Promoting the
QUALITY OF MEDICINES Plus

PQM+ Annual Report – Program Year 3

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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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Contents

Acronyms

2FDC	two drug, fixed-dose combination
4FDC	four-drug, fixed-dose combination
AEFI	adverse events following immunization
ANAB	American National Standards Society National Accreditation Board
API	active pharmaceutical ingredient
CAPA	corrective and preventive action
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
DT	dispersible tablets (amoxicillin)
EPI	Expanded Program on Immunization
EUA	emergency use authorization
FP	family planning
FPP	finished pharmaceutical product
GBT	WHO Global Benchmarking Tool for evaluation of national regulatory systems
GMP	Good Manufacturing Practice
HPLC	high-performance liquid chromatography
HR	human resources
IDP	institutional development plan
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

MOH	ministry of health
MQCL	medicines quality control laboratory
MRA	medicines regulatory authority
MTaPS	Medicines, Technologies, and Pharmaceutical Systems program
NCL	National Control Laboratory
NTD	neglected tropical disease
OpERA	Optimizing Efficiencies in Regulatory Agencies
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIRIMS	Pakistan Integrated Regulatory Information Management System
PMI	U.S. President's Malaria Initiative
PMS	post-marketing surveillance
PPE	personal protective equipment
PQM+	Promoting the Quality of Medicines Plus
PV	pharmacovigilance
QA	quality assurance
QC	quality control
QMS	quality management system
RBI	risk-based inspection
RIMS	regulatory information management system
RSS	regulatory system strengthening
RUTF	ready-to-use therapeutic food
SATTA	Stepwise Assessment Tool Towards Accreditation
SF	substandard or falsified
SOP	standard operating procedure
TB	tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWG	technical working group
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeia
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification

Letter from the Director

Program Year 3 (PY3) has been extraordinary for PQM+ and our partners and beneficiaries. We continued to advance our technical approaches and innovate new tools to improve medical product quality. For the past three years, we have helped build resilient quality assurance systems, and our impact has facilitated timely access to medical products to address COVID-19, maternal and child health (MCH), reproductive health, tuberculosis (TB), malaria, and neglected tropical diseases (NTDs) in partner countries in Africa, Asia, Central Asia, and Eastern Europe.

Nearly all 23 countries supported by PQM+ are engaged in the implementation of the World Health Organization (WHO) Global Benchmarking Tool (GBT) and working toward improvement in their capacity to regulate medical products. GBT enables countries, with support from WHO and technical partners like PQM+, to objectively evaluate a country's regulatory capacity and develop institutional development plans (IDPs) to take concrete steps to advance regulatory maturity and sustainably strengthen their regulatory systems. During PY3, PQM+ supported numerous GBT assessments and led implementation of interventions to address IDPs across all nine regulatory functional areas. Two PQM+ countries, Ghana and Nigeria, reached Maturity Level 3. PQM+ also supported laboratories in Ghana and Pakistan to achieve WHO prequalification status, signifying that those labs can generate reliable test results on the quality of medicines in their market.

Research activities in PY3 included a study designed to gather information on the storage conditions, use, and management of selected MCH commodities in Ghana, which could inform corrective measures for how these essential medicines are handled and preserved at the country and global levels. Our collaboration with USAID's Medicines, Technologies, and Pharmaceutical Systems (MTaPS) program resulted in the joint MTaPS/PQM+ guidance document that outlines the pathway for countries to digitalize regulatory information and defines minimum common standards for digital regulatory information management systems, forging new ground in an important and under-addressed regulatory domain with inputs from a multitude of stakeholders. Additionally, we drafted an advocacy brief on the adoption of minimum common standards for regulatory information management systems. We supported numerous national medicines regulatory authorities (NMRAs) and national quality control laboratories (NQCLs) in drafting strategic plans and sharing them with stakeholders to secure support. Highlighting this was our work with Mali's *Laboratoire National de la Santé* (National Health Laboratory) in sharing the lab's five-year strategic plan with external stakeholders to solicit their feedback and define how both parties could partner going forward. In Nepal, PQM+ started assessing pharmacists' awareness of and behaviors related to identification of substandard and falsified (SF) medicines.

Thought leadership, partnerships, and advocacy still are increasingly essential components of our mandate. During PY3, PQM+ provided expert feedback on four documents requested for comments by the World Health Organization (WHO): (1) the Global Model Regulatory Framework for Medical Devices including in vitro diagnostics (two rounds of input); (2) antimalarial drug resistance guidelines; (3) the Global Competency Framework for Regulators of Medical Products and (4) the WHO Biowaiver Project: Preparation for cycle V, prioritization of API 6 ingredients.

Looking ahead to PY4, we plan to successfully implement the U.S. Government's Initiative on Global Vaccines Access (Global VAX), COVID therapeutics, and regular work plan activities; bring more countries' regulatory functions to WHO Maturity Level (ML) 3; transition basic quality assurance (QA) functions; create more resilient, sustainable QA systems; mainstream risk-based approaches, reliance, and efficient regulatory systems; and entrench capacity for technology transfer and manufacturing support for new global health medical products.

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

Executive Summary

Throughout Program Year 3, the USAID-funded Promoting the Quality of Medicines Plus (PQM+) program worked in 23 countries and implemented 47 work plans, with 43 of them active at the end of Quarter 4. Of the active work plans, three are core-funded activities supporting the USAID Bureau for Global Health's Office of Infectious Disease for neglected tropical diseases (NTDs) and tuberculosis (TB) work and the Office of Maternal and Child Health and Nutrition for maternal and child health (MCH) support. A fourth "cross-bureau" funding stream supports the Office of Health Systems. Thirty-nine work plans are Mission buy-ins in 22 countries as well as a regional buy-in from USAID's Asia Bureau and seven COVID-19 work plans. New funding streams under the U.S. Government's Initiative for Global Vaccine Access (Global VAX) became active at the end of PY3 in six countries.

The goal of all the activities in these work plans is to sustainably strengthen medical product quality assurance (QA) systems in low- and middle-income countries (LMICs). As such, PQM+ helps ensure access to quality-assured medical products, including those needed for HIV/AIDS, TB, malaria, NTDs, COVID-19, other infectious diseases, reproductive health, and MNCH.

This report summarizes activities PQM+ conducted during Program Year 3 (October 1, 2021, to September 30, 2022) with an emphasis on developments in Quarter 4 (July 1 to September 30). These activities are delineated 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).

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

Technical Areas

Governance. Improving regulatory governance requires the effective and efficient establishment and implementation of quality assurance 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 partners' alignment. Through PQM+ support, stakeholders are becoming more effective in ensuring the quality and safety of medical products, increasing public trust, and freeing up valuable resources that can be used to expand health service coverage to their populations. PQM+'s objective in supporting countries to develop strategic plans is to enable public servants to define their strategic goals, identify necessary interventions to reach those goals, allocate adequate resources to execute a plan, and implement a monitoring and evaluation system to measure progress of regulatory oversight that ensures timely access to essential medicines and protection from SF products. Key highlights from PY3 governance activities follow.

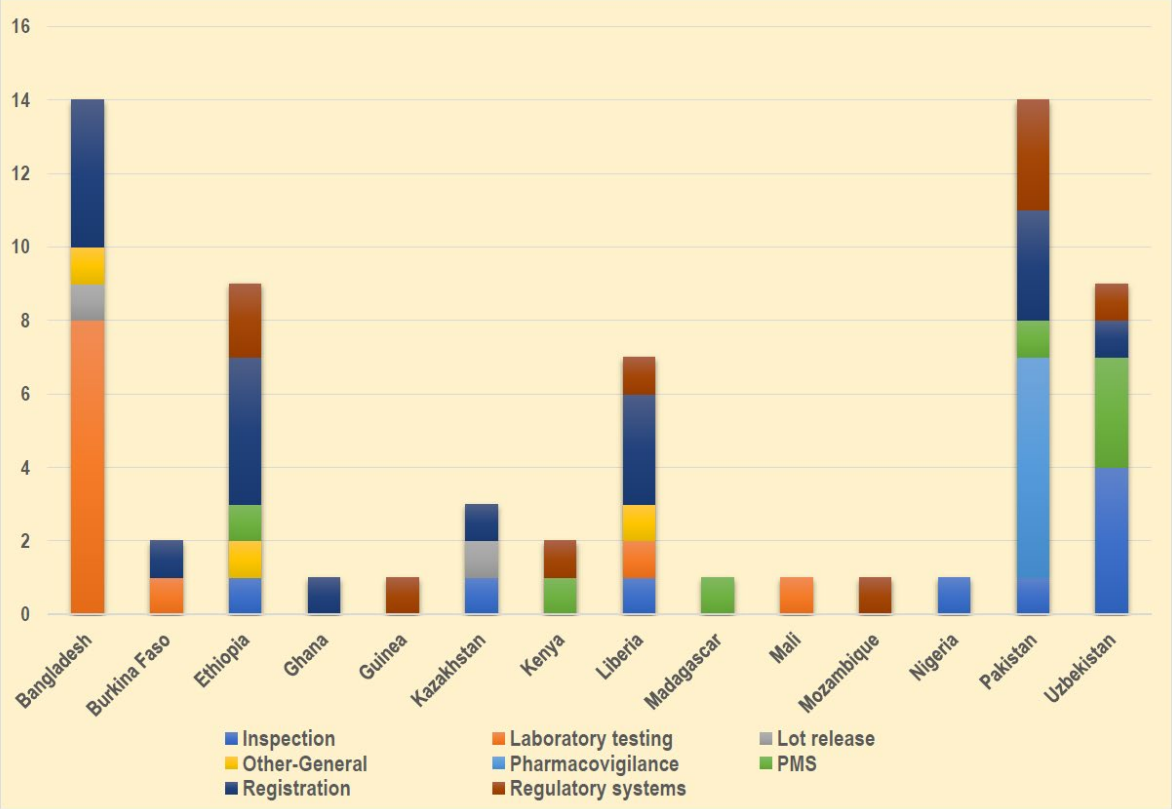
PQM+ collaborated with the World Health Organization (WHO) to develop a CIP support plan (originally known as the model strategic plan) to facilitate IDP implementation and reporting **by national medicines regulatory authorities (MRAs).** The support plan was piloted in Kazakhstan and will be duly piloted in a second country in PY4. The support plan ensures that: 1) the process for developing countries' specific institutional plans is streamlined and efficient since each of the parties of the coalition will be able to recognize the country's specific needs and expectations enabling them to adequately support the respective NMRAs and to actualize the IDP by bringing adequate required resources (technical and/or financial); and 2) the institutional plans will be more comprehensive, realistic and adequately costed. The support plan will also be used as a prime means for resource mobilization, both technical and financial.

PQM+ assisted MRAs to develop and disseminate strategic plans or strategies to strengthen regulatory capacity. During PY3, we supported work on this in Bangladesh, Burkina Faso, Liberia, Madagascar, Mali, and Rwanda.

PQM+ supported MRAs in several countries including Bangladesh, Liberia, and Senegal to develop **rules and regulations** to build the foundation for regulatory operations and functions and as part of the requirements in the WHO GBT regulatory system function. PQM+ provided technical assistance to 14 countries to strengthen governance, which covered policy and strategic plan development, plan implementation, development of regulatory frameworks, review and development of standard operating procedures (SOPs), and institutional performance improvement.

Figure 2 shows the number of policies and guidelines supported by PQM+ in PY3, broken down by regulatory function.

Figure 2. PQM+ PY3 Policy Work



To supplement and reinforce systems strengthening efforts on regulatory policy and governance, PQM+ conducted extensive training in PY3. For example, in Ethiopia, PQM+ collaborated with the Ethiopian Pharmaceutical Association to train more than 100 private sector health professionals on good distribution, storage, and dispensing practices. This work aims to reduce malpractice and contributes to minimizing the circulation of substandard and falsified medical products.

Other highlights include:

- As part of a larger Health Sector strategy led by the World Bank, PQM+ supported the Government of Uzbekistan to develop a Pharmaceutical Sector Strategy. The strategy was presented to the Uzbekistan's Minister of Health and will be written into a presidential decree.
- With support from the USAID Asia Bureau, PQM+ developed a framework and process for the selection of LMIC countries that are best suited to receive assistance to strengthen their local pharmaceutical production and regional export. , Selection criteria took into consideration countries' needs for improved access as well as their ability to rapidly increase the manufacturing of high-quality essential medicines. The team prioritized five countries for further qualitative research; and in PY4 will work with the Asia mission to identify two countries for a deep-dive analysis. This work also involves monitoring the need for regional supply chain resilience of certain health products and ingredients.

- PQM+ supported ministries of health and NMRAs to establish working groups in Nigeria, Nepal, and Pakistan that are helping to develop pharmaceutical sector strategies.
- PQM+ initiated work on the development of strategic plans for four NQCLs, two of which (Burkina Faso and Kenya) are nearing finalization. Strategic plans for quality control labs enable the creation of a common vision for laboratory system strengthening, articulate QA/QC system and human resource gaps, establish consensus on evidence-based solutions, help mobilize resources, and serve as a conduit for the alignment of key stakeholders. This culminates in the development and maintenance of a sustainable capacity to generate reliable test results and to meet the quality surveillance needs of the country.

Regulatory Systems Strengthening (RSS). A well-functioning regulatory authority uses clearly defined legislation, polices, guidelines, and procedures to establish, monitor, and modify its regulatory functions. Many PQM+ countries have assessed, or plan to assess, their ability to regulate medical products—including medicines, vaccines, and medical devices—using the WHO GBT. The GBT allows countries and WHO to systematically evaluate regulatory functional areas through key indicators. PQM+ supports regulatory authorities across all the nine regulatory functional areas to identify gaps and weaknesses and implement corrective measures.

Technical support from PQM+ (and the predecessor PQM) program contributed to both Ghana and Nigeria attaining **WHO Maturity Level (ML) 3**. In PY3, PQM+ also supported the regulatory functions of many other country MRAs toward achieving ML3, including Bangladesh, Kazakhstan, Kenya, Pakistan, Rwanda, and Senegal. Recognizing a gap in LMIC capacity for regulatory decision making during public health emergencies, PQM+ staff developed the **Guidance on Emergency Use Authorization for Vaccines** for National Regulatory Authorities and put it into practice at the country level in Burkina Faso and Ethiopia. Highlights during PY3 include use of the PQM+ **risk-based post-marketing surveillance (RB-PMS)** online tool Medicines Risk-based Surveillance (MedRS) in 16 PQM+ countries since its launch in July 2021: Benin, Burkina Faso, DRC, Ethiopia, Ghana, Guinea, Kazakhstan, Kenya, Liberia, Madagascar, Mali, Nepal, Nigeria, Rwanda, Senegal, and Uzbekistan. In PY3, several countries took regulatory enforcement actions as a result of identifying SF medicines through PMS activities, including Ghana, Kenya, and Liberia.

Tools featured this year in our work included the MedRS tool, NTD Medicines Information Dashboard (NTD|MID), RBI tool, competency gap analysis tool, and an Excel-based tool to analyze and track training activities.

Other new global tools we finalized were:

- A Proposed Model to Build Capacity for Emergency Use Authorization for Diagnostics.
- A Proposed Model to Build Capacity for Emergency Use Authorization for Vaccines.
- Minilab dexamethasone screening method and guideline (contributor).
- Validated method for testing nitrosamine impurities in rifapentine.

PQM+ work involving **medical devices** focused on regulation and manufacturing of medical oxygen in Bangladesh, training on regulatory and quality management systems (QMS) of medical devices testing in Kenya, and development of an e-Learning course on international standards and guidance for quality assurance of medical devices with focus on MNCH related products for release in PY4.

PQM+ began development of **risk-based inspection** (RBI) guidance, including a tool to optimize inspection practices of LMICs toward greater consistency and efficiency while encouraging the adoption of international standards in conducting regulatory inspections of manufacturers and supply chain distribution points. The tool consists of two modules, one for good manufacturing practice (GMP) and the other for good storage and distribution practice (GSDP). Inspections target manufacturers, importers, and distributors as well as retail pharmacy outlets, helping them to determine their level of compliance with international GMP and GSDP standards, respectively. In PY4, we will pilot the tool in selected PQM+ countries where there is strong interest, including Bangladesh, Ghana, Kazakhstan, Kenya, Nepal, Nigeria, and/or Pakistan. Following the pilots, PQM+ will revise the tool and guidance documents as needed and make them available to all interested MRAs.

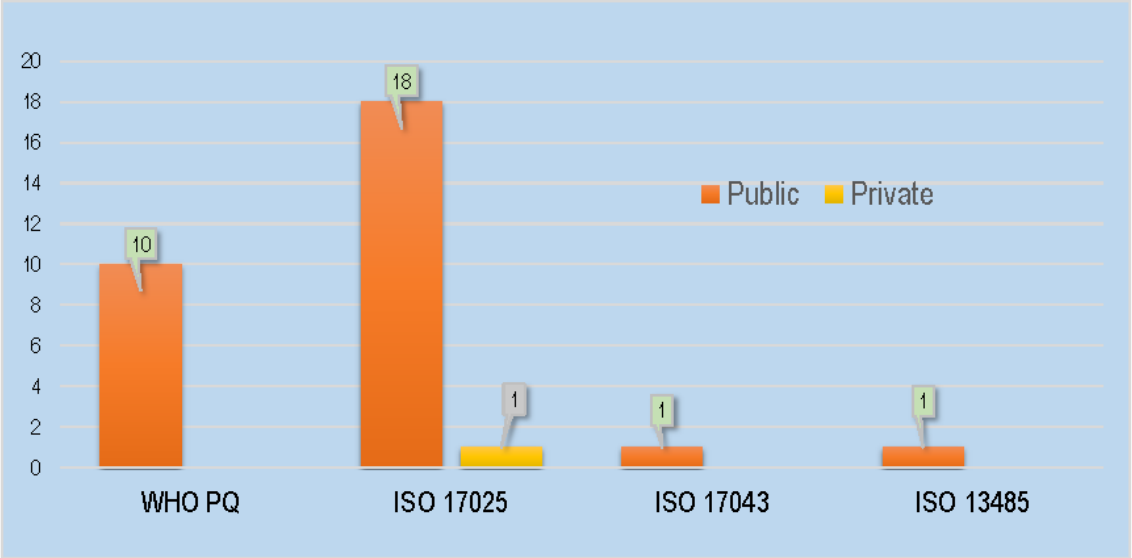
PQM+ teamed up with the U.S. FDA to develop and host a three-day online conference, **"Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines"** (August 16-18). The virtual conference was an exciting, unique collaboration among the FDA, USAID, WHO, and USP. It provided an important opportunity for regulators, industry, and USAID staff to learn directly from experts about FDA drug approval pathways and application review, including for new and generic drugs; the role of the FDA in international regulatory harmonization; collaboration among FDA, WHO, and NMRAs to support the drug approval process in LMICs; and the role of USAID's PQM+ program in strengthening regulatory systems in LMICs. The conference was an "undeniable success," according to the FDA's Small Business and Industry Assistance (SBIA), which led overall production of the conference.

Laboratory System Strengthening. Building capacity within the national control laboratory is a vital component of RSS and one of the nine WHO GBT regulatory functions. A fully functional national quality control laboratory is essential for a regulatory authority to be able to monitor and control the quality of medicines, vaccines, and medical products distributed in country. PQM+ provided ongoing support to NQCLs in 17 of 22 countries to comply with international standards and norms for medicines quality testing. PQM+ also supported training on medical device testing and development of SOPs in a number of countries including Mozambique, Bangladesh, Ethiopia, Pakistan, and Nigeria.

In PY3, nine laboratories were re-accredited for ISO 17025:2017. Re-accreditation indicates that a country is investing in the process, which contributes to building sustainability. Burma's NPT, Ethiopia's PQAD, three of Nigeria's NAFDAC labs, and NIPRID's NQCL maintained their scopes. Three other labs expanded their scopes—Bangladesh's physiochemical laboratory increased its scope by an additional four methods, Nigeria's vaccines and biologics lab increased from 14 to 23 methods, and Uzbekistan's Tashkent lab expanded from 105 to 115 methods. Tajikistan's Dushanbe laboratory upgraded its ISO 17025 accreditation (to 2017), Pakistan's IPH diagnostic lab attained ISO 15189, the first accreditation for a diagnostic laboratory achieved by a PQM+ (or PQM)-supported lab. Laboratories supported by PQM+ concluded ten post-marketing surveillance activities in PY3.

Figure 3 illustrates the number of accreditations that laboratories pursued with PQM+ support during PY3.

Figure 3. Laboratories Supported by PQM+ Toward Accreditation



In addition to aligning policies, procedures, and practices with international standards, the program aims to promote and facilitate sustainability of the laboratory. In eight countries, PQM+ led activities associated with establishing/implementing an equipment maintenance program within an NQCL. Internal capacity to maintain and calibrate laboratory equipment used to test the quality of medical products not only helps ensure that the equipment is operational for analysis, but it also aids in reducing the cost of equipment maintenance.

Collaboration with Partners. In March and September 2022, PQM+ collaborated with **USAID's Medicines, Technologies, and Pharmaceutical Systems program (MTaPS)** to deliver two hybrid (virtual and asynchronous) weeklong sessions of the PSS 101 blended course for USAID staff, titled "Virtual Pharmaceutical Systems Strengthening 101." The course broadened USAID health personnel's knowledge of pharmaceutical systems, including regulation, quality assurance, pharmacy practices, financing and priority setting, appropriate use, and combating antimicrobial resistance.

Through a joint work activity, PQM+ and MTaPS collaborated with WHO, selected MRAs, and USAID to identify and consolidate a repository of minimum common standards for medicines regulatory information management system (RIMS) for NMRAs. We also finalized a guidance document, advocacy brief, and information brief outlining the importance of minimum common standards for RIMS. A guidance document describing the pathway for countries to digitalize regulatory functions incorporating the minimum common standards is being finalized and set for dissemination to all interested MRAs globally.

Engagement of Program Partners included the following initiatives:

- The global community has limited information to estimate the burden that SF medicines impose on individuals, health care systems, and nations. Without it, governments cannot make informed decisions to invest in medicines quality assurance. To help address this gap, PQM+ collaborated with the University of Washington (UW), the University of North Carolina (UNC), and Harvard University to develop a model.to estimate the health and economic costs associated with SF medicines. That model was piloted in PY3 in Kenya.

- To assist the Government of Uzbekistan in its effort to capacitate the newly established Pharmaceutical Industry Park and the Pharmaceutical Technology University (PTU), PQM+ worked with Purdue University to conduct a needs assessment to inform the design and development of an appropriate curriculum for PTU in the areas of quality assurance of medicines and manufacturing. PQM+ also helped develop a product information report (PIR) and related job aides for gentamicin injection for newborns and children.
- With the Center for Innovation in Regulatory Science (CIRS), PQM+ deployed the Optimizing Efficiencies in Regulatory Agencies (OpERA) tool in Mali, Liberia, and Bangladesh to identify the weak regulatory processes that contribute to the inconsistent and delayed review of product applications (particularly the critical technical aspects that influence product quality). Utilizing OpERA tool assessment results will advance countries' WHO GBT ranking for market authorization and promote greater efficiencies and faster approval of health products in these countries.
- With Mahidol University, PQM+ conducted a landscape analysis of Regulatory Authorities in Association of Southeast Asian Nations (ASEAN) and South-East Asia Regulatory Network (SEARN) countries to determine future technical assistance. Also, in collaboration with Mahidol University, PQM+ conducted an NTD market landscape analysis in Asia.
- With Muhimbili University, we conducted the NTD market landscape analysis in Africa.
- PQM+ worked with professional associations in several countries to improve competencies in quality assurance and regulation of pharmaceuticals (e.g., in Ethiopia, Kenya, Liberia, Nigeria, and Uzbekistan).

In the area of **bioequivalence** (BE) studies, PQM+ supported various initiatives. In Bangladesh, PQM+ supported the implementation of a gap analysis and provided the necessary technical support to build the capacity/capability of a clinical research organization (CRO), which enabled it to conduct BE studies in accordance with international standards of GCP and GLP conformance. In Ghana, our BE work supported artemether/lumefantrine fixed dose combination (FDC) toward WHO prequalification (PQ). The PQM+ Asia Bureau completed the training of trainers (ToT) course materials in support to registration and specifically include generic complex active pharmaceutical ingredients (APIs), dossier evaluation of biologicals; and BA/BE for non-oral solid dosage forms. Other PQM+ BE work completed this year includes NTDs (as part of PQM+ support to Medopharm's praziquantel toward prequalification by WHO) and Core TB (as part of the Pakistan Schazoo's 4 FDC rifampicin / isoniazid / pyrazinamide / ethambutol toward PQ).

Our **workforce system strengthening** achievements included the development and adoption of Human Resources for Health tools, templates, and SOPs. PQM+ implemented capacity development activities and developed and handed over tools, templates and SOPs to support systematic workforce strengthening and institutionalization of good practices in Liberia, Madagascar, Mali, Nepal, and Rwanda. In Madagascar, PQM+ implemented the HR maturity assessment and transferred tools and templates to the Agence du Médicament de Madagascar (AMM) to support the execution of the Workforce Capacity Development Plan. This is intended to support the IDP and ultimately to enhance workforce WHO GBT indicators.

In PY3, we designed systems to **ensure staff competency development** including workforce capacity development activities required for countries to achieve and maintain GBT ML3 and ML4 in human resources. Toward that end, PQM+ developed a workforce competency gap

analysis tool based on the draft WHO global competency framework for regulators. It supported the development and adoption of a workforce competency framework for the regulatory authority in Rwanda. Training plan SOPs were developed, and an Excel-based tool was developed and adopted for tracking and analyzing training activities, thus enabling data-driven decision making by the Rwanda FDA on future training needs.

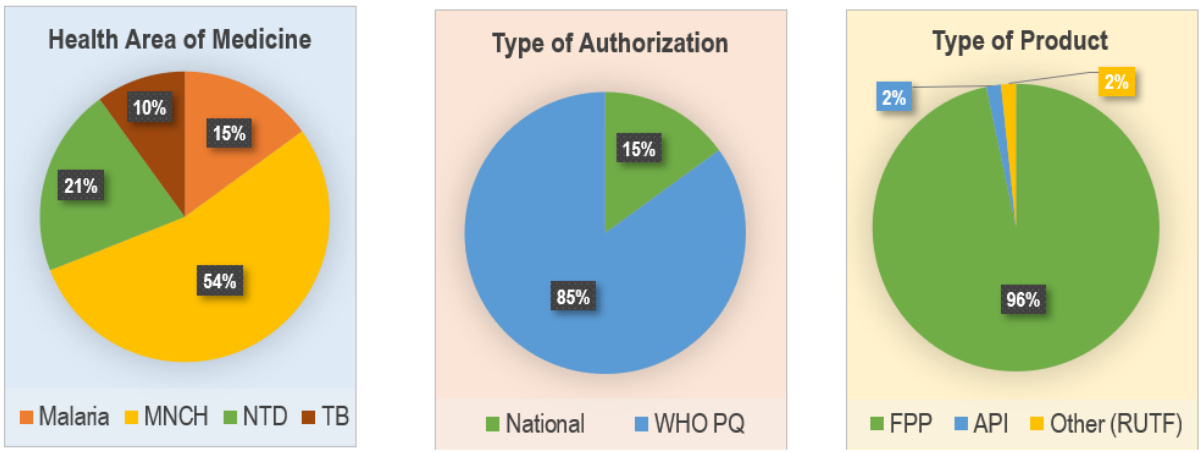
The WHO Workforce Indicators of Staffing Need (WISN) methodology and tool help determine the number of health workers for a given workload. It also helps to assess this workload in any particular facility. We applied the WISN methodology and tool in Liberia to three departments, including the QC laboratory within the Liberia Medicines and Health Products Regulatory Authority (LMHRA) and in Nepal at the National Medicines Laboratory (NML) to assess and determine staffing needs. The capacity development approach was successfully executed in both countries, with a transfer of the knowledge and skills to the various departments as well as the tools and templates required to carry out an independent staffing levels and balancing assessment in the future.

PQM+ collaborated with Kazakhstan's National Center for Expertise of Medicines and Medical Devices (NCEM) and the Scientific Education Center (SEC) staff in building competencies around the design, development, and implementation of training programs We also advised stakeholders about elements to take into consideration when considering the installation of a learning management system.

PQM+ supported human resources staff within a state-owned manufacturer (EDCL) in Bangladesh to conduct an organizational training needs assessment. HR staff within EDCL were trained on the use and then implementation of the assessment and data collection tools.

Chemistry Manufacturing, and Controls (CMC). PQM+ CMC technical assistance to manufacturers helps ensure product quality, efficacy, safety, and compliance with international QMS and GMP standards. Our objective is to partner with countries to increase the supply of quality-assured essential medical products of public health importance. As of September 30, PQM+ had supported 37 manufacturers from 11 countries pursuing 61 product authorizations/WHO PQ (see Figure 4).

Figure 4. PQM+ Support of Manufacturers Toward Market Authorization



FPP = finished pharmaceutical product; RUTF = ready-to-use therapeutic food

To this end, the PQM+ CMC team collaborated with PQM+ partner Virginia Commonwealth University to complete the development of a continuous manufacturing process to produce a TB active pharmaceutical ingredient (API) at a lower price relative to the conventional process. The lower cost API should lead to a lower finished product price.

The PQM+ CMC team conducted a cGMP assessment of a manufacturer in India for albendazole and executed an onsite assessment of a manufacturer in Uzbekistan for levofloxacin in 2022. We continued providing technical assistance to an Indian manufacturer for praziquantel tablets, including conducting a mock audit of the manufacturing facility in preparation for a WHO PQ visit conducted in November 2021, where the manufacturer was found to be GMP compliant. PQM+ completed the subaward contractual process to provide that manufacturer with cost sharing on the BE study; the subaward was approved in July 2022.

To address the dearth of registered TB medicines in Tajikistan, PQM+ promoted market opportunities in that country to WHO prequalified TB medicine manufacturers and tested a novel approach to facilitating their pursuit of local registration. PQM+ contracted a local company to assist the manufacturers in understanding and complying with registration requirements. In Q4, two manufacturers submitted nine TB medicine dossiers for approval in Tajikistan.

The PQM+ CMC team published an NTD expression of interest (EOI) and hosted kick-off meetings with the selected manufacturers, which included:

- Two manufacturers (in India and Nigeria) for mebendazole 500 mg tablets.
- One manufacturer (in India) for albendazole 400 mg tablets and ivermectin 3 mg tablets.
- Three manufacturers (in Bangladesh and Kenya) for azithromycin 500 mg tablets.
- One manufacturer (in India) for praziquantel 600 mg.

PQM+ held virtual meetings to help establish a working group for the Ethiopian CRO Regional Bioequivalence Centre Sh. Co. (RBEC) and discussed preparatory work for a future planned in-person meeting with stakeholders. Establishment of a CRO in Ethiopia will be a critical milestone in providing local and regional East African manufacturers with the first ever resource for manufacturers to conduct bioequivalence studies in the region.

The PQM+ CMC team published an EOI for local CROs in Bangladesh. Scoring has taken place and is being evaluated. In addition, the PQM+ CMC team completed a 10-part BE/bioavailability (BA) training series. The training is expected to improve the outcomes of manufacturers, NMRAs, CROs, and others receiving this training.

Building on the concept note submitted to the USAID Global Health Saving Lives Now team, PQM+ received an additional $1 million in funding to provide technical assistance for generic manufacturing of COVID therapeutics. The PQM+ technical team identified the leading manufacturers of nirmatrelvir/ritonavir, proposed which manufacturers to support, and recommended to the “Test to Treat” initiative, a cost-sharing model with other donors for the procurement of critical equipment necessary for the selected manufacturer to rapidly attain WHO PQ status.

Global Vaccines Initiative (Global VAX). In June, USAID invited PQM+ to provide support to the USG’s Global VAX in six African countries: Ghana, Kenya, Nigeria, Rwanda, Senegal, and South Africa. In PY3, we began laying the foundation for Global VAX to build regulatory and quality control laboratory capacity, provide strategic planning assistance, and support the nascent vaccine manufacturing industry in Africa. Start-up work included developing workplans

and organizing external kick-off meetings. We began implementing activities and planning for a joint workshop in South Africa with the Global VAX countries and the African vaccine manufacturing industry.

Learning, Advocacy, and Awareness. In Q4, PQM+ continued to develop and advance the use of evidence-based tools and approaches to improving medical product quality, as well as raise awareness of the importance of medical product quality assurance.

Research and Analysis: This quarter, PQM+ made important progress with numerous research-related activities, including:

- PQM+ piloted the SF medicine burden model in Kenya. A subcommittee of the PV/PMS Technical Working Group of Kenya engaged a variety of stakeholders from the Ministry of Health, the regulatory agency (PPB) and its QC laboratory, and academia to collect data on oxytocin quality in Kenya and outcomes of using poor-quality oxytocin. Results will be reviewed and follow-up actions decided early in FY2023.
- In Ghana, we designed a study to gather information on the storage conditions, use, and management of selected MCH commodities. The questionnaire and study protocol have been finalized and submitted for ethical approval.
- In Nepal, the program assessed pharmacists' awareness and behaviors related to identification of SF medicines.

Advocacy and Awareness: PQM+ supported various efforts to raise awareness of the importance of medical product quality assurance, including:

- PQM+ finalized a technical brief to help manufacturers identify and address impurities in the production of chlorhexidine. PQM+ disseminated the brief through manufacturing associations in Bangladesh, Nepal, and Pakistan, and will post it on the PQM+ website.
- Supported regulators to disseminate PMS results widely to garner attention for the importance of ongoing surveillance and the risk of SF medicines, including in the DRC and Kenya.
- Helped the Ghana FDA convene a workshop and sensitize local manufacturers and the Ghana Pharmaceutical Importers and Wholesaler Association on pharmaceutical traceability.
- Continued to support numerous NMRAs or NQCLs in drafting strategic plans and sharing them with stakeholders to secure support. Work this quarter included sharing the Mali Laboratoire National de la Santé (LNS) five-year strategic plan with external stakeholders to solicit their feedback and define how to partner going forward.
- Worked with the Department of Drug Administration (DDA) of Nepal to finalize messages on SF medicines to broadcast as public service announcements. National and local radio stations have started broadcasting these messages.

Thought Leadership: Throughout the year, PQM+ staff contributed to development of global guidelines and global discussions related to medicines quality.

- Provided input to global technical publications:
    - WHO Biowaiver Project: preparation for Cycle V.5: Prioritization of API 6 ingredients.
    - WHO Global Model Regulatory Framework for medical devices, including IVDs.
    - WHO antimalarial drug resistance guidelines.

- WHO Global competency framework for regulators of medical products.

- Contributed to expert working groups:
  - WHO TB Programme's Working Group open consultation on development of target regimen profiles for tuberculosis treatment.
  - Maternal Health Supplies Caucus of the Reproductive Health Supplies Coalition.
- Disseminated the report for the landscape analysis of Regulatory Authorities in Association of Southeast Asian Nations (ASEAN) and South-East Asia Regulatory Network (SEARN) countries to all 11 participating regulatory authorities.

Cross-Bureau Activities and Progress

PQM+'s Cross-Bureau activities focus primarily on raising awareness of the importance of medical product quality and developing new approaches to strengthen medicine regulatory functions. These activities, funded by the Office of Health Systems (OHS), fall under the following program objectives:

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

Highlights of Progress by PQM+ During Program Year 3

- Collaborated with the WHO to develop a model strategic plan (MSP) for NMRAs to operationalize their institutional development plans derived from country GBT assessments. The draft concept model IDP strategic plan, renamed the Model Strategic Plan for IDP Operationalization, was piloted in Kazakhstan.
- Conducted comprehensive research for development of a model local production and health product security strategy.
- Collaborated with MTaPS to deliver two virtual and asynchronous weeklong sessions, in March and September 2022, on the PSS 101 blended course titled "Virtual Pharmaceutical Systems Strengthening 101." Aimed to broaden USAID health personnel's knowledge of pharmaceutical systems, including regulation, pharmacy practices, financing and priority setting, appropriate use, and combating antimicrobial resistance.
- Launched a model (in Kenya for oxytocin and in Pakistan for amoxiclav) to estimate the economic and health costs of substandard and falsified (SF) medicines in LMICs.
- Collaborated with MTaPS, WHO, and USAID to identify and consolidate a repository of minimum common standards for pharmaceutical regulatory information management system for NMRAs. Finalized a guidance document, advocacy brief, and information brief outlining the importance of minimum common standards for RIMS.
- Developed a mini eLearning module on the regulatory authority's role in a pandemic or other public health emergency.

