with praziquantel. PQM+ will continue technical support for albendazole, and an onsite GMP assessment is under discussion.

- An onsite inspection for Bangladesh Manufacturer 2 was tentatively scheduled for late October and early November, pending approval of concurrence from the mission.
- TPQM+ worked with the IHI instructional designer and Purdue to begin development of the two new eLearning courses: 1) Pharmaceutical quality management system: elements and quality review practice and 2) GMP in QC laboratory and analytical method validation. Storyboarding of the first module is underway, and the course descriptor for the second module has been finalized.
- PQM+ developed and shared with USAID a 16-page executive summary of the NTD landscape analysis that includes information on the supply landscape, risks, need for diversification to inform donors and other stakeholders with planning investments. PQM+ is reviewing USAID comments to incorporate into a final draft.

Priority Activities for PY5, Q1

Next quarter, PQM+ plans to:

- Conduct site visits to Kenya Manufacturer 1 and
- Continue working with India Manufacturers 1 and 2 and Bangladesh Manufacturer 2.
- Incorporate USAID feedback into the executive summary of the NTD landscape analysis and disseminate.
- Continue instructional design for new eLearning modules on advanced GMP topics.

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 in Quarter 4

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

In PY4, Q4, PQM+ provided technical assistance to Pakistan Manufacturer #4 to address the gaps identified by WHO on their inspection visit for GMP compliance. The manufacturer is planning to submit the completed CAPA with supporting documents to WHO by the end of PY4.

PQM+ is also providing technical assistance to Pakistan Manufacturer #4 for the WHO prequalification (PQ) of two- drug fixed- dose combination (2FDC) TB medicines. In PY4, Q4, the manufacturer submitted the preliminary findings from the Bioequivalence study (BE) preliminary findings to WHO. WHO's initial review was positive, and WHO will complete a comprehensive review after submission of the full dossier. In the meantime, PQM+ is in the process of engaging an expert on BE study to review the study findings and see if the analysis or presentation of the study can be changed to make the study stronger.

PQM+ is also working with Pakistan Manufacturer #1, toward WHO PQ of four- drug- fixed dose combination (4FDC). WHO identified concerns with its 4FDC BE study report. In PY4, Q4, PQM+ initiated engagement with a BE expert to review the BE study and provide recommended changes to address WHO's concern.

In PY4, Q4, PQM+ conducted a landscape analysis for TB medicines production in South Africa. South African has a capable pharmaceutical industry that can potentially contribute to diversification of supply of quality- assured TB medicines globally, but specifically in Africa. PQM+ plans to finalize the landscape analysis report next quarter.

The technical assistance to South Africa Manufacturer #1 on WHO PQ of the Isoniazid API, was paused as the manufacturer is currently going through some infrastructural adjustment to its new GMP manufacturing facility. PQM+ anticipates that the facility will be ready in the next quarter and PQM+ will be able to provide TA toward GMP compliance to meet the WHO PQ requirements.

PQM+ in collaboration with the USP laboratory completed the analytical method for nitrosamine impurities in Rifapentine API and finished pharmaceutical product (FPP). PQM+ developed a report and PowerPoint on this. In PY4, Q4, PQM+ initiated collaboration with IntraHealth to convert the PowerPoint into training materials for regulatory authorities and manufacturers.

In PY4, Q4, PQM+ in collaboration with VCU, completed analytical tests on the samples developed by the USAID identified technology transfer recipient in their lab in India. The technology transfer recipient received guidance from VCU on alternative synthesis route for rifapentine API. After consultation with USAID, PQM+ also proposed another technology transfer recipient in Africa.

In PY4, Q4, PQM+ reviewed a proposal on rifamycin-S alternative synthesis route as a response to the request for proposal put out by PQM+ earlier this year. PQM+ is in the process of sending questions to the applicant for further clarification on the proposal.

In PY4, Q4, PQM+ completed the technical report from the consultative stakeholders' workshop for RBEC, a CRO in Ethiopia. The report was reviewed by technical experts and is currently being revised. The report includes the institutional development plan (IDP) that outlines the tasks and the responsible parties to enable RBEC to conduct the BE study.

Priority Activities for PY5, Q1

Next quarter, Core TB plans to:

- Continue to work with the Pakistan manufacturers to review their BE studies, and for Pakistan Manufacturer #1 to facilitate its CAPA submission and audit from WHO on its GMP compliance.
- IntraHealth will develop training slides on nitrosamine analysis methods for Rifapentine API and FPP
- Develop landscape analysis report for the South Africa manufacturers.
- Discuss approach e.g., EOI for technology transfer of rifapentine API technology to an African manufacturer.
- Finalize vendor for rifamycin-S technology transfer.
- Finalize technical report for RBEC, a CRO in Africa.

Program Support

Communications

Website: PY4 was the first full project year for the PQM+ stand-alone program website. It was a boost to finally launch this major communications platform and we developed a significant amount of new content to populate the site and build it out. The site now includes the new content as well as existing PQM+ and selected PQM content, which were migrated from the USP corporate site:

#	Content type
25	country pages
18	success stories
11	fact sheets
11	newsletters
8	press releases & journal articles
7	webinars
3	videos

This quarter, we launched 25 new pages, one for each PQM+ country, and added an interactive map to the Where We Work landing page. The country pages include a summary of the activities we implement, visuals, and links to success stories and videos related to that location. We also posted and disseminated the large test-to-treat resource, which includes scientific and technical information on COVID-19 therapeutics.

Importantly, we hired and onboarded our new communications specialist, Kaitlyn Markley, in late PY4 after more than a year of recruiting for the position. Kait brings needed content management system and website experience to our team, and in Q4 she received training on website platform Drupal 9, enabling us to transfer the bulk of site management and maintenance to the PQM+ communications team instead of relying on USP's IT department to process all requests for website updates.

Success stories: We published five success stories during PY4, with two released in Q4:

- Mali strengthens surveillance of medical products.
- Ethiopia expands laboratory capacity across the country.

Newsletter: PQM+ developed four quarterly newsletters during PY4, highlighting more than 50 milestones and activities. The summer issue had a strong open rate of 49 percent, spotlighting:

- Manufacturers in Nigeria and Pakistan achieved WHO prequalification to manufacture zinc sulfate, an essential medicine for newborn and child health.
- A West African national medicines quality control laboratory becomes the first to receive WHO-prequalified status in Ghana.
- Ethiopia's medical device lab achieves accreditation.
- A new dashboard facilitates access to NTD medicines data.

Social media: To highlight PQM+ activities and amplify our work to a variety of audiences, in Q4 we developed and shared 48 social media posts on Twitter and LinkedIn, garnering more than 3,316 total engagements (clicks, shares, comments, and reactions). Across PY4, we produced 78 LinkedIn posts, collecting 11,233 engagements and 110 tweets that accrued 2,070 engagements.

This quarter's top social media posts were:

- Kenya's protocol for monitoring the quality of malaria rapid diagnostic test kits.
- Weeklong PQM+ global retreat in Rockville, Maryland.
- Ghana's eCTD capacity-building workshop with vaccine manufacturers.

Videos: PQM+ published three videos during PY4 and disseminated them widely via social media and our newsletter. All videos performed well according to social media metrics, and we are planning to produce more of these popular communications vehicles in PY5.

Annex 1: Monitoring, Evaluation, and Learning Update

PQM+ reports on its performance monitoring indicators twice a year. The PQM+ Monitoring Results Table (below) presents results for FY2023 (PY4) 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.

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.

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 multisectoral groups are fully functional (i.e., they have scored 100%), PQM+ continues 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+ continues monitoring use of the tool/approach to ensure 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. 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, 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%, it has completed all milestones and should receive accreditation, pre-qualification, or market authorization.

Table A. 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

Performance indicators. The indicator **2.2m** tracks the independence of country counterparts in conducting RB-PMS. Independence means that the PQM+-supported TWG or MRA can (and do) use *on its own* the RB-PMS approach adopted from PQM+. The steps involved in carrying out an RB-PMS activity include: (1) developing the sampling plan using a risk-based approach, (2) developing the protocol, (3) training sample collectors on the new protocol, (4) managing sample collection, (5) assessing samples using the three-tiered assessment, (6) writing the report, and (7) disseminating the PMS results. For each PMS step, the TWG scores a 2 if it followed the risk-based procedures outlined in the protocol, used the appropriate tool/approach, and did the work independently without PQM+ support; a 1 if it followed all the correct procedures but still needed some PQM+ technical assistance; and a 0 if it did not follow the RB protocol or best practices or if PQM+ provided substantial support. The total possible score is 14. Scoring is conducted for each round of PMS. Although PQM+ does not score independence once counterparts reach 100%, it does attempt to track use of the approach and tool in subsequent rounds of PMS funded by counterparts or other donors.

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. To minimize duplication of the number of individuals trained, PQM+ counts trainees from each identifiable segment of the workforce (e.g., lab staff) only once each half year, even though those staff may have benefited from multiple trainings over that period.

PQM+ FY 2023 Monitoring Results

Table Legend

- (dash): No activity in the quarter

n/a: Not applicable

No target: Target not set / potential results could not be predicted

D/N/A: Data not available

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
OBJECTIVE 1: GOVERNANCE FOR MEDICAL PRODUCT QUALITY ASSURANCE SYSTEMS STRENGTHENED								
Overarching outcome								
1a. Number of regulatory actions taken by the MRA and other authorized entities to address substandard and falsified medical products in a PQM+-supported country or sub-national jurisdiction, by quarter								
Benin	D/N/A	0	No target	-	4	-	9	**13**
Burkina Faso	D/N/A	0	No target	-	-	-	1	**1**
Ghana	D/N/A	8	No target	-	12	-	-	**12**
Kenya PPB	D/N/A	1	No target	-	-	-	17	**17**
Liberia LMHRA	0	3	No target	-	6	-	-	**6**
Mali	D/N/A	5	No target	-	2	-	-	**2**
Nepal DDA	64[a]	13	No target	14[b]	6[b]	5[b]	-	**25[b]**
Pakistan DRAP	D/N/A	0	No target	11[b]	-	-	-	**11[b]**
Total 1a.				**25**	**30**	**5**	**27**	**87**

Government enforcement action in response to regulatory violations is a sign that the government is committed to keeping its citizens safe. PQM+ tracks MRA enforcement actions in response to SF medicines or regulatory violations. In most of the examples cited here, the enforcement actions were taken by MRAs in response to RB-PMSs completed in PY4. **Please note, no regulatory action has been taken yet for RB-PMSs that concluded in PY4 Q4 (see Annex 2). PQM+ will follow up with PMS TWGs and/or MRAs for that information when available.**

- Benin's MRA recalled: (a) 3 antimalarials found to be substandard (quinine Injection, quinine tablets, and artemether injection) and informed manufacturers whose product registrations had expired to renew those market authorizations in Q1; and (b) another 3 batches of quinine sulphate, 5 batches of quinine dichlorhydrate, and 1 batch of artemether in Q4.
- Burkina Faso sent a written notice to the offender.
- FDA Ghana issued a national alert on 19 samples (11 brands labeled for room temperature storage) of oxytocin injection that were unregistered and initiated a recall.

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total

- Kenya's PPB issued a recall of tamedol oral solution (paracetamol oral solution, 120 mg/5 ml, 60 mls) produced by a local manufacturer and a public alert regarding suspected SF radio contrast media-visipaque (iodixanol) 320mg/ml vials (16 batches).
- Liberia's LMHRA removed from circulation 11,275 Pks (6 batches) of poor-quality antimalarial and MNCH medicines (artemether lumefantrine, artemether injections, and oxytocin). This enforcement action resulted from the second and third rounds of RB-PMS. The estimated cost of the medicines removed was USD 56,000.
- Mali's MRA withdrew 23 vials of a non-conforming batch of diazepam, and quarantined magnesium sulphate.
- In response to its conventional PMS activities, Nepal's DDA recalled 13 products and suspended 1 market authorization in Q1 and recalled 6 medical products (2 of which were oral syrups for children) in Q2. Q3 results are due to DDA's pilot RB-PMS. During the quarter, paracetamol IV (2 brands) and metronidazole suspension (1 brand) were recalled. The other 2 recalls were due to inspection or conventional PMS activities.
- In Q1, Pakistan's DRAP recalled 9 batches of medicines (antibiotics, anti-infectives, anti-hypertensives, anti-emetics, anesthetics, and antimalarials) found by DTL Lahore to be contaminated and 2 lots of anti-hypertensives batches tested by DTL Rawalpindi.

Notes:

[a] Nepal's baseline comes from the government's annual report. The 64 enforcement actions include product recalls and the filing of legal cases due to violations of the Drug Act 2035. The baseline covers the period July 2019-July 2020, which overlaps with the start of PQM+. As the fiscal years of the U.S. and Nepal's governments are different, there will be an overlap or gap in the reporting periods for this baseline.

[b] Some or all results are not outcomes of RB-PMS activities.

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 that were developed or revised with PQM+ support, by quarter *(please refer to notes below for how to read this table)*

Bangladesh	0	6	3	0	**1**	0	**3**	**4**
National Drug Control Laboratory Five-Year Strategic Plan 2023-2028				-	*Drafting*	*Drafting*	*Adopted*	
Regulatory Framework 9050437739				-	-	-	*Drafted & Adopted*	
Regulatory Guidelines for Medical Devices Bangladesh (Revision-1)				-	-	-	*Drafting*	
Registration Guidelines for Medical Devices Bangladesh 2015 (Revision 1)				-	-	-	*Drafting*	
Strategic Investment Plan for Fifth Health, Population, and Nutrition Sector Program (HPNSP 2024-2029) (PY3)				Drafted	Submitted	Submitted	Submitted	
Vaccine Lot Release Guidelines (PY3)				Submitted	Submitted	Submitted	Submitted	
Code of Pharmaceutical Marketing Practices (PY3)				Submitted	Submitted	Submitted	Submitted	
Legislation for Laboratory Service Sub-Contracting in Bangladesh (PY2)				Submitted	Submitted	Submitted	Submitted	

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Benin	0	0	3	0	0	**1**	0	**1**
Collaborative Framework between ANCQ and ABRP (PY4)				-	-	*Drafted & Submitted*	*Submitted*	
Burkina Faso	0	1	2	0	0	0	0	**0**
Strategic Plan-ANSSEAT, 2022-2026 (PY3)				Drafting	Drafting	Drafting	Drafting	
Collaborative Framework between MRA and NQCL (PY2)				Drafting	Drafting	Drafting	Submitted	
Ethiopia	0	8	6	**1**	**3**	**2**	**1**	**7**
Guideline for Importation of Active Pharmaceutical Ingredients (APIs) and Raw Materials				*Drafting*	*Drafting*	*Submitted & Adopted*	-	
Stringent Regulatory Authorities Listing Guideline for GMP Waiver				-	*Drafting*	*Drafting*	*Submitted & Adopted*	
Guideline for Regulation of Advertisement and Promotion of Medicines				-	*Drafted & Adopted*	-	-	
National Pharmacovigilance Guideline				-	*Drafted*	*Submitted & Adopted*	-	
Good Manufacturing Practice Guideline for Pharmaceutical Products, 2nd Edition				-	-	*Drafted & Adopted*	-	
Reliance and Recognition Guidelines				-	-	-	*Drafted & Adopted*	
Risk Based Inspection Guideline for Medicines, Medical Devices, and Food at Ports of Entry				-	-	*Drafted & Submitted*	*Adopted*	
EFDA Business Risk Analysis Guidance (PY3)				Submitted	Submitted	Submitted	Submitted	
Medical Donations Control Directive (PY3)				Submitted	Adopted	-	-	
Medicine Repackaging, Packaging and Labeling Directive (PY2)				Submitted	Submitted	Submitted	Submitted	
Guidance on Waiver of GMP Inspection Based on SRA Procedure (PY2)				Submitted	Submitted	Submitted	Submitted	
Clinical Trial Directive* (PY2)				Drafted & Submitted	Submitted	Adopted	-	
Ghana	0	1	1	0	0	0	0	**0**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Pharmaceutical Traceability (GS1) Guidelines (PY3)				Drafting	Drafting	Drafting	Submitted & Adopted	
Guinea	0	1	1	0	0	**2**	0	**2**
Three-year Plan for Equipment Management and Capacity Building in Preparation for ISO 17025:2017 Accreditation				-	-	*Drafting*	*Drafting*	
Action Plan for Implementation of Three-Year Equipment Management and Capacity-Building Strategy toward ISO 17025:2017 Accreditation				-	-	*Drafting*	*Drafting*	
Kenya	0	0	No target	**1**	0	0	0	**1**
NQCL Strategic Plan 2023-2027 (PY3)				*Drafted*	*Submitted*	*Submitted*	*Adopted*	
Strategy for Post Marketing Surveillance of Health Products and Technologies in Kenya (PY3)				Submitted	Submitted	Submitted	Submitted	
Reliance Guideline on Regulatory Decision Making in Kenya (PY2)				Submitted	Submitted	Submitted	Submitted	
Lesotho	0	0	4	0	0	**3**	**9**	**12**
Guidelines for Pharmaceutical inspection				-	-	*Drafting*	*Drafting*	
Licensing Guideline				-	-	*Drafting*	*Drafting*	
National Guidelines for Good Manufacturing Practices				-	-	*Drafting*	*Drafting*	
Lesotho National Guideline for Post-Marketing Surveillance				-	-	-	*Drafting*	
Guidance for the Preparation and Submission of Dossiers in Common Technical Document Format				-	-	-	*Drafting*	
Guidelines for Medical Products Donations				-	-	-	*Drafting*	
Guidance on Submission of Applications for Registration in Common Technical Document Format: Quality				-	-	-	*Drafting*	
Guideline for Section 60 Applications to Import Unregistered Medicines				-	-	-	*Drafting*	
Guideline on Product Information and Labeling				-	-	-	*Drafting*	
Guideline for Evaluation of the Quality of the API and FPP: Notes for Assessors				-	-	-	*Drafting*	
Reliance Guideline for the Regulation of Medical Products				-	-	-	*Drafting*	
National Pharmaceutical Sector Strategic Plan II (NPSSP II)				-	-	-	*Drafting*	

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Liberia	0	7	5	0	0	**1**	0	**1**
Reliance Policy Test Results from Other Laboratory				-	-	*Drafting*	*Drafting*	
Regulations for Sub-Contracting of Testing Services (PY3)				Drafting	Submitted	Adopted	-	
Regulations on Defects and Quarantine of Medicinal Products (PY3)				Drafting	Submitted	Adopted	-	
Regulation for the Registration of Medical Devices (PY3)				Submitted	Submitted	Adopted	-	
LMHRA Reliance Policy on Marketing Authorization (PY3)				Drafting	Drafting	Drafting	Drafting	
LMHRA Reliance Policy on Foreign Inspection (PY3)				Drafting	Drafting	Drafting	Drafting	
Madagascar	0	1	2	0	**1**	0	0	**1**
Product Recall Guidelines				-	*Drafting*	*Submitted*	*Submitted*	
Mali	0	0	1	0	0	0	**1**	**1**
Resource Mobilization Plan for LNS Strategic Plan 2024-2028				-	-	-	*Drafting*	
LNS Strategic Plan 2024-2028 (PY3)				Drafting	Drafting	Drafting	Submitted & Adopted	
Nepal	0	0	4	0	0	**1**	0	**1**
NML Five-Year Strategy and Action 2023-2028				-	-	*Drafting*	*Drafting*	
Guideline, Product Recall (PY3)				Drafting	Drafting	Drafting	Drafting	
Guideline, Biological Product Manufacturing (PY3)				Drafting	Submitted	Submitted	Submitted	
Risk-Based Inspection Framework (PY3)				Drafting	Drafting	Drafting	Drafting	
GMP Code [revised] (PY2)				Adopted	-	-	-	
Risk-Based PMS Guideline (PY2)				Drafting	Drafting	Drafting	Drafting	
Nigeria	0	1	1	0	0	0	0	**0**
National Strategic Plan for the Pharmaceutical Manufacturing Sector (NSSP) (PY3)				Drafting	Drafting	Drafting	Drafting	
Pakistan	0	13	No target	0	**1**	**4**	**1**	**6**
Guidelines for Cold Chain Management Practices for Time and Temperature Sensitive Drug Products				-	*Drafting*	*Drafting*	*Drafting*	
Draft guidelines for Registration of Pharmaceutical Products				-	-	*Drafting*	*Drafting*	

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Draft guidelines for Drug Sales Licenses				-	-	*Drafting*	*Drafting*	
Guidelines on categorization of GMP deficiencies				-	-	*Drafting*	*Drafting*	
Guidance on Submission of Application on Form 5-F (CTD) for Registration of Biological Drug Products for Human Use				-	-	*Drafting*	*Drafting*	
Post-Registration Variation Guidelines for Pharmaceutical & Biological Products				-	-	-	*Drafting*	
Update of Biostudy Rule 2017				Drafting	Drafted	Adopted	-	
Therapeutic Goods (Federal Inspectors, Labs, and Federal Government Analysts) Rules				Adopted	-	-	-	
Revised guidelines for regulatory reliance				Drafted	Adopted	-	-	
Guidelines for Good Distribution Practices				Drafting	Drafting	Drafting	Drafting	
Quality policy for the inspectorate				Drafting	Drafting	Drafting	Drafting	
BE CRO Guideline				Drafting	Drafting	Drafting	Drafting	
AWaRE Regulatory Intervention s Guidance Document (PY3)				Submitted	Submitted	Submitted	Submitted	
Guidance Document for Pre-Marketing Risk Assessment (PY3)				Drafting	Drafting	Drafting	Drafting	
Guidance on Risk-Based Assessment of Pharmaceutical Generic Products (PY3)				Submitted	Submitted	Submitted	Submitted	
Outlines of Key Performance Indicators (KPI's) for DRAP (PY3)				Submitted	Submitted	Submitted	Submitted	
Roadmap for Benchmarking of Pharmaceutical Manufacturers (PY3)				Drafting	Drafting	Drafting	Drafting	
Procedures/Guidelines for Refurbished Equipment (PY2)				Submitted	Submitted	Submitted	Submitted	
Contract Manufacturing				Adopted	-	-	-	
Establishment Licensing Regulations & Inspection System				Adopted	-	-	-	
Fee for Regulatory Functions of DRAP				Adopted	-	-	-	
Guidance for risk-based post-license monitoring of biological products				Drafting	Drafting	Drafting	Drafting	
Guidance on GCP compliance inspection				Drafting	Drafting	Drafting	Drafting	
Guidance on IDMP (API and drug products)				Adopted	-	-	-	
Guideline on conflict of interest				Adopted	-	-	-	
Guideline on Good Review Practices				Adopted	-	-	-	

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Risk-based post-marketing surveillance plan on the existing RB-PMS framework				Drafting	Drafting	Drafting	Drafting	
Uzbekistan	0	0	2	**1**	0	**1**	0	**2**
Strategy for Licensing Process for Manufacturers and Wholesalers in Uzbekistan to Align with WHO and PIC/S Requirements				*Drafted & Submitted*	*Submitted*	*Submitted*	*Submitted*	
AEFI Surveillance Guideline				-	-	*Drafting*	*Drafting*	
Total 1.1a				**3**	**6**	**15**	**15**	**39**

A national policy and regulatory framework is essential to ensuring the quality of medical products in countries. PQM+ is helping countries develop or revise and submit for adoption medical product quality assurance legislation, policies, and guidelines.

How to read this table: Using Bangladesh as an example, there were no new policies in Q1 and Q3, 1 new policy in Q2, and 3 new policies in Q4. The red box contains the total number of new policies. **All new policies are italicized.** PQM+ continues to track older policies not yet adopted.

During PY4, the program supported a total of 39 new regulations and guidelines (see policies in italics). Twenty-seven new and previous policy submissions were approved during the year.

Note: This indicator captures policies, laws, regulations, and guidelines. Protocols developed under the COVID-19 TA/ARP buy-ins are not reported under this indicator but under the standard USAID COVID-19 indicator CV 2.6-22 and in the Development Information Solution (DIS) system.
* Ethiopia's Clinical Trial Application, Review, and Authorization Directive and Good Clinical Practice Directive, both from PY2, were merged in 2023 Q2.