Progress in Quarter 4

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

PQM+ continued to collaborate with USAID's MTaPS program on the minimum common standards for RIMS activity. This quarter, PQM+ and MTaPs finalized and disseminated the fourth consultative meeting report. Both programs finalized an advocacy brief outlining the importance of minimum common standards for RIMS and are working on a guidance document outlining the pathway for countries to digitalize regulatory functions incorporating the minimum common standards and information brief that outlines how to optimize the Pakistan Integrated Regulatory Information Management System (PIRIMS) to ensure alignment with the minimum common standards. PQM+ will begin dissemination when the products are finalized.

PQM+ collaborated with WHO to develop a model strategic plan (MSP) for IDP Operationalization for NMRAs to operationalize their institutional development plans derived

from country GBT assessments. This quarter, PQM+ completed the draft concept model IDP strategic plan, renamed it the Model Strategic Plan for IDP Operationalization, and piloted it in Kazakhstan. PQM+ will collaborate with WHO as requested on a second country launch of the MSP for IDP Operationalization in PY4. A second pilot could occur in Bangladesh, Nepal, Senegal, or South Africa.

PQM+ met with WHO on developing a model local production and health products security strategy to strengthen local manufacturing by helping countries boost infrastructure for local production of medical products to supply at the local and regional levels. PQM+ and WHO discussed the activity concept, but WHO budget requirements led to the organization's participation stalling and subsequently stopping. This led to delays in developing a draft Model Local Production and Health Products Security Strategy, now slated for finalization during PY4. This quarter, PQM+ completed comprehensive research to determine existing strategies and processes in target countries to identify gaps; compared strategies across low-, middle-, and high-income countries; developed a questionnaire; and compiled a list of key informants.

RBI is a methodology to optimize inspection programs toward greater efficiency. This quarter, PQM+ continued the RBI methodology activity, developing and finalizing a draft guidance document on RBI and creating a draft online RBI tool with GMP and GDP modules. In discussion with USAID, it was determined that once finalized, the tool would transition to GitHub as a long-term hosting solution. PQM+ drafted a scope of work for remaining deliverables to finalize both the guidance document and tool. The program will pilot the tool in selected PQM+ countries, which could include Bangladesh, Ghana, Kazakhstan, Kenya, Nepal, Nigeria, and Pakistan. Following the pilot phase, PQM+ will revise the tool and guidance documents as needed and finalize them, including assuring their compliance with Section 508 requirements.

Objective 3: Optimize and increase financial resources for medical product

In PY3, PQM+ developed a model to estimate the economic and health cost of substandard and falsified (SF) medicines in LMICs by convening an expert panel of PQM+ partners, including the University of Washington (UW), University of North Carolina (UNC), and Harvard University, as well as USAID. To conclude the pilot, the Kenya working group met for the fourth time on September 14 to review data for the key model variables and review results. While it was not a PY3 deliverable for this activity, PQM+ developed an SF burden model report and shared it with the Steering Group for comments. In PY4, PQM+ will incorporate these comments, finalize the report, and disseminate the results. The Steering Group has requested a one- to two-page brief of the report. The working group continues to find data on mortality related to postpartum hemorrhage without treatment and other general health outcomes such as disability- and quality-adjusted life years (DALYs and QALYs). PQM+ also launched the second pilot in Pakistan for amoxiclav, with an anticipated completion date of PY4, Q1. PQM+ supported procurement of columns and a donation of reference standards through the USP Preferential Access for Regulators Program. The sampling plan was developed; 45 sites were selected; five products were identified for sampling; and a testing protocol was developed. Additionally, nominations of members for the larger Steering Committee were made and members for the Core Technical Team were identified. Testing is underway. PQM+ extended UW's subaward and UNC and Harvard fixed-priced contracts until the end of PY4 Q1.

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

PQM+ continued partnering with MTaPS on the regulatory harmonization activity that began in PY2 to finalize and disseminate a set of minimum common standards for RIMS for NMRAs in LMICs. This quarter, PQM+ partnered with MTaPS and conducted stakeholder engagement meetings with global, regional, and national stakeholders and NMRAs in Africa and Asia to solicit feedback on the set of draft minimum common standards. The guidance document and advocacy brief outlining the importance of minimum common standards for RIMS and the information brief that reflects common standards to optimize the PIRIMS tool are being finalized. PQM+ developed a plan for dissemination upon completion of the deliverables.

PQM+ revised the Medicines Quality Assurance Module of USAID's Pharmaceutical Systems Strengthening Course ("PSS 101") with MTaPS. In Q3, PQM+ and MTaPS, in collaboration with USAID, agreed on a delivery date for the second virtual and asynchronous session on the PSS 101 blended course titled Virtual Pharmaceutical Systems Strengthening 101. The two programs delivered the second session the week of September 12. To boost participation, PQM+ shared the training information with all PQM+ activity managers. PQM+ also started developing a new module on the role of regulation during a health emergency. The module is planned for inclusion on the Global Health eLearning (GHeL) platform. PQM+ shared the full draft slide deck with USAID for review and feedback.

Priority Activities for PY4, Q1

PQM+ plans to:

- Disseminate the advocacy brief outlining the importance of minimum common standards for a RIMS guidance document and information brief that reflects common standards to optimize the PIRIMS tool.
- Transition to the USP IT hosting environment; conduct testing of the beta version of the RBI tool, incorporate revisions to the tool and guidance documents as needed, and ascertain Section 508 compliance.
- Conduct the following sub-activities for the SF modeling activity:
    - Complete orientation of the full pilot core group and the working group in Pakistan and
    - Complete testing.
- Finish the pilot in Pakistan, including:
    - Revise tool and guidance document as needed and disseminate it.
- Finalize the module on product quality assurance for the course on regulation during a pandemic or other public health emergency.

Activities and Progress by Country and Regional Buy-Ins

Africa Region

Benin

PQM+ works with the Beninois Agency for Pharmaceutical Regulation, *l'Agence Béninoise de Régulation Pharmaceutique* (ABRP), Benin's main regulatory body. ABRP develops and implements national pharmaceutical policy and regulations, registers medicines, approves licenses, inspects pharmaceutical establishments, and controls the advertisement and promotion of medicines, including herbal and traditional medicines. The national quality control laboratory, *l'Agence Nationale de Contrôle de la Qualité des Produits de Santé et de l'Eau* (ANCQ), collects and tests medicines at the points of entry into the country (land, sea, and air) or at the request of any national institution. PQM+ is helping ANCQ strengthen its quality management system (QMS) to achieve international recognition (ISO/IEC 17025 or WHO prequalification). This would assure the reliability of testing and increase public confidence in ANCQ test results.

Highlights of Progress by PQM+ During Program Year 3

- Supported the implementation of the first risk-based post-marketing surveillance of antimalarials, including training on the use of the MedRS tool, development of the RB-PMS protocol, procurement of minilabs and reagents, provision of needed logistics for sampling, and supervision of testing.
- Made notable progress in the implementation of the roadmap toward ISO/IEC 17025 accreditation of ANCQ:
  - 14 quality documents developed and
  - 44 technical personnel trained and QA and QC topics.
- Supported the institutionalization of an equipment preventive maintenance (EPM) program for ANCQ through:
  - Practical training on EPM,
  - Support to develop key protocols for EPM, and
  - Support to develop a list of spare parts for analytical equipment.

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 Q4, PQM+ supervised the screening and confirmatory testing of the 202 antimalaria samples collected from seven regions in Benin in Q3. The testing of the samples has been completed and the national quality control laboratory is developing the report of the results obtained. These results will not be nationally representative.

To help ANCQ evaluate progress in implementing its roadmap toward ISO/IEC 17025 accreditation, thereby further improving its quality management system, PQM+ supported and participated in ANCQ's management review meeting. Discussion included ANCQ's performance against its quality indicators, challenges encountered in meeting some of these indicators, and possible solutions. In PY4, during its support to ANCQ in implementing the accreditation roadmap, PQM+ will coach ANCQ's QA team to focus on indicators identified during the

meeting that did not progress in 2022. In addition to the management discussion on the quality indicators, ANCQ provided a formal update on its progress in implementing its roadmap. The laboratory is on track to be ready for an accreditation audit by December 2023.

During Q4, PQM+ provided a foundational training to ANCQ technical personnel on managing risks and opportunities. The 21 trainees (15 men, six women) learned about risk management processes and methodologies they can apply to their laboratory. Practical examples were also shared with the ANCQ team to facilitate the implementation of risk management in its laboratory.

Priority Activities in PY4, Q1

Next quarter, PQM+ plans to:

- Report and disseminate results of the 2022 RB-PMS for antimalarials.

Burkina Faso

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

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

Highlights of Progress by PQM+ During Program Year 3

- Supported the development and validation of a five-year strategic plan for LNSP, which included a business plan as well as a social welfare plan for staff conditions of service.
- Supported the institutionalization of an equipment preventive maintenance program for LNSP through:
  - Practical training on EPM,
  - Support to develop key protocols for EPM, and
  - Support to develop a list of spare parts for analytical equipment.
- Supported the calibration of key devices used for proposed accreditation scope techniques, a key requirement of the standards for which LNSP did not have the resources.
- Completed a baseline assessment and supported LNSP to finalize a new roadmap based on the findings.
- Made notable progress in the implemtation of the roadmap toward ISO/IEC 17025 accreditation of LNSP:
  - Completed training on measurement uncertainty;
  - Completed training on analytical method validation;
  - Developed five quality documents; and
  - Trained 67 technical personnel on QA and QC topics.
- Supported revision of the testing fees structure at LNCQM to ensure the laboratory is able to charge fees to improve its sustainability

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

LNSP's five-year strategic plan, developed with support of PQM+, was completed and validated in Q3. At the suggestion of the USAID Mission, the planned donor roundtable, organized by PQM+, to assist LNSP in starting the process of resource mobilization was postponed to November 2022 to ensure participation by key partners/donors and prepare for stronger visibility of the LNSP's needs to implement the strategic plan.

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

As LNSP continues implementing its roadmap toward ISO/IEC 17025 accreditation, PQM+ supported calibration of key analytical equipment and devices linked to LNSP's proposed accreditation scope – balances, ovens, refrigerators, standard weight sets, thermohygrometers, and thermometers. The calibration of these devices will ensure that they generate reliable data, a key requirement of the ISO/IEC 17025 standard that many government laboratories, including LNSP, struggle with due to financial constraints and the lack of an in-country accredited metrology services provider. The cost of this calibration was provided to the leadership of LNSP to include in their budget for 2023 and adequately plan to ensure it is done routinely.

To help LNSP's technical personnel implement another key and advanced requirement of the ISO/IEC 17025 standard, PQM+ provided supportive supervision to implement measurement uncertainty (MU). In Q2, PQM+ provided training on MU and helped LNSP develop an internal SOP for measurement uncertainty, which will help facilitate its implementation. The supportive supervision in Q4 was hands-on and focused on showing technical personnel how to calculate measurement uncertainties and include them in results generated by the laboratory. Through this support, the laboratory successfully calculated MU for high-performance liquid chromatography (HPLC), ultraviolet–visible spectroscopy (UV-Vis), loss on drying, volumetric titration, pH measurement, and dissolution and developed an uncertainty budget using the newly developed Excel spreadsheet calculator. Due to general challenges encountered with the sole-source vendor of the GPHF Pharma minilabs, Technologie Transfer Marburg (TTM), the minilabs for Burkina Faso were shipped in September 2022, despite being ordered in February 2022. These minilabs are required for screening the samples to be collected by the PMS-TWG. As a result, the sampling was put on hold. The minilabs have arrived in Burkina Faso; after customs clearance, the samplers training will take place the week of October 3, after which sampling will begin.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Support training of samplers for the 2022 RB-PMS focusing on antimalarials.
- Collaborate with USAID/PMI Burkina Faso to organize a roundtable on operationalization of LNSP's five-year strategic plan and advocate for support for its implementation.

Democratic Republic of Congo (DRC)

The widespread availability and distribution of non-quality-assured artemisinin combination therapies and non-artemisinin therapies[1] 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 by PQM+ During Program Year 3

- Supported the dissemination of the first RB-PMS of antimalarials completed in DRC, broadcast nationally. Out of the 303 samples collected from three provinces in DRC (Kinshasa, Tsopo and Maniema), 9 (3%) were found to be out of specification. These samples were quinine sulfate tablets, quinine oral solution (drops) and artemether injection. 22% of the samples collected were unregistered. These results are not nationally representative.
- Provided support to ACOREP's PMS-TWG to start implementing the second 2022 RB-PMS for antimalarials, including:
  - Development of the 2022 RB-PMS protocol,
  - Procurement of minilabs and laboratory reagents for testing, and
  - Supervising training of samplers, to be conducted by members of the PMS-TWG.
- Made notable progress in the implementation of the roadmap toward ISO/IEC 17025 accreditation of LNCQ-LAPHAKI, including:
  - Trained 115 technical personnel on QA and QC topics.
- Supported the institutionalization of an equipment preventive maintenance program at LNCQ-LAPHAKI through:
  - Practical training on EPM,
  - Support to develop key protocols for EPM, and
  - Support to develop a list of spare parts for analytical equipment.

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+ provided training for LNCQ-LAPHAKI on handling out-of-specification results. Given the importance of a laboratory safeguarding and ensuring the integrity of the data it generates, this training provided technical staff with the requisite knowledge on best practices in managing laboratory-generated results that are out of specification or indicate a failure in the quality of the product. This will equip trainees with the skills to ensure that the results they disseminate and report are of utmost integrity and reliability to inform the needed regulatory actions. The 24 participants included 14 men and 10 women.

Since LNCQ-LAPHAKI received new equipment in 2021 through another project, it now needs to start planning for their routine maintenance to ensure optimal performance and minimal downtime. PQM+ provided technical assistance to build the capacity of technical staff on basic

[1] 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.

preventive maintenance. PQM+ trained 32 participants (11 women and 19 men) on basic preventive maintenance, helped the maintenance team identify the spare parts required for each piece of equipment, and supported the development of basic equipment preventive maintenance protocols. This training will enable LNCQ-LAPHAKI's equipment maintenance team to be more self-sufficient.

In Q3, DPM announced that 3 percent of the antimalarial samples collected in the first round of its RB-PMS had failed testing. These included quinine sulfate tablets, quinine oral solution drops, and artemether injection. Twenty-two percent of samples were not registered. These results are not nationally representative; DPM has outlined steps to determine the source of SF and unregistered medicines and learn how they reached market, which will inform appropriate regulatory action.

Through Q4, PQM+ worked with the PMS-TWG to finalize the budget for the sampling of the antimalarials for the 2022 RB-PMS as well as the sampling plan. However, due to general supply chain disruptions leading to delays in shipment by the sole-source vendor of the GPHF Pharma minilabs, Technologie Transfer Marburg (TTM), the minilabs have not yet been shipped to DRC. These kits are required to screen the samples collected; therefore, sampling was put on hold because optimal screening should occur immediately after sampling to ensure correct evaluation of the quality at the point of sampling. The sampling will be scheduled when PQM+ is notified that the minilabs have been shipped to DRC.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Supervise sampling and testing of samples for the 2022 RB-PMS.

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 by PQM+ During Program Year 3

- Supported the EFDA's self-benchmarking assessment of four regulatory functions: licensing establishment (LE), regulatory inspection (RI), market surveillance and control (MC), and the national regulatory system (RS) using GBT tools.
- Supported EFDA laboratories to maintain 16 accredited test methods, including five condom test methods, and to implement the roadmap toward accreditation of branch EFDA laboratories.
- Supported implementation of RB-PMS through re-establishing the national TWG for PMS and training on the online version of the MedRS tool, procurement of lab supplies, and development of RB-PMS protocol, as well as sample collection and testing following the three-level testing approach.
- Supported the Ministry of Health (MOH) in developing the document "Strategies to Strengthen Local Manufacturers' Performance to EPSA's Award."
- Provided technical support in accreditation of the inspection function of EFDA for ISO/IEC17020.
- Supported improvements to the regulatory system by developing guidelines, directives, SOPs, and quality manuals. This helps with implementation of ISO9001 certification and compliance with WHO's GBT requirements.
- Collaborated with the Ethiopian Pharmaceutical Association (EPA) to train health professionals in the supply chain system on GDP/GSP requirements. The national accreditation office at Addis Ababa University accredited the module and about 250 health professionals received training in compliance with the national continuing professional development (CPD) requirement.
- Supported data entry of 277 GMP inspection reports to an Excel database and helped analyze and interpret the data. This aids in developing strategies for risk-based inspection of facilities for more efficient GMP inspections in the future.
- Identified two local pharmaceutical manufacturers and two products to move toward WHO PQ. A collaborative framework was developed between MOH, WHO, and PQM+ for prequalifying the selected products.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

Activity 1.1: Provide training to practitioners at private retail outlets on regulatory practice standards for storage and dispensing of medicines to ensure safety of patients: An effective medicines regulatory system is a central, albeit often invisible, part of reliable, quality health care services and high-performing medical product supply chain systems. Strong medical product regulation promotes and protects public health by ensuring that medical products are of the required quality, safety, and efficacy and thus cause more good than harm. Regulation also ensures the appropriate manufacture, storage, distribution, and dispensation of medical products; detection and adequate sanction of illegal/illicit manufacturing and trade; and availability of the information required to enable health professionals and patients to use medical products rationally. Finally, regulations ensure that promotion and advertising is fair, balanced, and aimed at rational use and that unjustified regulatory processes or regulatory hurdles do not hinder access to medical products.

In PY3, PQM+ planned to work with the EPA to train 240 practitioners at private medicine retail outlets to address critical gaps identified in the PY2 inspection. This training will be a model for federal and regional regulatory bodies and other partners to scale up to more outlets and

geographic locations. PQM+ will also work with EPA to make the training an accredited CPD course. The training will focus mainly on meeting regulatory requirements for good storage, distribution, and dispensing practices to rectify gaps identified during the PY2 inspection. This support will help reduce malpractice and contribute to minimizing the circulation of SF products that could endanger patient safety.

- In Q3, as part of implementing the activity related to the CPD training, PQM+ supported the EPA in developing a training module and training materials to guide health professionals in private outlets on good distribution, storage, and dispensing practices from a regulatory perspective. The developed training materials were submitted to the official accreditation body, the College of Health Sciences at Addis Ababa University, for review and approval. The college accredited the course and training started in Q4, with about 100 health professionals trained.
- In Q4, PQM+ extended the training for an additional 144 pharmacy practitioners; 244 pharmacy practitioners have completed this training and received certification. The overall report was written and archived as means of verification.

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

Activity 2.1: Support development of directives, guidelines, and standard operating procedures to streamline regulatory processes for improving access to quality-assured medicines to the population: 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 the adequate manufacture, storage, and distribution of medicines; and strengthening the fight against SF products. Unlike with other commodities, patients, consumers, and health professionals are not able to judge quality, safety, and efficacy of medical products. As a result, regulatory authorities are responsible for monitoring the quality of medical products circulating in the market through various regulatory procedures, including market authorization and PMS. Accredited QC laboratories are a key resource to test the quality of medical products and determine if they meet minimum requirements. PQM+ achievements included:

- Provided technical support to EFDA on self-benchmarking according to the WHO GBT for EFDA's market control, regulatory inspection, and licensing establishment regulatory functions. Based on the self-benchmarking exercise, PQM+ supported development of the IDP for each function. EFDA received feedback from WHO and PQM+ supported addressing feedback related to providing objective evidence for the related regulatory functions per the specific indicators.
- Supported the Medicine Inspection and Licensing Directorate for sustainable maintenance of the ISO17020:2012 requirements and support for preparation work was conducted for follow-up inspection of the directorate by the Ethiopian Accreditation Service (EAS), previously called the Ethiopian National Accreditation Office (ENAO), and with this support the accreditation is extended for additional one year.
- In PY2 PQM+ supported assessment of the five branch EFDA laboratories using the SATTA tool and developed branch-specific roadmaps toward ISO/IEC17025 accreditation. As part of implementing the roadmap, supportive supervision was provided to one of the five branch laboratories (East, Diredawa branch) to evaluate the overall progress of the laboratory and provide relevant technical support. The supportive

supervision was provided by a team from PQM+ and EFDA's main QA unit. As a follow-on, PQM+ customized 16 SOPs for the branch lab.

Activity 2.5: Increase participation of citizens in monitoring medicines quality in Ethiopia: The presence of accredited QC laboratories is a key resource to conduct testing for quality of medical products and determine if they meet minimum requirements for quality.

- As part of implementing RB-PMS, sample collectors were deployed and collected about 185 samples of antimalaria and MCH products. The individual products collected were identified during the MedRS scoring conducted in Q3 and were included in the approved RB-PMS protocol. Sample testing will be finalized in the next quarter. The results will not be nationally representative; see Annex 1A for more detail.

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

Activity 4.2: Build capacity of selected local pharmaceutical industries for achieving WHO PQ and local GMP certification: WHO PQ is a mechanism wherein WHO assesses the quality, safety, and efficacy of medical products.

- As part of the plan to build the technical capability of local pharmaceutical manufacturers for WHO PQ of selected products, PQM+ advertised an expression of interest (EOI) and received proposals from interested companies.
- PQM+ reviewed proposals submitted by local manufacturers and selected two manufacturers and two MCH products (magnesium sulfate injection and ceftriaxone injection) for support toward WHO PQ of the products. In addition, a three-partite collaborative framework between the Federal Ministry of Health, WHO, and PQM+ was drafted and is under review. The team from MOH, WHO, and PQM+ developed a detailed action plan for the support.

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 attempt to address issues through virtual communication, continuous discussion, and engagement with relevant government counterparts.
- The newly started pooled procurement of lab supplies has delayed supply of these items and the program has not received all supplies needed to start testing the PSM samples.

Ghana

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

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

Highlights of Progress by PQM+ During Program Year 3

- Supported the dissemination of the first RB-PMS of antimalarials completed in Ghana, which recorded failures of 45 percent for oxytocin, 6 percent for misoprostol, and 0.6 percent for antimalarials sampled. These results are not nationally representative.
  - Published a success story on this first RB-PMS.
- Provided support to FDA Ghana's PMS-TWG to start the implementation of the second RB-PMS on:
  - Developing the 2022 RB-PMS protocol,
  - Procuring minilabs and laboratory reagents for testing, and
  - Supervising training of samplers conducted by select members of the PMS-TWG.
- Supported FDA Ghana to develop its draft guidelines of pharmaceutical traceability.
- Supported FDA Ghana and the national GS1 TWG to sensitize manufacturers and the Pharmaceutical Importers and Wholesalers Association (PIWA) on GS1.
- Trained around 30 participants from six manufacturers of key GMP topics to improve their implementation of best practices in manufacturing to help improve the quality of the products they manufacture.
- Designed a study to gather information and understand the storage conditions, use and management of selected MCH commodities in 4 regions in the north of Ghana known as the zone of influence (ZOI). Finalized the questionnaire and submitted the study protocol for ethical approval.
- Identified one manufacturer for local production of amoxicillin dispersible tablets.

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

Due to general challenges encountered with the sole source vendor of the GPHF Pharma minilabs, Technologie Transfer Marburg (TTM), the minilabs for Ghana's second round of RB-PMS were shipped in September, despite being ordered in February 2022. Since these minilabs are required for the screening of the samples to be collected by the PMS-TWG, the sampling was put on hold. As the minilabs are now undergoing customs clearance in Ghana, the samplers will start sampling in October 2022.

The results of round 1 of Ghana's RB-PMS were announced in Q2, with 11 percent of samples failing screening. This led the FDA in Q4 to seize more than 5,476 vials of artesunate injection, two ampoules of artemether injection, 342 ampoules of oxytocin, and four packs of misoprostol and 150 misoprostol tablets. Providers in two regions received fines totaling around GHS 350,000. These RB-PMS results were not nationally representative; please see details in the table in Annex 1A.

Through Q4, PQM+ completed the assessment tool for the Zone of Influence (ZOI) study (in the four ZOI regions in northern Ghana), finalized the study protocol and submitted it for ethical approval. PQM + also trained the data collection consultants in preparation for the implementation of the study. In September 2022, PQM+ secured ethical approval and planned the data collection for October 2022.

In Q4, PQM+ provided technical assistance to Ghana Manufacturer 6[2] for product development for the 20/120mg formulation, for the compilation of the CTD dossier compilation and followed-up on the implementation of their roadmap towards WHO PQ for its artemether/lumefantrine formulation. Delays in the execution of key milestones in this roadmap resulted from factors such as.equipment breakdown, importing key raw materials, wavering commitment to cover the high costs of bioequivalence studies, and poor performance of some product formulation, prolonging the development of trial batches. Key milestones that are delayed include initiation of stability studies and the completion of module 2 of the CTD dossier. In addition, through the quarter, PQM+ has followed up with this manufacturer on the payment of the fees for bioequivalence studies which was completed in 2021. While the studies were completed by the CRO, Ghana Manufacturer 6 has not made the final payment to enable the CRO release the results. The results of this bioequivalence data is required as part of the compilation of the CTD dossier.

PQM+ also visited Ghana Manufacturer 3 in Q4 to follow up on progress of the implementation of their roadmap toward WHO PQ and to provide technical assistance for product development and the CTD dossier compilation. Some key milestones in the roadmap have been completed, notably development of analytical method validation protocol and compilation of module 1 of the CTD dossier; compilation of module 2 of the CTD dossier is ongoing. This manufacturer continues to demonstrate good progress and commitment.

In September, to consolidate support provided through the program year and allow an exchange of experiences among the manufacturers it supports, PQM+ organized a training in Accra on GMP. The training covered key topics to help the implementation of best practices to contribute to the manufacture of quality medical products at these manufacturers' facilities. The 27 participants (nine women and 18 men) from six manufacturers and FDA Ghana were trained on GMP inspections, good documentation practices, laboratory controls, validation, qualification, comparative dissolution studies, and pharmaceutical quality systems.

To kickstart the support to FDA Ghana to fulfill their role on the national GS1 TWG in the implementation of pharmaceutical traceability, PQM+ supported the agency to develop national guidelines for pharmaceutical traceability. A workshop convened staff from FDA Ghana, the CEO of GS1 Ghana, and PQM+ staff, including a technical advisor from PQM+ Pakistan, to share their experience with the Ghana team. In addition, PQM+ supported the sensitization of local manufacturers and the Ghana Pharmaceutical Importers and Wholesalers Association (PIWA) on pharmaceutical traceability.

With regard to the planned 2022 RB-PMS, due to general challenges encountered with the sole-source vendor of the GPHF Pharma minilabs, Technologie Transfer Marburg (TTM), the minilabs for Ghana were shipped in September, despite being ordered in February 2022. The

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

minilabs are required for screening the samples to be collected by the PMS-TWG. As a result, sampling was put on hold. As the minilabs are now undergoing customs clearance in Ouagadougou, the samplers training has been scheduled for October 3–5 and sampling will start the week of October 10.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Support the national PMS-TWG to conduct sampling of antimalarial and MNCH medicines for 2022 RB-PMS
- Initiate the data collection of the ZOI study on MNCH commodities

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 by PQM+ During Program Year 3

- Supported development and validation of a collaborative framework between LNCQM and DNPM that delineates agreed areas of collaboration and their individual responsibilities. The director of the DNPM participated LNCQM's first management review meeting in September, demonstrating his institution's commitment to this agreement.
- Conducted a training on dossier evaluation for DNPM's dossier evaluation committee.
- Procured five pieces of analytical equipment for the LNCQM.
- Made notable progress in the implementation of the roadmap toward ISO/IEC 17025 accreditation of LNCQM:
  - Trained 47 technical personnel trained on QA and QC topics, and
  - Drafted 20 quality documents drafted that are in varying stages of review and approval.
- Provided support to DNPM's PMS-TWG to start implementing the second RB-PMS, including support in:
  - Developing the 2022 RB-PMS protocol and
  - Procuring minilabs and laboratory reagents for testing.
- Supported the institutionalization of an equipment preventive maintenance program at LNCQM through:
  - Practical training on EPM,
  - Developing key protocols for EPM, and
  - Developing a list of spare parts for analytical equipment
- Supported the revision of the testing fees structure at LNCQM to ensure the laboratory is capable of charging fees that would improve its sustainability.

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 Q4, PQM+ provided support to LNCQM to implement its roadmap toward ISO/IEC 17025 accreditation. Given one of the weak areas at LNCQM is the management and maintenance of its equipment, which is critical to quality testing, PQM+ provided technical assistance to build the capacity of its technical staff on basic preventive maintenance. PQM+ also helped the maintenance team identify spare parts required for each of piece of equipment. The training, which reached 13 people (two women and 11 men), will enable LNCQM's equipment maintenance team to be more self-sufficient as they can now perform basic preventive maintenance that helps ensure equipment use optimization and less downtime. In addition to the training, PQM+ supported LNCQM to develop basic equipment preventive maintenance protocols to facilitate conducting basic equipment preventive maintenance.

In Q4, PQM+ supported Guinea LNCQM's maiden management review meeting, applying the SOP on management review developed with support from PQM+. This internal meeting (typically involving all staff of the NQCL) is a platform for the NQCL to examine the overall state of its QMS in the presence of top management. The ISO/IEC standard requires that this meeting occurs at least annually. As a demonstration of its commitment to the collaborative framework between LNCQM and DNPM validated in Q3, the DNPM director attended the meeting. Participants discussed LNCQM's performance against its quality indicators and presented a formal update on its progress in implementing its roadmap. During the visit, PQM+ coached and supervised LNCQM's internal audit using the SATTA they received training on in Q1 of PY3. The SATTA score of LNCQM for overall QMS performance increased to 37 percent from the initial score of 9 percent in October 2021.

In September, PQM+ conducted a training on dossier evaluation for the Guinea DNPM's dossier evaluation committee to reinforce competencies of their assessors (reviewers) in conducting regulatory dossier evaluation. Eleven participants (nine men and two women) had the opportunity to better understand the current scientific advancements and requirements for pharmaceutical products' dossier evaluation, strengthening their product dossier evaluation skills. Sample dossiers, case studies, exercises, and interactive, open discussions are designed to enable participants to understand the theoretical principles presented.

In Q4, USP-Ghana's testing laboratory completed confirmatory testing of the antimalaria samples and oral solid dosage forms of the MCH samples. Due to shipment challenges normally encountered with liquids, the oxytocin samples were assigned to the LNCQM analysts to test. Since this was the first time the LNCQM analysts were testing oxytocin injection, PQM+ supervised the initial stages. The analysts tested five batches with coaching provided by PQM+ and the rest of the sample testing is ongoing.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Complete the confirmatory testing of the RB-PMS samples.

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.

In Q4, PQM+ focused on improving governance for medical product QA systems, strengthening regulatory systems to assure the quality of medical products in Kenya and to advance the global medical product QA learning and operational agenda.

Highlights of Progress by PQM+ During Program Year 3

During PY3, PQM+ in Kenya achieved the following:

- Conducted testing of RB-PMS samples for antimalarial and reproductive, maternal, newborn, and child health (RMNCH) medicines.
- Completed the development of an online platform for self-directed learning for PPB.
- Supported the NQCL to develop a strategic plan for 2023–2027.
- Worked with PPB to review the PMS guidelines, PMS strategy, and PMS regulations that have now entrenched the pharmacovigilance / post-marketing surveillance technical working group (PV/PMS TWG) and RB-PMS as some of the interventions for assuring the quality of medicines in Kenya.
- Worked with the Pharmaceutical Society of Kenya to develop a curriculum and content for a competency-based curriculum on pharmaceutical regulation and QA for pharmacists practicing in Kenya.
- Supported Busia and Kisumu counties to develop interventions to assure the quality of antimalarials and other pharmaceuticals.
- Completed and disseminated analysis and synthesis of local data from eight rounds of previous PMS activities.
- Helped build the capacity of local manufacturers of malaria and RMNCH products on technical compliance and PPB's capacity on regulatory support.
- Supported development of a ministerial advisory note that advocated for policy support for local pharmaceutical manufacturers.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

The PQM+ program worked together with PPB, DNMP, two county governments and NQCL to execute key roles in the QA of medical products in the country. Achievements included:

- Supported PPB to develop a PMS strategy and a three-year costed workplan with a monitoring and evaluation framework for the PV/PMS TWG.

- Worked with Busia and Kisumu County teams to improve QA governance and to develop standard operating procedures (SOPs) on the QA of medicines in healthcare facilities in the two respective counties.
- Supported the development of NQCL's strategic plan that will run from 2022 to 2027.
- Participated as an observer during the ML3 assessment of PPB. This allowed PQM+ to identify key areas of support for PPB.
- Worked with PPB to strengthen their regulatory oversight for COVID-19 vaccine production through revision and development of guidelines and SOPs. This will also support PPB toward achievement of WHO GBT ML3.

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

PQM+ worked with PPB to set up a PV/PMS TWG to support it on quality monitoring of HPTs in Kenya. The TWG is now functional and participates in PV and PMS activities. The program:

- Worked with the PV/PMS TWG team to complete writing the report on RB-PMS for malaria and RMNCH medical products. Please see Annex 1A for more detail.
- Disseminated results of the RB-PMS of antimalarial and RMNCAH medical products to key stakeholders involved in QA of health commodities.
- With the PV/PMS TWG, participated in piloting a model on substandard and falsified (SF) medical products. The aim of the model is to reveal the health and economic impact of using SF oxytocin.

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

PQM+ collaborated with the Pharmaceutical Society of Kenya (PSK), to enhance the technical capacity of pharmacists in QA and regulation of pharmaceuticals in the country.

- PQM+ worked with PSK to develop a competency-based curriculum and content on pharmaceutical regulation and QA. The course will help pharmaceutical personnel in the country to improve their knowledge and skills on matters of QA and regulation of HPTs in the country.

Priority Activities for PY4, Q1

Next quarter, Kenya plans to:

- Work with PSK to complete the development of an in-service course on pharmaceutical regulation and QA for pharmacists.
- Continue supporting the PV/PMS TWG quarterly meetings and activities.
- Work with PPB to revise and/or develop guidelines, procedures, and checklists to meet the requirements of WHO GBT ML 3 requirements.
- Continue working with Busia and Kisumu counties to strengthen their capacity for QA of antimalarials and other HPTs.

PSK's CEO speaks at a workshop to develop a curriculum and content for a course on regulation and QA for pharmacists. (PQM+ Kenya photo)

Subject matter experts from PSK discuss contents of the curriculum on regulation and QA for pharmacists. (PQM+ Kenya photo)

Liberia

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

Highlights of Progress by PQM+ During Program Year 3

- Supported the LMHRA to disseminate seven new regulations promulgated by the LMHRA's board.
- Supported the LMHRA to disseminate its five-year strategic plan after LMHRA's board approved it.
- Supported the LMHRA to develop seven new regulations.
- Completed the workload indicators of staffing needs (WISN) assessment.
- Conducted an assessment on the LMHRA to determine feasibility to adopt an Integrated Regulatory Information Management System (IRIMS).
- Coordinated with USAID to donate laboratory equipment to the LMHRA worth more than USD $300,000. The President of Liberia attended the handover ceremony.
- Supported the LMHRA QC lab to recommence compendia testing.
- Developed a waste management plan for the LMHRA QC Laboratory.
- Supporting the LMHRA to set up a technical advisory committee (TAC) for medical products registration.
- Supported the LMHRA to clear its dossier backlog.
- Coordinated with the LMHRA and the Center for Innovation in Regulatory Science (CIRS) to complete an assessment of the LMHRA medicines registration process using the Optimizing Efficiencies in Regulatory Agencies (OpERA) tool.
- Coordinated with the LMHRA to release findings from PY2 RB-PMS.
- Conducted one round of RB-PMS.
- Coordinated with LMHRA to conduct a GMP gap assessment of a pharmaceutical manufacturer.
- Submitted to the school of pharmacy a curriculum of short courses to train health care workers in medical products QA in the short to medium term.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

This quarter, PQM+ supported the LMHRA to draft seven new regulations. When approved, the regulations will fulfill specific requirements stated in the IDP developed from the LMHRA 2021 WHO GBT assessment for medical products inspections, registration, and testing. PQM+ is coordinating with the LMHRA to review and finalize the draft regulations. This brings to 14 the number of regulations PQM+ has supported the LMHRA to draft.