1.2. Systems that facilitate transparency and accountability promoted

1.2c. PQM+-supported MRA disseminated results of its regulatory activities, by quarter								
Pakistan (inspection)	No	No	Yes	-	-	Yes	-	**Yes**
Uzbekistan (licensing)	Yes	Yes	Yes	Yes	No	-	-	**Yes**
Pakistan (lab testing**)**	No	Yes	Yes	-	-	Yes	-	**Yes**
Benin (RB-PMS)	No	No	Yes	-	Yes	-	Yes	**Yes**
Burkina Faso (RB-PMS)	Yes	Yes	Yes	-	-	-	Yes	**Yes**
Ethiopia (RB-PMS)	No	Yes	Yes	-	-	-	Yes	**Yes**
Guinea (RB-PMS)	No	No	Yes	-	-	-	Yes	**Yes**
Kazakhstan (Conventional PMS)	Yes	No	Yes	Yes	-	-	Yes	**Yes**
Liberia (RB-PMS)	No	Yes	Yes	-	-	Yes	-	**Yes**
Mali (RB-PMS)	Partially	Yes	Yes	-	Yes	-	-	**Yes**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Pakistan RB-(PMS)	No	Yes	Yes	-	-	Yes	-	Yes
Senegal (RB-PMS)	No	No	Yes	-	-	Yes	-	Yes
Kazakhstan (registration)	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes
Pakistan (registration)	Intermittent	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Uzbekistan (registration)	Yes	Yes	Yes	Yes	-	-	-	Yes
PQM+ promotes transparent and accountable systems in countries to increase public trust. The program encourages MRAs to disseminate (or continue disseminating) results of their regulatory activities (inspection, registration, licensing, and post-marketing surveillance). All countries that completed RB or conventional PMS have disseminated results from each round in written report formats, dissemination events, or on their websites. Also, MRAs in Kazakhstan, Pakistan, and Uzbekistan disseminated licensing, registration, and/or laboratory testing results in PY4.								
1.3. Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted								
1.3a. Score of PQM+-supported MRA on coordination and communication with other authorities involved in medical product regulatory oversight, by quarter								
Benin ABRP-ANCQ	0%	0%	50%	-	-	37.5%	75%	75%
Ethiopia EFDA-regional bodies	0%	37.5%	No target	-	87.5%	87.5%	87.5%	87.5%
Guinea DNPM-LNCQM	0%	75%	100%	-	75%	100%	-	100%
Uzbekistan WHO CRP	0%	100%	100%	100%	-	-	-	100%
PQM+ is promoting regular coordination and information-sharing among public sector stakeholders involved in medical product regulatory oversight in some countries. PQM+ tracks whether relevant public agencies have been identified, focal points named, coordination mechanism defined, and information exchanged. In Q1, Benin and Guinea partially/fully established collaboration between the MRA and NQCL. Ethiopia's national EFDA must coordinate with regional and city regulatory bodies; it is still identifying regional bodies with which to collaborate in some geographic areas. Uzbekistan's Agency continues to utilize the WHO CRP to register products; three were registered in PY4 (see indicator 2.3a).								
1.4. Links among the medical product quality assurance systems and other sectors developed and fortified								
1.4a. Percent of core functional components in place for a multisectoral group supported by PQM+ to advance medical product quality assurance, by quarter								
Technical Working Groups—Post Marketing Surveillance								
Benin	0%	90%	90%	90%	90%	60%	90%	90%
Burkina Faso	0%	90%	90%	90%	40%	90%	90%	90%

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
DRC	0%	90%	100%	40%	80%	90%	90%	**90%**
Ethiopia	0%	70%	90%	40%	40%	100%	100%	**100%**
Ghana	0%	90%	90%	40%	40%	80%	90%	**90%**
Guinea	0%	90%	100%	90%	70%	90%	90%	**90%**
Kenya	0%	100%	90%	80%	70%	70%	100%	**100%**
Liberia	0%	90%	No target	40%	90%	90%	40%	**40%**
Madagascar	0%	90%	90%	90%	90%	90%	90%	**90%**
Mali	0%	90%	90%	100%	90%	40%	40%	**40%**
Mozambique	0%	70%	90%	40%	40%	40%	90%	**90%**
Rwanda	0%	70%	90%	40%	80%	40%	80%	**80%**
Senegal	0%	90%	90%	40%	90%	90%	70%	**70%**
South Africa Global VAX	0%	0%	70%	50%	80%	80%	80%	**80%**
Other Multisector Groups								
Lesotho MRA TWG	0%	0%	100%	0%	20%	100%	100%	**100%**
Nepal Good Manufacturing Practice (GMP)/Inspection TWG	0%	80%	No target	80%	80%	80%	80%	**80%**
Nepal Laboratory Quality Assurance and Quality Control TWG (NML)	0%	90%	No target	-	90%	90%	90%	**90%**
Nepal Drug Advisory Group	0%	70%	70%	70%	70%	70%	70%	**70%**
Nigeria Bauchi State quality assurance committee	0%	70%	80%	-	70%	-	70%	**70%**
Nigeria Benue State quality assurance committee	0%	0%	30%	-	70%	-	70%	**70%**
Nigeria Ebonyi State quality assurance committee	0%	30%	80%	-	70%	-	70%	**70%**
Nigeria FCT State quality assurance committee	0%	0%	30%	-	0%	-	0%	**0%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Nigeria Kebbi State quality assurance committee	0%	0%	30%	-	70%	-	70%	**70%**
Nigeria Sokoto State quality assurance committee	0%	70%	80%	-	70%	-	70%	**70%**
Uzbekistan Quality Club	0%	100%	100%	100%	40%	40%	40%	**40%**

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 14 countries, PQM+ supported the development and functioning of multisectoral technical working groups (TWGs) to establish priorities for, oversee, and report results of RB-PMS activities. TWGs also make recommendations on enforcement actions to the MRA.

Of the PMS TWGs, only Kenya's has scored 100% for having all components in place, including MRA financing, to function sustainably. Other countries' TWGs are fully formed but lack self-financing. Some TWGs are helping to overcome the financing issue by holding virtual meetings (e.g., Ethiopia). A further note about the TWGs is that many do not need to meet every quarter—particularly during sample collection in the field and testing in the laboratory (hence the fluctuation in quarterly scores). The most important meetings are those for planning the protocol and deliberating on results and recommendations for the MRA. PMS stakeholders have shown commitment to the TWGs in many countries (see quotes in Annex 2). Moreover, Benin, Guinea, and Madagascar have instituted a regulatory provision to sustain the TWGs. Other TWGs (e.g., in Benin, Ethiopia, and Kenya) are applying the MedRS tool to other self-financed or non-PQM+ supported RB-PMSs—a sign of adoption and ownership of both tool and approach (see indicator 2a).

PQM+ also assists MRAs in coordinating multisector stakeholders involved in overall medical product QA. In PY4, Lesotho fully formed an MRA TWG. Nepal has instituted multisectoral inspection and laboratory QC TWGs and has a national drug advisory group. In Nigeria, PQM+ is involved in state- and national-level efforts to coordinate multistakeholder groups to advance medical product QA. In Uzbekistan, the Quality Club did not function for most of the year due to restructuring within the Agency.

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 products assessed by PQM+-supported MRA through post-marketing surveillance that failed, by quarter