PQM+ also coordinated with the LMHRA to complete the workload indicators of staffing needs (WISN) assessment. A draft assessment report has been submitted to the LMHRA for review. The draft report outlines several recommendations to improve LMHRA's current workforce.

In response to the first round of RB-PMS findings, LMHRA seized 36 cartons and 34 individual boxes of quinine injection (different batch numbers) in Q1, 750 quinine tablets from a pharmacy in Monrovia, and 25 boxes of quinine from a leading importer of pharmaceutical products in Q2. Also seized in Q2 were 28 boxes of amoxicillin from another pharmacy in Monrovia.

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

PQM+ coordinated with the LMHRA to conduct an environmental, health, and safety (EHS) inspection at the LMHRA QC laboratory. As a result, PQM+ supported the LMHRA to develop a laboratory waste management plan to enable lab staff to minimize the amount of waste generated inside the QC laboratory. In September, PQM+ conducted training on waste management and handling of expired goods

PQM+ supported the LMHRA QC Lab to recommence compendia testing by providing hands-on refresher training. Here are highlights from the training:

- Tested seven lots of oxytocin injections (pH, assay, identity, and related substances tests).
- Reviewed SOPs for the assurance of results and for techniques to be pursued for ISO/IEC 17025 Accreditation (TLC, HPLC, dissolution, FT-IR, uniformity of dosage units, and UV-Vis).

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

PQM+ worked with LMHRA to assess the progress of GMP compliance for the manufacture of quality-assured medicines in Liberia. PQM+ and LMHRA staff visited a manufacturer to observe and support the manufacturer in addressing significant findings/observations from the GMP inspection in Q2. The manufacturer has begun addressing significant observations.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Support the pharmacy school conduct a stakeholders meeting to agree on the draft curriculum;
- Continue to support the LMHRA Laboratory QMS;
- Continue the review of draft regulations;
- Conduct a stakeholder forum on the deployment of seven new regulations; and
- Complete the testing of PMS samples.

Madagascar

PQM+ collaborates with Madagascar's Medicines Regulatory Authority ("the Agency," *Agence du Médicament de Madagascar*) to strengthen its capacity to assure medicines and medical

product quality throughout the country. The Agency performs all regulatory functions through four technical departments: pharmaceutical inspection, registration, pharmacovigilance, and quality control. The National Pharmaceutical Quality Control Laboratory (LNCQM*, Laboratoire National de Contrôle de Qualité des Médicaments)* is part of the Agency's QC department. PQM+ is helping the Agency strengthen the LNCQM's capacity to prepare for ISO/IEC 17025 accreditation and WHO prequalification.

Highlights of Progress by PQM+ During Program Year 3

- Provided technical assistance to help LNCQM develop a national laboratory master plan aligned with the national pharmaceutical policy.
- Revised LNCQM's development plan to address gaps identified by WHO and PQM+ led SATTA assessments.
- Trained LNCQM staff on ISO 17025: 2017.
- Reviewed LNCQM's quality manual and eight SOPs.
- Completed a human resource assessment of AMM and developed a staff competency development plan.
- Provided technical assistance to develop LNCQM's calibration and maintenance program.
- Developed a risk management plan for LNCQM.
- Procured a dissolution tester, a critical piece of equipment, for LNCQM.
- Supported the establishment of a national multisectoral PMS-TWG with terms of reference.
- Worked with AMM to validate the national risk-based PMS guidelines.
- Developed the first round of an RB-PMS protocol using the MedRS tool.
- Finalized the SOP defining quality standards and regulatory actions to be taken by AMM based on RB-PMS findings.
- Trained LNCQM staff on the use of minilab kits; they then cascaded the training to other regions in Madagascar.
- Supported LNCQM to resume basic quality control testing activities by donating minilab kits, reagents, and consumables.

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

During PY3 Q4, PQM+ continued providing technical assistance to LNCQM to strengthen its capacity to generate quality-assured, reliable, and accurate data to facilitate regulatory and policy decisions aligned with national and international development goals. This was achieved in the following ways:

- Assisted LNCQM to develop a two-year master plan.
- Supported LNCQM to develop a laboratory plan based on gaps identified using the Stepwise Assessment Tool Towards Accreditation (SATTA).
- Supported LNCQM to finalize a workforce competency development plan.

- Supported LNCQM to finalize an equipment calibration and maintenance plan.
- Worked with LNCQM to develop a risk management plan.
- Commenced the process of procuring a dissolution tester for LNCQM. The dissolution tester will be delivered to LNCQM by the awarded vendor in October 2022.
- Worked with LNCQM to review the quality manual and procedures as per ISO/IEC 17025: 2017 and WHO prequalification requirements.

During PY3 Q4, PQM+ also continued offering technical support to the Medicines Regulatory Authority (*Agence du Médicament de Madagascar-AMM*) to implement a risk-based post-marketing surveillance system in the country. The achievements were:

- Commenced the process of procuring field-based product quality screening technologies including Minilab® kits, solvents and chemicals, reference standards, and other consumables to be used for RB-PMS activities. These will be delivered to AMM by vendors during Q1 of PY4.
- Developed a SOP defining quality standards and reliable regulatory actions to be taken by AMM based on risk-based PMS findings, to prevent poor quality medical products from reaching consumers.

Table 1: Status of Labs Accreditation in Madagascar

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	PT/LT	Official Inspection/ Pre-assessment
Laboratoire National de Contrôle de Qualité des Médicaments	ISO 17025:2017	Reviewed	Done	Done – to be completed after relocation to new premises	One proficiency testing program completed in 2021	To be completed in 2023 once LNCQM relocates to new premises

Priority Activities for PY4, Q1

Next quarter, Madagascar plans to:

- Hold a workshop for stakeholders to validate the LNCQM master plan and SOP defining quality standards and appropriate regulatory actions for AMM to take, based on the RB-PMS findings and the generalizability of the results.
- Start PY4 activities upon approval by USAID.

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 a Maturity Level 1 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, but it lacks both ISO/IEC 17025 accreditation and WHO prequalification.

PQM+ works with the DPM to strengthen its market surveillance function through establishing and operationalizing a PMS-TWG to implement RB-PMS and improve the capacity for medicine registration.

In addition, PQM+ has been providing tailored technical assistance to the Medicines Quality Control Laboratory within LNS to attain ISO/IEC 17025 accreditation. This would assure the reliability of testing, increase the public's confidence in test results, and help DPM take sound regulatory actions.

Highlights of Progress by PQM+ During Program Year 3

- Provided technical assistance to LNS's LCQM in preparation for and during its official accreditation audit. Provided continuous supportive supervision to help them implement the corrective action plan they submitted to the accreditation body, SOAC.
- Provided technical assistance to LNS microbiology laboratory to prepare to start conducting microbiology testing of pharmaceuticals. LNS did not conduct microbiological testing prior to PQM+ support. PQM+ completed a baseline assessment and trained the microbiology staff on basic QMS required for microbiological testing laboratories and on practical microbiological testing techniques for pharmaceuticals
- Completed a baseline assessment of LNS's medical devices laboratory to ascertain the requirement of its operationalization. An estimated budget to operationalize the medical devices laboratory has been developed.
- Provided training to LNS for the medical device analysts on the requirements of ISO 13485 and 17025.
- Supported LNS to draft a new five-year strategic plan.
- Supported the PMS-TWG to implementat the third RB-PMS of antimalarials and MCH medicines with technical support.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

In July 2022, a bombing just outside of Bamako led to the second cancellation of the strategic plan workshop. However, in September, PQM+ collaborated with LNS to convene a three-day workshop to draft the new five-year strategic plan. The workshop convened staff of LNS for the first two days to finalize strategic objectives, brainstorm on initiatives and activities, prioritize activities, and align and sequence activities to the broader strategic goals and other key stakeholders. The third day was a session with external stakeholders to review the strategic plan framework, collect feedback on the plan, and define how to partner going forward.

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

As part of its support to Mali LNS's accreditation progress, PQM+ supported the LCQM to finalize its corrective action plan for submission to the accreditation body, SOAC. In July, SOAC accepted LNS's CAPA plan and PQM+ guided LCQM on its implementation. All objective evidence was submitted to SOAC by LNS in August and this is still under review by SOAC with LNS making modifications suggested by SOAC as part of the review process.

In Q4, to further strengthen the capacity of the microbiology laboratory for testing of medicines, PQM+ provided technical assistance to the lab to finalize key QMS documents. These documents included an SOP for use of the autoclave, a new organigram of the microbiology lab, and SOPs for sampling (for QC testing) and for managing microbiology staff competence. In addition, building on the practical QC training provided by PQM+ to the microbiology lab in Q3, PQM+ convened a workshop to help the microbiology laboratory develop standard work

instructions required for sterile and non-sterile pharmaceutical products using the key techniques analysts were trained on for testing of pharmaceuticals – sterility testing, microbial enumeration test and bacterial endotoxin testing (BET). Given that LNS has no prior experience in microbiology testing of pharmaceutical products (LNS only conducted microbiological testing on food), these standard work instructions that provide stepwise instructions for these tests will facilitate implementation of microbiological testing of pharmaceuticals at LNS.

The implementation of Mali's third round of RB-PMS started in Q3. In Q4, 16 samplers (three women and 13 men) were trained by selected members of the PMS-TWG who planned the training and developed and executed the training materials. PQM+ supervised the training, after which antimalaria and MCH samples were collected from seven regions. LNS has started the screening of these samples.

Meanwhile, results of the second round of RB-PMS (in which 4 percent of medicines failed screening) led DPM to recall four lots of diazepam and one lot of combiart. These results are not nationally representative; please see Annex 1A for more detail.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Supervise the screening and confirmatory testing of the 2022 RB-PMS samples
- Support Mali's PMS-TWG to disseminate the 2022 RB-PMS results.

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 by PQM+ During Program Year 3

- Facilitated training of LNCQ and ANARME staff on ISO/IEC 17025:2017 standards, QMS, and documentation practices.
- Facilitated the development and review of key QMS documents as part of the support toward LNCQ ISO17025:2017 accreditation.
- Facilitated the establishment of ANARME-IP as an autonomous NMRA through publishing the ANARME-IP statutes in the official Government of Mozambique bulletin.
- Supported ANARME-IP toward ISO 9001:2015 certification through engagement of a certification agency.
- Developed a capacity building package for ANARME-IP technical staff on medical devices dossier review.
- Supported laboratory testing capacity strengthening of LNCQ through proficiency testing (PT), equipment and laboratory reagent procurement (TruScan Analyzer, reference standards, minilab supplies), and maintenance of laboratory equipment (Walters HPLC®, Water purifiers).

- Supported LNCQ to conduct self-audits of progress toward ISO 17025:2017 accreditation using the Stepwise Assessment Tool Towards Accreditation (SATTA) tool.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

In PY3, PQM+ continued to support DNF in its transition to ANARME-IP. This support culminated in the publication of the ANARME statutes in the official Government of Mozambique bulletin *Imprensa Nacional de Moçambique* on February 9. During Q3, PQM+ worked with ANARME-IP to identify and engage an ISO 9001:2015 certification agency, Bureau Veritas®, to provide audit and certification services. In Q4, PQM+:

- Reviewed a capacity development program on medical devices dossier review focusing on condoms. This followed a request from ANARME-IP Division of Medicines, Health and Biological Products Evaluation. Discussions are ongoing to schedule the training.
- Facilitated the ISO9001:2015 certification audit of ANARME, IP by Bureau Veritas®.

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

In PY3, PQM+ continued with laboratory systems strengthening work with LNCQ geared toward identifying and addressing gaps and preparing for ISO 17025:2017 accreditation. This included the development and review of key QMS documents and procedures. Additionally, to ensure that the laboratory provides accurate and valid results, PQM+ supported procurement of equipment and reagents (e.g., TruScan analyzers, minilab kits, and reagents for laboratory testing); supported maintenance of existing laboratory equipment (e.g., water purifiers, Walters HPLC®); and strengthened laboratory testing capacity through proficiency testing.

In Q4 PQM+:

- Finalized, with LNCQ, the plan for pending ISO 17025:2017-related training and other internal training requests. The materials were finalized and translated to Portuguese. Discussions are ongoing on scheduling the training dates.
- Liaised with LNCQ to determine priorities and areas of support for PY4 activities.

Table 2: 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 17025:2017	Initial gap assessment by PQM+ conducted and completed.	In progress	Development and review of most QMS documentation completed; pending some requiring direct in-person PQM+ subject matter expert support.	Two proficiency tests (PTs) conducted. Corrective action response for failed PT conducted; pending additional sample and reagents availability.	Not completed. CAPA is ongoing; completion expected in time for the ISO 17025:2017 audit in August 2023. PTs will take place in April/May 2023 and in-person technical support by PQM+ Technical Advisor is planned for March 2023.

Priority Activities for PY4, Q1

Next quarter, Mozambique plans to:

- Conduct the pending QMS training for LNCQ staff.
- Conduct an audit to determine the progress of LNCQ towards achieving ISO 17025:2017 accreditation.
- Support ANARME-IP to conduct RB-PMS for antiretroviral medicines, COVID-19 vaccines, and long-acting contraceptive implants.
- Engage with ANARME-IP to determine skills gaps and training needs for COVID-19 vaccine dossier review and emergency use approval (EUA), design and provide training as necessary.

Nigeria

PQM+ is focused on helping ensure the quality of medicines and other medical products in Nigeria, with an emphasis on malaria and MNCH 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 by PQM+ During Program Year 3

- Liaised with the Food and Drug Services (FDS) department of the Federal Ministry of Health (FMoH) in June to inaugurate the TWG on developing a national strategy for the pharmaceutical manufacturing sector (NSPP).
- Assisted the Pharmacist's Council of Nigeria (PCN) to obtain ISO 9001:2015 quality management system (QMS) certification on January 12; it is valid through January 11, 2025.
- Delivered up to 2,500 of copies of information, education, and communication (IEC) posters on identifying and using quality-assured medicines and consumables to community pharmacies and patent and proprietary medicine vendors.
- Provided technical assistance to the PCN to review and update its Pharmaceutical Inspectors' Manual.
- Conducted regulatory and quality assurance system (RQAS) gap assessments in Benue and Kebbi states and the FCT to identify areas of weaknesses in the availability of quality-assured medicines in medicines retail outlets.
- With NAFDAC, concluded a first round of RB-PMS of anti-malarial, MCH, and parenteral products, in the 11 PMI states and the Federal Capital Territory (FCT), with failures in artesunate-amodiaquine (10.1%), artemether-lumefantrine (9.2%), and sulfadoxine-pyrimethamine (7.5%). These results are not nationally representative.
- Conducted gap assessments of two NAFDAC medical devices laboratories using the SATTA as a first step in the pathway to scope expansion (in PY4) toward the quality control of medical devices and IVD test kits at both labs.
- Supported an exchange program for five microbiology lab staff of the National Institute for Pharmaceutical Research and Development (NIPRD) to NAFDAC's Drug Microbiology Laboratory to equip NIPRD staff to apply for a scope expansion of its QCL.
- The WHO PQ team accepted results of the test report on the risk of migration of ink and adhesive into magnesium sulfate 50%w/v injection following an evaluation report submitted by Nigeria Manufacturer 6.
- The WHO PQ team also accepted for, full evaluation, the product dossiers in the CTD format for SP and Zinc Sulfate dispersible tablets, earlier submitted by Nigeria Manufacturer 4.

- Nigeria Manufacturer 3 held a pre-dossier submission meeting with the WHO PQ team to review key areas in their SP dossier and get recommendations on areas of improvement before submission to WHO PQ for full evaluation.
- Prepared, facilitated, and delivered 17 trainings for more than 1,800 participants across supported manufacturers and the pharma industry at large, core flex partners and research institutes (CDDDP, NIPRD), regulators (PCN, NAFDAC), and operators of for-profit retail medicine outlets regulated by the PCN across the program states.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

PQM+ collaborated with the Food and Drug Services (FDS) department of the Federal Ministry of Health and other stakeholders to inaugurate a technical working group for the Pharma Sector Strategy Development.

- Conducted stakeholder analysis and commenced focused interviews of relevant stakeholders including MD/CEOs of identified manufacturers, leadership of the pharmaceutical manufacturing group of the manufacturing association of Nigeria (PMGMAN), representatives of other development partners, etc.

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

- Facilitated regulatory and quality assurance system (RQAS) sensitization training for 244 participants the PCN and operators of medicines retail outlets July 5–7 in Sokoto state.
- Collected samples for RB-PMS and submission to three accredited NAFDAC Laboratories for quality assessment, commenced August 15.
- Delivered a September workshop on harmonization of QMS documents and SOPs on medical devices and IVDs of two NAFDAC laboratories in preparation for the extension of the scope of accreditation to medical devices and IVDs.

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

PQM+ continued to provide support to manufacturers to produce quality-assured priority medical products (MNCH, antimalarial, and nutrition).

- Supported two manufacturers to prepare for scheduled WHO PQ inspections, specifically, the PQM+ team:
  - Supported Nigeria Manufacturer 4 to perform a desk review of its QMS/GMP documentation in preparation for the WHO PQ Inspection which took place between September 15-16, 2022, and September 19, 2022.
  - Supported the same manufacturer to review and update of the protocol used for the palatability study for zinc sulfate between September 20 - 28, 2022, as part of the response to the WHO PQ Audit report on the study sites.
  - Conducted a mock inspection at the a facility of Nigeria Manufacturer 5 in preparation for the WHO PQ inspection which took place between September 12-14, 2022.

- Conducted Workshop on Quality Risk Management CDDDP and Industry.
- Facilitated a GMP site Inspection training on the 17 elements of GMP for our core flex partner, CDDDP, and Nigeria Manufacturer 5.

Priority Activities for PY4, Q1

Next quarter, PQM+ Nigeria plans to:

- Conduct mock audits of two NAFDAC laboratories (Agulu and Yaba) in November 2022 in preparation for their scope expansion to medical devices and IVDs.
- Support both laboratories during assessment by the accreditation body in December 2022.
- Conduct a tailor-made training on various elements of quality assurance systems for CDDDP, one of our core-flex partners in PQM+ Nigeria.
- Conduct a hands-on capacity-building session on dossier compilation in the Common Technical Document (CTD) dossier format for Nigeria Manufacturer 2.
- Conduct a joint review, with the Nigeria Manufacturer 2 technical team, of product data such as *stability batches, process validation, analytical method development protocol etc.*, including hands-on training on the compilation of the above reports as required in module 3 of the CTD dossier format.
- Conduct an analysis of RUTF trial batches produced in Nigeria Manufacturer 3's commissioning plant.

Status of Lab Accreditation in Nigeria: All four QCLs (at NAFDAC) and one at NIPRD all have valid ISO/IEC 17025 accreditations in Nigeria for 2022. Two of the NAFDAC labs and the one at NIPRD are seeking scope expansions into medical devices and microbiology testing, as shown in Table 3.

Table 3: Scope Expansions for Labs Accreditation in Nigeria

Laboratory	Accreditation Sought	Initial Gap Assessment	CAPA	QMS	PT/LT	Official Inspection/ Pre-assessment
NAFDAC National Control Laboratory for Vaccines and Biologicals, Yaba, Lagos	Scope expansion into medical devices and in-vitro diagnostic kits	Done	Ongoing; expected December 2022	Ongoing; expected December 2022	Ongoing; expected December 2022	Not started; expected December 2022
NAFDAC Zonal Laboratory Agulu, Anambra State	Scope expansion into medical devices and in-vitro diagnostic kits	Done	Ongoing; expected December 2022	Ongoing; expected December 2022	Ongoing; expected December 2022	Not started; expected December 2022
NIPRD Quality Control Laboratory	Scope expansion into microbiology testing	Not applicable	Not applicable	Not completed; expected January 2023	Not completed; expected January 2023	Not started; expected January 2023

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 by PQM+ During Program Year 3

- Facilitated a workshop for Rwanda FDA and key multi-sectoral stakeholders to establish the national PMS TWG with terms of reference, trained the TWG members on principles of RB-PMS and use of MedRS tool, and developed a draft protocol for RB-PMS on RH/FP and MNCH medicines.
- Supported the development of five SOPs for RB-PMS that were adopted by Rwanda FDA.
- Presented a draft costing and advocacy plan for RB-PMS activities.
- Procured reference standards and replenished minilab supplies for Rwanda FDA QCL.
- Audited Rwanda FDA laboratory based on ISO 17025:2017 to identify gaps and updated the roadmap toward ISO/IEC 17025:2017 accreditation.
- Supported the revision of 37 QCL SOPs and quality manual to address gaps identified during PQM+ audit.
- Presented a draft costing and advocacy plan for QCL testing activities.
- Supported Rwanda FDA to review one GMP guideline used in desk review of dossiers submitted for GMP virtual assessment.
- Supported Rwanda Medical Supplies to develop 22 SOPs, update their quality manual, and develop a QA procurement framework.
- Collaborated with University of Rwanda through the Regional Centre of Excellence for Vaccines Immunization and Health Supply Chain Management to update and validate a master's program in pharmaceutical quality control and quality assurance.
- Supported Rwanda FDA to assess staff training needs and develop a competence framework with relevant training plan.

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+ works with Rwanda FDA to strengthen the medicines regulatory system in quality assurance areas including risk-based post-marketing surveillance RB-PMS and drug quality control lab strengthening. This contributes to improving the regulatory system and functions at

Rwanda FDA, an essential public health institution responsible for the public health safety in Rwanda.

In PY3, PQM+ provided technical assistance (TA) to Rwanda FDA to implement the RB-PMS approach using the MedRS tool. In the same TA, Rwanda FDA was supported to establish a multi-sectoral PMS technical working group (TWG), develop 5 risk-based PMS SOPs, and apply the MedRS tool to develop an RB-PMS protocol for family planning (FP), reproductive health (RH) and maternal, neonatal and child health medical products (MNCH). For planning and budgeting purposes, PQM+ supported Rwanda FDA to draft a costing and advocacy plan for the projected RB-PMS sampling and testing activities.

A functional and strong national pharmaceutical quality control laboratory is imperative to implement enforcement actions for poor-quality medicines identified following PMS or inspection and to ensure procured and donated essential medical products meet acceptable quality requirements.

To build the capacity of Rwanda FDA quality control testing, In PY3, PQM+ procured reference standards and replenished minilab supplies. In addition, PQM+ conducted a baseline assessment of the laboratory to help understand Rwanda FDA QCL's level of compliance with the ISO/IEC 17025:2017 standard. In response to the laboratory audit findings, PQM+ trained all 33 Rwanda FDA QCL and two University of Rwanda Laboratory teaching staff on ISO 17025:2017 based QMS and internal audit, supported them to review and update their quality manual and 37 SOPs, and developed a CAPA plan for critical observations made during the PQM+ audit.

To strengthen the capacity of Rwanda FDA in GMP regulatory inspection and oversight, PQM+ program supported Rwanda FDA to review their GMP guidelines, trained 36 participants from Rwanda FDA and local manufacturers on basic GMP principles, and supported Rwanda FDA to conduct desk assessments of 35 GMP dossiers for medical products submitted by manufacturers to Rwanda FDA for desk review as one of the assessments done by the regulator prior to granting registration approval.

In 2018, WHO supported the government of Rwanda to assess the medicines regulatory system using the Global Benchmarking Tool (GBT). Gaps identified among others included the training needs assessment report with a relevant training report. In PY3, PQM+ provided technical assistance to the Rwanda FDA to assess training needs and develop a competence framework with a relevant training plan.

Additional technical assistance offered to Rwanda FDA related to GloVax activities include the support to develop terms of reference for vaccines lot release (LR) technical working group (TWG), establishment of the vaccines LR TWG members, and review of the LR regulatory documents (guidelines and SOPs).

Table 4: Status of Labs Accreditation in Rwanda

Laboratory	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-assessment
Rwanda FDA QCLD	ISO 17025:2017	Completed	Initial gap assessment by PQM+ completed	Completed and submitted to Rwanda FDA for review.	Not applicable	CAPA is submitted and reviewed by Rwanda FDA. Follow-up visit for verification of CAPA will be carried out after 6 months.

To increase supply of quality-assured medical products, importers of medical products and capacity building institutions need to be supported. In Rwanda, procurement and distribution of medical products is done by a state-owned company known as Rwanda Medical Supply Limited (RMS LTD). To build the capacity of cadres involved in supply chain of medical products, the government of Rwanda in collaboration with the East African Community established the Regional Centre of Excellence for Vaccines Immunization and Health Supply Chain Management (RCE-VIHSCM) to provide capacity building to health supply chain professionals.

To put in place a robust quality assurance (QA) system for medicines and other medical products in the supply chain through importation or manufactured locally, in PY3, PQM+ trained and guided RMS LTD procurement and quality assurance team through suppliers' prequalification process to ensure the selected suppliers are able to provide quality-assured medical products. PQM+ also supported RMS LTD to review their quality manual, 22 SOPs, and developed a comprehensive QA framework.

To support the capacity building efforts, in PY3, PQM+ collaborated with RCE-VIHSCM to develop a master's program in pharmaceutical quality control and quality assurance.

Priority Activities for PY4, Q1

Next quarter, Rwanda plans to:

- Implement PY4 work plan activities after approval by USAID.
- Implement Glovax activities after feedback from Rwanda FDA on proposed activities.

Senegal

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

Highlights of Progress by PQM+ During Program Year 3

- Implemented the second RB-PMS for Senegal by supporting training on the new MedRS tool, development of a new RB-PMS protocol, procurement of minilabs and testing reagents, and provision of logistics for the sampling missions.
- Convened a training of trainers (ToT) on good documentation practices/ good laboratory practices and on the ISO/IEC 17025 standards
- Trained eight technical personnel on QA and QC topics, including:
  - measurement uncertainty and
  - analytical method validation.

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 Q4, PQM+ supported the implementation of the second RB-PMS protocol for antimalarials in Senegal with 247 samples collected from six regions (Dakar, Djourbel, Kaolack, Zigunchor, Kolda, and Kedougou). These results will not be nationally representative.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Conduct a baseline assessment of ARP per the ISO 9001 standard
- Convene a workshop on risks and opportunities
- Supervise the testing of the 2022 RB-PMS samples

Asia Region

Asia Bureau

PQM+'s technical assistance funded by USAID's Asia Bureau aims to promote regional regulatory convergence and reliance. PQM+ will work with regional health networks that include the Association of Southeast Asian Nations (ASEAN) Pharmaceutical Product Working Group (PPWG) and the South-East Asia Regulatory Network (SEARN) to strengthen regulatory and quality assurance systems. This work leverages the current PQM+ work in Southeast and Central Asia.

Highlights of Progress by PQM+ During Program Year 3

- Collaborated with partner Mahidol University to finalize the landscape analysis of the medical product QA system for SEARN and ASEAN member countries. Findings will provide the basis for the design of regional and country-specific activities, including the development of action plans to strengthen regulatory systems in Asia.
- Presented a proposal for PY3 planned activities at the 32nd ASEAN PPWG meeting and developed detailed implementation plans for PPWG's consent. Some planned activities will be jointly implemented with the MTaPS program. However, implementation is now planned for PY4 due PPWG consensus process delays.
- Built a framework for evaluating countries' capability in the region to optimize the local production of essential health products.
- Organized a virtual side session during the 2022 Prince Mahidol Award Conference with the objective to highlight critical considerations for equipping and preparing NMRAs regarding the current and future infectious disease pandemics and outbreaks by establishing fast-track and agile medical products approval processes, including emergency use authorization. Seven panelists from NMRAs, donors, academia, and implementing partners participated at the session and 89 people from 25 countries attended.

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+ initiated the development course materials and logistics preparations for the three proposed training of trainers (ToT) on product evaluation for registration of complex active pharmaceutical ingredients (APIs) (1), biological products (1), and bioavailability/bioequivalence (1). The PPWG approved the implementation of the latter two ToTs in August. PQM+ plans to conduct the approved TOTs in PY4Q1.

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

In PY3, PQM+ built a comprehensive framework for evaluating countries' capability in the region to optimize the local production of essential health products. The framework is comprised of three key domains—policy and regulatory environment, local manufacturing capability and exports, and local pharmaceutical market needs. Using the framework, this reporting quarter, PQM+ shortlisted 17 countries from a list of 34 eligible LMICs in the region to conduct a preliminary analysis which will form the basis for an in-depth market feasibility study of 1-2

countries. PQM+ also compiled a list of 24 key opinion leaders who will be interviewed in PY4Q1 to inform the preliminary analysis.

Priority Activities for PY4, Q1

Next quarter, PQM+ Asia Bureau plans to:

- Conduct the two approved TOTs (i.e., registration on biological products and bioavailability/bioequivalence).
- Initiate planning for a regional workshop to disseminate findings from the landscape analysis and action planning in SEARN countries. Pending ASEAN PPWG's approval, the team will also implement activities in ASEAN member states. The PPWG will meet in November 2022 to reach final agreement on remaining activity implementation plans.
- Initiate secondary research exercise to consolidate all relevant data points for short-listed countries.
- Conduct interviews of key opinion leaders and initiate the secondary analysis by consolidating all relevant data points for short-listed countries.

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 develop a draft regulatory framework document.

- PQM+ provided support to DGDA to form a 14-member task force involving the most relevant DGDA officials and assisted the committee to prepare the draft regulatory framework document.
- On September 22, the task force committee was revised due to changing the responsibility of assigned and relevant human resources.
- PQM+ met with the new task force committee and the head of nine functions at DGDA and shared the primary draft regulatory framework document.

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

- With technical assistance from PQM+, a technical working committee was formed comprising DGDA, NCL and PQM+ members to draft the strategic plan. On July 25, the working committee prepared a roadmap for completing the five-year strategic plan. Based on the roadmap, the fourth meeting took place July 26 at NCL. NCL/DGDA management reviewed the draft strategic plan and provided valuable comments. The 16 participants included nine women and seven men.

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

PQM+ supported DGDA to develop a plan for corrective and preventive action (CAPA) for nine functions of DGDA based on 274 observations from the WHO formal assessment from July 12 to 23, 2021.

- On July 31, PQM+ supported DGDA in updating the CAPA plan implementation progress of the nine functions for the WHO team meeting.
- Updated three SOPs for competency assessment, performance evaluation, and staff appraisal.
- On September 21, assisted NCL management to conduct a management review meeting.

PQM+ supported DGDA to develop the draft Regulatory Framework for Medical Devices:

- On August 16, PQM+ organized an online scientific session/training program for the DGDA and NCL staff on medical device regulation at the DGDA conference hall to enhance the knowledge of medical device regulations among the participants. Melody Scott, technical advisor on RSS, facilitated the session, with 25 participants (19 male and six female) attending.
- In September, developed a medical device regulation maturity level 1 (ML1) checklist derived from the WHO GBT tool.
- In September, identified key stakeholders of medical devices.

PQM+ provided technical support to DGDA's market surveillance and control (MC) department to adopt the MedRS tool for efficient implementation of RB-PMS.

- PQM+ is supporting DGDA's Technical Working Group (TWG) to finalize the sampling and testing protocol of first-line anti-TB medicine.
- On August 1, the Director General of DGDA visited the Chattogram Drug Administration Office and Central Drug Testing Laboratory (CDTL) to oversee the RB-PMS implementation progress. PQM+ CoP and technical officers joined the visit and facilitated the program. A CDTL official presented the report of testing RB-PMS samples from February through July 2022. They conducted surveillance of 113 post-marketing samples, including priority medicines, and found no SF medicines. DG encouraged the inspectors to perform more sampling and testing focusing on priority TB, MCH, FP, and antibiotics medicines.

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

- On July 20, conducted a meeting on the preparation of the Equipment Qualification qualification/Calibration Plan for the National Control Laboratory.
- On August 30-31 and September 1, assisted NCL representatives to face ANAB re-audit in the physicochemical lab. In this audit, the assessor observed four new scopes (resistance to crushing/hardness, diameter, thickness, and friability-loss of mass) for expanding the scopes. Unconditional approval has been declared after the assessor found no issues.
- On August 27, supported NCL to update the vendor qualification questionnaire for CS lab and Caltech.

PQM+ continued technical assistance to NCL to increase the capacity of vaccine testing.

- On July 14, supported an NCL analyst to perform in vitro potency testing of two lots of rabies vaccines in the animal laboratory.
- On August 14, supported an NCL analyst to perform in vivo potency testing of two lots of rabies vaccines in the animal laboratory.
- On August 17, supported an NCL analyst to perform in vitro potency testing of the TT vaccine in the animal laboratory.
- Reviewed and updated the laboratory SOP (management of sampling) addressing the feedback of the WHO consultant.
- From July 27 to 28, with technical assistance from the PQM+ program, two assistant directors of NCL conducted an internal audit in the microbiology and chemical department under the vaccine laboratory respectively. The audit team observed the physical structures, safety and security issues, administrative, technical, and supportive manpower, documentation, logistics, etc. in reference to ISO: 17025:2017. They provided an internal audit report with nine minor observations. Moreover, the audit team reviewed four observations of the May internal audit and closed them.
- On July 27, supported NCL to prepare the trend analysis of NCL and manufacturer's results (comparison) to check the consistency of the results.
- On July 31, supported NCL for method validation of hepatitis A potency test.
- PQM+ provided technical support to review the specification laboratory materials procurement funded by the World Bank.

PQM+ continued technical assistance to DGDA to implement the CDTL roadmap.

- On July 31, PQM+ provided training to the CDTL laboratory analysts on the daily calibration of the balance.
- On August 1, the Director General of DGDA and representatives from USAID, WHO, UNOPS, and PQM+ visited the CDTL to monitor current activity of the lab and the Chattogram Drug Administration Office, including functions of the minilab, progress of RB-PMS implementation, and CDTL's five-year roadmap. PQM+ supported DGDA and CDTL to organize the visit.
- On August 10, PQM+ organized a meeting with the health and engineering department (HED), UNOPS, WHO, DGDA and NCL to review the new laboratory design of CDTL. On August 17, PQM+ supported NCL to modify the new laboratory design according to the previous meeting recommendations and shared it with DG, DGDA

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

PQM+ continued technical support to Bangladesh Manufacturer 2 toward prequalification of first-line TB medicines. Notable developments are:

- From September 4 to 9, PQM+ conducted a GMP assessment and provided onsite technical support to the manufacturer. During the assessment visit, PQM+ HQ expert Mr. Teferi Bedane assessed the manufacturing site on activities related to 4FDC production to determine the level of compliance against the GMP requirements and discuss areas of improvement; product development and dossier preparation of 4FDC product (rifampicin/isoniazid/pyrazinamide/ethambutol). The manufacturer started the process of piloting a BE study, per the assessment recommendation, and completed the protocol for CRO submission.
- From September 11 to 13, a PQM+ HQ expert supported Bangladesh Manufacturer 2 in the product dossier preparation of azithromycin 500 mg tablet under core funding support of NTD products per the manufacturer's EOI submission.

PQM+ provided TA to a local contract research organization (CRO) towards building capacity to perform bioavailability and bioequivalence (BA/BE) studies.

- On July 25, PQM+ published an EOI in 'The Daily Prothom Alo' Bangla newspaper for submission of an application by locally registered CROs in Bangladesh. Accordingly, the PQM+ received a total of 5 interested applicants. Currently, the evaluation process is ongoing to select two potential CROs for providing further technical support to build their capacity in PY4.

PQM+ provided technical assistance to DGDA in preparation for the ending of TRIPS flexibilities

- On August 30, PQM+ organized a technical workshop to identify challenges and develop an action plan to mitigate challenges for the Bangladeshi pharmaceutical sector upon graduation from LDC. PQM+ is closely working with the relevant stakeholders [DGDA, Ministry of Commerce WTO Cell, Center for Policy Dialogue (CPD), Department of Patents, Design, and Trademarks (DPDT), Bangladesh Trade and Tariff Commission (BTTC), and USAID].
- On September 7, PQM+ supported DGDA to conduct a consultation workshop with the key personnel from relevant stakeholders and shared the primary draft action plan for the directorate. A total of 12 technical staff (11 men and one woman) attended the workshop to review the draft document.
- On September 18, PQM+ organized a follow-up meeting with the 12 technical experts (10 male and two female) and developed the final action plan.

PQM+ initiated establishing collaboration with the Bangladesh Association of Pharmaceutical Industries (BAPI) to raise awareness of GxP for manufacturers of API products.