Benin, rounds 1 (USAID) and 2 (WAHO)	D/N/A	*in progress*	No target	*in progress*	4%	*in progress*	2%	**4% / 2%**
Burkina Faso, round 2	D/N/A	0%	No target	*in progress*	*in progress*	*in progress*	1%	**1%**
Ethiopia, round 2	D/N/A	1%	No target	*in progress*	*in progress*	*in progress*	1%	**1%**
Ghana, round 2	D/N/A	11%	No target	*in progress*	*in progress*	*in progress*	30%	**30%**
Guinea, rounds 1 and 2	D/N/A	*in progress*	No target	*in progress*	*in progress*	*in progress*	19%, 22%	**19%, 22%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Kenya, round 2 (Global Fund)	D/N/A	n/a	No target	*in progress*	*in progress*	*in progress*	0%	**0%**
Liberia, rounds 2 and 3	D/N/A	29%	No target	*in progress*	16%	11%	-	**16%, 11%**
Mali, round 3	D/N/A	4%	No target	*in progress*	6%	-	-	**6%**
Nepal, round 2 (scale-up)	D/N/A	1%	No target	*in progress*	*in progress*	5%	-	**5%**
Nigeria, round 2	D/N/A	2%	No target	*in progress*	*in progress*	*in progress*	9%	**9%**
Senegal, round 2	D/N/A	1% (PY2)	No target	*in progress*	*in progress*	0%	-	**0%**
Note: The table above shows results of RB-PMS activities that concluded in PY4. Round 2 PMSs in Benin and Kenya were funded by other organizations (WAHO and Global Fund, respectively). However, TWGs utilized the MedRS tool to develop the protocols. In the case of Benin, PQM+ gave some technical assistance in developing the protocol. Although **results are not nationally representative**, they do signal problems with the quality of certain antimalarial and MNCH medicines. Countries listed above are already on round 3 or 4 of RB-PMS. Of note, SF rates are especially high in Ghana, Guinea, and Liberia. Refer to Annex 2 for more details.								
2d. Number of entities involved in medical product quality assurance that achieved ISO certification with PQM+ support, by quarter								
Mozambique ANARME (ISO 9001)	0	0	n/a	0	0	1	0	**1**
2.1. Sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies improved								
2.1a. Number of targeted recommendations in the country's WHO GBT institutional development plan addressed with PQM+ support, by quarter								
Ethiopia	0	9	13	4	-	-	-	**4**
Kenya Global VAX	0	0	No target	6	6	19	19	**50**
Liberia	0	n/a	No target	*in progress*	*in progress*	7	-	**7**
Pakistan	0	44	50	50				**50**
South Africa Global VAX	0	n/a	No target	4	0	0	2	**9**
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+ helps MRAs in several countries systematically address those recommendations. In PY4, PQM+ assisted: (a) Ethiopia's EFDA with inspection, market authorization, vigilance, and clinical trials recommendations; (b) Kenya's PPB in addressing 50 agreed-upon inspection, licensing, laboratory testing, and market surveillance and control recommendations; (c) Liberia's LMHRA on market surveillance and control, laboratory testing, market authorization, and regulatory systems recommendations; (d) Pakistan's DRAP in addressing 50 recommendations (11 related to the national regulatory system; 7 to market authorization; 4 to vigilance; 6 to market surveillance and control; 3 to licensing establishment; 6 to regulatory inspection; 3 to laboratory testing; 5 to clinical trials oversight; and 5 to lot release); and (e) South Africa's SAHPRA with addressing 9 recommendations (market surveillance and control and regulatory systems).								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
2.1d. Score on institutionalization of new approaches to inspecting facilities by PQM+-supported MRA, by quarter								
Ethiopia (inspection checklist)	0%	0%	83%	0%	100%	100%	100%	**100%**
Lesotho (inspection checklist)	0%	0%	50%	-	33%	33%	33%	**33%**
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 PY4, two MRAs were working to institutionalize use of an inspection checklist. Ethiopia's checklist is now fully institutionalized. Lesotho has begun developing a SOP and training program.								
2.1i. Percentage of milestones to prepare for PIC/S accession achieved by the Medicine Regulatory Authority with PQM+ support, by quarter								
Kazakhstan NCEM	10%	32%	60%	78.6%	80%	80%	80%	**80%**
Uzbekistan Agency	0%	20%	76%	20%	20%	20%	20%	**20%**
Kazakhstan and Uzbekistan are seeking PIC/S accession. This will indicate that their inspectorates meet PIC/S' harmonized GMP standards and quality systems. PQM+ tracks progress along the protracted journey toward meeting all accession requirements. Pakistan's DRAP has submitted its application to the PIC/S secretariat and Kazakhstan's NCEM is expected to do so in March 2024.								
2.1k. Number of standard operating procedures (SOPs) PQM+ helped the MRA develop or revise, by quarter								
Bangladesh	0	21	No target	2	3	0	14	**19**
Benin	0	0	3	0	0	0	7	**7**
Ethiopia	0	36	13	6	0	2	1	**9**
Kazakhstan	0	6	5	6	1	0	0	**7**
Nepal	0	0	4	0	0	0	4	**4**
Pakistan		0	No target	0	1	0	0	**1**
Rwanda	0	5	No target	0	1	0	0	**1**
Uzbekistan	0	7	10	2	2	2	1	**7**
Total 2.1k				**16**	**8**	**4**	**27**	**55**
Depending on their needs, PQM+ helps MRAs develop or update SOPs to carry out regulatory functions. SOPs help MRAs achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and noncompliance with regulations or requirements. In PY4, 8 project teams reported progress in developing or revising a total of 55 SOPs.								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
2.2. Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened								
2.2a. QC laboratory's score on the Stepwise Assessment Tool towards Accreditation (SATTA), by quarter								
Benin ANCQ	12%	n/a	50%	-	-	-	61%	**61%**
Burkina Faso ANSSEAT-DCM/PNA	29%	29%	60%	-	76%	-	85%	**85%**
Ethiopia Diredawa	15%	15%	No target	57%	-	-	-	**57%**
Liberia LMHRA QCL	47%	49%	No target	69%	-	-	-	**69%**
Nepal NML	37%	n/a	No target	-	55%	-	-	**55%**
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 of weakness (i.e., areas not compliant with WHO prequalification or ISO 17025:2017 standards). In PY4, PQM+ conducted midterm assessments of Benin's ANCQ, Ethiopia's Diredawa branch laboratory, and Nepal's NML, and performed mock audits of Burkina Faso's ANSSEAT-DCM/PNA in preparation for first time accreditation. Laboratories are also coached to use SATTA to conduct their own internal audits, which Liberia's LMHRA's QCL did in Q1. These internal scores can be used to track laboratories' accurate use of the tool as well as progress from the baseline.								
2.2b.1 and 2.2b.2. Number of PQM+-supported laboratories that achieved or maintained ISO accreditation or WHO PQ and number of methods, by quarter								
Ethiopia PQAD	PQAD (16)	PQAD (16)	PQAD (16)	0	0	17025:2017 (4 new methods)	-	**1 (4 new methods)**
Mali LCQM-LNS	0	0	ISO 17025:2017	1 (4) **new ISO 17025:2017**	-	-	-	**1 (4)**
Nigeria CDCL Yaba	0 (2022)	0	5	1 (new PQ)	-	-	-	**1**
Pakistan DTL Multan	0	0	1	0	1 (new PQ)	-	-	**1**
Pakistan DTL Lahore	0	0	1		1 (new PQ)	-	-	**1**
Uzbekistan Andijan	Natl. recertifi-cation 2019; ISO 17025: 2017, 2021	n/a	ISO 17025:2017 recertification	1 (118)	-	-	-	**1 (118)**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
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 PY4, 6 labs (some of which started receiving support under the predecessor PQM agreement) were re-accredited for ISO 17025:2017. These include PQAD (Ethiopia) and Andijan (Uzbekistan). Mali's LCQM-LNS obtained its first accreditation for 4 methods. NAFDAC's Central Drug Control Laboratory in Yaba also obtained WHO PQ status with PQM+'s support. Pakistan's DTL Multan and DTL Lahore both achieved WHO PQ in Q2.								
2.2c. Score on institutionalization of new quality assurance approaches/tools at PQM+-supported QC laboratory, by quarter								
Liberia LMHRA (training program)	0%	100%	100%	100%	100%	100%	100%	**100%**
Madagascar LNCQM (preventive maintenance program)	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	**33.3%**
The sustainability of PQM+'s laboratory strengthening work depends, in part, on whether laboratories "own" the new quality programs and systems that PQM+ has introduced. Having the capability to continually evaluate operational procedures, staff, and equipment allows a more reliable laboratory environment capable of producing accurate results in the most efficient way. PQM+ tracks institutionalization of new approaches and programs using the scoring rubric outlined in the notes above this table. In PY3, PQM+-supported Madagascar LNCQM's preventive maintenance program; no further progress was made in PY4. Liberia's LMHRA NCL's training program was fully institutionalized in PY3. USAID no longer funds this activity, but PQM+ continues monitoring the status (100%) to ensure sustainability.								
2.2g. Number of proficiency tests or inter-laboratory tests completed by the QC laboratory, by quarter								
Bangladesh	0	6	No target	0	0	0	3	**3**
Burma	D/N/A	0	4	2	0	0	0	**2**
Kazakhstan (Almaty & Karaganda)	D/N/A	4 each	Karaganda: 8, Almaty:16	0	2	6	1	**9**
Nepal NML	0	3	No target	0	0	0	2	**2**
Nigeria NIPRID QCL	0	0	No target	0	0	3	0	**3**
Total 2.2g				**2**	**2**	**9**	**6**	**19**
2.2h. Percentage of milestones toward accreditation or pre-qualification achieved by a PQM+-supported laboratory								
ISO 17025:2017								
Bangladesh CDTL	0%	35%	No target	40%	40%	40%	40%	**40%**
Bangladesh Plasma Plus Research & Testing Lab	0%	45%	No target	45%	45%	55%	55%	**55%**
Bangladesh Chittagong NQCL	0%	n/a	No target	-	-	-	40%	**40%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Benin ANCQ	0%	n/a	56%	10%	10%	10%	60%	**60%**
Burkina Faso ANSSEAT	0%	45%	60%	45%	55%	60%	85%	**85%**
Burma YSI Pharmaceuticals QCL	0%	40%	60%	40%	40%	40%	40%	**40%**
DRC LNCQ-LAPHAKI	29%	40%	100%	40%	40%	40%	40%	**40%**
Ethiopia Diredawa	0%	45%	90%	50%	50%	50%	55%	**55%**
Liberia LMHRA NQCL	0%	60%	No target	60%	60%	60%	60%	**60%**
Madagascar LQCM	0%	40%	45%	45%	45%	45%	45%	**45%**
Mali LCQM-LNS	0%	95%	No target	95%	95%	80%	80%	**80%**
Mali LCE-LNS	0%	30%	43%	30%	30%	30%	65%	**65%**
Mozambique DCQ	30%	45%	95%	45%	45%	50%	50%	**50%**
Nepal NML	0%	50%	100%	50%	50%	50%	50%	**50%**
Rwanda QCL (ISO 17025 & WHO PQ)	0%	60%	90%	60%	65%	65%	70%	**70%**
Senegal LNCM*	0%	n/a	60%	-	-	50%	50%	**50%**
WHO PQ								
Bangladesh Vaccine wing	10%	57%	No target	57%	57%	80%	85%	**85%**
Kazakhstan Almaty	0%	95%	No target	95%	95%	95%	95%	**95%**
International accreditation enhances a laboratory's technical competence and reputation and assures compliance with established standards. Achieving ISO accreditation or WHO PQ is a lengthy process (see Table A in notes above MEL table). The closer a laboratory is to 100%, the more milestones it has completed. Regarding the drop in scores for Mali, at the time of reporting, LCQM had not done the PT for the year. Thus, the score fell from 95% to 80%. * For more than a year, LNCM and the MRA in Senegal underwent restructuring to become one agency. PQM+ could not undertake most planned activities. The restructuring is now completed, and the new agency is called ARP (Agence de Regulation Pharmaceutique). PQM+ resumed full implementation in PY4.								
2.2i. Number of standard operating procedures (SOPs) developed by QC laboratory as a result of PQM+ support, by quarter								
Bangladesh Vaccine & CDT labs	0	43	No target	2	12	0	5	**19**
Ethiopia Diredawa & PQAD	0	14	30	29	2	0	5	**36**
Ghana FDA	0	0	No target	0	0	0	4	**4**
Kazakhstan Almaty	0	9	19	5	0	18	1	**24**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Madagascar LNCQM	0	8	No target	3	5	2	1	**11**
Nepal NML	0	28	No target	4	2	4	0	**10**
Nigeria Agulu	0	0	No target	2	0	0	0	**2**
Tajikistan Dushanbe	0	2	No target	2	0	0	0	**2**
Total 2.2i				**47**	**21**	**24**	**16**	**108**
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 PY4, PQM+ supported the development or revision of 108 SOPs in 10 laboratories.								
2.2m. Score on technical independence of country in conducting risk-based post-marketing surveillance (RB-PMS)								
Benin rounds 1 & 2	75%	n/a	50%	-	75% (r. 1)	-	91.7% (r. 2)	**91.7%**
Burkina Faso round 2	75%	75%	90%	-	-	-	92.9%	**92.9%**
DRC, round 2	75%	75%	100%	-	-	-	92.9%	**92.9%**
Ethiopia, round 2	58.3%	58.3%	85.7%	-	-	-	78.6%	**78.6%**
Ghana, round 2	83.3%	83.3%	90%	-	-	-	92.9%	**92.9%**
Guinea, round 2	58.3%	58.3%	77%	-	-	-	92.9%	**92.9%**
Kenya	64.3%	n/a	No target	-	-	-	100%	**100%**
Liberia, rounds 2 & 3	58.3%	58.3%	No target	-	71.4% (r. 2)	92.9% (r. 3)	-	**92.9%**
Mali, round 3	83.3%	83.3%	No target	-	85.7%	-	-	**85.7%**
Senegal, round 2	58.3%	58.3%	60%	-	-	-	92.9%	**92.9%**
After each round of RB-PMS, PQM+ scores the extent to which counterparts can (and do) use *on their own* the RB-PMS approach adopted from PQM+ (see notes above for scoring). The indicator tracks *performance* (not impact), so the baseline is the score for round 1 RB-PMS. In PY4, most of the countries above completed their second round of RB-PMS. The scores generally show improvement mainly in the use of the MedRS tool and training of samplers. In a few cases such as Kenya the TWG has used the risk-based method and MedRS tool to carry out other PMS activities not funded by USAID/PQM+. Similarly, the second Benin round was funded by WAHO. Since June of last year, Kenya's TWG surveilled public health products (antimalarials, antiretrovirals and anti-tuberculosis), malaria rapid diagnostic kits, and selected health products and technologies (antimicrobials, analgesics, antihistamines, anticancer and contraceptives) using the knowledge and skills acquired from PQM+. The TWG is now technically independent (100%) in RB-PMS. PQM+ will continue tracking other RB-PMSs that use the MedRS tool even after PQM+ support, as this signals adoption and application of the approach to other medicines and ownership of the RB-PMS program.								
2.2n. Percentage of core processes for which the NQCL has documentation, by quarter								
Benin ANCQ	0%	70%	100%				83.33%	**83.33%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Burkina Faso ANSSEAT	0%	93%	100%				96.67%	**96.67%**
DRC LNCQ-LAPHAKI	D/N/A	50%	100%				100%	**100%**
Ethiopia Diredawa	4.3%	D/N/A	100%	82.14%	93.1%	93.1%	93.33%	**93.33%**
Guinea LNCQM	D/N/A	40%	No target				60%	**60%**
Madagascar LNCQM	46.4%	82.29%	96.4%	89.29%	89.29%	85.71%	92.86%	**92.86%**
Mozambique DCQ	6.9%	89.66%	100%	86.21%	86.21%	86.21%	93.1%	**93.1%**
Nepal NML	D/N/A	37.04%	No target	39.29%	57.14%	78.57%	78.57%	**78.57%**
Rwanda NQCL	D/N/A	90%	100%	93.33%	93.33%	93.33%	100%	**100%**
Senegal LNCM	D/N/A	96.67%	100%	-	-	-	90%	**90%**
A laboratory's QMS consists of processes that must be followed to meet requirements on a consistent basis. There are at least 28-29 core processes every laboratory should have documented (see notes above table). Generally, a laboratory can only achieve international recognition (e.g., ISO 17025 or WHO PQ) once it has a comprehensive QMS in place, so PQM+ generally tracks this indicator only for laboratories that have not yet achieved ISO accreditation or WHO PQ. Nine of the 10 PQM+-supported laboratories listed above have three-quarters or more of the core processes required.								
2.2o (annual). Did NQCL complete management oversight tasks in the last year?								
Benin ANCQ	No	Yes	Yes	-	-	-	Yes	**Yes**
Burkina Faso ANSSEAT	No	No	Yes	-	-	-	Yes/partially	**Partially**
DRC LNCQ-LAPHAKI	No	Yes	Yes	-	-	-	Yes	**Yes**
Ethiopia Diredawa	No	D/N/A	Yes	-	-	-	No	**No**
Guinea LNCQM	No	Yes	Yes	-	-	-	Yes	**Yes**
Madagascar LNCQM	No	No	Partial	-	-	-	No	**No**
Mozambique DCQ	No	No	Yes	-	-	Yes	-	**Yes**
Nepal NML	No	Yes	Yes	-	Yes	-	-	**Yes**
Rwanda NQCL	D/N/A	Yes	Yes	-	-	-	Yes	**Yes**
Senegal LNCM	D/N/A	Yes	Yes	-	-	-	No	**No**
As part of regular management oversight of laboratories' quality management system, an internal audit and management review should be conducted every year. Based on available information, PQM+-supported laboratories that performed this annual activity are shown above. As explained for indicator 2.2n, PQM+								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
does not track this indicator for laboratories that have achieved international recognition, which signals, among other things, that the laboratory is conducting these oversight tasks.								
2.2p. Percentage of core techniques in which at least 2 staff are competent, by quarter								
Benin ANCQ	0%	100%	100%				92.31%	**92.31%**
Burkina Faso ANSSEAT	70%	70%	80%				100%	**100%**
DRC LNCQ-LAPHAKI	0%	80%	2				84.62%	**84.62%**
Ethiopia Diredawa	70%	D/N/A	80%	88.89%	90%	90%	90%	**90%**
Guinea LNCQM	D/N/A	40%	No target				50%	**50%**
Madagascar LNCQM	40%	50%	No target	50%			70%	**70%**
Mozambique DCQ	88.9%	88.9%	88.9%	88.9%	88.9%	88.9%	100%	**100%**
Nepal NML	D/N/A	100%	No target	100%	100%	100%	100%	**100%**
Rwanda NQCL	D/N/A	N/A	71.4%	57.14%	57.14%	64.29%	64.29%	**64.29%**
Senegal LNCM	D/N/A	90%	100%				76.92%	**76.92%**
PQM+ tracks how well *unaccredited* NQCLs can provide reliable, accurate results. One important measure of this is the extent to which NQCL staff are competent to conduct 10 core tests: dissolution, Fourier transform infrared spectrometry, HPLC, Karl Fischer titration, loss on drying, pH measurement, thin layer chromatography, UV spectroscopy, uniformity of dosage unit, and volumetric titrimetry. Before their capability is externally assessed, the NQCL's Quality Manager assesses whether at least two staff can perform these tests. Of the laboratories reporting scores on this metric in PY4, those in Burkina Faso, Mozambique, and Nepal have at least two staff who can perform all core tests.								
2.2r (annual). Percentage of calibration requirements fulfilled								
Burkina Faso ANSSEAT	D/N/A	N/A	No target				100%	**100%**
Ethiopia Diredawa	0%	N/A	100%			100%		**100%**
Madagascar LNCQM	0%	N/A	No target				0%	**0%**
Mozambique DCQ	100%	100%	100%				0%	**0%**
Nepal NML	D/N/A	N/A	No target		50%			**50%**
Rwanda NQCL	0%	N/A	100%	50%		100%		**100%**
To yield reliable results, a laboratories' equipment must be regularly calibrated. PQM+ is helping laboratories in the above countries institutionalize programs to calibrate their equipment on a fixed schedule. Several countries achieved this in PY4.								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
2.3. Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported								
2.3a. Number of regulatory decisions using reliance, by quarter								
Uzbekistan Agency	0	6	6	3	0	0	0	**3**
In PY4 Q1, with no technical assistance from PQM+, Uzbekistan's Agency used the WHO CRP process to register three vaccines—Tetanus Toxoid vaccine, ROTASIL (liquid), and the BCG vaccine. This signals that the WHO CRP process is sustainable and working for products other than TB.								
2.3c. Score on institutionalization of use of a reliance method/mechanism at PQM+-supported MRA, by quarter								
Uzbekistan Agency	0%	100%	100%	100%	100%	100%	100%	**100%**
In PY3, Uzbekistan's Agency fully institutionalized the WHO CRP. The Agency used this approach to register vaccines in PY4 (see indicator 2.3a).								
2.4. Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported								
2.4d. Number of regulatory functions for which data are managed in an electronic regulatory information management system, by quarter								
Pakistan	0	2 (licensing, registration)	2 (lab testing, PV)	0	1	0	1	**2**
In Q2, Pakistan's DRAP completed its interface with NQCLs. Manufacturers were notified to upload their finished product specifications and validated testing methods for FPP within 30 days to inform lab testing. In Q4, the interface to support data sharing between DRAP and provincial QC laboratories for PMS testing of medicines was completed and users trained.								
2.5. Competence, efficiency, and expansion of the medical product quality assurance workforce improved								
2.5a. Number of in-service training programs that address quality assurance/quality control topics delivered with PQM+ support, by quarter								
Asia Bureau	0	0	2	1	1	0	0	**2**
Bangladesh (w/ COVID-19 Vaccine)	0	21	No target	3	10	9	15	**37**
Benin	0	7	8	1	4	5	2	**12**
Burkina Faso (w/ ARP)	0	14	12	1	1	4	3	**9**
Burma	0	8	13	0	3	2	0	**5**
Cross Bureau	0	2	No target	0	0	1	0	**1**
DRC	0	12	5	0	2	3	3	**8**
Ethiopia (w/ ARP, COVID-19 Supplemental)	0	12	9	5	6	2	6	**19**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Ghana (w/ COVID-19 Vaccine, Global VAX)	0	7	No target	0	8	12	3	**23**
Guinea	0	10	8	1	1	0	3	**5**
Kazakhstan (w/ ARP)	0		8	2	4	4	0	**10**
Kenya (Global VAX)	0	2	2	0	0	1	0	**1**
Lesotho	0	0	0	0	0	0	1	**1**
Liberia	0	11	No target	1	2	1	0	**4**
Madagascar	0	6	4	0	1	1	3	**5**
Mali	0	8	15	0	2	2	1	**5**
Mozambique (w/ ARP)	0	1	4	1	0	0	2	**3**
Nepal	0	19	No target	3	6	3	2	**14**
Nigeria (w/ Global VAX)	0	17	No target	4	6	11	6	**27**
Pakistan	0	12	No target	2	4	1	2	**9**
Panama	0	0	3	0	0	1	10	**11**
Rwanda (w/ Global VAX)	0	3	12	0	3	2	2	**7**
Senegal (w/ Global VAX)	0	4	No target	3	5	4	3	**15**
South Africa Global VAX	0	0	5	1	2	1	1	**5**
Tajikistan	0	2	No target	0	0	1	0	**1**
Uzbekistan	0	5	8	0	0	1	4	**5**
Total 2.5a				**29**	**71**	**72**	**72**	**244**
2.5b. Number of individuals who successfully completed PQM+-supported in-service training				**Q1&Q2 F**	**Q1&Q2 M**	**Q3&Q4 F**	**Q3&Q4 M**	
Asia Bureau	0	*See note b	*See note b	19	6	-	-	
Bangladesh (w/ COVID-19 Vaccine)	0			40	82	54	121	
Benin	0			9	21	6	16	
Burkina Faso (w/ ARP)	0			15	14	18	18	

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Burma	0			32	4	24	2	
DRC	0			23	29	32	53	
Ethiopia (w/ ARP, COVID-19 Supplemental)	0			179	325	58	146	
Ghana (w/ COVID-19 Vaccine, Global VAX)	0			25	47	191	173	
Guinea	0			9	21	6	16	
Kazakhstan (w/ ARP)	0			68	16	96	46	
Kenya (Global VAX)	0			-	-	4	11	
Liberia	0			11	44	1	14	
Madagascar	0			18	3	3	2	
Mali	0			6	5	5	12	
Mozambique (w/ ARP)	0			7	3	26	11	
Nepal	0			68	168	33	28	
Nigeria (w/ Global VAX)	0			919	267	910	245	
Pakistan	0			90	114	57	131	
Panama	0			-	-	34	14	
Rwanda (w/ Global VAX)	0			17	31	23	42	
Senegal (w/ Global VAX)	0			74	69	41	27	
South Africa Global VAX	0			11	6	13	24	
Tajikistan	0			-	-	5	14	
Uzbekistan	0			-	-	13	24	
Total (disaggregated)				**1,640**	**1,283**	**1,662**	**1,313**	
Gender percentages (female)				**56.9%**	**43.1%**	**55.3%**	**44.7%**	

Note a: PQM+ does not maintain databases of unique individuals trained. Instead, PQM+ analyzes the categories of trainees and attempts to de-duplicate the number of people trained across half years (Q1 combined with Q2, and Q3 combined with Q4). PQM+ does not total the number of people trained across these

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
two periods because this would increase likely duplication of the number of people trained. In PY4, PQM+ trained almost 3,000 people each half year. In terms of gender balance, slightly more than half of trainees are female. **Note b:** Under the PY3 column, this indicator is difficult to sum, given note a. Targets for people trained have been removed as they may appear much higher than quarterly numbers.								
2.5c. Number of counterpart training programs or courses developed or revised to address quality assurance/quality control topics with PQM+ support, by quarter								
Ethiopia COVID-19 Supplemental	0	0	1	0	0	1	0	**1**
Ghana Global VAX	0	0	1	0	1	0	0	**1**
Total 2.5c				**0**	**1**	**1**	**0**	**2**
PQM+ is helping counterparts develop short QA/QC courses, modules, and curricula so they can provide training in medical product QA/QC, pharmaceutical practices, good manufacturing practices, and regulatory science. This is creating sustainable sources of workforce capacity building in their countries. In PY4, EFDA (Ethiopia) developed a continuing professional development pharmacovigilance course on detecting and reporting SF products and Ghana FDA developed a trainer of trainers' course on good storage and distribution practices (GSDP).								
2.5d. Score for PQM+-supported MRA institutionalization of a workforce development intervention, by quarter								
Nepal (skills program)	0%	50%	50%	50%	50%	50%	50%	**50%**
2.5e. The PQM+-supported laboratory instituted a workforce development intervention, by quarter								
Nepal (staffing program)	17%	33.3%	No target	33.3%	50%	66.7%	66.7%	**66.7%**
Nepal (skills program)	17%	66.7%	No target	66.7%	66.7%	66.7%	66.7%	**66.7%**
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) assessing counterparts' human resources across on or more of 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 workforce development intervention. PQM+ scores each of these components on the pathways selected for improvement to determine how much the counterpart has institutionalized the intervention. A score of 100% means the program has been fully incorporated into national and/or counterpart practices. In PY4, Nepal's NML made significant progress on its staffing program.								
2.5f-Ken. Kenya workforce development (new indicator for Kenya), by quarter								
Number of new staff supported by PQM+ who were contracted by PPB	0	n/a	25	-	-	25	-	**25**
Number of new staff supported by PQM+ who successfully completed initial training	0	n/a	25	-	-	25	-	**25**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Number of new staff supported by PQM+ assigned to positions at PPB	0	n/a	25	-	-	25	-	25
In Kenya, PQM+ is helping PPB build the workforce required to perform key regulatory functions. In Q3, PQM+ helped PPB recruit and onboard 25 new technical staff. These staff have been assigned to departments within PPB and are helping to clear the backlog of regulatory tasks.								
2.5g. Organizations that participated in a study tour (new indicator), by quarter								
Burkina Faso (Manuf. #1)	0	0	No target	0	0	0	1	1
Ghana (FDA, 2 Universities, DEK consortium, and Manufacturer)	0	0	No target	5	0	2	0	7
Kenya (PPB and NQCL)	0	0	No target	2	0	2	0	4
Madagascar (AMM and LNCQM)	0	0	No target	0	2	0	0	2
Nigeria (NAFDAC)	0	0	No target	1	0	1	0	2
Rwanda (FDA and NQCL)	0	0	No target	0	0	2	0	2
Senegal (MRA ARP and university)	0	0	No target	2	0	1	2	5
South Africa (SAHPRA)	0	0	No target	0	0	1	0	1
Total 2.5g				**10**	**2**	**9**	**3**	**24**
PQM+ supports counterparts in directly observing and interacting with entities in other countries that are more advanced in performing similar activities. This year, PQM+ supported 24 such study tours.								
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. Score on institutionalization of risk-based approaches at PQM+-supported MRA, by quarter								
RB Inspection								
Nepal DDA	17%	50%	83%	50%	50%	50%	50%	50%
Rwanda FDA	0%	n/a	83.3%	0%	0%	66.7%	66.7%	66.7%
RB PMS								
Bangladesh DGDA	0%	33%	90%	33%	33%	66.7%	66.7%	66.7%
Benin	0%	0%	50%	0%	66.7%	66.7%	66.7%	66.7%
Burkina Faso ANRP	0%	83.3%	90%	83.3%	83.3%	100%	100%	100%*

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
DRC DPM	0%	33.3%	75%	33.3%	33.3%	83.3%	83.3%	**83.3%**
Ethiopia EFDA	0%	50%	83%	50%	100%	100%	100%	**100%***
Ghana FDA	0%	66.7%	80%	66.7%	66.7%	66.7%	66.7%	**66.7%**
Guinea	0%	0%	83.3%	0%	0%	66.7%	66.7%	**66.7%**
Kazakhstan NCEM	0%	16.7%	100%	16.7%	16.7%	16.7%	16.7%	**16.7%**
Kenya PPB	0%	100%	100%	100%	100%	100%	100%	**100%***
Lesotho	0%	n/a	No target	0%	0%	0%	16.7%	**16.7%**
Liberia LMHRA	0%	66.7%	No target	66.7%	66.7%	66.7%	66.7%	**66.7%**
Madagascar	0%	16.7%	33%	16.7%	16.7%	83.3%	83.3%	**83.3%**
Mali DPM	0%	83.3%	100%	83.3%	83.3%	100%	100%	**100%***
Mozambique	0%	0%	50%	16.7%	16.7%	16.7%	16.7%	**16.7%**
Nepal DDA	0%	50%	50%	50%	50%	50%	50%	**50%**
Pakistan DRAP	0%	100%	n/a	100%	100%	100%	100%	**100%***
Rwanda FDA	0%	33.3%	83.3%	33.3%	50%	50%	50%	**50%**
Senegal ARP	0%	83.3%	90%	83.3%	83.3%	83.3%	83.3%	**83.3%**

For institutionalization indicators, PQM+ tracks whether the counterpart has SOPs describing how to implement the new approach or use the new tool, can train its staff on the SOPs, and tracks implementation or results from using the approach or tool. PQM+ is working to institutionalize risk-based approaches at 18 MRAs. Most MRAs are well on their way to fully institutionalizing risk-based inspection and/or PMS.