- On August 3-4, in collaboration with PQM+, the Bangladesh Association of Pharmaceutical Industries (BAPI) organized a two-day training program to promote competency for API manufacturing in Bangladesh in Dhaka. A total of 53 (49 male and four female) participants from DGDA, API manufacturing industries, and university academics attended the training.

Priority Activities for PY4, Q1

- Support DGDA to finalize the draft regulatory framework document
- Technical assistance to DGDA to reduce anticipated risks of using non-WHO prequalified medicines
- Arrange ToT for master trainers in the training pool for enhancing competency to manufacture API in Bangladesh
- Continue to assist DGDA in addressing CAPAs based on WHO formal assessment observation.
- Complete the CRO selection process and conduct assessment
- Conduct gap assessment and provide training on medical device regulation.
- Develop training materials on data integrity, the introduction of QMS for EDCL

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 by PQM+ During Program Year 3

- Facilitated the ISO 17025 annual surveillance of DFDA Nay Pyi Taw Pharmaceutical Chemistry (PC) Laboratory
- Organized the hybrid metrology training at DFDA Nay Pyi Taw PC Laboratory
- Organized the hybrid measurement uncertainty training for analysts from DFDA Nay Pyi Taw PC Laboratory
- Screened and selected one local manufacturer to provide technical assistance to strengthen its cGMP to improve the quality of locally manufactured antimalarial medicines and completed desk review of its site master file
- Conducted initial assessment at the manufacturer's QC laboratory to prepare for ISO 17025:2017 accreditation
- Organized three technical webinars in collaboration with USP Reference Standards Laboratory, USP Education, and USP General Chapters.

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+ organized an in-person training on introduction of ISO 17025:2017 standards, Good Laboratory Practices, Documentation Practices, High Performance Liquid Chromatography, Good Weighing Practices, and measurement of pH at DFDA Yangon Laboratory and the QC laboratory of the manufacturer that PQM+ is supporting in July.

- Analysts trained included 16 from DFDA Yangon Laboratory, two from DFDA Nay Pyi Taw Laboratory, two from DFDA Mandalay Laboratory, and 13 from the manufacturer's QC laboratory.
- PQM+ introduced new training tools: short explanatory videos and interactive quizzes to increase participant engagement and improve knowledge transfer.
- This was the first in-person training for PQM+ in Burma since the beginning of the COVID-19 pandemic.

PQM+ organized a technical webinar on USP General Chapter <621>: Chromatography in collaboration with USP Education and USP General Chapters in August.

- 23 analysts (17 female, three male, three unreported) attended the technical webinar after completing pre-reads.
- USP Education provided access to its course materials free of charge to registered DFDA analysts
- USP General Chapter team provided a subject matter expert to lead the webinar and answer questions from the DFDA analysts.

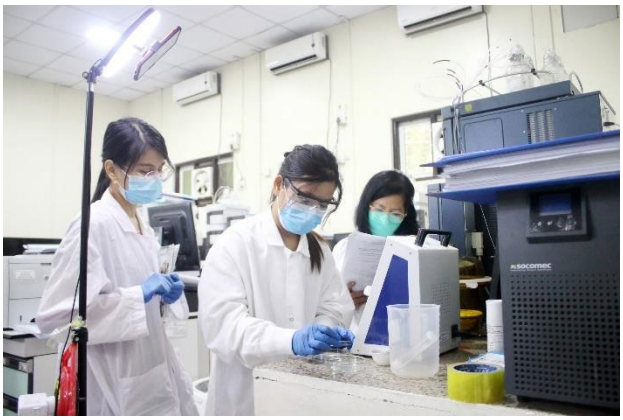
PQM+ facilitated the ISO 17025:2017 reaccreditation assessment of DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory in September.

- ANAB conducted a 2.5-day virtual assessment and witnessed method demonstration by DFDA analysts.
- Over the course of the assessment, ANAB did not find any nonconformities and granted reaccreditation in nine scopes of testing. One scope of testing is pending due to an equipment breakdown prior to the assessment. ANAB will reassess the remaining scope after DFDA completes the repair.
- This is the first reaccreditation assessment for the current Quality Assurance Team at DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory which DFDA formed after it lost more than 60 percent of the workforce at the laboratory in 2021.

Priority Activities for PY4, Q1

Next quarter, PQM+ Burma plans to:

- Organize an in-person data integrity training at DFDA Nay Pyi Taw Pharmaceutical Chemistry Laboratory
- Conduct an on-site cGMP assessment at Burma Manufacturer 1
- Organize a QC training at DFDA Yangon Laboratory and the manufacturer's QC Laboratory
- Organize a technical webinar on <1225/1226> Analytical Method Validation and Verification in collaboration with USP Education and USP General Chapters

Left: Yenny Francisca delivers an in-person QMS training at the QC laboratory of Burma Manufacturer 1. Right: DFDA analysts demonstrate the melting point determination during the remote ISO 17025 reaccreditation assessment.

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.

During PY3, many activities continued as an extension of the previous year, while new activities include strengthening the public manufacturer Nepal Aushadhi Limited and introducing quality procurement guidelines for the national health insurance system.

Highlights of Progress by PQM+ During Program Year 3

- Supported revision of the national code on GMP and four relevant supplemental guidance measures.
- Worked with stakeholders and the MRA to develop a policy paper on pharmaceutical reform in Nepal, later shared in government- and donor-led forums.
- Worked with DDA's inspection division to develop a risk-based inspection plan for the inspection of manufacturers first by developing an RBI framework and ranking of the 24 selected manufacturers.
- Coordinated with the central and regional DDA offices to facilitate the first pilot of RB-PMS of MNCH and is supporting development of guidelines and SOPs.
- Continued to support NML toward achieving ISO 17025 accreditation by upgrading equipment, water purification system, training technical staff, upgrading data management systems and most importantly contributing to development of quality processes by helping to develop and implement critical SOPs for quality management system.
    - Trained NML staff on eight technical topics
    - Supported drafting/revision of 30 SOPs;16 are in the implementation phase.
- Completed a training needs assessment at DDA and NML and finalized staffing needs analysis of NML. The reports from these studies have been approved for further use by the regulatory agencies.
- Facilitated a learning visit for DDA and NML to Pakistan to understand about adoption of international standards, information management system for effective regulation of medical products.

- Collaborated with DDA to complete detailed assessment reports of six private manufacturers and a CAPA progress review for WHO PQ. A roadmap agreement with a private manufacturer for zinc sulfate has been signed.
- Upgraded the water treatment system and microbiology section at Nepal's only public manufacturer to meet national GMP requirements.
- Completed an assessment report and developed guidelines for QA in procurement of medicines for a local government body in Nepal.
- Collaborated with DDA to design and public service announcements to be broadcast through national and regional radio stations to raise public awareness of the dangers of SF medicines.
- Worked with DDA's branch office in Biratnagar to organize training on visual identification of SF medicines to community pharmacists in Province 1.
- Partnered with Nepal Health Research Council (NHRC) to organize a session on strategies for improving the quality of medicines and research on the pharmaceutical sector for NHRC's National Summit.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

PQM+ is collaborating with DDA and Ministry of Health and Population (MoHP) to improve medicine related legislation, policies, and regulations and promote collaboration among different stakeholders. PQM+ collaborated with MTaPS to provide inputs into the revision of the Drug Law and National Medicines Policy as well as to update the maturity level action plan under the leadership of DDA to track the progress against WHO GBT recommendations.

Inspection TWG meeting for review of GMP supplemental guidance

Revision of national GMP and GSDP codes: PQM+ supported the revision of current GMP code and has supported the drafting of four supplemental guidelines to the GMP code on biologicals, heating, ventilation and air conditioning (HVAC), hazardous substances, and water treatment systems. The guidelines which are in Nepali have been reviewed by the Inspection TWG and the revised GMP code are in process of approval. Similarly, PQM+ participated in a stakeholder meeting to discuss revised Code on Sales and Distribution of Drugs and newly drafted Good Sales and Distribution Practices (GSDP) organized by DDA with the support from the MTaPS program.

Minister for Health and Population in a drug advisory group meeting

Drug Advisory Group meeting: PQM+ supported DDA in organizing a high-level advisory group meeting comprising representatives of national-level health organizations, professional bodies and councils, academia, and private sector entities with

the aim to discuss the existing structure, working mechanism, and policy procedure to regulate the medical products in the nation to align with international standards. Following this, PQM+ facilitated another smaller meeting that led to the development of a policy brief on pharmaceutical sector reform in Nepal, which has been shared in different government and donor forums.

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

Strengthen risk-based (RB) inspection of DDA: Working with DDA's inspection technical working group (TWG) meeting, PQM+ facilitated the development of the risk-based inspection framework and risk-based inspection plan. PQM+ worked with DDA to set up and analyze data of selected 24 manufacturers and rank the manufacturers on the basis of risk criteria. Based on the risk analysis, PQM+ assisted DDA to develop a risk-based inspection plan that will guide the inspection of high-risk manufacturers. Furthermore, PQM+ is also facilitating development of four SOPs related to inspection and guidelines and SOPs for recall of medicines. Additionally, in coordination with a technology firm Avatour, PQM+ organized a demonstration of remote inspection technology for DDA and NML, which can be useful for remote inspection.

Strengthen RB-PMS of DDA: PQM+ supported DDA's Management Division to conduct its first ever risk-based PMS. The program supported DDA, NML, Logistic Management Division, and Family Welfare Division to identify 10 medicines, taking into consideration the risks related to prevalence of health problems, supply chain issues, dosage forms with complex formulations, and stability concerns. The RB-PMS pilot surveyed 90 samples of nine MNCH and one FP medicines from 68 facilities in Province 1 of Nepal. The pilot, which was not nationally or provincially representative, had a 95% confidence interval and 10% error. Sampling outlets were randomly chosen. To facilitate the piloting of RB-PMS, PQM+ conducted preparatory training and workshops with DDA and NML officials on MedRS tool application, protocol design and logistics and sampling to prepare them for field work for medicines sample collection. Furthermore, the program facilitated resource support such as chemicals, consumables to NML for testing of those samples. Side by side, in collaboration with the RB-PMS TWG, PQM+ supported drafting of an RB-PMS guideline and two SOPs to facilitate the institutionalization of RB-PMS.

DDA officials participate in the RB-PMS field visit.

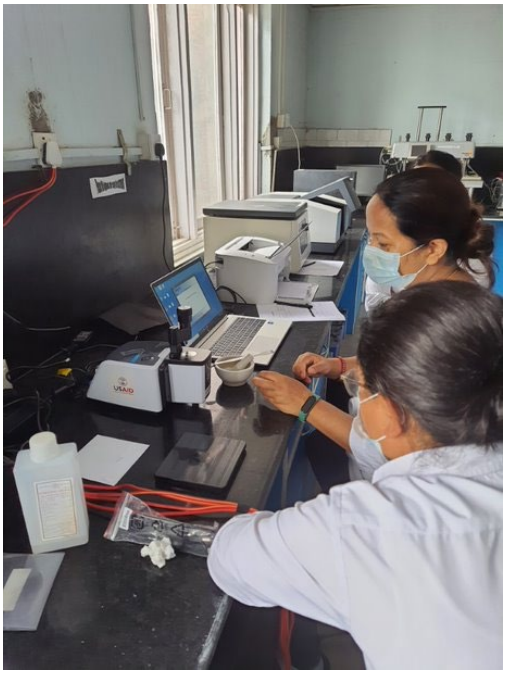
Support NML toward ISO 17025 accreditation: PQM+ is focused on supporting activities in the IDP that was developed and agreed to facilitate NML to achieve ISO 17025 accreditation.

- *Equipment and premises:* PQM+ helped NML to increase their testing capacity by supporting the procurement, setting up of critical laboratory equipment, such as Fourier-transform infrared spectroscopy (FTIR), ultrapure water purification system, and a pH cum conductivity meter. PQM+ finalized a warehouse assessment of lab chemicals, standards,

and samples at NML and the report will guide PQM+ interventions to strengthen NML's warehouse.

- *Documentation:* PQM+ helped NML to prioritize SOPs for drafting, review, and approval. In all, 30 SOPs (including six from last year) were drafted or revised according to NML's priority. Of those, NML has approved, trained, and implemented 16 SOPs this year.
- *Data management and control:* PQM+ procured services to upgrade the laboratory data networks to strengthen the data and inventory management system. PQM+ is supporting NML to acquire a centralized electronic data server that will connect critical lab equipment data so as to maintain the integrity and safety of analytical records. Similarly, PQM+ has successfully set up an operationalized inventory management system at NML and supported management and storage of laboratory inventory stocks in the process. NML is now managing this system independently.

Training plan and training: PQM+ supported NML to finalize a yearly training plan based on the priority topics identified by NML. In the year 2021/22 PQM+ facilitated eight technical trainings with a total of 147 participants.



NML personnel use PQM+ supported FTIR equipment for analysis.

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

- Training needs assessment and training plan for NML: PQM+ completed training needs assessment of NML and facilitated the development of training plan for NML.
- Training needs assessment and training plan for DDA: PQM+ facilitated information training needs assessment and development of training plan for DDA.
- Staffing needs analysis: PQM+ facilitated the formation of a working group at NML that worked with IntraHealth consultants to analyze the time inputs for NML activities and come up with the staffing needs analysis for NML.

DDA and NML reviewed and approved the assessment reports and plans and have further instructed their department to use the findings in their planning and operations processes.

Nepal's NMRA delegation visits Pakistan.

Strengthening of local HTP manufacturers: PQM+ in coordination with DDA advertised an expression of interest for local HTP manufacturers in Nepal for technical assistance to meet ISO standards. PQM+ organized a training session to the local

manufacturers on ISO standards requirements. Currently, PQM+ is assessing the manufacturers who have applied for technical assistance.

Regulatory authority visit to Pakistan: PQM+ Nepal facilitated a visit of Nepal's MRA and MoHP officials to Pakistan to observe and learn from Pakistan MRA's about adoption of international standards and information management system to regulate medical products. Similarly, the Nepal delegation visited the health technology product testing facility, drug testing laboratory, and a manufacturer in the process of obtaining WHO prequalification for zinc sulfate.

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.

WHO prequalification roadmap signing with Nepal Manufacturer 2 for zinc sulfate.

Private manufacturers: In the year PQM+ conducted rapid and detailed assessments of six private manufacturers and drafted CAPA plans for five Nepali private manufacturers to build a roadmap to obtain the WHO prequalification for selected medicines. PQM+ and private manufacturer Nepal Manufacturer 2 signed a roadmap agreement to achieve WHO prequalification for zinc sulfate. Similarly, PQM+ organized a five-day training workshop on dossier preparation for the selected products to 20 technical personnel of manufacturers.

To enhance manufacturers' technical capacity, PQM+ conducted three two-day trainings on advanced GMP topics; 147 technical staff from manufacturers across Nepal attended.

PQM+ supported water treatment system improvement at Nepal Manufacturer 6.

Public manufacturer: PQM+ focused on three technical components to support the country's only public pharmaceutical company to achieve compliance towards national GMP. First, PQM+ supported the company to complete upgrades of its water treatment facility to meet industry requirements. Second, PQM+ and the company completed redesign of the microbiology section by improving the air handling unit and clean room in accordance with the regulatory standards. Third, PQM+ is currently supporting the company for calibration, qualification and validation of equipment and systems that are critical for GMP certification. PQM+ organized training on water system validation and good documentation practices exclusively for company personnel.

Nepal pharmaceutical manufacturing strategy: PQM+ is collaborating with DDA and other national stakeholders such as pharmaceutical producers' association to develop Nepal pharmaceutical manufacturing strategy. PQM+ has developed a concept paper on the strategy

and this will be further discussed with different stakeholders in future forums. Similarly, PQM+ engaged consortium partner IQVIA to conduct a landscape analysis of the Nepali medicines market. After a long review, the report is under finalization.

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

Sharing quality assurance assessment report and guidelines for medical products to a local government.

- PQM+ completed the assessment of the medical product procurement process of a local government unit and has drafted a guideline. PQM+ disseminated the assessment report and guidelines with the local government body. Additionally, PQM+ is assessing the processes at national and provincial levels of the country to look at broader and specific issues of quality assurance in medical commodities procurement processes.
- PQM+ is working with the Health Insurance Board to assess government-owned health facilities that provide health services through the insurance scheme. Though PQM+ completed an assessment, the guideline development is on hold as the government is reviewing and restructuring the heath service through insurance.

Objective 5: Global Medical Product Quality Assurance Learning and Operational Agenda Advanced

PQM+ has worked with DDA to develop messages on substandard and falsified (SF) medicines to broadcast as public service announcements. After the review and approval of the messages, the messages are starting to be broadcast through national and local radio stations.

A DDA officer speaks during a training for community pharmacists on visual identification of substandard and falsified medicines.

PQM+ designed a research study for pre- and post-training assessments of community pharmacists' awareness and behaviors on the identification of SF medicines. The study which has been approved by PQM+ HQ and Nepal Health Research Council is being conducted in conjunction with the training to community pharmacists on the visual identification of SF medicines. DDA's Biratnagar branch office and PQM+ jointly conducted the training on the above-mentioned topic to the community pharmacists in Province 1. DDA facilitated some of the sessions .

Similarly, PQM+ worked with NHRC to plan and moderate a session relating to strategies for improving the quality of medicines and research in the pharmaceutical sector in Nepal during NHRC's National Summit of Health and Population Scientists in Nepal. In the two-hour sessions, three presentations were made on:

- Pharmaceutical sectoral reform for quality-assured medicines
- Overcoming SF medicines challenges and strengthening bioavailability and bioequivalence in the local context
- International trend in pharmaceutical research and development

Priority Activities for PY4

Next quarter will mark the start of Nepal workplan for PY4. Priority activities are:

- Work with the DDA on the approval and dissemination of guidelines and codes related to GMP, RB-PMS, disposal of unwanted pharmaceutical GMP code and development of Nepal Pharmaceutical Manufacturing Strategy. The topics will also be discussed in high-level consultation meetings that DDA will organize with the support of PQM+.
- Continue to strengthen the PMS, inspection and registration functions of DDA by strengthening the information system and developing procedures and a training curriculum.
- Support NML to begin the application process to be audited for ISO 17025 accreditation. PQM+ will finalize the QMS implementation, equipment and premises optimization, and training of lab personnel, as well as support NML to develop a five-year lab strategy.
- Work with manufacturers on meeting the criteria for WHO PQ for selected medicines. PQM+ will continue to support the public manufacturer to meet national GMP standards focusing on the validation of their manufacturing units.
- Work with selected local government units to implement QA procedures in medical products procurement through technical committees and capacity building.
- Collaborate with professional councils to provide training to their members and develop training curricula for visual identification of SF medicines and support information dissemination through local media and stakeholder workshops.

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.

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance systems improved

Activity 1.1: Continue support for the implementation of the regulatory framework to handle regulatory actions based on the National AWaRE list. PQM+ Supported DRAP to develop a regulatory framework for risk-based decision-making on AMR based on the AWaRe List. The regulatory framework provides guidance to DRAP for monitoring and control AMR by taking appropriate regulatory intervention. PQM+ also supported development of an online antimicrobial consumption monitoring dashboard in PIRIMS that provides ready information on quantity of material imported, quantity of products manufactured, and number of Manufacturers registered. This dashboard equipped DRAP for annual AMC trend analysis from the data. In addition, to further strengthen the coordination and information exchange, PQM+ facilitated the signing of a formal letter of understanding by DRAP, NIH, and PQM+ on AMR. NIH is the national focal point with responsibility for collecting antimicrobial utilization (AMU) data from health care facilities and retail sites. PQM+ will provide technical assistance on the AMC dashboard. The key achievements follow:

- Trained DRAP staff on the regulatory framework for risk-based regulatory decisions on AMR.
- Draft amendment of provincial drug sales rules for monitoring and control the sales of antimicrobial drugs.

Activity 1.2: Support DRAP's Accession to the Pharmaceutical Inspection Co-operation Scheme (PIC/S). PQM+ is providing technical assistance to DRAP on a gap assessment and developing a CAPA plan to address observations identified in its PIC/S gap assessment, as well as in developing an implementation plan to adopt and institutionalize PIC/S guidelines and procedures. DRAP's accession to PIC/S would help standardize and improve existing drug inspection procedures and strengthen Pakistan's medical product quality assurance.

PIC/S gap assessment at DRAP

Activity 1.3: Support DRAP in Adoption of Data Standards for Pharmaceutical Products. PQM+ supported DRAP to adopt the remaining two IDMP data standards on Substance Identification **(ISO 11238)** and Medicinal Product Identification **(ISO 11615)** in 2022. PQM+ helps DRAP develop a roadmap to adopt data standards, laying out the steps to support adoption across its regulatory functions. The program provided training to DRAP trainers on the standards and support DRAP in training manufacturers on the remaining data standards. PQM+ will also ensure these data standards are incorporated into PIRIMS.

- Training on IDMP Data Standards of DRAP, Islamabad (August 11)
- Training on IDMP Data Standards of Pharma Industry, Lahore (August 22)
- Training on IDMP Data Standards of Pharma Industry, Karachi (August 19)
- Development of IDMP Roadmap

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

Activity 2.1: Develop national capacity to conduct bioequivalence studies. PQM+ is supporting local BE centers/CROs for national capacity building to conduct Clinical studies and bioequivalence studies within the country. The main aim of the activity was to develop a roadmap for a stepwise implementation of BE studies in Pakistan. Earlier, in a meeting with DRAP officials, PQM+ team presented a draft roadmap for the implementation of BE studies in Pakistan. Considering the dynamics of Pakistan, PQM+ proposed several steps that could be taken for a smooth and phase-wise implementation of BE studies in Pakistan. The final guidelines document has been uploaded on DRAP's web portal for stakeholder consultation. PQM+'s international consultant will organize a virtual meeting with DRAP and stakeholders. After incorporating the comments/feedback from the stakeholders, these guidelines would be adopted.

The key achievements by PQM+ in Q4 are:

- Uploaded the final guidelines document on DRAP's web portal for stakeholder consultation.
- Selected two BE centers (below) for technical assistance to conduct BE studies per international best practices. The letters of understanding were reviewed by the selected centers and shared with USP's HQ for legal review.
    - Institute of Biological, Biochemical, and Pharmaceutical Sciences (IBBPS), Dow University of Health Sciences, Karachi
    - Center for Bioequivalence Studies and Bioassay Research (CBSBR)
- Conducted a meeting with DRAP management to develop an appropriate BE policy implementation strategy considering the challenges of the local Pharma industry.
- Visited CBSCR--ICCBS (International Center for Chemical and Biological Sciences) CRO and IBBPS CRO at DOW University of Health Sciences, Karachi (September 17)
- Training conducted on Bio-Equivalence Studies Guidelines, and Protocol Design of BE centers (September 16)

Activity 2.2: Development of a National Pharmaceutical Strategy. In August, PQM+ completed a draft of the National Pharmaceutical Strategy and held initial validation meetings with private sector partners. The draft will be presented to all stakeholders through the working group platform for feedback and finalization.

PQM+ organized a meeting with the new BOI Chairman Salik Husain on August 30. He endorsed the initiative of the strategy development exercise and asked PQM+ to debrief the new team at BOI, including the secretary and executive director general, on the strategy initiative, its background, progress to date, and next steps. A meeting with the new secretary and executive director general took place September 1. PQM+ continued active coordination

with development partners interested in the pharmaceutical space by conducting coordination meetings with the FCDO-funded REMIT program and IFC in August and September.

Private Sector Engagement (PSE). During the reporting quarter Q4, program year (PY3) the program undertook 3 new initiatives to address the priority areas identified by DRAP in its institutional needs assessment exercise.

Responding to a request from the Biologicals team at DRAP, PQM+ organized a training on Lot Release in partnership with BATL, at the Northeastern University in Boston. PQM+ has collaborated with APACMed and identified an initiative by APACMed to create an e-Learning hub (ELH) portal for capacity building on key regulatory areas. While the ELH offers subscription-fee based access to a comprehensive regulatory curriculum, PQM+ was able to successfully negotiate a free-of-cost membership for DRAP's medical devices team so they can take advantage of this ELH. To facilitate access and use by the DRAP medical devices team, PQM organized a webinar in partnership with APACMed to orient the DRAP team to the new ELH platform and how to use it. PQM+ is also facilitating a pilot on Reliance between the Medical Devices Authority (MDA) of Malaysia and Medical Devices Department of DRAP. PQM+ facilitated the participation of DRAP in a daylong event with the MDA on August 4.

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

Activity 3.1: Optimize allocation and use of regulatory investments through risk-based approaches. Key achievements, during the reporting quarter, are as follows:

- Training of DRAP staff on cost recovery user fee model

Activity 3.2: Provide support to five labs of Punjab to reduce costs and improve efficiencies. Key achievements during the reporting quarter follow.

National Quality Control Laboratory Network

Table 5: Status of Labs Accreditation in Pakistan

Lab	Accreditation Sought	Initial Gap Assessment	CAPA	QMS	PT/LT	Official Inspection/ Pre-Assessment
IPH Lab	ISO 15189 (Awarded)	Completed	Completed	Completed	Completed	Completed Final assessment completed. CAPA completed and submitted to PNAC. Final certificate awarded.
Appellate lab	ISO 17025	Completed	Ongoing	Developed, under implementation through training. SOPs are under issuance phase from QA department.	Completed	Application for ISO17025 has been submitted to PNAC.

Lab	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-Assessment
DTL Rawalpindi	WHO PQ	Completed	Completed	CAPA plan is currently under review	Submitted and approved	WHO Inspection conducted July 25-26. Report received from WHO. Currently working on CAPA.
DTL Multan	WHO PQ	Completed	Completed	Completed	Submitted and approved	Completed. Peer audit CAPA submitted to WHO for review. CAPA Report for WHO Peer audit has been revised and submitted to WHO for review. WHO (PQ) inspection is Scheduled in Dec 2022.
	ISO 17043 (PT)	Completed	Completed	Completed (reviewed by PQM+ after pre-assessment by PNAC)	Completed	Final assessment date awaited from PNAC.
DTL Lahore	WHO PQ	Completed	Completed	Completed and submitted	Submitted and approved	Mock inspection by PQM+ conducted September 28-29, 2022. WHO PQ inspection scheduled in Dec 22.
	(ISO 17025:2017 (Calibration)	Completed	Initial gap assessment by PQM+ completed	Completed	N/A	Lab has deferred the inspection for calibration scope till Dec 2022.
CDL Karachi	WHO PQ	Completed	Completed	Completed and submitted	Submitted and approved	WHO PQ report has been received and lab has started working on CAPA plan.

Lab	Accreditation Sought	QMS	Initial Gap Assessment	CAPA	LIF	Official Inspection/ Pre-Assessment
						PQM+ team is providing TA in development of CAPA action plan against WHO PQ report. CDL requested an extension for 20 days on deadline for the submission of CAPA.
DTL Bahawalpur	WHO PQ	Completed	Completed	Completed and submitted	Submitted and approved (reviewed and revised by PQM+)	Peer audit CAPA is developed and submitted to WHO PQ for review. Waiting for WHO PQ inspection date.

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

Activity 4.2: Private sector engagement to increase the supply of quality-assured priority medical products.

Table 6: Status of WHO PQ of Medicines in Pakistan

Manufacturer	Accreditation sought	Initial Gap Assessment	CAPA	Product Development	Dossier compilation	Dossier Submission/ Acceptance	Official Inspection (WHO PQ)
Pakistan Manufacturer 2 (amoxicillin dispersible tablet (DT))	WHO PQ	Completed	Revised CAPA is under development. Met with manufacturer to discuss CAPA guidance. Providing TA to Mector biweekly for execution of CAPA action plan. Fresh bio-batch from API manufacturer is under development.	Completed	In process (additional testing requirements against API manufacturer are being fulfilled)		
Pakistan Manufacturer 8 (zinc DT/ oral liquid)	WHO PQ	Completed	Revised CAPA submitted to PQM+, follow-up visit pending for verification. Dossier finalized and reviewed by PQM+ team, except palatability study protocol and report.	Competed	In process (dossier completed, palatability study awaited)	Pre-meeting for dossier submission took place with WHO	

Manufacturer	Accreditation sought	Initial Gap Assessment	CAPA	Product Development	Dossier compilation	Dossier Submission/ Acceptance	Official Inspection (WHO PQ)
Pakistan Manufacturer 6 (amoxicillin dispersible tablet [DT])	WHO PQ	Completed	CAPA plan has been submitted to PQM+ for review.	In process (manufacturer procuring reference product and API/materials for product development)	Reference product purchase process initiated.		
Pakistan Manufacturer 7 (zinc DT/ oral liquid)	WHO PQ	Completed	CAPA submitted to PQM+ for review. Changing target molecule from zinc sulfate tablet to levofloxacin 5000 mg tablet. Waiting for 6-month point of stability study. Dossier for target product under development, to be finalized by end of October. PQM+ will review the final dossier.	In process (manufacturer procuring reference product and API/materials for product development)	Reference product purchase process initiated.		
Pakistan Manufacturer 5 (zinc DT/ oral liquid)	WHO PQ	Completed	Completed	Completed	Completed	Completed	WHO PQ inspection occurred Sept. 12-16. Waiting for WHO PQ inspection report.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Support labs and manufacturers for WHO PQ accreditation;
- Implement the CAPA for the PIC/S gap assessment at DRAP;
- Facilitate the ISO accreditation of NQCL;
- Review preparations for the WHO final audit at DRAP on IDPs; and
- Develop two case studies and a policy brief documenting best practices from countries that have successfully promoted their pharmaceutical sectors for the government or regulating authority.

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 a risk-based post-marketing surveillance system.

Highlights of Progress by PQM+ During Program Year 3

- Signed the terms of reference with the NCEM to strengthen their regulatory functions and work toward WHO GBT ML 3.
- Reviewed and provided input on the support plan for GMP inspectorate, vaccine testing, PMS, and lot release to NCEM as required by WHO following the GBT assessment.
- Assisted and participated in the WHO prequalification audit for the Almaty MQCL.
- Continued technical assistance to the pharmaceutical inspectorate's progress toward preparation for PIC/S accession, according to the roadmap developed with PQM+ support.
- Continued technical assistance to NCEM's scientific educational center to boost its workforce development capacity.
- Initiated technical assistance to the committee toward achieving QMS 9001, per the requirement of the WHO GBT.
- Provided a comprehensive training on RB-PMS and the MedRS tool to the NCEM to build their capacity and understanding of RB-PMS.

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+ signed terms of reference with NCEM of Kazakhstan to provide technical assistance to the NCEM to address the gaps identified by WHO as part of the WHO GBT assessment. The terms of reference for collaboration between USP (through PQM+) and NCEM was facilitated by WHO. Following the GBT assessment in Q2, WHO tasked NCEM with submitting support plans for the gaps identified during the assessment. In Q4, PQM+ reviewed, provided feedback to, and gave input on the support plan developed by NCEM in the areas of PMS, inspection, laboratory testing, and lot release functions. The NCEM submitted the support plan to WHO.

In Q4, PQM+ continued technical assistance to the Almaty and Karaganda MQCLs to help them achieve and maintain WHO prequalification (PQ).

- WHO PQ team conducted the inspection of Almaty MQCL July 19-22. PQM+ participated in the inspection and continued providing technical assistance to the Almaty MQCL in the development and implementation of a CAPA plan prepared by the lab after the WHO PQ audit to address gaps identified during the audit.

- PQM+ provided technical assistance to the Karaganda and Almaty MQCLs to develop their capacity in computerized systems validation (CSV). WHO identified CSV as an area for support. In Q4, Almaty MQCL had several technical consultations with PQM+ on validation protocols and reports for the laboratory equipment. PQM+ also provided a remote technical training on WHO Technical Report Series (TRS) on Validation of Computerized Systems on September 22 to Almaty and Karaganda MQCL
- PQM+ collaborated with the Almaty and Karaganda MQCL to organize a regional educational visit for a five-person delegation from the Uzbekistan laboratory team from September 26 to October 1 at the Almaty MQCL in Kazakhstan. The team from Uzbekistan as well as a large Kazakhstan team from Almaty, Karaganda, and Taraz MQCLs also joined. The team toured the Almaty MQCL and observed demonstrations at the laboratory and received didactic training on the laboratory best practices. The team from Almaty and Karaganda also shared best practices and lessons learned in their preparation for WHO PQ.

PQM+ is supporting Kazakhstan in strengthening the inspectorate and preparing for ascension to PIC/S. PIC/S membership will facilitate reliance and open access to the GMP inspection mechanism with other PIC/S member countries; resources for capacity development; and access to quality-assured medicines in the country. PQM+ continued technical assistance toward advancing on the roadmap to PIC/S ascension. In PY3 Q4, PQM+ helped GMP inspectorate in preparation of their newly developed quality PQM+ is supporting Kazakhstan in strengthening the inspectorate and preparing for ascension to PIC/S. PIC/S membership will facilitate reliance and open access to the Good Manufacturing Practices (GMP) inspection mechanism with other PIC/S member countries; resources for capacity development; and access to quality-assured medicines in the country. PQM+ continued technical assistance toward advancing on the roadmap to PIC/S ascension. In PY3 Q4, PQM+ helped GMP inspectorate in preparation of their newly developed quality management system for launching.

- In Q4, PQM+ held regular calls with the PIC/S working group. The participants discussed: key areas for PIC/S preparation in 2022, detailed roadmap implementation progress, WHO GBT – update, priority areas in inspection, liaising with licensing unit and other questions.
- On July 28 – 29, PQM+ provided a virtual training for the NCEM and the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan on engineering systems of manufacturers, Part 2, focused on HVAC. The training was provided for two days, three hours each day, and was attended by 34 people. The training covered key concepts related to HVAC, HVAC design and construction, HVAC parameters, its qualification, and inspection approach.
- On September 12-16, PQM+ PIC/S expert visited Kazakhstan to work with PIC/S working group. During his visit the following topics were discussed:
    - Relevant WHO GBT indicators discussion
    - Training on Qualification and Validation (8 hours)
    - Review of Quality Management System of the Inspectorate
    - Preparation to WHO observed inspection
    - Meeting with the Committee and NCEM top management.
- Assistance was provided in the preparation and conduct of two distant inspections in China, focused on sterile medicines and biologicals.

PQM+ continued technical assistance to NCEM in strengthening the PMS system by building on the work conducted in the previous quarters.

- NCEM faced challenges in implementing RB-PMS, as it requires changes in the legislation and resources for sample purchasing. NCEM that it will be difficult to fully implement RB-PMS in 2022. PQM+ will work with the NCEM to define what realistically could be implemented in short- and mid-terms.
- PQM+ conducted a review of the NCEM SOP on PMS and commented on its compliance to the WHO GBT requirements.
- PQM+ also reviewed the Support Plan which describes support from PQM+ for achieving ML 3 by Kazakhstan MRA on the PMS Function.

PQM+ continued work with the NCEM's scientific educational center (SEC). The center is important to ensure the sustainability of PQM+'s efforts to build the capacity of the medicine's regulatory workforce in Kazakhstan.

- On September 21 and 22, PQM+ conducted training for SEC on application of a competency framework. The workshop described the components of a competency system; explained applications of the competency framework; and how to apply assessment methods. This training will help SEC to conduct competency-based assessment of their training participants.

One gap identified during the WHO GBT assessment was that the Committee needs to establish the QMS according to ISO 9001, as they are involved in regulatory function. In Q4, PQM+ provided technical assistance to the Committee in establishing QMS according to ISO 9001.

- PQM+ continued technical assistance on development of the QMS of the Committee and held meetings with the Committee staff.
- PQM+ met with the Committee staff for discussion of the problem on the relationship between inspection, licensing, and state control systems which do not meet PIC/s and WHO requirements. PQM+ made recommendations to the Committee in bringing the legislation of licensing and state control processes to ensure their orientation towards final consumers and compliance with WHO and PIC/s requirements.

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

Kazakhstan has two associations of local pharmaceutical manufacturers. PQM+ initiated engagement with the Kazakhstan Pharmaceutical Manufacturers' Associations to understand the training needs of the manufacturers specifically in terms of improving their GMP compliance. PQM+ developed a questionnaire to assess the training needs of the local manufacturers and provided it to the SEC for review. SEC is reviewing the questionnaire. Once the questionnaire is finalized PQM+ and SEC will work with the manufacturers to conduct a survey. This survey will inform the priorities for GMP trainings to be prepared by SEC with PQM technical assistance.

Priority Activities for PY4, Q1

- Assist Almaty MQCL with the WHO PQ inspection CAPA Plan development and implementation
- Visit to Karaganda MQCL to provide technical assistance

- Continue technical assistance to the PIC/S working group in the areas outlined in the PIC/S accession roadmap
- Visit to provide a coaching inspection to the Inspectorate before WHO observed inspection
- Continue technical assistance to the NCEM on developing approaches and procedures for RB-PMS
- Continue technical assistance to the SEC to build capacity on workforce development
- Assist the Committee in establishing ISO 9001 QMS
- Assess the training needs of the local manufacturers
- Continue technical assistance to the NCEM in preparation for the next WHO GBT assessment.

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 by PQM+ During Program Year 3

- Completed assessment of the Dushanbe MQCL and developed a CAPA. Dushanbe MQCL received ISO 17025: 2017 accreditation.
- Completed assessment of the registration system and completed two SOPs on screening application and evaluation of assessment.
- Submitted dossier for nine WHO-prequalified TB medicines for registration in Tajikistan.

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 Q3, PQM+ completed an assessment and developed an assessment report and action plan for addressing identified gaps at the Dushanbe MQCL. In Q3, PQM+ also developed and delivered one day training on the root cause analysis Standard Operating Procedure (SOP). In Q4, the Dushanbe MQCL is now using the root causes analysis SOP. The MQCL was required to be accredited according to ISO 17025:2017 by the National Accreditation Centre in 2022. In Q3, PQM+ provided training comparing the old and new version of ISO 17025. PQM+ in collaboration with the Dushanbe MQCL developed a corrective and preventive action plan (CAPA). In Q4, the MQCL received ISO 17025:2017 accreditation. In Q4, as per the CAPA, PQM+ supported the development of two SOPs, Control of documents and Control of records. The SOPs are under consideration of the management of the MQCL.

In Q3, the State service and PQM+ agreed that improvement of the regulatory process and communication to improve the efficiency in the registration system is a priority. The Technical Working Group (TWG) on registration from the state service agreed to concentrate in developing two SOPs on screening application and evaluation of assessment State service. PQM+ supported the development of two SOPs on screening application and evaluation of assessment and are under review of the State Service management.

To encourage the WHO PQed manufacturers to apply for registration of their products in Tajikistan, in Q2 &3, PQM+ selected a local company Shifoi Sino that worked with the WHO prequalified manufacturers and, on their behalf, to compile and submit dossiers for registration in Tajikistan. In parallell, PQM+ was also coordinating closely with GDF to identify potential manufacturers of WHO prequalified TB medicines interested in registration of their products for Tajikistan. Two WHO PQed manufacturers Lupin and Svizera expressed interest in registering the TB medicines in Tajikistan. The local company Shifoi Sino worked with the companies and, on their behalf, compiled and submitted 9 TB medicines dossiers for approval in Tajikistan.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Implement activities with MQCL according to CAPA plan
- Approval of submitted SOPs by the State Service and developing of new SOPs
- Approval of nine TB medicines in Tajikistan

Uzbekistan

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

Progress in Quarter 4

Objective 1: Governance for medical product quality assurance system improved

PQM+ is providing technical assistance to the Ministry of Health (MoH) in development of the pharmaceuticals and medical devices strategic block of the MoH's Health Strategy 2030. PQM+ through desk review, working group, and meeting with various public and private sector stakeholders gathered information for the pharmaceutical and medical devices situational analysis. PQM+ identified and documented major findings from the situation analyses, challenges, and strategy recommendations for pharmaceutical strategy and medical devices block. PQM+ presented the findings and recommendations to the Minister of Health and deputy ministries. In

Q4, PQM+ submitted the final pharmaceutical and medical device sector situational analysis and recommendations and a pharmaceutical roadmap for the health strategy 2030.

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

In Q4, PQM+ continued TA to the Agency to help them to advocate to the cabinet of ministers to adopt the EUA clause. In Q4, PQM+ also prepared for training for the registration working group on how to write SOPs and implement documents and record control. This training was requested by the Agency director. The training will focus on the importance of documentation; key requirements for writing an effective SOP; and good documentation practices.

To date, PQM+ has facilitated the registration of six WHO Prequalified TB medicines through WHO CRP. Application for one more medicine was submitted to the State Center for WHO CRP Registration – Clofazimine that is currently under review.

In Q4, PQM+ continued to work with the newly established GxP Center, responsible for the GMP inspection. PQM+ continued to engage with the working group on the development of updated version of the GMP guideline, training programs for inspectors, and SOP on QMS and inspection process. In Q4, PQM+ facilitated several meetings with the working group; reviewed and finalized QMS SOPs. In Q4, the PQM+ technical advisor visited Tashkent and met with the senior management of the inspectorate and its various units to discuss changes in the organization structure, and redistribution of responsibilities, including area of licensing and handling of quality defects. The technical advisor also provided a one-day training to the working group on qualification and validation, attended by 21 inspectors.

In Q4, PQM+ conducted training on CAPA development and monitoring for Andijan and Tashkent MQCL. Following the training, the labs developed CAPA. PQM+ facilitated a workshop to discuss, review, and finalize the CAPA. Both labs have started implementation of their CAPA. In Q4, PQM+ also organized an educational visit for five representatives from the two labs to travel to Almaty MQCL in Kazakhstan. Recently, Almaty MQCL completed a WHO audit for prequalification. The delegation from Uzbekistan toured the Almaty MQCL and observed demonstration of best practices. PQM+ also provided training on best practices for the laboratory. Almaty and Karaganda MQCL also shared best practices and lessons learned from their preparation of WHO Prequalification. In Q4, PQM+ finalized the recommendations on the Urgench laboratory design to comply with the best practices and submitted them to the Agency.

In Q3, PQM+ hired and oriented an expert for QMS for ISO9001 who to develop the capacity of the QMS group to help support the Agency including the state center in developing QMS according to ISO9001.In Q4, PQM+ completed an audit of the management system of the Agency including the state center. The identified several areas for improvement to comply with the requirements of the ISO 9001:2015. PQM+ also developed and finalized a report with the audit process and findings. PQM+ also facilitated the development of an implementation plan to address the gaps at the state center. The implementation plan is divided into three phases starting from consultations and workshops on developing policies and procedures to development, implementation and monitoring of these policies and procedures.

In Q2, a presidential decree on development of the pharmaceutical industry was issued and a working group was established for PMS. In Q3, the working group, with PQM+ guidance drafted regulations for PMS. The regulation, however, was not approved because of limited financial resources. In Q4, PQM+ proposed to initiate a pilot for the PMS. As part of the first stage of the

pilot, PQM+ delivered a training on PMS and MedRS in Tashkent, providing an overview of the risk-based PMS approach and how to use the MedRS tool. A total of 22 staff from the State Center (the medicines regulatory agency) attended the workshop and participated in the risk estimation for 30 selected TB medicines, 14 regions/provinces and about 130 cities/districts in the country using the MedRS tool. Plans are underway to develop a draft protocol based on the data generated during the workshop. The protocol will allow the PMS team within the State Center to conduct a pilot RB-PMS activity, the first of its kind in Uzbekistan. The scope of the surveillance will focus on 2 selected TB medicines, sampled from Level 3 (private sector retail outlets), which includes about 11,200 facilities that are stratified based on their geographical and facility risk. Sampling will be done from about 137 randomly selected facilities. A training of sample collectors was planned for October 2022, with sampling to follow based on MRA staff availability.

PQM+ is working with Purdue University to provide technical assistance to the pharmaceutical technology university at the Tashkent Pharma Park. In Q3, Purdue conducted an electronic survey of the university and other stakeholders on their needs. In Q4, Purdue designed and delivered an introductory training on the pharmaceutical process and product design for 20 faculty members from the university.

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

In Q4, PQM+ continued to provide technical assistance to Uzbekistan Manufacturer 2 on the prequalification of their TB drug levofloxacin. It has completed work on laboratory-scale batches and continues to study the stability of the drug, which will last six months. A report on the evaluation of the production of finished products of levofloxacin in accordance with GMP requirements was provided. Work on corrective and preventive actions has begun with plans to produce three batches of production scale to validate the production processes.

The local Uzbekistan pharmaceutical industry should be GMP-compliant before accession to PIC/S; training will assist the local industry in understanding the GMP requirements and facilitate achievement of GMP compliance. To address this, PQM+ procured a company to deliver GMP training materials to the Uzbekistan pharmaceutical industry.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Conduct training on how to develop SOPs for the registration working group.
- Continue TA to the PIC/S working group in its preparation for the PIC/S accession, including strengthening QMS and building the GxP inspectorate staff's capacity.
- Continue to work with 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 90001:2015.
- Continue technical assistance to the RB-PMS working group to conduct the RB-PMS pilot in Uzbekistan.
- Design and deliver foundation courses for Tashkent Pharma University.
- Continue technical assistance to Uzbekistan Manufacturer 2 for product development, and dossier preparation.
- Initiate GMP training for local Uzbekistan pharmaceutical manufacturers.

COVID-19

Bangladesh

Coordination and Operations for COVID-19 Vaccines

PQM+ is working to establish and strengthen the relationship among key stakeholders monitoring the rollout of COVID-19 vaccines. On July 24, 2022, PQM+ organized a consultative meeting on the formation of a TWG for the implementation of RB-PMS on COVID-19 vaccine quality with officials from the national regulatory authority, the DGDA, including the director of the Marketing Surveillance and Control (MC) department, to understand the preliminary role and responsibility of relevant stakeholders. The 14 participants included 10 men and four women. In August, PQM+ organized the first TWG meeting, with 14 participants (10 men, four women), including the MC department director and representatives from DGDA, the Expanded Program on Immunization (EPI), UNICEF, WHO, Bangladesh Medical Research Council (BMRC), and PQM+. The main discussion points addressed the MC department's need to establish RB-PMS to monitor the quality of domestically produced vaccines, imported vaccines, and to monitor severe adverse events following immunization (AEFI) of COVID-19 vaccines by the Pharmacovigilance (PV) and Safety Surveillance Cell at DGDA and initiate cold chain management and sampling at different locations. It was also agreed that the MC Department should build vaccine testing capacity at the NCL, with support from WHO, UNICEF, and PQM+, and ensure the cold chain is in place for vaccine samples.

The following month, PQM+ organized the second TWG meeting focused on NCL readiness and cold chain management with 16 relevant stakeholders (13 men, three women) of DGDA, EPI, WHO, and BMRC. Members decided that EPI will provide required training to DGDA inspectors for sample collection and technical specification review of refrigerators and freezers for cold chain management. PQM+ will coordinate the support for cold chain management validation through December 2022. Finally, PQM+ supported DGDA in Q4 to draft the human vaccine registration guidelines. The draft guideline is under review by the PQM+ technical team, after which PQM+ will finalize the document with DGDA.

Laboratory Systems

In support of the NCL laboratory, PQM+ reviewed and updated quality testing protocols for eight COVID-19 medical products: favipiravir tablets, dexamethasone tablets, hydroxychloroquine sulfate tablets, ivermectin tablets, lopinavir capsules, ritonavir capsules, oseltamivir phosphate capsules, and remdesivir injection. PQM+ also provided technical support to the NCL to test the eight COVID-19 medical products following the approved protocols. All physicochemical quality tests results for the selected medical products met the predefined specification. This type of testing will help the NCL support DGDA in its PMS of these products on the market.

PQM+ is also working with the NCL to establish a personal protective equipment (PPE) testing laboratory. PQM+ procured and set up two types of testing equipment—a medical mask gas exchange pressure difference tester and a particulate filtration efficiency (PFE) tester—for the NCL. PQM+ supported NCL to develop two SOPs for the new equipment and prepared a visual inspection checklist to ensure the release of quality surgical masks. In September, PQM+ trained NCL analysts on the medical device testing equipment based on the SOPs and visual inspection checklists that were developed. Ten participants (seven men, three women) attended the training.

PQM+ is supporting the DGDA to build the capacity of the NCL in vaccine testing. PQM+ supported NCL for qualification of nine items of equipment and calibration of eight items of equipment. PQM+ procured several items of equipment for the NCL, including an inverted microscope, accessories, and supplies for cell lines such as a CO_2 cylinder and liquid nitrogen tank. The supplier was on schedule to complete qualification of the inverted microscope by October 2022. NCL received the COVISHIELD testing method from the manufacturer at the beginning of the pandemic. Based on that method, NCL arranged all reagents, equipment, and cell lines to perform method validation. After completion of the method validation, routine testing of the vaccine will begin. PQM+ is supporting NCL to develop a COVID-19 vaccine testing capacity building plan, including the timeline for the testing, equipment qualification, availability of testing reagents, the feasibility of a testing laboratory, and training of NCL staff. This plan emphasizes identification and assay tests for COVID-19 vaccines.

During Q4, PQM+ conducted four capacity building trainings for the NCL vaccine laboratory. These included:

- a knowledge-sharing session on a data logger for temperature monitoring during qualification to enhance technical knowledge; nine participants included six men and three women;
- a training on calibration and qualification of equipment, with 13 participants (nine men and four women);
- a training on vaccine testing capacity strengthening (COVISHIELD), which provided an overview of the capacity building plan, the status of activity implementation, and the timeline for final capacitation of the NCL to test COVID-19 vaccines; the 15 participants included 12 men and three women; and
- a training on activation of cell line culture and QMS for 15 participants (12 men, three women).

Burkina Faso

Immunization Readiness and Implementation

PQM+ is working to support the ANRP to strengthen its AEFI surveillance system and build its capacity to grant regulatory approval for COVID-19 vaccines in alignment with international norms (e.g., WHO's COVID vaccine safety monitoring guidelines) and the country's National Vaccine Deployment Plan. In Q2, PQM+ conducted a ToT on AEFI for 26 health care workers from 13 regions representing the national immunization program, *Direction de la Prévention par la Vaccination* (DPV). In Q3, these trainees cascaded the training to other vaccination staff from two regions in the country, Central and South-Central.

In Q4, the ToT trainees cascaded the AEFI training to two additional regions, Plateau Centrale and Northern. As with the other cascaded trainings, PQM+ oversaw the training and provided the needed logistics and the health care workers originally trained by PQM+ delivered the training. In Plateau Centrale, 20 health care workers (11 men, nine women) received training. In the Northern region, 25 health care workers (19 men, six women) received training. Topics covered in both cascaded training were: general information about COVID-19 vaccines; pharmacovigilance of COVID-19 vaccines; immunization errors; notification of adverse reactions; the AEFI notification circuit and tools in Burkina Faso; serious AEFI investigation; and a practical exercise on filling in notification tools. The encouraging post-test results (averaging above 80 percent) indicated that this training improved the knowledge of the participants on AEFIs, strengthened their capacity on AEFI notifications and the use of the notification tools.

This is expected to lead to improvement in AEFI notifications for the COVID-19 vaccines being administered in Burkina Faso.

PQM+ is also working with ANRP to build its EUA systems. ANRP grants marketing authorization for drugs, vaccines, and other medical products based on the expert opinion of the Technical Commission for the Approval of Health Products (CHPS). The agency uses a short and rapid emergency approval process for the COVID-19 vaccine, but the committee had inadequate knowledge to apply the key considerations for granting this approval. ANRP therefore requested assistance to build the capacity of the technical experts responsible for providing advice on emergency approvals to ANRP. As a result, in Q3, PQM+ developed a training curriculum on EUA based on the needs and gaps in ANRP's knowledge/systems gathered through a training needs assessment conducted by PQM+. Using this customized training curriculum, PQM+ trained 23 regulatory staff.

In Q4, leveraging the training provided in the previous quarter, PQM+ supported ANRP to convene a workshop to draft and finalize regulatory guidelines for granting EUA in Burkina Faso. These guidelines, when implemented, will enable ANRP to adhere to international best practices for granting EUAs, including for any new COVID-19 vaccines or therapeutics the Ministry of Health seeks to import. In addition to the guidelines, PQM+ supported ANRP to review and revise, where needed, the ministerial decree asserting "*the conditions for issuing authorizations for the emergency use of vaccines, medical devices and other health products in a health emergency situation in Burkina Faso*" to align with the new regulatory guidelines. Two workshops took place, first to revise and subsequently to validate the text by the 25 members of the ANRP's experts committee for health products assessment and registration. Given the importance of this legal text, the technical advisor to the Minister of Health attended both workshops. The ministerial decree provides the legal framework for granting emergency approvals for health products while the guidelines describe the processes and considerations for granting emergency use authorizations in Burkina Faso.

PQM+ is supporting ANRP to improve its lot release function, for which no procedure is currently in place. For each lot of vaccines being imported, the medicines regulatory authority is required to, at a minimum, review the manufacturer's lot summary protocol (LSP); if the LSP is satisfactory, the MRA will release that lot to the public. ANRP did not have the processes or the skills to perform this function. During Q4, PQM+ provided a face-to-face training in Ouagadougou on lot release, specifically how to conduct lot release through the review of the vaccine manufacturer's LSPs, a key component required of an MRA to release imported vaccine lots. During this workshop, PQM+ also worked with ANRP to draft an SOP for lot release and checklists to facilitate implementation. Fourteen people [five men, nine women) from ANRP and LNSP attended.

A key challenge could hinder implementation of the processes that PQM+ is assisting ANRP to put in place. It is unclear to ANRP which entity physically has the LSPs for all imported vaccines. The LSPs were initially confirmed as being with the vaccination program, but it later became apparent that they did not have them. ANRP is checking with UNICEF. Beyond the technical assistance PQM+ is providing, ANRP needs systems to access to the LSPs to effectively perform the lot release function.

Laboratory Systems

PQM+ is working to build the capacity of LNSP, the national quality control lab, to test COVID-19 vaccines. In Q4, PQM+ issued a purchase order to the selected vendor for 12 pieces of equipment and 26 types of consumables for LNSP to test the COVID-19 vaccines to facilitate lot

release and periodically test the quality of circulating vaccines along the supply chain. Delivery and installation of these pieces of equipment were expected before the end of 2022. Upon installation, PQM+ will build LNSP analysts' capacity to use the equipment to test vaccines.

Ethiopia

Policy, Planning, and Coordination

PQM+ is supporting EFDA to increase access to quality-assured COVID-19 vaccines to Ethiopian citizens through facilitating the proper regulatory review and timely implementation of EUA procedures for COVID-19 vaccines. As part of implementing this activity, PQM+ and EFDA conducted a training in July on Ethiopia's EUA current process for medical products and vaccines for 26 participants (16 men, 10 women) from the EFDA's Medicine Registration and Licensing Directorate. This training will help EFDA to speed up registration of COVID-19 products, as well as products for future public health emergencies, while ensuring adequate regulatory oversight for quality, safety, and efficacy.

Pharmacovigilance

PQM+ is working to strengthen product quality defect reporting through adverse drug reaction (ADR) reports. 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 real-time. As it stands now, the system is not widely used, but can be a valuable source of information if used on a regular basis. This quarter, PQM+ worked with EFDA to provide training on detecting and reporting of product defects to 50 health care providers (32 men, 18 women) who are working on COVID-19 vaccine active surveillance sites. The training took place August 23 and 24, 2022, in Bishoftu, Ethiopia. PQM+ and experts from the immunization program and pharmaceutical supply services team presented on basic principles for cold chain management of COVID-19 vaccines at distribution sites and at the health facility level, which helped participants understand the various types of vaccines and their specific cold chain requirements. After the training, participants could identify quality issues that may arise due to poor handling of vaccines in the supply chain, allowing them to detect and report any suspected quality defect. EFDA experts also demonstrated the reporting system and tools developed by its national pharmacovigilance center, so health care workers are familiar with using the proper reporting channel.

PQM+ also provided technical support to EFDA's pharmacovigilance center on strengthening AEFI processes for COVID-19 vaccines by assessing the current AEFI monitoring system and identifying the gaps. In June, PQM+ collaborated with EFDA to train 65 data collectors and supervisors (50 men, 15 women) from branch regulatory authorities and regional health bureaus under the supervision of EFDA's pharmacovigilance expert team. Workshop participants enriched and finalized the data collection tools developed by EFDA with support from PQM+, WHO, and Chemonics. They learned about the data collection process and had hands-on experience assessing 62 administrative offices and 60 health facilities across 10 regions. After this training, with support from PQM+, the EFDA pharmacovigilance center also finalized its report on the national AEFI monitoring system. The assessment identified gaps in the system at various levels (health facility, woreda/district health office, regional health bureaus, EFDA branch offices) and provided recommendations on appropriate actions. EFDA will disseminate the report and plan appropriate interventions in collaboration with these stakeholders.

PQM+ is building the capacity of the national safety advisory committee (NSAC), an independent committee comprising clinical experts, to review serious adverse events (SAE). In June, following the third distribution of COVID-19 vaccines in Ethiopia, the national pharmacovigilance center received around 14,300 AEFI reports. Of these, 19 were identified as SAEs. It is necessary for the committee to finalize the investigations of serious AEFIs and conduct the causality assessment in a timely manner. A delay in conducting the causality analysis may negatively affect the execution of corrective measures. In Q4, PQM+ facilitated a causality assessment workshop on July 19 and 20, 2022, in Bishoftu for 27 participants (20 men, seven women) from the NSAC. At the workshop, the NASC staff were able to review the reports and classified 10 SAEs (the only reports of the 19 SAEs submitted that contained all information needed) from COVID-19 vaccines and provided recommendations to the regulatory authority for an effective safety monitoring of vaccines and prevention of unnecessary patient harm. NASC used the WHO online causality assessment tool and categorized five of the 10 reports as consistent which indicates a possibility of the adverse event being related to vaccination. Four reports were categorized as coincidental, with inconsistent causal association with the vaccination, and one was categorized as indeterminate. To date, PQM+ has supported the advisory committee to review 40 SAE reports.

Ghana

Immunization Readiness and Implementation

PQM+ is supporting the Ghana Food and Drug Authority (Ghana FDA) with its cohort event monitoring (CEM) of COVID-19 vaccine distribution, expected to last eight months. A total of approximately 10,000 participants are expected to be enrolled and followed on predetermined days post the first and second doses of the COVID-19 vaccine.

In Q4, PQM+ continued monitoring the implementation of the CEM. However, due to low-risk perception in the country resulting from the relaxation of COVID-19 protection protocols, vaccine uptake is still very low, decreasing participant enrollments in the study. Data from WHO's country office suggests that vaccine uptake spikes mainly when campaigns are active, and a routine increase in COVID-19 vaccinations was rare in the country.

PQM+ planned to support FDA Ghana with 6,000 enrollments and reached 85 percent of that goal (5,118 enrollments). Most of these (3,925) enrolled during the first phase of this project supported through COVID technical assistance funds and the rest (1,193) enrolled under the second phase of this project through COVID American Rescue Plan (ARP) funds.

As a result, PQM+ agreed with FDA Ghana in July to discontinue new enrollments at the end of that month and focus on following up with enrolled vaccinated individuals to gather AEFI data. This will prevent unnecessary costs related to maintaining the study sites where enrollments were not occurring. This completes the COVID-19 ARP work.

Region/Site	# of Participants
Ashanti	599
Central	746
Volta	423
Bono East	650
Northern	1,000
Greater Accra (Mamprobi Site)	968
Greater Accra (Tema General Hospital Site)	732
Total Enrolled	7,418 (74.2% of target)
Total Enrolled with direct PQM+ support	5,118

Laboratory Systems

PQM+ received Global VAX funding in support of the Ghana FDA strengthening its lab capacity to complete independent lot release of COVID-19 mRNA vaccines. The Ghana Global VAX work plan received approval in late September 2022. PQM+ convened an in-person kick-off meeting in Accra at Ghana FDA's premises to present the activities in the approved work plan to the Ghana FDA CEO and her management team. All activities aligned with the technical assistance interventions agreed on during the work planning process. PQM+ presented proposed timelines for implementation and Ghana FDA designated points of contact for each intervention to work directly with the PQM+ technical team.

A QC testing laboratory that meets international requirements for good laboratory practices enables 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, PMS, and lot release. Ghana's QC testing laboratory is accredited under ISO/IEC 17025 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 FDA Ghana QC laboratory to test the viral vector platform COVID-19 vaccines. However, the QC laboratory requires additional equipment, accessories, and consumables for the QC testing of mRNA COVID-19 vaccines. In addition, the QC analysts' capacity needs further building to enable them to test the COVID-19 vaccines per the manufacturers' methods.

In September 2022, PQM+ completed a rapid assessment of Ghana FDA's QCL, the Center for Laboratory Services and Research (CLSR). The assessment covered the physicochemical and microbiological testing laboratory units in Accra as well as the proposed molecular biology facility at Ghana FDA's new office building in Tema. The PQM+ team evaluated the physical space for both physicochemical and microbiological analysis, staff knowledge of vaccine testing and equipment already available at CLSR for testing biological products, and Ghana FDA's preparedness to test COVID-19 vaccines, specifically mRNA vaccines.

PQM+ also worked with the FDA Ghana laboratory team to finalize the list of equipment required for the testing of mRNA COVID-19 vaccines, such as the Pfizer-BioNTech vaccine. Based on this final list, the team initiated a procurement request for six pieces of equipment.

Kazakhstan

Immunization Readiness and Implementation

PQM+ is supporting the National Center for Expertise for Medicines, Medical Devices, and Medical Equipment (NCEM) in strengthening vaccine surveillance systems to ensure the system can detect, investigate, and analyze AEFIs and adverse events of special interest (AESIs) to ensure an appropriate and rapid response. This activity tasks PQM+ with conducting a situational analysis of the PV system in Kazakhstan in alignment with the WHO's recent GBT assessment and providing related technical assistance in support of Kazakhstan's effort to reach ML3, specifically in its vigilance functions. In Q4, PQM+ collaborated with the NCEM to finalize the three-year PV roadmap. This document includes the importance of PV regulation and procedures analysis and development; national PV center human resources analysis and development; integration of PV in national health programs, including the immunization program; pathways for reporting; validation of reporting forms; adverse event reporting forms and PV curriculum for PV staff at the national, regional, and local level.

PQM+ also initiated the creation of a working group on PV for the WHO GBT audit preliminarily scheduled for December 2022 to achieve ML3 to improve vaccine safety surveillance. The working group consists of representatives from the Committee, NCEM, and the immunization program. PQM+ also reviewed the support plan for WHO GBT vigilance function along with those for other regulatory functions. The support plan lists the recommended activities to address the identified WHO GBT gaps and meet the WHO GBT ML3.

PQM+ is providing technical assistance to NCEM in strengthening its lot release (LR) systems, which allow for the continuous quality and safety monitoring of biological products through a regulatory release system on a lot-by-lot basis. This is a relatively new area for NCEM, as it has not been assessed by the WHO team as part of the WHO GBT process. In Q4, PQM+ completed the review of several Kazakhstan-specific lot release documents and identified the need for lot release legal provisions, regulations, and guidelines. Suggested action items included: review of WHO guidance document on vaccines lot release, development of detailed lot release procedure, and development of criteria for recognition of results from external testing laboratories. PQM+ reviewed the regulation documents and SOPs and made recommendations to align with the WHO GBT requirements. PQM+ also reviewed and updated the WHO GBT Support Plan for achieving ML3 for the lot release and lab testing functions.

Also, this quarter, PQM+'s vaccine testing expert traveled to Almaty to assess the capacity of the laboratory there to perform vaccine testing. The visit identified the lab's ability to perform general testing of the QazVac vaccine and inability to perform identity and potency tests. The PQM+ expert also visited research center laboratories for immunogenicity testing of the QazVac vaccine, finding that the research center laboratories had the necessary infrastructure, but the staff required capacity building. WHO GBT indicators for laboratory testing were also assessed and strengths and areas for improvement were identified. PQM+ proposed 40 recommendations (IDPs). Options for QazVac potency testing were analyzed with findings suggesting that enzyme-linked immunosorbent assay (ELISA) test following immunization of animals is the best solution for potency testing of vaccines. ELISA testing requires biosafety laboratory 2 (BSL2) conditions and can be a long-term solution for potency testing of the QazVac vaccine at the manufacturing site and at the NCEM's laboratory in Almaty. PQM+ informed top management at NCEM about the testing options and the WHO GBT analysis. As introducing the ELISA method requires time, subcontracting an out-of-country laboratory was proposed as a short-term

solution. PQM+ will continue to discuss with NCEM options for establishing effective methods of vaccine testing for the QazVac vaccine.

Kenya

Policy, Planning, and Coordination

PQM+ is strengthening the PPB and the NQCL to provide the regulatory oversight required to assure the quality, safety, and efficacy of COVID-19 vaccines and other biologics throughout their production, storage, distribution, and use in Kenya. In addition, PQM+ interventions will support PPB and NQCL toward the achievement of WHO GBT ML3 for medicines regulatory authorities. In Q4, as part of these activities, PQM+ is supporting PPB to update and develop guidelines and procedures for licensing and inspection of COVID-19 vaccine manufacturing facilities. PPB shared findings from the WHO-GBT assessment conducted at the end of June 2022. Subsequently, PQM+ started its technical review of PPB's guidelines and SOPs to align them with the WHO GBT findings and recommendations. The updated or newly developed regulatory documents will ensure that PPB can bridge the WHO GBT assessment findings and effectively regulate vaccine manufacturing facilities. One of the findings of the June 2022 WHO GBT assessment was inadequate training for PPB personnel who carry out the GMP inspections and licensing functions. Thus, PQM+ will train the PPB inspectorate and vaccine manufacturing staff (including from the Kenya Biovax Institute) on GMP compliance for inspection and licensing in the following quarter.

PQM+ is also supporting PPB to establish and institutionalize a vaccines lot release function. Lot release is a new function for PPB and is critical to ensure that Kenya can support the production and release of vaccines for both internal and export use. Developing lot release guidelines and SOPs will enable the regulator to develop a real-time system that continuously monitors vaccine quality through review and testing. This quarter, PQM+ had discussions with the contact person for the lot release function at PPB and is reviewing the proposed guidelines and SOPs. PQM+ will facilitate a training for PPB staff on the new lot release documents.

Finally, PQM+ began facilitating Kenya's participation in a training on biomanufacturing hosted in South Africa in early December. Three organizations from Kenya will attend. PPB has nominated two delegates whose participation is supported by PQM+/Global VAX; NQCL has nominated three participants and is able to sponsor two of them; the government-owned Kenya Biovax Institute (KBI), Kenya's intended recipient of the mRNA vaccine technology transfer from the South Africa hub, has indicated they will sponsor the participation of two staff members.

Laboratory Systems

As part of this project, PQM+ plans to assess the NQCL's capacity to support lot release and testing of COVID-19 vaccines. The NQCL needs to develop capacity for testing of vaccines to support Kenya to produce quality assured vaccines. In Q4, PQM+ started its support to the NQCL to develop their strategic plan for 2022–2027. The strategic plan will identify the key priorities for NQCL in testing of vaccines and outline the associated funding sources. In addition, PQM+ began preparatory work for the rapid assessment of NQCL planned for November 2022. The assessment will be conducted onsite by PQM+ technical experts and include an assessment of the NQCL's available equipment and processes for testing the vaccines that local manufactures will be manufacturing.

Nigeria

Policy, Planning, and Coordination

PQM+ received Global VAX funding to strengthen 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. To this end, PQM+ facilitated the formation a NAFDAC technical working group comprising six members (five men, one woman), including the NAFDAC Chief Executive Officer and directors of associated directorates (i.e., Regulation and Regulatory Affairs, Laboratory Services, Pharmacovigilance / Post-Marketing Surveillance, and Drug Evaluation and Research). NAFDAC attained ML3 in March 2022 in eight of the nine regulatory functions and is working toward ML3 for lot release (LR), in line with the Nigerian Vaccine Policy objectives. Attaining WHO GBT ML3 is necessary for effective regulation of the qualify and efficacy of vaccines manufactured in country for internal use and for export to other countries. In addition, NAFDAC has an action plan to attain WHO GBT ML4. A gap assessment of NAFDAC's current regulatory activities and LR function status will be conducted in November 2022 by two PQM+ subject matter experts on vaccines and other biologicals supported by the PQM+ Nigeria team.

To build the capacity of regulators and manufacturers across the six target Global VAX countries, PQM+ is arranging a joint biomanufacturing training program at key facilities and institutions in South Africa. PQM+/Global VAX is supporting the participation of five NAFDAC staff (two women, three men) at the South Africa Biomanufacturing Workshop.

Laboratory Systems

PQM+ is working to strengthen NAFDAC's laboratory testing function for vaccines. NAFDAC upgraded the National Control Laboratory for Vaccines and other Biologics (NCLVB) in August 2022 to the status of a full/stand-alone directorate (now Vaccines, Biologics, and Medical Devices Laboratory Services Directorate – VBM-LS). This is in preparation for enhanced regulatory activities and to entrench effectiveness and full-fledged functionality for the attainment of ML4 status.

PQM+ is supporting the laboratory to expand its 14 scopes of accreditation on physicochemical and microbiological testing of vaccines, other biologicals, and rapid diagnostic tests (RDTs), medical devices, and in-vitro diagnostics (IVDs), including PPE. PQM+ began procuring equipment for NCLVB to support vaccine testing, including an osmometer with particle analyzer.

Pakistan

Coordination and Operations

PQM+ is supporting DRAP to strengthen its COVID-19 vaccine vigilance. This quarter, PQM+ collaborated with DRAP to develop an online AEFI and PV reporting portal for vaccine suppliers with marketing authorization to share documents and report real-time AEFI data. PQM+ also developed a user manual and in July trained 10 DRAP staff (nine men, one woman) on the new AEFI/PV Module on the Pakistan Integrated Regulatory Information Management System (PIRIMS). During the training, the PQM+ team gave an overview of the AEFI/PV module in PIRIMS that contains further submodules for data submission methods, including risk management plans for vaccines, AEFI reporting, periodic vaccine safety updates, detected

signals of adverse events, and safety communications. The PQM+ trainer gave a live demo on submission, including exporting data electronically. This portal equipped DRAP to collect and export AEFI data from PIRIMS to VigiFlow electronically, which will enable faster, more efficient, and real-time data reporting in VigiFlow with less hassle of manual entries.

Immunization Readiness and Implementation

In collaboration with national stakeholders, PQM+ developed a National Action Plan for AEFI surveillance for COVID-19 vaccines. In Q4, following the approval of the Federal Directorate of Immunization (FDI), PQM+ printed and disseminated 290 copies of the AEFI Guidelines and National Action Plan among relevant federal and regional stakeholders (from a list provided by FDI) for implementation. The guidelines and national action plan lay out the roles and responsibilities of key AEFI stakeholders, such as DRAP, FDI, Provincial Healthcare Commissions, and other stakeholders. The guidelines are expected to enhance AEFI surveillance for COVID-19 vaccines and all other vaccines and contribute to enhancing the overall safety of vaccination and immunization efforts in Pakistan. PQM+'s support to private health care facilities, including training provided in Q3, has already increased their engagement in AEFI reporting. PQM+ has now completed all COVID-19 vaccine activities in Pakistan, per its work plan.

Rwanda

Policy, Planning, and Coordination

PQM+ received Global VAX funding to provide technical assistance to Rwanda FDA to strengthen its capacity to provide regulatory oversight of COVID-19 vaccines imported into the country and expected to be manufactured locally soon. This will help assure the efficacy, quality, and safety of COVID-19 vaccines and biological products used in Rwanda. As of September 18, 2022, 26,080,356 doses of COVID-19 vaccines have been administered in Rwanda. On September 6, Rwanda FDA and PQM+ held a kickoff meeting where PQM+ presented the approved Global VAX work plan activities and their timelines. Rwanda FDA agreed to assign focal persons for these activities, which include: 1) building the capacity of Rwanda FDA to implement a COVID-19 vaccines lot release function; 2) building the capacity of the Rwanda National Quality Control Laboratory (NQCL) to support COVID-19 vaccine lot release and testing; 3) strengthening Rwanda FDA capacity to conduct risk-based post-marketing surveillance of COVID-19 vaccines; 4) assisting local manufacturers to comply with regulatory requirements for COVID-19 vaccine manufacturing and marketing authorization; 5) training Rwanda FDA to inspect vaccine manufacturers and review vaccine dossiers; and 6) supporting participation of Rwanda FDA staff in a biomanufacturing study tour to a vaccine-manufacturing country with a mature, WHO-listed authority.