***100%:** In PY4, MRAs in **Burkina Faso, Ethiopia**, and **Mali** fully institutionalized RB-PMS. **Kenya** and **Pakistan** continued to maintain their capacity (both institutionalized the approach in 2022 Q2 and Q4, respectively). **Note: Once MRAs fully institutionalize the new approach, it means PQM+ no longer actively supports the effort, but simply monitors whether the counterpart sustains the practice.**

	DRC (PMS)	Madagascar (PMS)	Senegal (PMS)	Bangladesh (PMS)	Benin (PMS)	Ghana (PMS)	Guinea (PMS)	Liberia (PMS)	Nepal (inspection/PMS)	Rwanda inspection/PMS)
SOPs	Yes	Yes	Yes	Yes	No	No	No	Developing	Developing (both)	Developing/Yes
Training	Developing	Yes	Developing	Developing	Developing	Yes	Developing	Developing	Developing (both)	Developing (both)
Tracking system	Yes	Developing	Yes	Developing	Yes	Yes	Yes	Yes	Developing (both)	Yes/No

16.7%: Countries in the early stage of RB-PMS implementation include **Kazakhstan, Lesotho**, and **Mozambique**, all of which are developing SOPs.

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
3.2. Sustainable resources mobilized								
3.2b. The PQM+-supported MRA or NQCL shared analysis of its costs to support review of the fee structure or to improve budgeting and planning, by quarter								
Burkina Faso ANSSEAT	D/N/A	No	n/a	Yes	-	-	-	**Yes**
PQM+ and USAID Burkina Faso supported ANSSEAT in convening a donors' roundtable in Q1 to encourage development partners to provide financial and/or technical support for the agency's strategic plan. Several development partners participated in the workshop and expressed interest in some areas of the strategic plan. ANSSEAT developed a roadmap for resource mobilization and mapped the development partners to key activities in the plan.								
3.2d. Number of instances of additional resource mobilization or optimization as a result of PQM+ support (new indicator), by year								
Nepal	0	D/N/A	No target	-	-	-	6	**6**
Pakistan	0	D/N/A	No target	-	1	-	-	**1**
In Nepal, 3 private pharmaceutical manufacturers have leveraged resources due to PQM+'s technical assistance. These include investments in GMP compliance (updating QA SOPs, procurement of quality API and equipment for QA/QC/safety, and renovating buildings to meet quality, safety, and environmental standards). Two local governments have increased their budgets to procure enough QA essential medicines to distribute the medicines free of charge through their local public health systems. They have also allocated more money to improve storage practices in their medicine stores and storage in local health facilities. Both are working with PQM+ to assure quality procurement of medicines. Finally, DDA increased its RB-PMS budget to procure medicines in FY 2021/22 (maintained in FY 2022/23). In Pakistan, due to PQM+'s intervention, WHO agreed to waive the palatability study for a medicine produced by a Pakistani manufacturer pursuing WHO PQ of the product; this resulted in savings of $52,000 for that manufacturer.								
OBJECTIVE 4: SUPPLY OF QUALITY-ASSURED ESSENTIAL MEDICAL PRODUCTS OF PUBLIC HEALTH IMPORTANCE INCREASED								
High-Level Outcome								
4c. Number of USAID priority medical products supported by PQM+ that received market authorization, by quarter								
Nigeria	0	0	No target	1	0	1	0	**2**
Pakistan	0	0	No target	0	0	0	2	**2**
Tajikistan	0	0	No target	4	5	0	0	**9**
Total 4c.				**5**	**5**	**1**	**2**	**13**
In PY4, PQM+ supported 13 priority medical products in receiving market authorization (MA). This included WHO PQ for zinc sulphate in Q3 by a Nigerian manufacturer, the first West African manufacturer to obtain WHO PQ for this product. Nutribuddy - Ready-to-Use Therapeutic Food also obtained MA in Nigeria. Pakistan obtained two WHO PQs for zinc sulphate, one for syrup and one for DT. In Tajikistan, 9 anti-TB medicines were given market authorization.								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
4.1. Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/dossiers supported								
4.1b. Number of product dossiers submitted by PQM+-supported manufacturers for a USAID-priority medical product, by quarter								
Tajikistan (TB medicines)	0	9	16	0	5	0	0	**5**
In Tajikistan, two PQM+-facilitated foreign companies are working with WHO prequalified manufacturers to compile and submit dossiers for registration in Tajikistan. As a result, three manufacturers successfully submitted 5 more anti-TB dossiers to the MRA. These dossiers are for: (a) isoniazid tablets BP 100 mg-first line pediatric dose, (b) ethambutol hydrochloride tablets BP 100 mg-first line pediatric dose, (c) rifampicin 75 mg, isoniazid 50 mg, and pyrazinamide 150 mg dispersible tablets-first line pediatric dose, (d) isoniazid 300 – first line for prevention, and (e) linezolid tablets USP 600mg-second line.								
4.1c Percentage of milestones to market authorization/PQ achieved, by quarter								
Bangladesh, Manuf. #2 (4FDC anti-TB)	D/N/A	47.5%	No target	47.5%	47.5%	55%	55%	**55%**
Burkina Faso, Manuf. #1 (ALu 20/120 mcg)	0%	n/a	30%	0%	10%	17.5%	17.5%	**17.5%**
Core NTD, India Manuf. #3 (praziquantel)	0%	85%	100%	85%	80%	80%	80%	**80%**
Core TB, Pakistan Manuf. #4 (2FDC anti-TB)	0%	53.8%	50%	42.5%	70%	70%	70%	**70%**
Core TB, Pakistan Manuf. #1 (4FDC anti-TB)	0%	17.5%	No target	-	17.5%	17.5%	17.5%	**17.5%**
Ethiopia, Manuf. #5 (magnesium sulphate inj.)	0%	n/a	78%	-	-	10%	10%	**10%**
Ethiopia, Manuf. #8 (TBD)	0%	n/a	78%	-	-	10%	10%	**10%**
Ghana, Manuf. #3 (ALu 20/120 mcg)	0%	35%	No target	35%	35%	35%	35%	**35%**
Ghana Manuf. #9 (oxytocin)	0%	17.5%	No target	17.5%	17.5%	17.5%	35%	**35%**
Ghana, Manuf. #6 (ALu 20/120 mcg)	0%	35%	No target	35%	35%	35%	35%	**35%**
Nepal, Manuf #4 (amox DT 250 mg)	0%	42.5%	No target	35%	35%	35%	35%	**35%**
Nepal,Manuf. #3 (azithromycin)	0%	42.5%	No target	35%	35%	35%	35%	**35%**
Nepal, Manuf. #5 (azithromycin)	0%	42.5%	No target	35%	35%	35%	42.5%	**42.5%**
Nepal, Manuf. #1 (azithromycin)	0%	42.5%	No target	35%	35%	35%	42.5%	**42.5%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Nepal Manuf. #2 (zinc sulfate)	0%	42.5%	No target	35%	35%	35%	42.5%	**42.5%**
Nigeria, Manuf. #2 (amox DT 250 mg)	D/N/A	32.5% (adjusted)	No target	32.5%	32.5%	32.5%	32.5%	**32.5%**
Nigeria, Manuf. #3 (ALu 20/120 mcg)	D/N/A	30%	No target	40%	40%	40%	40%	**40%**
Nigeria, Manuf. #3 (SP)	D/N/A	30%	No target	80%	80%	80%	80%	**80%**
Nigeria, Manuf. #4 (ALu 20/120 mcg)	D/N/A	40%	No target	40%	40%	40%	40%	**40%**
Nigeria, Manuf. #4 (zinc sulfate 20 mg)	D/N/A	70%	No target	70%	85%	90%	100%	**100%**
Nigeria, Manuf. #4 (sulfadoxine & pyrimethamine)	D/N/A	70%	No target	85%	85%	95%	90%	**90%**
Nigeria, Manuf. #5 (ALu 80/480 mcg)	D/N/A	10%	No target	40%	40%	40%	40%	**40%**
Nigeria, Manuf. #6 (mag. sulphate inj.)	D/N/A	80%	No target	60%	60%	60%	60%	**60%**
Nigeria, Manuf. #6 (oxytocin 10iu/mL)	D/N/A	50%	No target	45%	45%	45%	45%	**45%**
Nigeria, Manuf. #7 (amox DT 250 mg)	D/N/A	50%	No target	40%	40%	40%	40%	**40%**
Pakistan, Manuf. #2 (amox DT 125 mg)	D/N/A	35%	No target	35%	35%	42.5%	42.5%	**42.5%**
Pakistan, Manuf. #2 (amox DT 250 mg)	D/N/A	35%	No target	35%	35%	42.5%	42.5%	**42.5%**
Pakistan, Manuf. #5 (zinc sulfate syrup)	D/N/A	57.5%	No target	85%	85%	95%	100%	**100%**
Pakistan, Manuf. #5 (zinc sulfate tablet))	D/N/A	57.5%	No target	85%	85%	95%	100%	**100%**
Pakistan, Manuf. #6 (amox DT 125 mg)	D/N/A	35%	No target	35%	35%	35%	35%	**35%**
Pakistan, Manuf. #6 (amox DT 250 mg)	D/N/A	35%	No target	35%	35%	35%	35%	**35%**
Pakistan, Manuf. #7 (zinc sulfate)	D/N/A	35%	No target	35%	35%	35%	35%	**35%**
Pakistan, Manuf. #8 (zinc sulfate)	D/N/A	47.5%	No target	47.5%	47.5%	47.5%	57.5%	**57.5%**
Uzbekistan, Manuf. #22 (levofloxacin)	D/N/A	50%	No target	50%	50%	50%	50%	**50%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Achievement of market authorization or WHO prequalification for a new medical product is a long process with many stages (Table A, Annex 1). For this reason, PQM+ tracks and reports progress in achieving major milestones. Manufacturers can be at any phase for an extended period, for example, when various studies are being conducted. In PY4, the scores of Nigerian manufacturers 6 and 7 dropped due to packaging issues with MgSO4 injection and delays in the maintenance of their facilities.								
4.4. Health coverage schemes that incorporate medical product quality requirements supported								
4.4a. Number of medicine policies, laws, regulations, guidelines, or procedures (SOPs) developed or revised to incorporate quality assurance requirements with PQM+ support, by quarter								
Kenya (SOPs developed for Busia County)	0	0	2	0	0	0	13	**13**
Lesotho National Medicines Policy 2022 (drafting)	0	0	No target	0	0	1	0	**1**
Lesotho National Guideline for Good Storage and Distribution Practices (drafting)	0	0	No target	0	0	0	1	**1**
Pakistan Guidelines for Cold Chain Management Practices for Time and Temperature Sensitive Drug Products (drafted & released for comment)	0	1	No target	0	1	0	0	**1**
Total 4.4a				**0**	**1**	**1**	**14**	**16**
The bulk of PQM+'s policy work focuses on regulatory policies (indicator 1.1a). In several countries, PQM+ is also helping to develop policies and guidelines for managing the medicines supply chain. These are reported under this indicator. In PY4, PQM+ began helping governments in Lesotho and Pakistan to develop such policies. Thirteen SOPs related to supply chain management were developed in Kenya.								
4.5. Monograph development and use supported								
4.5a. Number of monographs or product information reports on USAID priority medical products that were supported by PQM+ and completed, by quarter								
Core MNCH	0	0	1	0	1	0	0	**1**
This year, PQM+/USP completed a monograph on the MNCH product gentamicin.								
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 innovations with tested efficacy that were adopted, by quarter								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
COVID-19 Therapeutics – resource on Covid test to treat therapeutics	D/N/A	0	1	0	0	0	1	1
Core MNCH - medical devices elearning course; job aids on gentamicin (English & French)	D/N/A	0	2	0	1	2	2	5
Core NTD – NTD MID	D/N/A	0	1	0	0	0	1	1
Core TB - alternate synthesis of rifapentine API	D/N/A	2	1	0	0	0	1	1
Ghana Global VAX – Advocacy toolkit	D/N/A	0	3	0	0	1	0	1
South Africa Global VAX – competency needs assessment tool, MedRS for vaccines	D/N/A	0	3	1	0	1	0	2
Total 5.1a				1	1	4	5	11
This year, PQM+ developed and shared the following innovations: (a) the medical devices elearning course and job aids for registration and lab testing of gentamicin (English and French versions of both) for Core MNCH; (b) the NTD MID for Core NTD; and (c) an alternative approach to synthesizing rifapentine API (now being transferred to an African manufacturer) for Core TB. At the country level, PQM+ Kenya developed a generic PMS protocol of medical devices that included malaria rapid diagnostic tests. The South Africa Global VAX buy-in developed a competency needs assessment tool, and the Ghana Global VAX an advocacy toolkit.								
5.1b. Number of entities that used global tools, by quarter								
Ethiopia (SATTA) - Diredawa	0	0	1	1	-	-	-	1
Nepal (SATTA) - NML	0	0	1	-	1	-	-	1
Kenya (SF medicine burden model) - PMS TWG	0	0	1	1	-	-	-	1
Benin (MedRS) - PMS TWG	0	0	1	-	1	-	-	1
Madagascar (MedRS) - PMS TWG	0	1	0	-	-	-	1	1
Mozambique (Guidance on RB-PMS)	0	0	0	-	-	-	1	1
Nepal (MedRS) - DDA, PMS Dept.	0	1	1	-	-	1	-	1
Uzbekistan (MedRS) - Agency	0	0	1	1	-	-	-	1