In addition, this quarter, PQM+ started to build the capacity of the Rwanda FDA to undertake a COVID-19 vaccines lot release function. PQM+ helped Rwanda FDA to develop the terms of reference (ToR) for a TWG responsible for lot release. The establishment of a dedicated TWG will facilitate Rwanda FDA's efforts in operationalizing a vaccines lot release function with greater efficiency.

Senegal

Policy, Planning, and Coordination

PQM+ received Global VAX funding to support the medicines regulatory authority to reach ML3. The Senegal Global VAX workplan was approved in late July 2022. In August, PQM+ convened a virtual kick-off to present the activities in the approved workplan to the Director General of the Senegalese regulatory authority (ARP) and its management/technical staff. During this meeting, PQM+ and ARP agreed to convene a co-creation workshop to jointly develop the implementation plan and ensure both parties are aligned on implementation methodologies, timelines, and preventing duplication of support provided by other partners. The co-creation workshop took place in Dakar in September 2022.

ARP has its institutional development and action plans to attain WHO GBT ML3. With the support of various financial partners and the government of Senegal, starting in January 2022, ARP had started work on implementing the action plan. There was, therefore, the need to map the specific regulatory documents (laws, guidelines, procedures, manuals) still needed and the status of regulatory processes that exist or are under development to the regulatory functions to be supported under the Global VAX project. This will allow PQM+ to address and prioritize those normative and regulatory gaps during implementation. In September 2022, PQM+ met with the Senegalese ARP technical managers responsible for key regulatory functions to be supported under this project – laboratory testing, lot release, vigilance, marketing authorization, and market surveillance and control – to map out work that has already been completed to implement their GBT IDPs and understand what is still required in terms of new regulatory processes and documents. This mapping will assist PQM+ with implementing the project by ensuring the activities align with current priorities and needs of ARP to attain WHO GBT ML3.

Laboratory Systems

PQM+ is also working to strengthen the laboratory testing function and equip and build capacity for testing of biologics. Senegal has an NQCL with some capacity to test biologics, specifically the yellow fever vaccines that Institut Pasteur Dakar (IPD) produces in-country. This laboratory, however, requires new equipment, accessories, and consumables to test COVID-19 vaccines. In addition, the laboratory analysts' capacity needs further building to enable them to test the COVID-19 vaccines per the manufacturers' methods. PQM+ reviewed the equipment list submitted by ARP's *Direction de Contrôle Qualité* (DCQ) for procurement under this project for the testing of mRNA vaccines and noted that most of the equipment on the list were basic items typically used in physicochemical laboratories, not necessarily specific to testing mRNA vaccines. During a virtual meeting with the heads of QA, QC, and vaccines testing, PQM+ confirmed that ARP does not have access to the technical dossiers of the five COVID-19 vaccines granted EUA in Senegal (Pfizer-BioNTech, Moderna, AstraZeneca, Johnson and Johnson, and Sinopharm) and therefore did not know what equipment was required. As a result, PQM+ developed a comprehensive list of equipment required for testing mRNA vaccines, leveraging its experience in providing similar support to other countries. This list was then shared with the DCQ for review against their existing equipment. The PQM+ technical team and the NQCL will review this list during the rapid assessment scheduled for October 2022 and prioritize what to procure under Global VAX.

South Africa

Policy, Planning, and Coordination

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. The work plan was approved August 17, 2022. In preparation for the South African Global VAX activities, an external kick-off and orientation meeting with SAHPRA took place September 12. The aim of the meeting was to introduce all stakeholders to the workplan activities and the PQM+ subject matter experts who will implement the activities. This kick-off meeting set the tone for a collaborative approach toward achieving the workplan objectives. Attendees included nine in-person participants representing PQM+ and SAHPRA senior managers. Online attendees included 38 participants covering PQM+ leadership and subject matter experts, the SAHPRA CEO, SAHPRA senior management, QC laboratory representatives, senior advisors for SAHPRA, and a USAID representative.

To build the capacity of regulators and manufacturers across the six target countries, PQM+ is arranging a joint biomanufacturing training program at key facilities and institutions in South Africa. This activity will enable PQM+ to effectively and efficiently engage with the relevant African continental agencies and multilateral technical organizations to mobilize technical resources in support of this program and the participating African countries. The regional vaccine manufacturing workshop is planned for December 6-9. 2022 in Cape Town, South Africa. This quarter, PQM+ has identified an appropriate venue for the 70 to100 planned in-person attendees. The workshop aims to target regulators from the Global VAX countries, but is open to all interested parties, including regulators and vaccine manufacturers from the African continent, and aims to create a community of practice and knowledge sharing.

Laboratory Systems

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 QC testing: North-West University - Centre for Quality Assurance of Medicines (NWU – CENQAM) for small molecules and University of the Free State - National Control Laboratory for Biological Products (UFS NCLBP) for biologics. In September, the PQM+ technical team assessed these laboratories against SAHPRA's needs. Additionally, the program assessed the potential for a new laboratory for QC testing of small molecule medicines at the University of Witwatersrand. This laboratory is under development and has the potential to offer QC support to SAHPRA once finished and accredited. Final reports of the laboratory assessments will be made available in the following quarter.

Uzbekistan

Surveillance, Case Finding, Rapid Response Teams, Case Investigation, and Contact Tracing

PQM+ is supporting the Agency (Uzbekistan's medicines regulatory authority) in strengthening PV and vaccine surveillance systems. PQM+ is working with the Services for Sanitary and Epidemiological Well-being (SSEW), which oversees the National Immunization Program (NIP),

the Agency, and its State Center of Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment (the State Center) and other national and international stakeholders. PQM+ is also working with the WHO Collaborating Center (RCC) in Morocco. In previous quarters, PQM+ collaborated with the WHO RCC to strengthen pharmacovigilance and vaccine safety surveillance activities between Agency and NIP as the Agency had no designated group on PV. This included a study tour to the WHO RCC in Q3, where participants visited the Moroccan immunization program and the Moroccan medicines regulatory authority to discuss and learn from the best practices of collaborative work on vaccines safety surveillance. On June 8, 2022, after the study tour, the Director of the Agency signed the Order of MOH #102 that approved a pharmacovigilance department with six staff units. The Cabinet of Ministers (CoM) also approved an updated resolution that approves establishing a training center for healthcare providers on addressing and identification of AEFIs within the NIP. Both decisions will help strengthen the vaccines safety system in Uzbekistan.

In Q4, PQM+ continued to provide technical assistance to the Agency and NIP to work toward bridging and centralizing all AEFI activities in Uzbekistan. PQM+ is planning a weeklong trip at the end of October for senior leadership from the Agency, NIP, and the Cabinet of Ministers (CoM) to Morocco to assess how AEFI procedures and mechanisms operate in the country. The participants from Uzbekistan will meet again with the RCC team to develop a roadmap that will effectively regulate and centralize all PV and AEFI-related processes in Uzbekistan. The roadmap will inform the procedures to be included in legislation on PV, such as the detection, assessment, monitoring, and prevention of any reporting procedures for adverse related events following any medicine, especially vaccines, and ways through which the PV department, NIP, and health care providers will work in maintaining drug safety to the public in Uzbekistan.

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.

Highlights of Achievements in Program Year 3

- Completed a technical brief describing impurities in chlorhexidine and how manufacturers can address them during chlorhexidine production; USAID approval is pending.
- Collaborated with MTaPS and GHSC- PSM – organized a series of consultative meetings to identify bottlenecks and actions to increase access to and use of quality-assured medicines for newborn and child health. In Q4, the programs collaborated on a call-to-action paper identifying priority actions for partners and country stakeholders.
- Finalized the development of the e-learning course on MCH medical device quality assurance for manufacturers and regulators, intended to describe basic regulatory frameworks and important QA requirements and concepts to inform programmatic and funding decisions to advance the delivery and safe use of MNCH devices. This course will be hosted on the USP learning management system (LMS) system and linked to the global health eLearning (GHeL) platform and USAID University.
- Finalized the landscape analysis of potential manufacturers of amoxicillin dispersible tablets in Africa with partner Muhimbili University in Tanzania.

Progress in Quarter 4

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

In Q4, PQM+ initiated the subaward process with Purdue University to develop a product information report (PIR) for gentamicin injection for newborns and children and related job aides. The PIR is intended to support informed decision-making regarding product development, scale-up, and manufacturing by proactively identifying and addressing potential manufacturing issues. Building on this PIR, in program year (PY) 4 Q1 PQM+ will develop the related job aids to support product registration and inspection functions of NMRAs.

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

This quarter, PQM+ addressed USAID's feedback and finalized the technical brief describing the impurities in chlorhexidine and how manufacturers can address them during chlorhexidine production. The goal of this brief is to share information with local manufacturers to increase the supply of quality-assured sources for the product. PQM+ shared this brief with teams in Pakistan, Nepal, and Bangladesh to disseminate to their local manufacturing associations and will make it available on the PQM+ website.

PQM+ met with USAID, Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) and MTaPS on July 14 and discussed PQM+'s proposal to rework deliverables 1-3 under milestone 6 of the Every Newborn Action Plan (ENAP). The action plan aims to enable all countries to ensure timely procurement, equitable distribution, and access; ascertain appropriate use and maintenance of commodities and products (equipment, technologies, and diagnostics) to facilitate the delivery of high-quality, affordable newborn care; and reduce preventable stillbirths and reduce neonatal mortality.

PQM+ suggested the following deliverables under milestone 6: 1) a global framework/guidance; 2) adaption of the framework/guidance into country contexts; 3) and implementation of guidance including identification of innovations for successful implementation in both the public and private sectors. Meeting participants agreed to complete deliverable 2 by December and to phase deliverable 3 in during PY4.

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

In Q3, PQM+ collaborated with MTaPS and GHSC- PSM – to organize a series of consultative meetings to identify actions to increase access to and appropriate use of quality-assured medicines for newborn and child health. This quarter, PQM+, MTaPS, and GHSC-PSM consolidated inputs from the consultative meetings, fleshed out messaging and structure of the call-to-action paper, and shared an outline of the paper with USAID on July 29, 2022. The three programs also met to review a consolidated draft of the paper. PQM+ has provided all requested inputs towards finalizing the call-to-action paper.

Medical devices are essential for quality care of newborn health, yet information regarding sourcing, procurement, maintenance, and general availability is scarce. PQM+ also met with USAID and GHSC - PSM to discuss a landscape assessment of medical devices for newborn health. PQM+ initiated the preparatory work for a landscape assessment to inform the work of the medical devices sub-group of ENAP. The ENAP devices and medicines working groups are defining the list of commodities that will inform PQM+ work on this activity. The preparatory work includes development of study questions for a literature review of medical devices, methodology, medical device categories and tracer list (to align with ENAP priority devices) to inform a larger landscape assessment activity for medical devices in PY4. PQM+ finalized the development of the e-learning course on international standards and guidance for quality assurance of medical devices with a focus on MNCH medical devices examples. The learning objectives of this course are to be able to 1) define medical devices and identify their characteristics; 2) explain the importance of international standards and industry best practices to ensure safety and medical device quality; and 3) define the quality assurance and activities required to monitor post-market safety and performance. PQM+ shared the course outline for USAID review. Once finalized, this module will be hosted on the USP learning management system (LMS) system and linked to the global health eLearning GHeL platform and USAID University. This course is designed for anyone who works in medical products production and quality assurance, including manufacturers and regulatory authorities.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Complete development of a gentamicin injection PIR for children and newborns and related job aides.

- Respond to any additional requests for the call-to-action paper with MTaPS and GHSC-PSM.
- Utilize the medical devices landscape questionnaire in an additional 1-2 PQM+ countries to inform the larger activity in 2023.

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.

Highlights of Achievements in Program Year 3

- Continued to support manufacturer India Manufacturer 3 with onsite inspection and repeat BE study to achieve approval by WHO's Prequalification of Medicines Program for praziquantel 600mg film-coated tablets.
- Completed the NTD market landscape analysis in Africa and Asia to better understand the local supply and demands of NTD API and FPP with partners Muhimbili University in Tanzania and Mahidol University in Thailand.
- In quarter 4, abstracts of PQM+'s NTD market landscape analysis and NTD dashboard were accepted by the American Society of Tropical Medicine and Hygiene for an oral presentation at the 2022 Annual Meeting October 30 – November 3, 2022, in Seattle, Washington.

Progress in Quarter 4

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

The overall goal of the Core NTD program is to improve the availability of affordable, safe, effective, quality assured NTD medical products for patients in need. To increase the availability of quality assured NTD medicines, PQM+ continues to support manufacturers with direct technical assistance and to raise awareness of the WHO prequalification (PQ) program.

This quarter, for albendazole 400mg tablets, PQM+ conducted a mock GMP assessment of the manufacturer's facility between July 4- 8, 2022 as part of the technical support milestone toward full PQ. The WHO PQ onsite inspection took place between August 8-12, 2022, and per the manufacturers there were no critical observations; PQM+ is awaiting WHO's formal inspection report for any follow-up CAPA support to the company.

For praziquantel 600mg film-coated tablets, WHO issued a conditional PQ approval in April 2021 for the product pending onsite inspection and repeat bioequivalence study (BE) Study. This quarter PQM+ completed the subaward extension for partial financial support to the manufacturer to cover the cost of the BE study. The BE study is ongoing; study subjects dosing

was completed between July 22- August 12, 2022, the samples were sent for analysis, and a preliminary report is expected to be completed by end of this quarter. PQM+ is currently preparing to conduct a remote inspection of the CRO since they recently passed a successful in-person inspection conducted by the United States Food and Drug Administration. PQM+ also extended the BE study specialist's fixed price agreement to allow for BE study completion, review, and submission to the WHO PQ team.

In PY3/4 to identify and provide support to newly identified manufacturers of NTD medical products to increase the global supply of quality-assured products, PQM+ has published an expression of interest (EOI) for eight NTD products for local manufacturers. This quarter, PQM+ in collaboration with USAID identified seven manufacturers who will receive technical assistance towards WHO PQ in PY4. This quarter PQM+ reached out to the selected manufacturers to discuss support needs and conducted an onsite assessment on one manufacturer of Azithromycin 500 mg tablet.

PQM+ engaged two core flex partners, Muhimbili University in Tanzania and Mahidol University in Thailand, to conduct an NTD market landscape analysis in Africa and Asia to better understand the local supply and demands of NTD API and FPP in the two regions. This quarter, PQM+ finalized the NTD market landscape analyses of Africa and Asia report aimed to better understand the NTD markets for both API and FPP. PQM+ is currently addressing USAID's feedback on the combined report upon which it will be finalized and disseminated.

An abstract of PQM+'s NTD market landscape analysis was accepted by American Society of Tropical Medicine and Hygiene (ASTMH) for an oral presentation at the 2022 Annual Meeting (October 30 – November 3 in Seattle, Washington). PQM+ identified staff to attend and present at this conference.

PQM+ continued the development and enhancement efforts of the publicly available NTD database and dashboard 'NTD|MID' for regulators, manufacturers, procurement agencies, suppliers, donor communities, and other interested parties in planning for procurement, supply, and use of NTD medical products. PQM+ is currently in the final stages of finalizing version two, which will only capture expanded publicly available data for FPPs approved by WHO listed authorities (WLA) majority level (ML) 3 and ML 4 (stringent regulatory authorities). PQM+ also identified a 508-compliance vendor and is currently working on finalizing a contract to make the tool 508-compliant. Once the tool is 508 compliant it will be soft launched via a webinar targeting a wide stakeholder audience. PQM+ also began the process of extending the NTD dashboard program developer's contract until March 2023 to allow time for USP IT to take over the tool hosting and maintenance.

PQM+'s NTD dashboard abstract was also accepted for an oral presentation at the ASTMH conference. PQM+ identified staff to attend and present at this conference.

To increase awareness among African manufacturers about the WHO PQ program, PQM+ has been planning a three-day workshop, co-organized with the WHO Local Production and Assistance (LPA) unit in Mombasa, Kenya between Oct 11-13,2022. This quarter PQM+ identified the venue for the workshop, finalized the concept note, began identifying presenters, and started the logistical planning to allow for remote participation.

PQM+ continued efforts to promote and disseminate the repackaged GMP e-learning course and sent reminders to 10,214 individuals registered for the GMP course to complete it. PQM+ also finalized the GMP course information handout and dissemination strategy and shared it with USAID for their review, once finalized these guidelines will be disseminated in PY4.

Priority Activities for PY4, Q1

Next quarter, PQM+ plans to:

- Continue ongoing technical assistance to supported manufacturers until full WHO PQ is attained.
    - For albendazole, PQM+ will address CAPAs as needed.
    - For praziquantel, PQM+ plans to finalize the BE study.
- Finalize and launch the NTD dashboard for public users and collect feedback for improvement.
- Finalize and disseminate the NTD market landscape analysis in Africa and Asia reports.
- Deliver the WHO PQ advocacy workshop.

Tuberculosis (TB)

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

Highlights of Progress by PQM+ During Program Year 3

- Collaborated with U.S. FDA to organize an online conference, *Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines*. USAID's Atul Gawande was a keynote speaker. The audience included 2,173 registrants from 127 countries, with 3,458 total attendees.
- Provided technical assistance to one manufacturer of a 4 FDC medicine in Pakistan and successfully submitted the application for WHO pre-qualification, then helped the company respond to WHO's additional questions.
- Through the subaward agreement, VCU is close to completion of the development of an optimal and cost-effective manufacturing process for rifapentine API, which will eventually improve the cost of the finished product.
- Completed the method development and validation to quantify nitrosamine impurities in the rifapentine drug substance and drug product.
- Provided technical assistance to one manufacturer of isoniazid API in South Africa in preparation of the drug substance master file for submission to WHO.
- Initiated technical assistance to Core-flex partner R-BEC in developing their capacity to conduct a BE study and established a TWG of key stakeholders, including MoH, EFDA, the regional WHO office, and other concerned institutions in Ethiopia.

Progress in Quarter 4

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

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

To address this, PQM+ teamed up with the U.S. FDA to develop and host a three-day online conference, “Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines” (August 16-18). The conference kicked off with five notable keynote speakers:

- Janet Woodcock, M.D. Principal Deputy Commissioner Office, FDA.
- Dr. Atul Gawande, Assistant Administrator for Global Health USAID.
- Tereza Kasaeva, MD, PhD Director Global TB Programme, WHO.
- Rogerio Gaspar, PhD Director of Regulation and Prequalification, WHO; and
- Ronald T. Piervincenzi, PhD, CEO, USP.

Jude Nwokike, PQM+ Director, opened the technical portion of the conference with an overview of the PQM+ program. The virtual conference was an exciting, unique collaboration among the FDA, USAID, WHO, and USP. It provided an important opportunity for regulators, industry, and USAID staff to learn directly from experts about:

- FDA drug approval pathways and application review, including for new and generic drugs.
- The role of the FDA in international regulatory harmonization.
- Collaboration among FDA, WHO, and NMRAs to support the drug approval process in LMICs.
- The role of USAID’s PQM+ program in strengthening regulatory systems in LMICs.

The conference was an “undeniable success,” according to the FDA’s Small Business and Industry Assistance (SBIA), which led overall production of the conference. The interim statistics reflect a large global audience (2,173 registrants from 127 countries, with 3,458 total attendees) and widespread participation, including by USAID countries:

Top 10 countries by number of registrations (includes five PQM+ countries, in bold)

1. United States: 826	2. India: 240
3. Pakistan: 122	**4. Nigeria: 70**
5. Ghana: 60	**6. Kenya: 43**
7. Canada: 43	8. Egypt: 40
9. Rwanda: 32	10. Switzerland: 32

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

In Q4, PQM+ continued to support two pharmaceutical manufacturers of first line, fixed-dose combination (4FDC) TB medicines in Pakistan. Previously, PQM+'s technical assistance to one manufacturer enabled the finalized compilation of a dossier, including the report on a completed stability study and bioequivalence study. This was an important milestone toward prequalification of the product and ensuring that TB patients in Pakistan have access to locally produced quality-assured TB medicines. As a result, the 4FDC dossier of Pakistan Manufacturer 4 has been submitted to WHO and accepted by WHO for full assessment. In Q1, PQM+ provided technical assistance to the manufacturer in responding to the first-round additional data and comments requested from WHO. In Q2 and Q3, PQM+ continued to work with Pakistan Manufacturer 4 and submitted the pending dossier question to WHO on March 11, 2022. Further additional data has been also clarified during April 2022 and the dossier is now at final stage of approval. In Q4, as part of full prequalification, WHO conducted an onsite inspection during September 19-23, 2022. The PQM+ team will continue to provide technical assistance towards full prequalification of the product.

Another Pakistani manufacturer, Pakistan Manufacturer 1, received technical support on the update of its dossier along with stability studies of the 4FDC product. PQM+ has reviewed the updated dossier and held a meeting with the manufacturer to discuss comments. The manufacturer is correcting the missing information as per the comments provided by PQM+. It will arrange the pre-submission meeting with WHO. The manufacturer will submit the updated dossier along with the stability data for review by PQM+ prior to submitting the material to WHO. The PQM+ team will continue to provide technical assistance through full prequalification of the product.

During Q4, PQM+ in collaboration with the USP laboratory team completed the validation of methods to test for nitrosamines impurities in rifapentine and rifampicin TB medicines. The USP laboratory finalized the laboratory report for the LC/MS/MS method development/validation for the Rifapentine API and tablets. In Q4, the USP laboratory team also prepared to develop the Rifampicin validation method.

In Q4, PQM+ provided ongoing technical collaboration work with Virginia Commonwealth University (VCU) subaward for phase 2 on optimization, scale up, and integration of the synthesis process on developing an alternative route to produce Active Pharmaceutical Ingredient (API) for a priority TB product. During the laboratory phase, in PY3 Q4, the team successfully identified a synthesis route and demonstrated each step of the target continuous manufacturing process. In Q4, PQM+ is working on finalizing criteria for identifying a manufacturer for the technology transfer, the next step after Phase 2. PQM+ is also parallelly exploring potential manufacturers for technology transfer.

In Q2, PQM+ signed a non-disclosure agreement with one of the manufacturers based in Africa, which currently produces two TB active pharmaceutical ingredients (API). Based on the initial review, the manufacturer has the potential to implement innovative approaches for manufacturing of TB APIs. In Q3, PQM+ held an onsite in-person meeting with the company. In Q4, PQM+ prepared for a technical assistance visit in October to work towards prequalification of their TB API product, which will be an important step towards diversification of the global supply of TB APIs.

The bioequivalence study report is a critical document used as evidence to justify the interchangeability and effectiveness between two products in the dossier submitted for

marketing authorization. The Regional Bioequivalence Centre Sh. Co. (RBEC) that is in Ethiopia is a public-private partnership (PPP) organization established in 2012 as a contract research organization (CRO) for East African pharmaceutical manufacturers to improve the quality and effectiveness of essential medicines. Through the clinical and bioanalytical laboratory services provided by RBEC, the center will aim to play a fundamental role in the region to fulfill the continent's unmet needs for the supply of safe, effective, and quality assured medicines that will be made accessible to the people of the continent. As such PQM+ will work with RBEC through a technical working group to identify the bottlenecks hindering RBEC from delivering BE studies for Ethiopia and the African continent. In Q3, PQM+ facilitated the first TWG meeting and together with RBEC laid out the plan of action for the assessment, identification of gaps, and action planning to address the gaps. In Q4, PQM+ conducted a full quorum of TWG discussion. As a next step, the TWG agreed to develop a concept note for the upcoming stakeholder's workshop. The TWG members are also gathering documents for desk review to develop the background for the workshop and technical report writing that will serve as a foundation to build the capacity of RBEC.

Priority Activities for PY4, Q1

Next quarter, PQM+ will:

- Follow up with the manufacturer in Pakistan to review the updated dossier along with the stability data for review by PQM+ prior to submitting to WHO
- Follow up with the manufacturer in Pakistan to respond to the CAPA to the WHO audit completed in Q4.
- Continue joint work with VCU on Phase 2 of the manufacturing process optimization for a priority TB product.
- Continue to map out the collaboration with the manufacturer in South Africa and conduct the onsite assessment on GMP and preparation of drug master file.
- Finalizing the RBEC TWG concept note and plan for a stakeholders' workshop to develop the technical report.
- Identify additional new finished product manufacturers of TB medicines including rifapentine, bedaquiline, delamanid, and pretomanid and other priority TB products.

Program Support

Communications

Social media: To highlight PQM+ activities and help amplify our work, PQM+ shared 25 posts this quarter via Twitter and LinkedIn. Our posts earned more than 900 engagements. Top tweets were about the Pakistan diagnostic lab success story, the Global VAX press release, and Ethiopia's National Pharmaceutical Association. Top LinkedIn posts were about the Nepal/Pakistan exchange visit and the Global Vax press release. Over the past year, we have posted 60 tweets and 43 LinkedIn posts. They earned 1,500 engagements, including 998 likes, 433 retweets, 18 quote tweets, and 55 link clicks.

Success stories: We published three success stories in Q4 – two from Pakistan and one from Ghana:

Pakistan's Diagnostic Laboratories

Pakistan Remdesivir Technology Transfer

Ghana RB-PMS Dissemination

Newsletter: PQM+ shared its eighth newsletter this quarter, which had a 47 percent open rate. This issue spotlighted the joint FDA-PQM+ global webinar, Ghana's first RB-PMS exercise, building manufacturing capacity in Nepal, and GMP inspections in Nigeria.

Website: USAID shared results from the security scan of the new PQM+ website. Our web and IT teams made all requested updates.

Staff: PQM+ continues to recruit applicants for two full-time communications positions.

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 FY2022 for PQM+ country and core buy-ins. Results are organized by PQM+ objectives and sub-objectives. Country and core buy-ins do not report on all PQM+ indicators, but on selected indicators that reflect the focus of their programs.

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+ will continue monitoring their sustainable operation.

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

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

times, and dossier compilation two times more than the other manufacturing activities. Scores and weights are used to calculate the overall percentage of milestones achieved. The total possible score for each set of activities is 20 (100%). When a QC laboratory or manufacturer achieves a score of 100%, it has completed all milestones and should receive accreditation, pre-qualification, or market authorization.

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

PMS. Details of the PMS activities concluded in PY3, and any known MRA enforcement actions are described in the table in Annex 1A.

Performance indicators. PQM+ has introduced indicator **2.2m** to track the independence of country counterparts in conducting RB-PMS. Independence means the PQM+-supported TWG and/or MRA can (and do) use *on its/their 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. An additional component of this indicator is PQM+ funding (0 if PQM+ funds are used, 2 if they are not used). The total possible score is 16. Scoring is conducted for each round of PMS.

PQM+ is also tracking the performance of laboratories. To that end, the program has introduced the following new indicators:

- **2.2n.** Number of core processes for which the NQCL has documentation. Typically, there are 28 or 29 core processes, in addition to the Quality Manual, that all laboratories should possess. These include:

    1. Document control
    2. Record control
    3. Internal audit (program)
    4. Management review
    5. Training program
    6. Environmental criteria & monitoring
    7. Equipment handling, maintenance & calibration
    15. Validity of results confirmation
    16. Report generation, review & distribution
    17. Complaint /feedback handling
    18. Nonconforming work
    19. Risk & opportunity identification
    20. Corrective actions & improvements
    21. Confidentiality & impartiality
    22. Change control
    23. Reference standard handling

8. Equipment operation (i.e., procedures for operating all lab equipment)
9. Measurement uncertainty/traceability
10. Service & product providers
11. Requests, tenders & contract review
12. Method selection, verification & validation
13. Sampling
14. Handling of samples (test items)
24. Reagent handling
25. Atypical & OOS results
26. Housekeeping
27. Information systems/data processing equipment
28. Safety procedures
29. Subcontracting *(not all laboratories)*

- **2.2o.** NQCL completed QMS management oversight tasks in the last year. An internal audit and management review are usually conducted by the laboratory's quality manager at least once a year.
- **2.2p.** Number of core methods in which at least two staff are competent, per the NQCL quality manager. Different kinds of laboratories rely on different core methods. For instance, there are ten core methods for physiochemical laboratories

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

PY3 Challenges.

1. Delays in minilab shipments to African countries led to considerable delays in PMS activities across the board.
2. Funding issues caused work slowdowns in Liberia, Mozambique, and Madagascar.

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

PQM+ FY2022 Monitoring Results

Table Legend

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

N/A: Data are not available.

TBC: Data will be collected.

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

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

0: No results achieved.

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

New PY3: Counterpart is new to PY3.

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
OBJECTIVE 1: GOVERNANCE FOR MEDICAL PRODUCT QUALITY ASSURANCE SYSTEMS STRENGTHENED								
1.1. Evidence-based medical product quality assurance legislation, policies, and regulations developed, updated, and/or implemented								
1.1a. Number of policies, laws, regulations, and guidelines on medical product quality assurance developed or revised with PQM+ support and submitted for adoption, by quarter								
Bangladesh	0	1	6	0	2	1	1	**4**
Legislation for Laboratory Service Sub-Contracting in Bangladesh (PY2)				Drafting	Drafting	Drafting	Drafting	
Vaccine Lot Release Guideline in Bangladesh (PY3)				-	Drafting	Drafting	Drafting	
Ethical Marketing and Promotion Guidelines for Pharmaceutical Products (PY3)				-	Drafting	Drafting	Drafting	
Code of Pharmaceutical Marketing Practices (PY3)				-	-	Revising	Revising	
Regulatory Framework for Medical Devices (PY3)							Drafting	
Bangladesh COVID-19	0	3	No target	0	0	1	1	**2**
Guideline for RB-PMS of COVID-19 Vaccines (PY2)				Adopted				
Bangladesh EUA/No Objection Certificate (NOC) Guideline for Vaccines (PY2)				Adopted				
Medical Oxygen Regulations Guidelines (PY3)				-	-	Drafting		
Guideline on Registration of Human Vaccine (PY3)							Drafting	
Burkina Faso	0	1	1	0	0	0	0	**0**
Collaborative Framework between ANRP and LNSP (PY2)					Submitted			
Burkina Faso COVID ARP				0	0	0	1	**1**
Regulatory guidelines for granting EUA (PY3)							Drafting	
Ethiopia	0	9	2	3	4	1	0	**8**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Medicines and Medical Devices Import, Export, and Wholesale Directive (PY2)				Adopted				
Directive for Medicines GMP Inspection Procedures (PY2)				Adopted				
Guidance for Cold Supply Chain (PY2)					Submitted			
Directive—Medicine Packaging, Repackaging, and Labeling (PY2)						Submitted		
Directive—Good Clinical Practice (PY2)					Submitted			
Directive—Clinical Trial Application, Review, and Authorization (PY2)					Submitted			
Guidance on Waiver of GMP Inspection Based on SRA Procedure (PY2)					Submitted			
Strategies to Strengthen Local Manufacturers' Performance on EPSA's Award (PY3)				Drafted & Adopted				
Guideline Reliance of Regulatory Decisions Based on Reports of Regulatory Authorities in Other Countries (PY3)				Drafted & Submitted				
Variation Guideline for Vaccines (PY3)				Drafted & Adopted				
Special Conditions Import Permission Directive (PY3)					Drafted & Submitted			
Medical Donations Control Directive (PY3)					Drafted & Submitted			
Medicine Authorization Directive for Registration of Medicine (PY3)					Drafted & Submitted			
GMP Guideline for Traditional Medicines (PY3)					Drafted & Submitted			
EFDA Business Risk Analysis Guidance						Drafted & Submitted		
Ghana	0	0	1	-	-	-	1	1
GS1 Pharmaceutical Traceability Guidelines							Drafting	
Guinea	0	0	1	0	0	1	0	1
Collaborative framework between DNPM and LNCQM (PY3)				-	-	Drafted	Adopted	
Kazakhstan	0	5 (adjusted)	2	0	1	0	0	1
Good Manufacturing Practice Guideline of Eurasian Economic Union (PY2)							Submitted	
Codex for People Health (PY2)					Adopted			
Rules on pharmaceutical inspections/good pharmaceutical practices (PY3)				-	Revised	Adopted		
Kazakhstan COVID-19 ARP	0	0	No target	0	1	0	0	1

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Order 282—Rules of Quality Assessment of Medicines and Medical Devices Registered in Kazakhstan (requirements for quality assessment of vaccines) (PY3)				-	Revised	Revised	Adopted	
Kenya	0	2	3	0	0	0	0	0
Guideline for Development, Review and Approval of Regulatory Instruments (PY2)				Adopted				
RB-PMS Guideline (PY2)					Adopted			
Liberia	0	7	11	7	0	0	0	7
Regulation on LMHRA Consideration of Decisions, Information and Data from Other NCLs (PY3)				Drafting	Drafting	Drafting	Drafting	
Regulation to Allow Sub-Contracting of Testing Services (PY3)				Drafting	Drafting	Drafting	Drafting	
LMHRA Reliance Policy on Inspection (PY3)				Drafting	Drafting	Drafting	Drafting	
Regulation for Quarantine (PY3)				Drafting	Drafting	Drafting	Drafting	
Regulation for the Registration of Medical Devices (PY3)				Drafting	Drafting	Drafting	Drafting	
LMHRA Reliance Policy on Marketing Authorization (PY3)				Drafting	Drafting	Drafting	Drafting	
Regulations for Product Variations (PY3)				Drafting	Drafting	Drafting	Drafting	
Regulations for Labeling of Medicines and Health Products (PY2)						Adopted		
Regulations for Product Recall of Medicines & Health Products (PY2)						Adopted		
Regulations for Disposal of Unfit Pharmaceutical and Health Products (PY2)						Adopted		
Regulations for Donated Medicines and Health Products (PY2)						Adopted		
Regulations for Advertising and Promotion of Medicines and Health Products (PY2)						Adopted		
Regulations for Importation and Exportation of Drugs (PY2)						Adopted		
Regulations for the Registration of Medicines and Health Products (PY2)						Adopted		
Madagascar	0	0	No target	0	1	0	0	1
RB-BMS guidelines (PY3)					Drafted-adopted			
Nepal	0	2	7	2	4	0	0	6
GMP Code [revised] (PY2)				Submitted				
Risk-Based PMS Guideline (PY2)				Drafting	Drafting	Drafting	Drafting	
Guideline—Product Recall (PY3)				Drafted	Submitted			
Risk-Based Inspection Framework (PY3)				Drafted	Submitted			

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Guideline—Biological Product Manufacturing (PY3)					Drafting	Drafting	Drafting	
Guideline—Handling & Manufacturing of Hazardous Substances (PY3)					Drafting	Drafting	Drafting	
Guideline—Heating, Ventilation, and Air Conditioning System (PY3)					Drafting	Drafting	Drafting	
Guideline—Water for Pharmaceutical Use (PY3)					Drafting	Drafting	Drafting	
Pakistan	0	3 (adjusted)	4	4 (adjusted)	0 (adjusted)	1	1	6
Contract Manufacturing Amendment to Drug Rules 1976 (PY2)				Adopted				
Fee for Regulatory Functions of DRAP				Adopted				
Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods				Adopted				
Guidance on IDMP (API and Drug Products) (PY1)				Adopted				
Guidance Document for Pre-Marketing Risk Assessment (PY3)				Drafting				
AWaRE Regulatory Intervention Guidance Document (PY3)				Drafted	Submitted			
Outline of Key Performance Indicators (KPIs) for DRAP (PY3)				Drafted	Submitted			
2nd Amendment – Contract Manufacturing Drug Rules (PY3)				Revised & Adopted				
Guidance on Risk-Based Assessment of Pharmaceutical Generic Products (PY3)						Drafted & Submitted		
Roadmap for Benchmarking Pharmaceutical Manufacturers (PY3)							Drafted	
Pakistan COVID-19 Vaccines	0	7	No target	2	1	4	0	7
Guidance Document for Risk Based Post-Licensure Monitoring of Biological Products (PY3)					Drafted & Adopted			
Guidance for Reporting of Adverse Event Following Immunization (AEFI) by Emergency Use Authorization (EUA) Holders (PY3)						Drafted & Submitted	Adopted	
Guidance for EUA holders for preparation of Risk Management Plans and Periodic Safety Reports for COVID-19 Vaccines (PY3)						Drafted & Submitted	Adopted	
National Guidelines for Adverse Events Following Immunization (AEFI) Surveillance-COVID-19 Vaccine (PY3)				Revised	Submitted	Adopted		
National Action Plan for AEFI Surveillance For COVID-19 Vaccines (PY3)				Drafted	Submitted	Adopted		
AEFI Data Management and Evaluation (PY3)						Drafted & Submitted		
AEFI Desk Guide (PY3)						Drafted & Adopted		
Uzbekistan	0	4	3	0	1	3	2	6