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
South Africa Global VAX (MedRS vaccine module) - SAHPRA	0	0	1	-	-	1	-	1
Total 5.1b				3	2	2	2	9
PQM+ was able to track counterpart use of a PQM or PQM+ tool, mainly SATTA and MedRS and, in one instance, the SF medicine burden model (for the Kenya pilot) in several countries.								
5.2. Research and analysis to support medical product quality assurance systems strengthening conducted								
5.2a. Number of technical publications/presentations, by quarter								
Africa Bureau AMA	0	0	5	0	0	1	4	5
Asia Bureau	0	2	No target	0	1	1	0	2
Bangladesh	0	5	6	0	0	0	3	3
Burma	0	3	4	2	1	0	0	3
Core MNCH	0	2	5	3	2	0	2	7
Core NTD	0	0	1	0	0	0	1	1
Core TB	0	0	No target	1	0	0	0	1
Cross Bureau	0	11	No target	1	0	2	9	12
Ethiopia	0	3	No target	0	1	0	0	1
Ghana	0	0	No target	0	1	0	0	1
Kenya	0	6	2	0	1	0	0	1
Nigeria	0	0	No target	3	0	0	0	3
Pakistan	0	10	n/a	0	1	0	1	2
PQM+ Global	0	4	No target	0	0	1	3	4
Uzbekistan	0	6	No target	1	0	0	0	1
Total 5.2a				11	8	5	23	47
PQM+ buy-ins continued to produce and disseminate many technical reports and presentations on medical product quality assurance throughout the year. Particularly noteworthy were contributions from the Africa Bureau support for the African Medicines Agency and Cross-Bureau support for the African Laboratory Network.								

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
5.2e. Number of modules that were completed, by quarter								
Core NTD (GMP eLearning module completions)	0	1,790	2,500	873	283	457	499	**2,112**
Core MNCH (medical device eLearning module completions)	0	n/a	No target	156	22	24	59	**261**
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 or activities around medical product quality that were supported by PQM+, by quarter								
Bangladesh	0	0	3	0	2	2	4	**8**
Burkina Faso COVID ARP	0	0	0	0	1	0	0	**1**
Core MNCH	0	1	No target	0	0	1	0	**1**
Core NTD	0	1	2	1	0	0	1	**2**
Ethiopia ARP	0	0	0	1	0	0	0	**1**
Ethiopia COVID-19 Supplemental	0	0	5	0	0	3	1	**4**
Ghana Global VAX	0	0	2	0	0	0	8	**8**
Liberia	0	2	0	1	0	0	0	**1**
Madagascar	0	0	No target	0	0	1	0	**1**
Nepal	0	3	4	2	0	2	1	**5**
Rwanda	0	0	1	0	1	0	0	**1**
Uzbekistan	0	7	6	2	0	0	0	**2**
Total 5.3a.				**7**	**4**	**9**	**15**	**35**
PQM+ awareness and advocacy work included participation in global activities. For example, Core MNCH participated in events to promote the Call-to-Action paper via webinars for USAID missions, USAID/W, and members of the Child Health Task Force advocating for a series of actions to improve uptake of amoxicillin and gentamicin for children and newborns. Country-level activities ranged from convincing decision makers to explore how to improve TB medicine quality in the private sector in Bangladesh to sharing messages about vaccine safety to an estimated 2 million people in Ethiopia.								
5.3b. Number of instances of media coverage of PQM+-supported medical product quality assurance-related events or topics, by quarter								
Asia Bureau (Twitter)	0	0	No target	0	0	1	0	**1**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Bangladesh (Twitter, LinkedIn, Newsletter)	0	7	3	1	6	3	7	17
Benin (Twitter, LinkedIn)	0	2	1	0	3	1	0	4
Burkina Faso (Twitter, LinkedIn)	0	1	1	1	2	2	1	6
Burma (Twitter, LinkedIn. Video, Newsletter)	0	0	4	3	5	2	0	10
Core MNCH (Social, media, Twitter, LinkedIn)	0	0	No target	0	2	3	0	5
Cross Bureau (Twitter, LinkedIn)	0	1	No target	1	2	0	0	3
Core NTD (Twitter, LinkedIn, Newsletter)	0	1	No target	0	3		5	8
Core TB (Twitter, LinkedIn)	0	0	No target	0	2	1	0	3
COVID-19 therapeutics	0	n/a	No target	0	1	0	0	1
DRC (Twitter)	0	3	No target	0	0	3	0	3
Ethiopia (Twitter, LinkedIn, Newsletter)	0	6	No target	6	2	5	10	23
Ghana (Twitter, LinkedIn, Success Story, Newsletter)	0	8	1	9	6	7	9	31
Guinea (Twitter, LinkedIn)	0	0	No target	0	0	3		3
Kazakhstan (Twitter, LinkedIn)	0	3	4	1	3	4	0	8
Kenya (Twitter, LinkedIn)	0	4	No target	11	1	3	6	21
Liberia (Twitter, LinkedIn)	0	10	No target	0	2	7	0	9
Madagascar (Twitter, Newsletter)	0	2	No target	0	1	1	3	5
Mali (Twitter, LinkedIn, Success Story, Newsletter)	0	1	1	0	5	2	3	10
Mozambique ((Twitter, LinkedIn)	0	2	No target	0	0	0	2	2
Nepal (Twitter, LinkedIn, Newsletter)	0	3	No target	3	9	3	5	20
Nigeria (Twitter, LinkedIn, Newsletter)	0	5	No target	13	4	5	13	35

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
Pakistan (Twitter, LinkedIn, Success Story, Newsletter)	0	0	No target	7	7	8	4	**26**
Panama (Twitter, LinkedIn)	0	0	No target	0	0	2	0	**2**
Rwanda (Twitter, LinkedIn)	0	3	No target	2	2	2	0	**6**
Senegal ((Twitter, LinkedIn)	0	2	1	7	3	3	0	**13**
South Africa (Twitter, LinkedIn)	0	1	No target	21	1	2	0	**24**
Tajikistan (Twitter, Newsletter)	0	0	3	1	2	0	0	**3**
Uzbekistan (Twitter, LinkedIn, Success Story, Newsletter)	0	15	10	13	9	6	7	**35**
Total 5.3b				**100**	**83**	**79**	**75**	**337**
PQM+ continues to publicize its work around medical product quality assurance. In PY4, there were over 330 instances of (mainly social) media coverage. This does not include PQM+ team members' independent use of social media that mentions our work.								
5.3c-g Number of global collaborations, by quarter								
Africa Bureau AMA tech committees	0	0	No target	0	0	0	2	**2**
Asia Bureau (SEARN Regional Action Plan; SEARN CIP)	0	0	No target	0	0	0	2	**2**
Core MNCH (UNICEF supply division; RHSC)	0	2	No target	0	0	0	2	**2**
Cross Bureau (AMQF, AUDA-NEPAD)	0	0	No target	0	0	0	2	**2**
PQM+ Global (Expert advisory panel, Intl. Pharmacopoeia & Pharmaceutical Preparations)	0	7	No target	0	0	0	1	**1**
Total 5.3c-g				**0**	**0**	**0**	**9**	**9**
PQM+ is a trusted partner of several regional or global entities. In PY4, PQM+ supported 2 AMA technical committees, SEARN, the UNICEF supply division, RHSC, AMQF, AUDA-NEPAD, and the Expert Advisory Panel on International Pharmacopoeia and Pharmaceutical Preparations. Note that these ongoing collaborations are reported at the end of the year and not by quarter.								
GVX 2.1.1 Percentage of task force components in place								
South Africa	0%	n/a	70%	0%	60%	70%	70%	**70%**

Indicator Code and Name	Baseline	PY3 Actual	PY4 Target	PY4 Q1	PY4 Q2	PY4 Q3	PY4 Q4	PY4 Total
In South Africa, PQM+ helped SAHPRA establish a task force to begin implementing a network of laboratories. The task force identified a leader for the group, established terms of reference, and held meetings as needed to advance plans for a laboratory network.								
GVX 2.2.2 Laboratory gap assessment								
Ghana	No	n/a	Yes	Yes	-	-	-	**Yes**
Kenya	No	n/a	Yes	-	-	Yes	-	**Yes**
Nigeria	No	n/a	Yes	Yes	-	-	-	**Yes**
Senegal	No	n/a	Yes	Yes	-	-	-	**Yes**
South Africa	No	n/a	Yes	-	Yes	-	-	**Yes**
As part of its Global Vax support, PQM+ conducted assessments to identify gaps in the laboratory performance of 5 buy-ins. The assessments helped identify areas that need strengthening to enhance the laboratories' capacity to test the quality of biological products.								
GVX 2.2.3 # tests for biological products for which at least 2 analysts are competent								
Ghana	3	n/a	5	-	-	-	5	**5**
Nigeria	D/N/A	n/a	4	8	8	12	-	**28**
Senegal	3	n/a	No Target	-	-	-	5	**5**
Total GVX 2.2.3				**8**	**8**	**12**	**10**	**38**

Annex 2: RB-PMS rounds of antimalarials and MNCH medicines concluded in PY4

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
BENIN r. 1 (Q2)	**Malaria** ▪ AL tablet (39) ▪ Artemether inj (26) ▪ Artesunate inj (52) ▪ Quinine sulfate tab (28) ▪ Quinine dihydrochloride inj (46) ▪ SP (11) **Total=202**	**4.5% (9 samples)**	**Registration status:** ▪ 18% of samples unregistered ▪ 8% of samples expired MA ▪ 20% of AL expired MA ▪ Quinine sulfate highest rate of unregistered products (75%) **Failed medicine:** ▪ Artemether injectable (1 of 26 samples) (3.8%) ▪ Quinine dihydrochloride injectable (5 of 46 samples) (10.9%) ▪ Quinine sulfate tablets (3 of 28 samples) (10.7%)	API for all failed samples were out of specification (OOS) per pharmacopeial standards.	In Q2: Recalled SF antimalarials; manufacturers with expired product registrations informed to renew market authorizations
"...Market surveillance particularly based on risk is proven economical, effective, and efficient." – ***Benin TWG, PMS report***					
BURKINA FASO r. 2 (Q4)	**Malaria** ▪ Artesunate injection (52) ▪ Artemether injection (8) ▪ Quinine injection (6), and tablet (20) ▪ AL tablet & suspensions (127) ▪ Dihydroartemisinin / Piperaquine tablet & suspensions (18) ▪ Sulfadoxine / Pyrimethamine tablet (30) ▪ Sulfadoxine / Pyrimethamine / Amodiaquine (24) **Total=285**	**0.7% (2 samples)**	**Registration status:** ▪ 19.7% of 76 brands unregistered. **Failed medicine:** ▪ Artemether + lumefantrine (2 of 127 samples) (1.6%)	Impurities noted in one sample and API in both samples was OOS.	In Q4: Written notice sent to offenders
"The update available to [___] in the district, was of great interest, facilitating the identification and administrative procedures. We also note good collaboration with the different actors, the majority of whom have become familiar with the activity. The test compliance rate was 99.29%. These encouraging results indicate					

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
*proper application of the regulatory provisions put in place. This activity was of an undeniable contribution to the national coverage of monitoring the quality of antimalarial drugs and strengthening indicators. The hope is that the PMS can be extended to other therapeutic classes." – **Burkina Faso TWG, PMS report*** *PMS report noted poor storage conditions at collection sites—insufficient storage space, pallets, and shelves; cardboard directly on the floor and/or glued to the wall; improper temperature, humidity, ventilation, and light exposure. Temperatures recorded during collections varied from 25 to 40°C and humidity levels were from 25% to 78%.*					
ETHIOPIA r. 2 (Q4)	**Malaria** ▪ Artemether/Lumefantrine 120 mg dispersible tablets (34) ▪ Primaquine tablets (8) **Total=42** **MNCH** ▪ Pediatric Cotrimoxazole Susp (25) ▪ Cefalexin Oral Susp (15) ▪ Gentamycin Inj (29) ▪ Magnesium Sulfate Inj. (12) ▪ Oxytocin Inj. (10) **Total=91** **Grand Total=133**	**Malaria: 0%** **MNCH: 1.1% (1 sample)**	**Registration status:** ▪ **Malaria:** 14% of samples unregistered ▪ **MNCH:** 35% of samples unregistered **Failed medicine:** ▪ Magnesium sulfate injection (1 of 12 samples) (8.3%)	Sample failed assay test (possibly manufacturing process)	In Q1, 2024*: ▪ PMS report noted that, even though EFDA authorized an artesunate injection product for 24 months, the product's shelf life was labeled 36 months without passing the legal variation process. EFDA therefore recalled the product from the market. **NOTE: At times there can be a gap between results and action.*
*"The information obtained through the survey has led to a better understanding of the quality and regulatory status of antimalarial and MNCH medicines circulating in Ethiopia and will be used as an input for EFDA (regional regulatory bodies) to take relevant regulatory measures/ actions." - **Ethiopia TWG, PMS report***					
GHANA r. 2 (Q4)	**Malaria** ▪ Artesunate injection (67) **MNCH** ▪ Oxytocin Inj. (43) ▪ Misoprostol tabs (32) ▪ Ergometrine inj. (1) **Total=76** **Grand Total=143**	**Malaria: 4.5% (3 samples)** **MNCH: 29% (17 of 59 samples tested)**	**Registration status:** ▪ **Malaria:** 3% of samples unregistered ▪ **MNCH:** 25% of samples unregistered **Failed medicine:** ▪ Artesunate inj. (3 of 67 samples) (4.5%) ▪ Oxytocin inj. (only 26 samples tested; 17 of 26 samples) (65%)	▪ Artesunate samples failed assay test; one sample failed uniformity of content. ▪ Failure of oxytocin due to faulty manufacturing process (e.g., filling of vials).	In Q4: ▪ Product recalls, seizures, and regulatory sanctions in the form of administrative charges applied to companies involved in the importation, sale, and distribution of unregistered and nonconforming products. ▪ Stocks of the recalled and seized products safely

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
				▪ Oxytocin failed assay on the high side of the approved pharmaceutical dosage limit.	disposed of under the supervision of FDA. ▪ FDA also revoked the marketing authorization of companies who failed to file for variation (in manufacturing site and storage conditions).
Report notes unavailability of some medicines in facilities as well as lack of cooperation of some community-based health planning and services compounds. These hindered the sampling exercise. The TWG recommended surveilling border regions to rid the market of unregistered products, and sensitizing facility owners on good storage practices.					
GUINEA **r. 1 (Q2)**	**Malaria** ▪ Artesunate 60mg (26) and 100mg (8) ▪ Quinine (sulfate) 300mg (26) ▪ Artemether 80mg/MI (15) ▪ Quinine (hydrocloride) 300mg/ml (5) ▪ Sulfadoxine/Pyrimethamine 500mg/25mg (20) ▪ Artemether / Lumefantrine 20mg/120mg (35) **Total=135** **MNCH** ▪ Oxytocin 10 UI/ml (24) ▪ Magnesium sulfate (6) ▪ Amoxicillin (sodium) 250 mg (10) ▪ Dexamethasone 4mg/ml (8) **Total=48** **Grand Total=183**	**Malaria: 7.4% (10 samples)** **MNCH: 47.9% (23 samples)**	**Failed medicine:** ▪ Quinine (hydrocloride) (1 sample of 5) (20%) ▪ Artesunate 60mg (3 of 26 samples) (11.5%) ▪ SP (1 of 20 samples) (5%) ▪ Amoxicillin (3 of 10 samples) (30%) ▪ Oxytocin (20 of 24 samples) (83%)	▪ Antibiotics: presence of contaminants and API OOS ▪ Antimalarials and oxytocin: API OOS	▪ No enforcement action ▪ PMS TWG recommended regulatory action against non-compliant drugs. ▪ TWG also recommended strengthening QA system (infrastructure, equipment, training in good storage practices, and distribution of medicines).
"The collection of samples [for] the PMS 2021…made it possible to inquire about several realities on the availability of stock [and] on the functionality of certain health establishments." - ***Guinea TWG, PMS report***					
GUINEA **r. 2 (Q4)**	**Malaria** ▪ Artesunate 60mg (6) ▪ Artemether 40mg (4)	**Malaria: 7.4% (7 samples)**	**Failed Antimalarials:** ▪ 1 Quinine 300mg (1 of 27 samples) (3.7%)	▪ Antibiotics: presence of	▪ No enforcement action. ▪ Same as r. 1

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
	▪ Quinine (sulfate) 300mg (19) ▪ Quinine (hydrocloride) 300mg/ml (8) ▪ Sulfadoxine/Pyrimethamine 500mg/25mg (22) ▪ Artemether/Lumefantrine 20mg/120mg Comprime (36) **Total=95** **MNCH** ▪ Oxytocin Inj. (13) ▪ Dexamethasone 4mg/ml (16) ▪ Amoxicillin (sodium) 250 mg (9) ▪ Amoxicillin (sodium) 500 mg (12) ▪ Sulfate de Magnesium 10% (9) ▪ Polyvidone solution 10% (13) **Total=72** **Grand Total=167**	**MNCH: 41.7% (30 samples)**	▪ SP (6 of 22 samples) (27.3%) **Failed MNCH medicines:** ▪ 4 dexamethasone (4 of 16 samples) (25%) ▪ 5 Amoxicillin (5 of 21 samples) (23.8%) ▪ 10 Oxytocin (10 of 13 samples) (76.9%) ▪ Polyvidone Iodine (11 of 13 samples) (84.6%)	contaminants and underdosing ▪ Antimalarials: label ▪ Oxytocin: Underdosing in active principle	▪ PMS recommendations same as round 1 (NOTE: rounds 1 and 2 were disseminated at the same time).
PMS report notes poor storage conditions and good practices in certain health establishments.					
LIBERIA r. 2 (Q2)	**Malaria** ▪ Artesunate 60/120mg/ml Injection (14) ▪ Artemether 20mg/80mg/ml Injection (30) ▪ Artemether 20mg/120mg Lumefantrine susp. (28) ▪ Quinine Dihydrochloride 600mg/2ml injection (29) **Total=101** **MNCH** ▪ Oxytocin Injection (20) ▪ Magnesium Sulphate Injection (19) ▪ Ergometrine Maleate tablet (6) **Total=45** **Grand Total=146**	**Malaria: 13.5% (13 of 96 samples tested)** **MNCH: 31% (10 of 32 samples tested)**	**Registration status:** ▪ 26% unregistered products **Failed medicines:** ▪ Artesunate (5 of 14 samples) (35.7) ▪ Artemether (5 of 30 samples) (16.7%) ▪ Artemether-lumefantrine (3 of 28 samples) (10.7%) ▪ Oxytocin (4 of 20 samples) (20%) ▪ All ergometrine (100%)	▪ Ergometrine failed accepted pH level and assay limits. ▪ Oxytocin failed impurity test. ▪ Others failed assay test.	In Q2: ▪ Recalled 249 pks. AL from 2 batches; 8,170 pks. arte. inj., 2 batches ▪ 11,275 pks, of poor-quality antimalarial and MNCH removed from circulation (worth USD56,000). ▪ Meeting with TWG members & marketing authorization holders to present and acquaint them with RB-PMS results. ▪ Activated PMS surveillance unit to move into MA holders' warehouses to quarantine

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
					failed products not yet distributed. ▪ Set up two teams of LMHRA inspectors and staff to inspect & confiscate/ quarantine all failed products in Liberia. Teams also charged with conducting awareness in marketplaces & communities regarding failed products.
"LMHRA should encourage frequent communication and meetings of national TWG members from line agencies, ministries, etc., to discuss the actions associated with RB-PMS activities to implement effective regional generic RB-PMS activities." - ***Liberia TWG, PMS report***					
LIBERIA r. 3 (Q2)	**Malaria** ▪ Artesunate 60/120mg/ml Injection (16) ▪ Artemether 20mg/80mg/ml Injection (29) ▪ Artemether 20mg/120mg Lumefantrine tabs (17) ▪ Quinine (51) ▪ Amodiaquine Hydrochloride (3) ▪ Sulfadoxine/Pyrimethamine (11) **Total=127** **MNCH** ▪ Amoxicillin capsules / suspension (30) ▪ Ampicillin capsules / suspension (17) ▪ Metronidazole (28) **Total=75** **Grand Total=202**	**Malaria: 13.4% (17 samples)** **MNCH: 6.7% (5 samples)**	**Registration status:** ▪ 23% samples unregistered **Failed medicines:** ▪ Artemether (3 of 29 samples) (10.3%) ▪ Quinine (8 of 51 samples) (15.7%) ▪ AL (1 of 17 samples) (5.9%) ▪ Amodiaquine (3 of 3 samples) (100%) ▪ SP (2 of 11 samples) (18%) ▪ Ampicillin (1 of 17 samples) (5.9%) ▪ Metronidazole (4 of 28 samples) (14.3%)	Artemether, SP, and metronidazole samples failed assay test. Others failed Levels 1 or 2 screening.	In Q2: ▪ Same as r. 2 (rounds 2 and 3 were disseminated at the same time, in Q2).
"The PMS technical work in Liberia has demonstrated that national regulatory authorities can be more effective, efficient, and transparent in addressing poor-quality medicines while working together with other key stakeholders." - ***Liberia TWG, PMS report***					

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
MALI **r. 3 (Q2)**	**Malaria** ▪ Injectable artemether+lumefantrine ▪ Quinine injection **Total=190** **MNCH** ▪ Oxytocin injection ▪ Diazepam injection ▪ Mg sulphate inj. **Total=151** **Grand Total=341*** **Number of medicine samples collected unavailable*	**Malaria: 2% (4 samples)** **MNCH: 10% (15 samples)**	**Registration status:** ▪ 68% of samples unregistered ▪ 56.8% antimalarials unregistered (70.5% of quinine inj., 55% artemether inj., 45% artemether + lumefantrine 45%) ▪ 81.5% of MNCH unregistered (all diazepam, 69% mag sulfate, 68% oxytocin) **Failed medicines:*** ▪ Artemether + lumefantrine (4 samples) ▪ 6 diazepam (6 samples) ▪ Mag sulfate (9 samples) ** Number of medicine samples collected unavailable, hence, unable to calculate failure rate per medicine.*	Non-compliance of the 19 failed samples were due to the absence of active ingredient and a pH OOS.	In Q2: ▪ Withdrew / purchased offending batch of diazepam 10mg/2ml injectable ▪ Sensitized pharmacists, managers of DV referral health center-community health center, and wholesalers
"In view of the scarcity of resources, this risk-based sampling and analysis technique (RB-PMS) must be continued, optimized, and sustained to ensure health and guarantee access to quality medicines for health and the well-being of populations." - ***Mali TWG, PMS report***					
SENEGAL **r. 2 (Q3)**	▪ Artemether/Lumefantrine tablet (n=69) ▪ AL oral suspension (n=34) ▪ Artemether injection (n=27) ▪ Artesunate injection (n=47) ▪ Artesunate/sulfamethoxypyrazine/ pyrimethamine tablet (n=21) ▪ Artesunate/amodiaquine tablet (n=24) ▪ Sulfadoxine/pyrimethamine/amodiaquine dispersible tablet (n=27)	**0%**	All passed	n/a	n/a

Country	Medicines sampled (#)	SF rate	Results	Cause of medicine failure	MRA enforcement action
	Total=249				
"Good collaboration between managers at the site level of samples." – TWG, PMS report *"Good storage conditions for medicinal products, sites ventilated or air-conditioned." – Senegal TWG, PMS report*					

Notes:

1. The SF rate is the percentage of the total number of samples collected per medicine class that failed.
2. The failure rate for specific medicines is the total number of that specific medicine that failed as a percentage of total number of samples of that specific medicine that were collected.