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Resolution of Cabinet Ministers #213 (procedure for registration of medicines, medical devices, & medical equipment) (PY3)							Revised	
Regulations related to GxP Activities (finalizing GMP Guideline) (PY3)					Revising	Revising	Revising	
Order #102, Ministry of Health (establishment of PMS department in Certification Body/State Center on Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment) (PY3)						Drafted & Adopted		
Order #102, Ministry of Health (establishment of QMS department in State Center on Expertise and Standardization of Medicines, Medical Devices, and Medical Equipment) (PY3)						Drafted & Adopted		
Order, Ministry of Health, regulation of PMS (PY3)						Drafted & Submitted	Adopted	
Order of the Agency on the Development of Pharmaceutical Industry (PY3)							Drafting	
Uzbekistan COVID-19 ARP	0	0	No target	0	1	1	0	**2**
Standard on Good Pharmacovigilance Practice (PY3)					Drafting			
Order of MOH #102 (establishment of Pharmacovigilance department) (PY3)						Drafted & Adopted		
Total 1.1a				**18**	**16**	**13**	**7**	**54**
A national policy and regulatory framework is essential to ensuring the quality of medical products in countries. PQM+ is helping 12 countries develop or revise and submit for adoption medical product quality assurance legislation, policies, and guidelines. During PY3, the program supported a total of 54 new regulations and guidelines. Thirty-five PY1, PY2, and PY3 policies were adopted during the year and 20 are in the submission phase. **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.								
1.2. Systems that facilitate transparency and accountability promoted								
1.2c. PQM+-supported MRA disseminated results of its regulatory activities, by quarter								
Burkina Faso (PMS, round 1)	PMS results/ MRA report	No	Yes	-	Yes	-	-	**Yes**
DRC (PMS, round 1)	No	n/a	Yes	-	-	Yes	-	**Yes**
Ethiopia (PMS, round 1)	No	No	Yes	Yes	-	-	-	**Yes**
Ghana (PMS-round 1)	Yes	No	Yes	-	Yes	-	-	**Yes**
Kazakhstan NCEM (inspection)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Yes**
Kazakhstan NCEM (licensing)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Yes**
Kazakhstan NCEM (registration)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	**Yes**
Liberia (PMS, round 1)	No	No	Yes	-	Yes	-	-	**Yes**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Kenya (PMS, round1)	Yes	-	Yes	-	-	-	Yes	Yes
Mali (PMS, round 2)	Partial	Yes	Yes	-	Yes	-	-	Yes
Pakistan (inspection)		n/a	Yes	-	-	-	Yes	Yes
Pakistan (licensing)			Yes	-	-	-	Yes	Yes
Pakistan (registration)			Yes	-	-	-	Yes	Yes
Pakistan (PMS)			Yes	-	-	-	Yes	Yes
Uzbekistan Agency (licensing)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Uzbekistan Agency (registration)	Yes	Yes	Yes	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 first or second rounds of RB-PMS have disseminated their results in written report formats, dissemination events, or on their websites. MRAs in Kazakhstan and Uzbekistan have continued disseminating the results of its regulatory activities. PQM+ Pakistan helped the regulatory authority develop and share its annual report for the previous year.								
1.3. Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted								
1.3a. PQM+-supported MRA in coordinating and communicating with other authorities involved in medical product regulatory oversight, by quarter (result captures percent of coordination components in place)								
Bangladesh, Coalition of Interested Persons	100%	100%	100%	100%	100%	100%	100%	100%
Guinea DNPM-LNCQM	0%	-	87.5%	75%	75%	75%	75%	75%
Pakistan AEFI stakeholder committees - Baluchistan	0%	n/a	100%	-	-	100%		100%
Pakistan AEFI stakeholder committees - KP	0%	n/a	100%	-	-	100%		100%
Pakistan AEFI stakeholder committees - Punjab	0%	n/a	100%	-	-	100%		100%
Pakistan AEFI stakeholder committees - Sindh	0%	n/a	100%	-	-	100%		100%
Uzbekistan WHO CPAR	0%	Not PY2 indicator	100%	100% (adjusted)	100%	100%	100%	100%
PQM+ is promoting regular coordination and information-sharing among public sector and other stakeholders involved in medical product regulatory oversight in some countries. PQM+ tracks whether public agencies have been identified, focal points named, coordination mechanism defined, and information exchanged. During PY3, the CIP in Bangladesh continued to function. Coordination between the regulatory authority and the national QC laboratory continued. Pakistan established AEFI stakeholder committees in four areas of the country. Uzbekistan's Agency is currently coordinating with the National TB Program and Global Drug Facility to encourage manufacturers of WHO PQ products to register their products in Uzbekistan through CPAR.								
1.4. Links among the medical product quality assurance systems and other sectors developed and fortified								

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
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%	100%	90%	90%	90%	90%	**90%**
Burkina Faso	0%	70%	90%	90%	90%	90%	90%	**90%**
DRC	0%	90%	90%	90%	90%	90%		**90%**
Ethiopia	0%			0%	0%	70%		**70%**
Ghana	0%	90%	90%	-	90%	-	-	**90%**
Guinea	0%	90%	90%	90%	90%	90%	90%	**90%**
Kenya	0%	90%	90%	90%	90%	90%	100%	**100%**
Liberia	0%	90%	90%	90%	90%	90%	-	**90%**
Madagascar	0%	n/a	20%	10%	70%	90%	90%	**90%**
Mali	0%	90%	90%	90%	90%	-	-	**90%**
Mozambique	0%	70% (adjusted)	No target	70%	70%			**70%**
Nepal	0%	80%	No target	80%	80%	80%	80%	**80%**
Rwanda	0%	n/a	90%	0%	70%	70%	70%	**70%**
Senegal	0%	90%	90%		90%	-	90%	**90%**
Other Multisector Groups								
Burkina Faso ANRP QA/QC workshop	N/A	90%	100%	-	90%	-	-	**90%**
Liberia LMHRA's Technical Advisory Committee (TAC)	TBC	n/a	20%	-	10%	90%	-	**90%**
Nepal Good Manufacturing Practice (GMP)/Inspection TWG	0%	40%	No target	80%	-	80%	80%	**80%**
Nepal Laboratory Quality Assurance and Quality Control TWG (NML)	0%	0%	No target	-	-	-	90%	**90%**
Nigeria Bauchi state QA committee	0%	N/A	60%	70%	70%	-	-	**70%**
Nigeria Ebonyi state QA committee	0%	N/A	60%	30%	30%	-	-	**30%**
Nigeria Sokoto state QA committee	0%	N/A	60%	70%	70%	-	-	**70%**
Nigeria TWG, National Strategy for Pharmaceutical Manufacturing Sector	0%	0%	80%	-	10%	80%	80%	**80%**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Pakistan Working Group, Ministry of Planning on Healthcare Investments	0%	0%		-	90%			90%
Uzbekistan Quality Club	0%	30%	100%	100%	90%	90%	100%	100%
PQM+ promotes coordination and collaboration among the various counterparts and sectors (e.g., health programs, regulatory agency, laboratories, industry, civil society) involved in medical product quality. In 14 countries, PQM+ is supporting the development and functioning of technical working groups (TWGs) to establish priorities for, oversee, and report results of RB-PMS activities. TWGs also make recommendations for enforcement action to the MRA. In PY3, two new PMS TWGs were established in Madagascar and Rwanda. Of the PMS TWGs, only the one in Kenya scored 100% for having all the components in place to function sustainably as a TWG because as it is now being financed by the MRA. Other countries' PMS TWGs are in various stages of development, with many just lacking self-financing. PQM+ also assists MRAs in coordinating multisector stakeholders involved in overall medical product QA. In PY2, PQM+ helped the ANRP of Burkina Faso develop a national medicines QA/QC workshop. One workshop was held in PY2 and a second one in PY3 Q2. PQM+ is no longer supporting this group. In Liberia, PQM+ is reforming the LMHRA's expert committee (originally set up to provide independent medical and scientific advice on the safety, quality, and efficacy of medicines) with a new TAC. Nepal and Nigeria introduced new groups in PY3, which they intend to institutionalize. Nepal is instituting multisectoral inspection and laboratory QC TWGs. In Nigeria, PQM+ is involved in state- and national-level efforts to coordinate multisectoral groups to advance medical product QA. At the national level, a TWG is developing a national strategy for thepharmaceutical manufacturing sector. In Q2, Pakistan's working group on enhancing efficiency-seeking investments held its first meeting. Uzbekistan's Quality Club is fully functional and has been holding meetings, including an Uzbek-American pharmaceutical summit in Rockville, MD in Q2.								
OBJECTIVE 2: COUNTRY AND REGIONAL REGULATORY SYSTEMS TO ASSURE THE QUALITY OF MEDICAL PRODUCTS IN THE PUBLIC AND PRIVATE SECTORS IMPROVED								
Overarching Outcome								
2a. Percent of medical product samples assessed by PQM+-supported MRA through post-marketing surveillance that failed, by quarter								
Burkina Faso, round 1	-	-	No target		0%			0%
DRC, round 1	-	n/a	No target			3%		3%
Ethiopia, round 1	-	-	No target			5.9%		5.9%
Ghana, round 1	-	-	No target		11%			11%
Kenya, round 1	-	-	No target				0%	0%
Liberia, round 1	-	-	No target		29%			29%
Mali, round 2	-	3%	No target		4%			4%
Others (convenience sampling/not nationally representative)								
Bangladesh (conventional PMS with risk-based testing)	N/A	3%	No target	0%	0%	0%	0%	0%
Nepal (conventional PMS)	N/A	10%	No target				1%	1%
Nigeria, round 1 (1 province)	-	-	No target				5.1%	5.1%
Note: The table above shows results of RB-PMS activities that concluded in PY3 (for further details, see Annex 1A). The results may be nationally representative of medicines outlets (indicating that percentage of outlets had SF medicines at the time), but they are not nationally representative of the percentage of *a specific medicine class* that was SF								

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
(since samples from specific medicine classes are a subset of the total sample and are too small to be nationally representative). Even if not nationally representative, the results signal problems with the quality of certain anti-malarial and MNCH medicines and the high prevalence of unregistered medicines in some African countries (notably, Mali, Burkina Faso, Liberia, and Ghana). Of note, two RB-PMS rounds in Mali show a relatively low medicines' failure rate (1-4% for malaria products and 2-4% for MNCH products) combined with high rates of unregistered medicines (69-74%). Liberia's failure rate is almost 30%. Finally, Ethiopia's round 1 sample collection was unduly small due to security issues and a shortage of medicines at the time. The small sample size means surveillance may not have been able to detect failures effectively. Several rounds of RB-PMS, which began in PY3 are **ongoing (see Annex 1A): Benin** round 1 (writing the report); **Burkina Faso, DRC, and Ghana** round 2 (sampling postponed due to delays in the arrival of minilabs); **Ethiopia** round 2, **Guinea** round 1, **Liberia** 2 rounds, **Madagascar** round 1, **Mali** round 3, **Nepal** round 1, **Senegal** round 2.								
2.1. Sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies improved								
2.1a. Number of recommendations in the country's WHO GBT Institutional Development Plan addressed with PQM+ support during the year								
Ethiopia	0	4	No target	0	0	9	0	**9**
Kazakhstan	0	12	9	-	9	0	0	**9**
Rwanda	0	n/a	8	3	1	2	2	**8**
The regulatory functions of many MRAs in LMICs have been benchmarked against global standards per the WHO Global Benchmarking Tool. Institutional development plans (IDPs) are developed with recommendations on how to improve each regulatory function (and its score). PQM+ is helping MRAs in several countries systematically address those recommendations. PQM+ assisted Rwanda's FDA in addressing 6 of 8 agreed upon recommendations. PQM+ completed work on 3 PMS, 2 registration, and 4 inspection agreed-upon recommendations in Kazakhstan, and 9 agreed upon recommendations in Ethiopia.								
2.1b. Score on institutionalization of new approaches to authorizing use of medical products at PQM+-supported MRA, by quarter								
Bangladesh DGDA (GRP)	0%	33.3%	35%	83.3%	83.3%	83.3%	83.3%	**83.3%**
Uzbekistan Agency (dossier quality checklist)	12.5%	33.3%	55%	33.3%	33.3%	33.3%	33.3%	**33.3%**
Uzbekistan Agency (fast track registration)	0%	33.3%	100%	-	-	83.3%	83.3%	**83.3%**
2.1d. Score on institutionalization of new inspection approaches by PQM+-supported MRA, by quarter								
Bangladesh DGDA (inspection checklist)	0%	33.3%	35%	67%	83.3%	83.3%	83.3%	**83.3%**
Kazakhstan NCEM (inspection checklist)	0%	Not PY2 indicator	No target	33.3%	50%	50%	50%	**50%**
Kazakhstan NCEM (remote inspection)	0%	Not PY2 indicator	No target	83.3%	83.3%	83.3%	83.3%	**83.3%**
PQM+ works to institutionalize the use of new approaches and tools to strengthen MRAs' regulatory functions. A score of 6 (or 100%) means the tool/approach has been fully incorporated into MRA practices (see scoring convention above). In PY3, Bangladesh, Kazakhstan and Uzbekistan worked to institutionalize a variety of new approaches or tools related to registering new medicines and inspecting facilities.								
2.1k. Number of standard operating procedures and quality assurance manuals developed or updated and adopted by project supported regulatory authority, by quarter								

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Bangladesh DGDA (regulatory systems, GrevP, CPAR, RB-PMS, competency assessment, performance evaluation, staff appraisal)	0	47	3	15	3	2	1	**21**
Ethiopia EFDA (inspection)	0	40	15	27	0	9	0	**36**
Kazakhstan NCEM (inspection)	0	11 inspection	5 RB-PMS, 8 inspection	0	6 inspection	0	0	**6**
Madagascar (PMS)Madagascar (regulatory actions based on PMS)	0	n/a		0	0	0	1	**1**
Nepal (RB-PMS and RB inspection)	0			0	0	0	5	**5**
Nigeria PCN (inspection manual)	0		1	0	1	0	0	**1**
Pakistan COVID-19 Vaccines	0			0	0	0	6	**6**
Rwanda (RB-PMS)	0	n/a		0	5	0	0	**5**
Tajikistan (registration)	0			0	0	0	2	**2**
Uzbekistan Agency (registration, laboratory testing)	0	6	27	3	0	4	0	**7**
Total 2.1k				**45**	**15**	**15**	**15**	**90**
PQM+ helps MRAs develop or update and adopt SOPs to carry out regulatory functions, depending on their needs. SOPs help MRAs achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and noncompliance with regulations or requirements. In PY3, the project assisted MRAs in 10 countries with 90 SOPs.								
2.2. Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened								
2.2a. PQM+-supported QC laboratory score on SATTA								
Official PQM+ score (baseline)								
Burkina Faso LNSP	29%	n/a	No target	-	29%	-	-	**29%**
DRC LNCQ-LAPHAKI NQCL	36%	n/a	No target	-	-	36%	-	**36%**
Ethiopia Diredawa	15%	n/a	No target	-	-	-	15%	**15%**
Liberia LMHRA QCL	47%	47%	No target	-	49%	-	-	**49%**
Liberia National Standard Laboratory	48%	New PY3	No target	-	48%	-	-	**48%**
Madagascar LNCQM	37%	New PY3	No target	-	-	37%	-	**37%**
Mali LNS	21%	21%	No target	61%	-	-	-	**61%**
Mali Microbiology Laboratory	37%	New PY3	No target	-	37%	-	-	**37%**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Nigeria NAFDAC Medical Devices, Agulu & IVDs QC lab Yaba	TBC	TBC	No target	-	-	70%	-	**70%**
Rwanda	65%	New PY3	No target	-	-	65%	-	**65%**
Senegal NQCL	72%	-	No target	-	-	72%	-	**72%**
Tajikistan Dushanbe MQCL	34%	n/a	No target	-	34% (adjusted)	-	-	**34%**
Laboratory self-assessment score								
Guinea LNCQM	6%	-	No target	-	-	-	37%	**37%**
Mozambique DCQ	13%	13%	No target	21% (adjusted)	55%	91%	-	**91%**
PQM+ strengthens QC laboratories so they can generate accurate and consistent test results for medical products. The program usually commences support for a laboratory by conducting a detailed baseline assessment using the SATTA tool to identify areas that are weak (i.e., not compliant with WHO prequalification or ISO 17025:2017 standards). In PY3, PQM+ completed SATTAs for 13 laboratories. PQM+ uses these results to develop roadmaps to address gaps. Laboratories are coached to use SATTA to conduct their own internal audits. These internal scores can be used to track laboratories' accurate use of the tool as well as progress from the baseline. Four countries (Benin, Ethiopia, Guinea and Mozambique) have used SATTA to conduct internal audits, two (Guinea and Mozambique) starting this year.								
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								
Bangladesh Physiochemical Lab	ISO 17025:2017 (10 methods)	ISO 17025:2017 (12 methods	ISO 17025:2017 re-accredited	-	-	-	ISO 17025:2017 – re-accredited (16)	**ISO 17025:2017 – re-accredited (16 methods)**
Burma Nay Pyi Taw PCL	ISO 17025:2017 (10 methods)	ISO 17025:2017 re-accredited (10 methods)	ISO 17025:2017 re- accredited (10 methods)	-	-	-	ISO 17025:2017 reaccredited (9* methods)	**ISO 17025:2017 re-accredited (9* methods)**
Ethiopia PQAD	ISO 17025:2017 re-accredited (16 methods)	ISO 17025:2017 re-accredited (16 methods)	ISO 17025:2017 re-accredited (16 methods)	-	-	-	ISO 17025:2017 re-accredited (16 methods)	**ISO 17025:2017 re-accredited (16 methods)**
Nigeria NAFDAC Vaccines and Biologics Lab	ISO 17025:2017 (10 methods)	ISO 17025:2017 reaccredited (14 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (23 methods)	-	-	-	**ISO 17025:2017 reaccredited (23 methods)**
Nigeria NAFDAC zonal lab, Agulu	ISO 17025:2017 (7 methods)	ISO 17025:2017 reaccredited (16 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (16 methods)	-	-	-	**ISO 17025:2017 reaccredited (16 methods)**
Nigeria NAFDAC zonal lab, Kaduna	ISO 17025:2017 (7 methods)	ISO 17025:2017 reaccredited (16 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (16 methods)	-	-	-	**ISO 17025:2017 reaccredited (16 methods)**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Nigeria NAFDAC zonal lab, Yaba	ISO 17025:2017 (7 methods)	ISO 17025:2017 reaccredited (17 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (17 methods)	-	-	-	**ISO 17025:2017 reaccredited (17 methods)**
Nigeria NIPRID NQCL	ISO 17025:2017 (6 methods)	ISO 17025:2017 (6 methods)	ISO 17025:2017 reaccreditation	ISO 17025:2017 reaccredited (6 methods)	-	-	-	**ISO 17025:2017 reaccredited (6 methods)**
Pakistan IPH Diagnostic Lab	Not accredited	-	National ISO 15189 (1 type of test)	-	-	-	**NEW** National ISO 15189 accredited (1 type of test)	**National ISO 15189 accredited (1 type of test)**
Tajikistan Dushanbe	ISO 17025:2005	n/a	ISO 17025:2017	-	-	-	**NEW** National ISO 17025:2017 (methods N/A)	**National ISO 17025:2017 (methods N/A)**
Uzbekistan Tashkent	National ISO 17025:2017 accreditation (105 methods)	-	National ISO 17025:2017 accreditation (115 methods)	National ISO 17025:2017 accredited (115 methods)	-	-	-	**National ISO 17025:2017 reaccredited (115 methods)**

PQM+ helps laboratories achieve international (or national) accreditation or WHO prequalification as evidence of their quality and competence. Having to renew accreditation means that laboratories must continue to meet the rigorous standards of the accrediting body. In PY3, 9 labs (previously supported by PQM or now supported by PQM+) were re-accredited for ISO 17025:2017. Pakistan's IPH diagnostic lab achieved ISO 15189, the first such accreditation for a diagnostic lab supported by PQM or PQM+. Tajikistan's Dushanbe laboratory upgraded its ISO 17025 accreditation (to 2017). Burma's NPT, Ethiopia's PQAD, three of Nigeria's NAFDAC labs and NIPRID's NQCL maintained their scopes. Three expanded their scopes—Bangladesh's physiochemical laboratory increased by 4 methods, Nigeria's vaccines & biologics lab went from 14 to 23 methods, and Uzbekistan's Tashkent lab went from 105 to 115 methods.

* 1 testing scope is pending due to equipment breakdown prior to the assessment. ANAB will re-assess once Burma's DFDA repairs the equipment.

2.2c. Score on institutionalization of new quality assurance approaches/tools at PQM+-supported QC laboratory, by quarter

Training program								
Burma Nay Pyi Taw PCL	0%	-	66%	-	-	-	50%	**50%**
Burma YSI Pharmaceuticals QCL	0%	New PY3	83.3%	-	-	-	83.3%	**83.3%**
Liberia LMHRA QCL	TBC	83.3%	No target	83.3%	100%	-	-	**100%**
Calibration program								
Burkina Faso (SOPs)	0%	33.3%	No target	33.3%	33.3%	33.3%	33.3%	**33.3%**
Burma Nay Pyi Taw	50%	83.3%	83.3%	83.3%	83.3%	83.3%	83.3%	**83.3%**
Liberia LMHRA QCL	0%	33.3%	No target	33.3%	33.3%	33.3%	33.3%	**33.3%**
Mali LNS	0%	33.3%	No target	50%	50%	50%	50%	**50%**
Senegal LNCM	0%	83.3%	No target	83.3%	83.3%	83.3%	83.3%	**83.3%**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Uzbekistan Andijan & Tashkent	0%	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%	33.3%
Preventive maintenance program								
Benin ANCQ	0%	0%	No target	0%	0%	0%	16.7%	16.7%
Burma Nay Pyi Taw	0%	0%	66%	-	-	-	33.3%	33.3%
Burma YSI Pharmaceuticals QCL	TBC	New PY3	No target	-	-	-	33.3%	33.3%
Guinea LNCQM	0%	0%	100%	-	-	-	33.3%	33.3%
Liberia LMHRA QCL	0%	50%	No target	50%	50%	50%	50%	50%
Madagascar LNCQM	0%	0%	No target	0%	16.7%	16.7%	33.3%	33.3%
Mali LNS	0%	33.3%	No target	33.3%	33.3%	33.3%	33.3%	33.3%
Senegal LNCM	0%	83.3%	No target	83.3%	83.3%	83.3%	83.3%	83.3%
Uzbekistan Andijan	0%	16.7%	33.3%	16.7%	16.7%	16.7%	16.7%	16.7%
Uzbekistan Tashkent	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	33.3%
Internal performance review								
Benin ANCQ	0%	66.7%	100%	66.7%	66.7%	66.7%	66.7%	66.7%
Guinea LNCQM	0%	0%	100%	-	-	-	33.3%	33.3%
Liberia LMHRA QCL	0%	16.7%	50%	-	16.7%	16.7%	16.7%	16.7%
Mali LNS	0%	33.3%	No target	33.3%	33.3%	33.3%	33.3%	33.3%
Uzbekistan Andijan	0%	16.7%	No target	16.7%	16.7%	16.7%	16.7%	16.7%
Uzbekistan Tashkent	0%	33.3%	No target	33.3%	33.3%	33.3%	33.3%	33.3%
Competency assessment program								
Liberia LMHRA QCL	0%	16.7%	No target	16.7%	16.7%	16.7%	16.7%	16.7%
Uzbekistan (Andijan & Tashkent)	0%	33.3%	50%	33.3%	33.3%	33.3%	33.3%	33.3%
The sustainability of PQM+'s laboratory strengthening work depends, in part, on whether laboratories "own" the new quality programs and systems 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. In PY3, PQM+-supported labs in Burma began institutionalizing training programs, while in Liberia, the NQCL fully institutionalized such a program. Work on preventive maintenance and/or calibration programs moved forward in laboratories in Benin, Burkina Faso, Burma, Guinea, Liberia, Madagascar, Mali, Senegal and Uzbekistan. The labs in Benin, Guinea, Liberia, Mali and Uzbekistan are putting in place internal performance review programs. The labs in Liberia and Uzbekistan are putting in place competency assessment programs.								
2.2d. Number of non-laboratory entities involved in medical product quality assurance that achieved ISO accreditation/certification with PQM+ support, by quarter								
Ethiopia EFDA Medicine Inspection Directorate (ISO 17020:2012)	0	0		0	1	-	-	1

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Nigeria Pharmacy Council of Nigeria (ISO 9001:2015)	0	0	No target	0	1	-	-	1
In addition to helping laboratories achieve ISO accreditation, PQM+ helps other entities meet international standards that demonstrate the consistency and quality of their operations. In Q2, the Ethiopia EFDA Medicine Inspection Directorate achieved ISO 17020:2012 certification, which signifies that it meets requirements for competence in performing inspection and for the impartiality and consistency of its inspection activities. This is the first such accreditation for a regulatory authority that was supported by PQM+ or PQM. Also, in Q2, the PQM+-supported Pharmacists' Council of Nigeria received certification for meeting ISO 9001:2015 standards for its quality management system.								
2.2g. Number of proficiency / inter-laboratory tests completed by the QC laboratory and passed by one or more staff, by quarter								
Bangladesh Physiochemical lab	0	5	No target	1	7	-	-	8
Bangladesh Vaccine lab	0	1	No target	2	-	-	-	2
Ethiopia PQAD	TBC	2	No target				16	16
Kazakhstan Almaty	TBC	9	No target	-	-	4	-	4
Kazakhstan Karaganda	TBC	12	No target	-	-	4	-	4
Mali LNS	TBD	0	No target	-	-	5	-	5
Nepal NML	0	0	2	-	-	3	-	3
Total				**3**	**7**	**16**	**16**	**42**

In PY3, one or more staff at the following laboratories completed the following PTs:

- **Bangladesh**, Physiochemical Laboratory: PTs pertaining to tablet testing and sildenafil in supplements
- **Bangladesh**, Vaccine Laboratory: sterility and microbial enumeration PTs
- **Kazakhstan**, Almaty: 1 PT (EDQM optical rotation); 2 ILTs (average mass, mass uniformity, microbiological purity); relative density, dry residue; dimensions, strength test for medical devices
- **Kazakhstan**, Karaganda: ILTs—average mass, mass uniformity; dissolution test; disintegration test; water content
- **Mali**, LNS: dissolution, pH, LOD, KF, infrared spectrometry
- **Nepal**, NML: dissolution, assay, identification

2.2h. Percentage of milestones toward accreditation/WHO PQ achieved by a PQM+-supported laboratory, by quarter								
ISO 17025:2017								
Bangladesh Central DTL	0%	N/A		-	5%	30%	35%	35%
Bangladesh Plasma Plus Research & Testing Lab (& WHO PQ)	0%	n/a	No target	-	-	29%	45%	45%
Benin ANCQ	0%	0%	56%	-	-	10%	40%	40%
Burkina Faso LNSP	0%	0%	56%	-	-	45%	45%	45%
Burma YSI Pharmaceuticals QCL	0%	New PY3	40%	-	10%	10%	40%	40%
DRC LNCQ-LAPHAKI	29%	n/a	64%	-	-	40%	40%	40%

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Ethiopia Diredawa	0%	40%	No target	40%	40%	40%	45%	45%
Guinea LNCQM	0%	0%	40%	-	-	-	40%	40%
Liberia LMHRA QCL	0%	35%	40%	40%	40%	60%	60%	60%
Liberia National Standards Lab	0%	New PY3	10%	-	10%	10%	10%	10%
Madagascar LQCM	0%	n/a	10%	5%	10%	15%	40%	40%
Mali LNS	0%	90%	100%	90%	90%	95%	95%	95%
Mali Microbiology	0%	New PY3	45%	-	-	-	30%	30%
Mozambique DCQ	30%	30%	No target	45%	45%	45%	45%	45%
Nepal NML	0%	45%	55%	45%	45%	50%	50%	50%
Pakistan Appellate Lab	10%	65%	No target	65%	65%	80%	80%	80%
Pakistan DTL, Punjab, Lahore (calibration)	0%	0%	No target	-	10%	95%	95%	95%
Rwanda QCL (& WHO PQ)	0%	n/a	40%	%	5%	35%	60%	60%
WHO PQ								
Bangladesh Microbiology Laboratory	10%	-	35%	5%	25%	55%	85%	85%
Bangladesh Vaccine Chemical Lab	10%	-	70%	7%	36%	36%	57%	57%
Kazakhstan Almaty	78%	90%	CAPAs	90%	90%	90%	99%	99%
Pakistan CDL Karachi			No target			95%	95%	95%
Pakistan DTL Punjab, Bahawalpur	95%	95%	No target	95%	95%	95%	95%	95%
Pakistan DTL, Punjab, Lahore			No target			95%	95%	95%
Pakistan DTL, Punjab, Multan	95%	95%	No target	95%	95%	85%	85%	85%
Pakistan DTL, Punjab, Rawalpindi	N/A	100%	-	100%	100%	85%	85%	85%
Other accreditations								
Pakistan DTL, Punjab, Multan, ISO 17043	N/A	75%	No target	75%	75%	95%	95%	95%
Pakistan Institute Medical Sciences Diagnostic Lab, ISO 15189	0%	10%	100%	80%	60%	60%	60%	60%

International accreditation enhances a laboratory's technical competence and reputation and assures compliance with established standards. Achieving ISO accreditation/WHO PQ is a lengthy process (see Table A2 above). The closer a laboratory is to 100%, the more milestones it has completed. Of note, in PY2, PQM+ is helping Pakistan DTL Lahore pursue ISO 17025:2017 accreditation for calibration services, and Pakistan Institute Medical Sciences laboratory pursue ISO 15189 for diagnostic testing.

2.2i. Number of standard operating procedures and quality assurance manuals developed or updated and adopted by PQM+-supported laboratory, by quarter

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Bangladesh CDTL, vaccine, & Plasma Plus laboratories	0	34 (3 laboratories)	21 (all labs)	12	11	10	10	**43**
Benin ANCQ	0	1	3	0	0	0	4	**4**
Burkina Faso	0	3	3	0	0	0	3	**3**
DRC LNCQ-LAPHAKI	0	n/a	1	0	0	0	1	**1**
Ethiopia-Diredawa branch	0	n/a	No target	0	0	0	14	**14**
Guinea	0	0	10	0	0	0	7	**7**
Kazakhstan Almaty	0	24 (2 labs)	3 QMS	0	9	0	0	**9**
Liberia LMHRA QCL	0	36	10	0	6	6	0	**12**
Madagascar LNCQM		n/a		0	0	0	8	**8**
Mali Microbiology Laboratory	0	2	10	0	0	0	4	**4**
Mozambique DCQ	0	0	No target	0	6	17	3	**26**
Nepal NML	0	7	7	3	5	17	3	**28**
Rwanda QCL	0	n/a	No target	0	0	0	37	**37**
Tajikistan Dushanbe	0	n/a	No target	0	0	2	0	**2**
Uzbekistan Andijan	0	0		1	0	0	0	**1**
Total 2.2i				**17**	**37**	**52**	**136**	**242**
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 PY3, PQM+ supported the development or revision of 242 SOPs in 17 laboratories.								
2.2m. Score on independence of counterpart(s) in conducting PQM+-supported risk-based post-marketing surveillance (RB-PMS) approach								
Burkina Faso, round 1	TBC	0%	No target		78.6%			78.6%
DRC, round 1	TBC	0%	No target			78.6%		78.6%
Ethiopia, round 1	TBC	0%	No target				64.3%	64.3%
Ghana, round 1	TBC	0%	No target		85.7%			85.7%
Kenya, round 1	50%	0%	No target			64.3%		64.3%
Liberia, round 1	TBC	0%	No target		50%			50%
Nigeria, round 1	62.5%	-	No target				64.3%	64.3%
Mali, round 2	TBC	42.9%	No target		85.7%			85.7%

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
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 PY3, the countries above completed at least the first round of RB-PMS. The scores show that counterparts (1) initially rely on PQM+ technical assistance to develop the sampling plan and PMS protocol (this is expected since the risk-based approach and use of the MedRS tool is new to all) and (2) can independently collect and test samples, finalize the report, and disseminate results. Note that until the MRA is paying the full cost of the PMS, it will not be able to score 100% for this indicator. Also note that the MRA may be covering the cost of PMS of other medicines (i.e., medicines that are not priorities of USAID health programs).								
2.2n. Number of core processes for which the NQCL has documentation, by quarter								
Benin ANCQ	TBC	TBC	No target			66.67%	70%	**70%**
Burkina Faso LNSP	TBC	TBC	No target			53.33%		**53.33%**
Burma YSI Pharmaceuticals	TBC	TBC	No target				70%	**70%**
DRC LNCQ-LAPHAKI	TBC	TBC	No target			96.67%		**96.67%**
Guinea LNCQM	TBC	TBC	No target				40%	**40%**
Liberia LMHRA QCL	TBC	TBC	No target			42.86%		**42.86%**
Madagascar LNCQM	TBC	TBC	No target			89.29%		**89.29%**
Mali LNS	TBC	TBC	No target			96.67%	100%	**100%**
Mali Medical Devices Laboratory	TBC	TBC	No target				93.1%	**93.1%**
Mali Microbiology Laboratory	TBC	TBC	No target				82.76%	**82.76%**
Mozambique	TBC	TBC	No target				93.1%	**93.1%**
Nepal NML	TBC	TBC	No target			7.41%	37.04%	**37.04%**
Rwanda	TBC	TBC	No target				90%	**90%**
Senegal LNCM	TBC	TBC	No target			96.67%		**96.67%**
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). Mali's LNS fully documented its processes in Q4. Nine of the other 13 PQM+-supported laboratories that reported on this indicator have documented two-thirds or more of the core processes required.								
2.2o. Did the NQCL complete QMS management oversight tasks in the last year?								
Bangladesh Vaccine Lab (Chemical & Microbiology depts.)	TBC	TBC	Yes		Yes		Yes	**Yes**
Benin ANCQ	TBC	TBC	Yes				Yes	**Yes**
Burkina Faso LNSP	TBC	TBC	Yes			No		**No**
Burma YSI Pharmaceuticals	TBC	TBC	Yes				Yes	**Yes**
DRC LNCQ-LAPHAKI	TBC	TBC	Yes			Yes		**Yes**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Guinea LNCQM	0	No	Yes	-	-	-	Yes	Yes
Liberia LMHRA QCL	TBC	TBC	Yes				No	No
Madagascar LNCQM	TBC	TBC	Yes				No	No
Mali LNS	0	N/A	Yes			No	Yes	Yes
Nepal NML	0	No	Yes				Yes	Yes
Senegal LNCM	TBC	TBC	Yes			Yes		Yes
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.								
2.2p. Percentage of core tests in which at least two staff are competent, per the NQCL quality manager								
Bangladesh Central DTL	TBC	TBC	No target				70%	70%
Benin ANCQ	TBC	TBC	No target			100%		100%
Burkina Faso LNSP	TBC	TBC	No target			70%		70%
Burma YSI Pharmaceuticals	TBC	TBC	No target				90%	90%
DRC LNCQ-LAPHAKI	TBC	TBC	No target			80%		80%
Guinea LNCQM	TBC	TBC	No target			40%		40%
Liberia LMHRA QCL	TBC	TBC	No target			60%		60%
Madagascar LNCQM	TBC	TBC	No target			50%		50%
Mali LNS	TBC	TBC	No target			100%		100%
Mozambique DCQ	TBC	TBC	No target				100%	100%
Nepal NML	TBC	TBC	No target			100%		100%
Senegal LNCM	TBC	TBC	No target			90%		90%
PQM+ tracks how well national quality control laboratories that are not yet accredited are able to 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 (to ensure someone is available to perform the test if a staff person is absent) can perform these tests. Of the laboratories reporting scores for this metric, Benin ANCQ, Mali LNS, Mozambique DCQ, and Nepal NML can now perform all core tests. **Note:** this indicator scores only *unaccredited* laboratories.								
2.3. Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported								
2.3a. Regulatory decisions using reliance, by quarter								
Uzbekistan (registration)	0	0	4	2	0	0	4	6

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
In PY3, Uzbekistan's Agency registered two products [protionamide and cycloserine] in Q1 and 4 additional first line WHO PQ TB medicines in Q4 through the WHO's collaborative procedure for registration (CPAR). A seventh medicine (clofazimine) is currently under review by the State Center. Using CPAR substantially reduces the time and cost of registering new medicines. In Uzbekistan, without CPAR, it took the regulatory agency 155 days on average to assess and make a determination on a dossier, while it cost a company $10,000 to register a medicine. With CPAR, the review and decision period dropped to 60 days. Because the agency does not need to retest WHO PQ'd medicines, the cost of registering a product dropped by 40% to $6,000.								
2.3c. Score on institutionalization of use of a reliance method/mechanism at PQM+ supported MRA, by quarter								
Uzbekistan Agency (WHO CPAR)	25%	83.3%	100%	83.3%	83.3%	83.3%	100%	**100%**
PQM+ is helping the MRA in Uzbekistan institutionalize use of the WHO CPAR. This will enable the Agency to use assessment and inspection outputs from the WHO prequalification process to reduce duplicative regulatory work and save time. A score of 100% means the procedure has been fully incorporated into counterpart practices (see scoring convention in notes above table). Uzbekistan's Agency has now fully institutionalized CPAR and is using this approach to register products in country (see indicator 2.3a).								
2.4. Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported								
2.4b. Number of data standards adopted by PQM+ supported MRA, by quarter								
Pakistan DRAP (ISO 11238 and ISO 11615)	0	4	No target	-	-	-	2	**2**
2.5a. Number of in-service training programs that address quality assurance/quality control topics delivered with PQM+ support, by quarter								
Bangladesh (with ARP)	0	41	19	5	3	4	9	**21**
Benin	0	4	6	1	2	3	1	**7**
Burkina Faso (with ARP)	0	8	4	1	1	8	4	**14**
Burma	0	2	5	1	0	4	3	**8**
DRC	0	4	4	4	3	3	2	**12**
Ethiopia (with ARP)	0	6	4	2	2	5	3	**12**
Ghana (with ARP)	0	5 (adjusted)	4	3	1	1	1	**6**
Ghana COVID-19 ARP	0	0	No target	1	0	0	0	**1**
Guinea	0	6	7	3	2	1	4	**10**
Kazakhstan (with ARP)	0	9	4	3	2	4	6	**15**
Kenya	0	1	1	1	1	0	0	**2**
Liberia	0	11	6	2	5	2	2	**11**
Madagascar	0	n/a	1	1	2	2	1	**6**
Mali	0	10 (adjusted)	6 or 4?	3	1	1	3	**8**
Mozambique	0	2	No target	1	0	0	0	**1**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Nepal	0	4	13	3	5	5	6	19
Nigeria	0	8	No target	4	2	6	5	17
Pakistan (with COVID-19)	0	18	No target	6	10	4	1	21
Rwanda	0	n/a	2	0	1	2	0	3
Senegal	0	3	4	2	1	1	0	4
Tajikistan	0	n/a	No target	0	0	2	0	2
Uzbekistan (with ARP)	0	11	5	2	2	0	1	5
Cross-Bureau	0	n/a	No target		1	0	1	2
Total 2.5a				**49**	**47**	**58**	**54**	**208**
2.5b. Number of individuals who successfully completed a PQM+-supported in-service training program, by quarter				**F / M**	**F / M**	**F / M**	**F / M**	
Bangladesh	0	At least 184	403	14 / 30	9 / 17	12 / 52	9 / 26	**See note below**
Benin	0			4 / 10	11 / 16	3 / 10	7 / 14	
Burkina Faso	0			3 / 5	10 / 16	36 / 65	29 / 39	
Burma	0	At least 105	50	14 / 1 (rev.)		22 / 3	28 / 5	
DRC	0		65	19 / 30	19 / 28	19 / 29	14 / 20	
Ethiopia	0			10 / 45	23 / 50	66 / 160	74 / 102	
Ghana	0	33	33	15 / 36	1 / 7	8 / 24	9 / 18	
Guinea	0			2 / 28	2 / 9	3 / 12	7 / 18	
Kazakhstan	0	At least 131	200	80 / 15	35 / 10	28 / 8	38 / 9	
Kenya	0			15 / 15	1 / 9			
Liberia	0		35	7 / 37	15 / 45	7 / 16	4 / 15	
Madagascar	0	n/a		7 / 1	6 / 4	24 / 13	3 / 3	
Mali	0			7 / 7	4 / 7	7 / 2	7 / 15	
Mozambique	0			12 / 8				
Nepal	0			17 / 26	11 / 20	14 / 99	45 / 53	
Nigeria	0			66 / 84	11 / 14	488 / 747	125 / 286	
Pakistan	0		350	21 / 18	65 / 165	16 / 84	1 / 9	

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Rwanda	0	n/a			16 / 21	14 / 22		
Senegal	0	44	44	8 / 9	10 / 5	5 / 3		
Tajikistan	0	n/a		-	-	8 / 12		
Uzbekistan	0	At least 79	150	15 / 8	1 / 3		9 / 12	
Cross Bureau							17 / 27	
Total (disaggregated)				**F: 339 (44.7%) M: 419 (55.3%)**	**F: 250 (35.9%) M: 446 (64.1%)**	**F: 780 (36.4%) M: 1,361 63.6%)**	**F: 426 (38.8%) M: 671 61.2%)**	
Grand total 2.5b				**744**	**696**	**2,141**	**1,097**	

Despite constraints on travel and in-person meetings experienced in many countries, PQM+ maintained a robust program of training for its various counterparts in all countries. The percentage of female trainees are as follows: Q1—44.7%; Q2—35.9%; Q3—36.4%; and Q4—38.8%. The number of people trained in Q3 and Q4 increased substantially, largely reflecting some very large-scale training at the state level in Nigeria.

Note: PQM+ does not total the number of people trained across reporting periods because this would duplicate the number of people trained. Rather, within a given reporting period, PQM+ attempts to de-duplicate the number of people trained within that reporting period.

Of special note, PQM+ trained faculty at the Pharmaceutical Technology University in Uzbekistan on the pharmaceutical process and product design. It is anticipated that this training of university faculty will sustainably improve the quality of education of students of these faculty members going forward.

2.5c. Number of training programs developed or revised to address quality assurance / quality control topics with PQM+ support, by quarter

Ethiopia	0	0	1	0	0	1	0	**1**
Kenya	0	1	10	0	9	0	1	**10**
Pakistan	0	0	1	0	0	1	0	**1**
Rwanda	0	n/a	1	0	0	0	1	**1**
Uzbekistan	0	0	1	0	0	0	1	**1**
Total				**0**	**9**	**2**	**3**	**14**

PQM+ is helping counterparts develop short QA/QC courses, modules, and curricula to so that they can provide training in medical product QA/QC, pharmaceutical practices, good manufacturing practices, and regulatory science. This will prepare them to build workforce capacity in their countries in the future. Below are PY3 results:

- **Ethiopia:** Helped Ethiopia Pharmacy Association develop a training module and materials to train health professionals in private outlets on good distribution, dispensing, and storage practices. The College of Health Sciences, Addis Ababa, has accredited the training materials.
- **Kenya:** Helped develop content for 9 e-learning courses for Kenya PPB's self-directed learning platform; and (with the Pharmaceutical Society of Kenya) a 10-module competency-based curriculum on pharmaceutical regulation and quality assurance for pharmacists.
- **Pakistan:** Developed a curriculum for a university-level Certificate in Regulatory Science
- **Rwanda**: With the University of Rwanda and Regional Centre of Excellence for Vaccines Immunization and Health Supply Chain Management, updated and validated a master's program in pharmaceutical quality control and quality assurance.

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
▪ **Uzbekistan**: Surveyed faculty of Pharmaceutical Technology University in Tashkent Pharma Park about their educational needs and developed and delivered an introductory course "Introduction to Development, Quality, Clinical, Manufacturing, and Regulatory Topics in pharmaceuticals."								
2.5d. Score on institutionalization of workforce development approaches/tools adopted by PQM+ supported MRA, by quarter								
Kazakhstan SEC (skills program)	0%	0%	No target	-	-	-	16.7%	**16.7%**
Liberia LMHRA (staffing program)	0%	0%	50%	0%	16.7% (adjusted)	33.3%	33.3%	**33.3%**
Liberia LMHRA (skills program)	0%	50%	50%	50%	66.7%	66.7%	66.7%	**66.7%**
Madagascar Agency (skills program)	0%	n/a	100%	-	16.7%	33.3%	33.3%	**33.3%**
Nepal DDA (skills program)	0%	16.7%	50%	16.7%	16.7%	33.3%	50%	**50%**
Rwanda FDA (skills program)	0%	n/a	100%	16.7% (adjusted)	33.3% (adjusted)	66.7%	100%	**100%**
2.5e. Score on institutionalization of workforce development approaches/tools adopted by PQM+ supported QC laboratory, by quarter								
Madagascar LNCQM (skills program)	0%	n/a	100%	-	16.7%	33.3%	33.3%	**33.3%**
Mali (staff motivation program)	0%	33.3%	66.6%	33.3%	33.3%	33.3%	33.3%	**33.3%**
Nepal NML (skills program)	17%	-	50%	-	16.7%	33.3%	50%	**50%**
Nepal NML (staffing program)	17%	-	50%	-	-	33.3%	50%	**50%**
Rwanda FDA QCL (skills program)	0%	n/a	100%	16.7%	33.3%	66.7%	100%	**100%**
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. ▪ **Kazakhstan:** PQM+ is building SEC's capacity to assess the competency of the regulatory workforce and training needs of manufacturers on GMP. ▪ For both the staffing and skills programs at **Liberia's** LMHRA, HR assessments have been done and record keeping systems are in place. An intervention is being planned. ▪ In **Madagascar** (Agency and LNCQM), PQM+ has assessed human resources. ▪ In **Nepal,** DDA and NML HR assessments have been completed and a training plan accepted by DDA; an intervention and record management system for the lab are currently being developed. ▪ **Rwanda** fully institutionalized skills programs for the NQCL and MRA in Q4.								
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								
Kazakhstan NCEM	0%	50%	83%	50%	50%	50%	50%	**50%**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Nepal DDA	17%	33.3%	50%	33.3%	33.3%	33.3%	50%	50%
Uzbekistan Agency	0%	16.7%	33.3%	16.7%	16.7%	16.7%	16.7%	16.7%
RB-PMS								
Bangladesh DGDA	0%	83.3%	90%	83.3%	83.3%	83.3%	83.3%	83.3%
Burkina Faso ANRP	0%	83.3%	83.3%	83.3%	83.3%	83.3%	83.3%	83.3%
DRC DPM	0%	33.3% (adjusted)	75%	33.3%	33.3%	33.3%	33.3%	33.3%
Ethiopia EFDA	0%	50%	No target	50%	50%	50%	50%	50%
Ghana FDA	0%	33.3% (adjusted)	83.3%	33.3%	33.3%	33.3%	66.7%	66.7%
Kenya PPB	0%	66.7%	100%	66.7%	83.3%	100%	100%	100%
Liberia LMHRA	0%	33.3%	83%	33.3%	33.3%	83.3%	83.3%	83.3%
Mali DPM	0%	50%	66.7%	50%	50%	50%	66.7%	66.7%
Nepal DDA	17%	33.3%	50%	33.3%	50%	50%	50%	50%
Rwanda FDA	0%	n/a	66.7%	-	16.7%	33.3%	66.7%	66.7%
Senegal DPM	0%	66.7%	No target	66.7%	66.7%	66.7%	66.7%	66.7%
For institutionalization indicators, PQM+ tracks whether the counterpart has SOPs describing how to implement the new approach or use the new tool, is able to train its staff on the SOPs, and tracks implementation or results from implementing the intervention. PQM+ is working to institutionalize risk-based approaches at 13 MRAs. Nepal's DDA has begun developing RBI-related SOPs, a basic training curriculum, and a tracking system that displays risk rankings of manufacturers. Regarding RB-PMS, Kenya's PPB fully institutionalized the approach in PY3; Rwanda very quickly developed an implementation tracker and is preparing SOPs and internal training. At the end of Q4, Ghana has yet to develop RB-PMS SOPs and Mali needs to institute a means to track the results of the program. Nepal's DDA has begun work on SOPs, training, and a tracker, while Liberia's LMHRA can now train on and track the results of RB-PMS and is developing the SOP.								
3.2. Sustainable resources mobilized								
3.2b. PQM+-supported MRA analyzed its costs in the reporting period to support review of the fee structure or to improve budgeting & planning								
Burkina Faso (laboratory costs)	N/A	-	Yes	-	-	-	Yes	Yes
Guinea (laboratory costs)	N/A	-	Yes	-	-	-	Yes	Yes
Kenya PPB, laboratory testing (PY2)	No	-	Not PY3 indicator	No	Yes	-	-	Yes
Liberia LMHRA (registration costs)	No	-	Yes	-	-	Yes	-	Yes
Pakistan (cost recovery user fee model)				-	-	-	Yes	Yes

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
PQM+ supports MRAs and their QC laboratories in analyzing and reporting their costs. MRAs and QC laboratories can use these cost analyses to justify budget requests or changes in user fees. In PY3, PQM+ helped the NQCLs in Burkina Faso, Guinea, and Kenya analyze their laboratory costs and Liberia's LMHRA calculate its registration costs. To date, 6 countries (Bangladesh, Burkina Faso, Ethiopia, Guinea, Kenya, and Liberia) have analyzed laboratory testing costs, Ethiopia has calculated PMS costs, and Liberia has reviewed registration costs.								
OBJECTIVE 4: SUPPLY OF QUALITY-ASSURED ESSENTIAL MEDICAL PRODUCTS OF PUBLIC HEALTH IMPORTANCE INCREASED								
4a. Number of treatments of quality-assured medicine produced by PQM+-supported manufacturer								
Nigeria – Chlorhexidine gel			No target	-	1.26 million	-		**1.26 million**
Nigeria – Amoxicillin DT			No target	-	600,000	-		**600,000**
Nigeria – Co-trimoxazole			No target	-	75,000	-		**75,000**
PQM+-supported manufacturers produced the following medicines in PY3: ● Enough Chlorhexidine gel to prevent 1.26 million umbilical cord infections in newborns (1.26 million in the first half of the year and XXX in the second). ● Enough Amoxicillin DT to treat 600,000 severe pneumonia infections in children 2 – 12 months (600,000 in the first half of the year and XXX in the second) ● Enough Co-trimoxazole to treat 75,000 opportunistic infections in children > 5 years living with HIV/AIDS (75,000 in the first half of the year and XXX in the second) Note that many other PQM and PQM+-supported manufacturers continue to manufacture quality-assured medicines, but PQM+ in many cases is not able to obtain production data from these manufacturers.								
4.1. Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/dossiers supported								
4.1b. Number of product dossiers submitted by PQM+-supported manufacturers for a USAID-priority medical product, by quarter								
Core NTD	0	1	1	1	-	-	-	**1**
Tajikistan (TB medicines)	0	0	No target	-	-	-	9	**9**
In PY3, Core TB's support for NTD pharmaceutical manufacturers resulted in submission of one dossier in Q1 for Albendazole. Also, to increase registration and availability of quality-assured anti-TB medicines in Tajikistan, PQM+ selected two foreign companies to work with WHO prequalified manufacturers and, on their behalf, to compile and submit dossiers for registration in Tajikistan. This support resulted in two manufacturers successfully registering nine anti-TB medicines.								
4.1c. Percentage of milestones toward market authorization or WHO prequalification achieved by PQM+-supported manufacturer, by quarter								
Bangladesh ACI Ltd.**, 4FDC	N/A	32.5%	50%	42.5%	42.5%	42.5%	32.5%	**32.5%**
Core NTD, India-Mepro, albendazole chewable 400 mg	N/A	65%	No target	65%	65%	65%	85%	**85%**
Ghana Amponsah Efah, Alu 20/120 mcg	0%	17.5% (adjusted)	No target	35%	35%	35%	35%	**35%**
Ghana Atlantic Life Science Pharmaceutical, Oxytocin 10iu/mL	0%	17.5% (adjusted)	No target	17.5%	17.5%	17.5%	17.5%	**17.5%**
Ghana Entrance Pharmaceuticals, Alu 20/120 mcg	0%	0% (adjusted)	No target	35%	35%	35%	35%	**35%**
Ghana Entrance Pharmaceuticals, Alu 80/480 mcg	0%	25%	No target	25%	25%	25%	25%	**25%**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Ghana Ernest Chemists, Alu 20/120 mg	0%	17.5% (adjusted)	No target	17.5%	17.5%	17.5%	17.5%	**17.5%**
Ghana Kinapharma, iron folic acid tablet	0%	New PY3	No target	-	-	10%	10%	**10%**
Ghana M&G Pharmaceuticals Ltd., Amoxicillin DT 125 mg	0%	New PY3	No target	-	10%	10%	10%	**10%**
Ghana M&G Pharmaceuticals Ltd., zinc sulphate DT 10mg/20mg	0%	New PY3	No target	-	10%	10%	10%	**10%**
Nepal Chemidrug, Amoxicillin DT 125 mg/250	0%	Not PY2 indicator	No target	-	32.5%	42.5%	42.5%	**42.5%**
Nepal DJPL, Azithromycin 500 mg	0%	Not PY2 indicator	No target	-	32.5%	42.5%	42.5%	**42.5%**
Nepal DJPL, Zinc sulphate 20 mg	0%	Not PY2 indicator	No target	-	32.5%	42.5%	42.5%	**42.5%**
Nepal Magnus, Azithromycin 500 mg	0%	Not PY2 indicator	No target	-	32.5%	42.5%	42.5%	**42.5%**
Nepal Omnica, Zinc sulphate 20 mg	0%	Not PY2 indicator	No target	-	32.5%	42.5%	42.5%	**42.5%**
Nepal Quest, Azithromycin 500 mg	0%	Not PY2 indicator	No target	-	32.5%	42.5%	42.5%	**42.5%**
Nigeria DailyNeed amox DT 125 mg	N/A	25%	No target	25%	25%	25%	25%	**25%**
Nigeria DailyNeed amox DT 250 mg	N/A	25%	No target	25%	25%	35%	35%	**35%**
Nigeria Emzor Alu 20/120 mcg	N/A	22.5%	No target	22.5%	22.5%	30%	30%	**30%**
Nigeria Emzor SP 500+25	N/A	22.5%	No target	22.5%	22.5%	30%	30%	**30%**
Nigeria Juhel magnesium sulphate inj	N/A	70% (adjusted)	No target	70%	70%	80%	80%	**80%**
Nigeria Juhel oxytocin 10iu/mL	N/A	50%	No target	50%	50%	50%	50%	**50%**
Nigeria May & Baker Alu 20/120 mcg	N/A	10%	No target	10%	10%	42.5%	42.5%	**42.5%**
Nigeria May & Baker Alu 80/480 mcg	N/A	0%	No target	10%	10%	10%	10%	**10%**
Nigeria Nemel amox DT 125 mg	N/A	50%	No target	50%	50%	50%	50%	**50%**
Nigeria Nemel amox DT 250 mg	N/A	50%	No target	50%	50%	50%	50%	**50%**
Nigeria Swiss Pharma Alu 20/120 mcg	N/A	42.5%	No target	42.5%	42.5%	42.5%	42.5%	**42.5%**
Nigeria Swiss Pharma SP 500+25	N/A	65%	No target	65%	65%	70%	70%	**70%**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Nigeria Swiss Pharma zinc sulphate 20 mg	N/A	65%	No target	70%	70%	70%	70%	**70%**
Pakistan CSH Pharma, amoxicillin DT 250 mg	N/A	New PY3	No target	-	-	35%	35%	**35%**
Pakistan Dynatis, zinc sulphate 20 mg	N/A	New PY3	No target	-	-	57.5%	57.5%	**57.5%**
Pakistan Mector, amoxicillin DT 250 mg	N/A	New PY3	No target	-	-	35%	35%	**35%**
Pakistan NextPharma, zinc sulphate 20 mg	N/A	New PY3	No target	-	-	52.5%	52.5%	**52.5%**
Pakistan PharmaEVO, zinc sulphate 20 mg	N/A	New PY3	No target	-	-	57.5%	57.5%	**57.5%**
Pakistan Schazoo, 4FDC anti-TB medicine	N/A	New PY3	No target	-	-	50%	50%	**50%**
Uzbekistan Nobel, levofloxacin	N/A	35% (adjusted)	50%	50% (adjusted)	50%	50%	50%	**50%**
Achievement of market authorization or WHO prequalification for a new medical product is a long process with many stages (see Table A.2 above). For this reason, PQM+ tracks and reports progress in achieving the major milestones. Manufacturers can be at any phase for an extended period of time, for example, while the various studies are being completed. Of note, in PY3, PQM+ began working with 5 new manufacturers in Nepal (3 new products), 2 new manufacturers in Ghana (three new products), and 6 manufacturers in Pakistan (3 products). PQM+ also provides ongoing support to 6 manufacturers in Nigeria pursuing WHO PQ of their products. **PQM+ was supporting ACI/2DC anti-TB meds in PY2. However, as of PY3, PQM+ is only supporting ACI to produce 4FDC. PY2 reporting was for 2DC; reporting for PY3 and beyond is for 4FDC ONLY.								
4.3. Capacity for market intelligence and analytics of public health pharmaceutical markets increased								
4.3a. Number of market profiles or market analyses for priority medical products developed by PQM+, by quarter								
Core MNCH, *Survey of Manufacturers of Amoxicillin and Beta-Lactam Products in Africa*	0	0	Not PY3 indicator	0	1	0	0	**1**
4.4. Capacity for market intelligence and analytics of public health pharmaceutical markets increased								
4.4a. Health coverage schemes that incorporate medical product quality requirements supported, by quarter [ADAPTATION: Medicines policies]								
Nepal – developed guideline on QA in procurement; contributed to National Medicines Policy				0	0	0	2	**2**
Pakistan – draft National Medicines Policy Implementation Plan				0	0	0	1	**1**
Rwanda – procurement framework and SOPs for Rwanda Medical Supplies				0	0	1	0	**1**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
PQM+ helps host governments develop and implement National Medicines Policy (in Nepal, in PY3), and helps procurement agencies incorporate quality requirements into their procurement policies, procedures, and decisions to help improve the quality of medicines available to the public. There were two examples of work to improve procurement – in Nepal and Rwanda.								
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 supported by PQM+, by quarter								
Core TB (validated method for testing nitrosamine impurities in rifapentine)	0	0	1	0	0	0	1	**1**
Cross Bureau (minilab dexamethasone screening method & guideline)	0	3	1	0	0	1	0	**1**
Cross Bureau Covid-19 (models to build capacity for EUA for vaccines and IVDs)	0	0	2	2	0	0	0	**2**
Cross Bureau (minimum common standards for RIMS)				0	0	0	1	**1**
Ethiopia (2 cold chain checklists, Excel database for GMP inspection findings)	0	0	No target	0	3	0	0	**3**
Ethiopia ARP (RB-inspection checklist)	0	0	1	0	1	0	0	**1**
Kazakhstan (competency framework for adult learning)	0			-	-	-	1	**1**
Kenya (self-directed online learning platform)	0	0	1	0	0	1	0	**1**
Nigeria (job aids on drug QA for patent medicine shops & community pharmacies)	0	0	No target	2	0	0	0	**2**
Pakistan (GMP inspection report template)	0	0	1	1	0	0	0	**1**
Pakistan COVID-19 Vaccine (to monitor & respond to AEFIs)	0	0	1	1	0	0	0	**1**
Rwanda (MRA training tracking tool with dashboard)	0	n/a	No target	0	0	0	1	**1**
Total 5.1a				**6**	**4**	**2**	**3**	**15**
PQM+ develops new processes or tools (not previously used by counterparts) to improve medical product quality, enhance efficiency, or improve sustainability. In PY3, PQM+ supported 16 such tools. On a global level, these included a method for testing nitrosamine impurities in rifapentine; a screening method and guideline for dexamethasone								

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
using minilab; and models to build capacity for EUA for vaccines and IVDs. There were also numerous instances of counterparts developing and adopting use of tools to improve or facilitate their work. The PQM+ buy-ins in Ethiopia, Kenya, Liberia, Nigeria, Pakistan, and Rwanda reported new approaches/tools this year.								
5.1b. Number of PQM+-supported entities that adopted a PQM+-promoted global tool, by quarter								
Bangladesh-MedRS	0	0	1	0	0	0	1	**1**
DRC-MedRS	0	0	1	0	0	1	0	**1**
Ethiopia-*Guidance Document on RB-PMS of MNCH Products*	0	0	2	0	0	2	0	**2**
Ethiopia-MedRS	0	0	1	0	0	1	0	**1**
Ghana-*Guidance Document on RB-PMS of MNCH Products*	0	0	1	0	1	0	0	**1**
Guinea LNCQM-SATTA	0	0	1	0	0	0	1	**1**
Liberia-*Guidance Document on RB-PMS of MNCH Products*	0	0	1	1	0	0	0	**1**
Madagascar-MedRS	0	n/a	1	0	1	0	0	**1**
Mali Microbiology Laboratory-SATTA	0	0	1	0	1	0	0	**1**
Mozambique LNCQ-SATTA	0	n/a	1	0	0	0	1	**1**
Nepal DDA-MedRS	0	0	Not PY3 indicator	0	1	0	0	**1**
Nigeria-MedRS	0	0	1	0	0	0	1	**1**
Rwanda FDA-MedRS	0	n/a	1	0	1	0	0	**1**
Senegal LNCM-SATTA	0	0	1	0	0	1	0	**1**
Total 5.1b				**1**	**5**	**5**	**4**	**15**
With core funding, PQM and PQM+ have developed numerous approaches and tools that can be used by many countries to improve or assure medical product quality. Country buy-ins then introduce these tools to counterparts, who adopt them in their ongoing work. Examples are provided here. Training in the use of SATTA is part of PQM+'s lab strengthening strategy. Adoption of the tool will help laboratory staff conduct routine internal audits to identify areas for improvement. Four laboratories in Guinea, Mali, Mozambique, and Senegal adopted SATTA for internal audits in PY3. The MedRS tool is one of the keys to PQM+'s RB-PMS approach. It helps MRAs and TWGs develop risk-based sampling strategies to support PMS while maximizing available resources. In PY3, 7 additional countries (shown) adopted the tool. PQM+ offers an online version of the tool (MedRSv2). Thus far, 17 countries have subscribed and are using the online tool for PMS; 12 have completed at least one round of PMS using the tool. The *Guidance Document on RB-PMS of MNCH Products* (published by the Core MNCH Program in PY2) was used by MRAs in Ethiopia, Ghana, and Liberia this year.								
5.2. Research and analysis to support medical product quality assurance systems strengthening conducted								
5.2a. Number of technical publications or technical presentations authored by PQM+, by quarter								
Asia Bureau	0	0	No target	0	1 pres., 1 pub.	0	0	**2**
Bangladesh ARP	0	0	1	0	0	1 pres.	0	**1**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Burkina Faso	0	1	1	0	1 pub.	0	0	1
Burma	0	1	No target	1 pres.	0	1 pres.	1 pres.	3
Core MNCH	0	2	No target	0	1 pub.	1 pub.	2 pubs.	4
Core TB	0	1	No target	0	0	1 pub.	0	1
Cross Bureau	0	2	No target	3 pubs.	1 pub.	1 pres.	2 pubs.	7
Ethiopia	0	4	1	2 pres.	0	0	0	2
Ethiopia ARP	0	0	2	0	1 pub	0	1 pub	2
Kazakhstan	0	3	1	2 pres.	0	0	0	2
Kazakhstan ARP	0	0	1	1 pub.	0	0	1 pub	2
Kenya	0	5	3	1 pres.	3 pub.	2 pres.	0	6
Liberia	0	2	1	0	1 pres.	0	0	1
Nepal	0	0	No target	0	0	0	2 pubs.	2
Nigeria	0	0	No target	1 pub.	0	0	0	1
PQMPlus Global	0	3	No target	1 pub.	0	1 pub.	0	2
Pakistan	0	4	4	0	1 pres., 2 pub.	0	2 pres., 3 pub.	8
Pakistan COVID-19		7	No target	1 pres.	0	0	0	1
Pakistan COVID-19 Vaccine		0	No target	2 pres.	0	0	1 pres.	3
Uzbekistan	0	1	2	3 pres.	2 pres.	2 pres., 1 pub.	0	8
PQM+ Global			No target	1 pub.		1 pub.	2 pub.	4
Total 5.2a				**19**	**14**	**12**	**17**	**62**
PQM+ conducted 28 workshop and conference presentations and produced 34 new technical publications in PY3. In PY3, these numbers include PQM+ providing expert feedback on four WHO frameworks or guidelines: WHO Global Model Regulatory Framework for medical devices including IVDs (2 rounds of input); WHO antimalarial drug resistance guidelines; WHO Global competency framework for regulators of medical products; and WHO Biowaiver Project: preparation for Cycle V.5: Prioritization of API 6 ingredients.								
5.2e. Number of modules in the Foundations of GMP eLearning course that were completed, by quarter								
Core NTD	4,000	3,469	150	37	590	399	764	1,790
Users completed a total of 1,790 Foundations of GMP e-learning modules in PY3. Since April 2021, PQM+ has sent out reminders periodically to users who have not completed their modules. It appears this strategy may be helping to boost completion rates.								
5.3. Advocacy on the importance of medical product quality assurance for public health, including the link between medical product quality and AMR								

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
5.3a. Number of awareness-raising or advocacy activities around medical product quality supported by PQM+, by quarter								
Core MNCH	0	1	No target	0	0	1	0	**1**
Core NTD	0	0	No target	0	0	1	0	**1**
Core TB	0	0	No target	0	0	0	1	**1**
Cross Bureau	0	3	No target	0	0	4	0	**4**
Kazakhstan	0	1	1	0	0	0	1	**1**
Kenya	0	0	No target	0	1	0	0	**1**
Liberia	0	0	No target	0	0	2	0	**2**
Nepal	0	0	No target	0	0	0	3	**3**
Nigeria	0	0	No target	1	0	0	0	**1**
Uzbekistan	0	4	2	3	2	1	1	**7**
Total				**3**	**3**	**9**	**7**	**22**

Examples of PQM+ awareness-raising or advocacy activities include the following:

- **Core MNCH:** Presentation on quality bottleneck at amoxicillin DT and gentamicin consultative meetings
- **Core NTD:** West Africa Healthcare Show 2022 Accra, Ghana
- **Core TB:** US FDA webinar, attended by 3,458 people with registrants from 127 countries
- **Cross Bureau:** CEPI presentation/vaccine initiative; panelist at International Pharmaceutical Federation webinar; 2 SF cost model working group meetings in Kenya
- **Kazakhstan:** Visit from Uzbekistan lab team
- **Kenya:** Workshop to finalize ministerial advisory note
- **Liberia:** Donor's meeting in Monrovia for purposes of advocacy; USAID donation of lab equipment worth US$300,000+ to LMHRA, attended by the President of Liberia
- **Nepal:** PQM+ and DDA designed and aired public service announcements on national and regional radio stations (public awareness on dangers of SF medicines); DDA/NML learning visit to Pakistan to understand adoption of international standards & information management system for effective regulation of medical products; worked with Nepal Health Research Council on session (strategies for improving the quality of medicines and research in Nepal pharmaceutical sector) at NHRC's National Summit of Health and Population Scientists in Nepal.
- **Nigeria:** Delivered 2,500 IEC posters on identifying QA medicines to pharmacies & medicine vendors.
- **Uzbekistan:** Launch of Quality Club; hand over of HPLC to Andijan MQCL (with USAID participation); USAID visit to Tashkent Pharma Park; Uzbek-American pharmaceutical summit in Rockville, MD; World TB Day; advocacy around adopting EUA clause in policy; participation in international pharmaceutical forum

5.3b. Number of instances of media coverage of PQM+-supported medical product quality assurance-related events or topics, by quarter								
Bangladesh	0	13	10	8		2		**10**
Benin	0	0	1	1	1			**2**
Burkina Faso	0	9	No target		1			**1**
Core NTD	0	3	No target		1			**1**
DRC	0	0	No target		1	2		**3**
Ethiopia	0	6	No target	1		2	3	**6**

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Ghana	0	2	No target	2	2	2	2	8
Kazakhstan	0	8	2	1	2	1		4
Kenya	0	7	2	3			3	6
Liberia	0	8	No target	1	1	2		4
Madagascar	0	n/a	1		2			2
Mali	0	4	2	1				1
Mozambique	0	0	No target		2			2
Nepal- social media	0	19	No target				3	3
Nigeria- social media	0	5	No target			1	4	5
Pakistan	0	31	No target			2	5	7
Pakistan COVID-19	0	6	No target	4				4
Pakistan COVID-19 Vaccine	0	0	No target	1				1
Rwanda- social media	0	n/a	No target			1	2	3
Senegal- social media	0	1	No target			1	1	2
South Africa Global VAX- social media	0	n/a	No target				1	1
Uzbekistan	0	10	6	3	7	1	4	15
Total 5.3b				**26**	**20**	**17**	**28**	**91**
External Partnerships								
CC.PPP.a. Number of new external partnerships that PQM+ helped establish, by quarter								
Bangladesh	0	1	7	4 (adjusted)	0	0	0	4
In Q1, PQM+ established the following partnerships: National TB Control Program of DGHS (collaborative work to implement TB activities); Bangladesh Association of Pharmaceutical Industries (partner for API/seminars on GxP); Bangabandhu Sheikh Mujib Medical University and Healthcare Pharmaceuticals (a for-profit business)—partners for vaccine testing to support NCL, DGDA.								
Burma	0	0	1	0	1	0	0	1
Working with YSI Pharmaceuticals to strengthen its cGMP & prepare its laboratory for ISO 17025:2017 accreditation.								
Core MNCH	0	0	1	0	1	0	0	1
PQM+ established a partnership with Newborn Essential Solutions and Technologies 360 (a PVO developing and delivering a bundle of high-quality products and services for hospital-based newborn care). Discussing development of a guidance document on quality testing methods for priority MNCH medical devices.								
Cross Bureau	0	0	No target	0	0	1	0	1

Indicator Code and Name	Baseline	PY2 Actual	PY3 Target	PY3Q1	PY3Q2	PY3Q3	PY3Q4	PY3 Total
Coalition for Epidemic Preparedness Innovations (PQM+ and USP Presentation to CEPI in Q3)								
Ethiopia	0	8	No target	0	1	0	0	1
Collaborated with Ethiopian Pharmaceutical Association to develop continuous professional development materials and training on GSP and GDP. The official accreditation body, College of Health Sciences at Addis Ababa University, reviewed and accredited the course in Q3.								
Ghana	0	4	2	0	1	1	0	2
PQM+ began work with two local for-profit companies, Kinapharma and M&G Pharmaceuticals, to manufacture products for market authorization.								
Kazakhstan	0	0	2	0	2	0	0	2
Began engaging pharmaceutical manufacturers' association and TB manufacturers to understand the needs of manufacturers in improving their GMP compliance. Outcomes: coordination of pharmaceutical manufacturers' association with NCEM/SEC to ensure manufacturers are current on GMP requirements, training needs assessment, identification of TA needs of TB manufacturers.								
Liberia	0	0	2	0	0	1	1	2
Local manufacturer (Global Pharmaceutical) addressing findings from LMHRA's GMP inspection; School of Pharmacy, University of Liberia curriculum of short courses to train health care workers in medical products QA in the short-to-medium term								
Nepal	0	0	No target	0	5	0	2	7
Working with 5 manufacturers to obtain WHO prequalification for selected medicines; Health Insurance Board to assess government-owned health facilities that provide health services through the insurance scheme; assisting the country's public pharmaceutical company to achieve GMP compliance.								
Nigeria	0	2	No target	1	0	0	0	1
Established partnerships with Pharmaceutical Manufacturers' Group of the Manufacturers' Association of Nigeria (PMGMAN) in PY1.In PY3, PQM+ trained PMGMAN members on the fundamentals of validation to increase GMP knowledge and skills within the industry.								
Pakistan	0	5	2	0	2	0	0	2
Healthcare Devices Association (domestic organization) and MECOMED (international medical devices association). Latter provided training on EU medical device regulations.								
Rwanda	0	n/a	1	0	1	0	0	1
Collaborated with University of Rwanda through the Regional Centre of Excellence for Vaccines Immunization and Health Supply Chain Management; updated and validated a master's program in pharmaceutical quality control and quality assurance.								
Tajikistan	0	n/a	No target	0	0	2	0	2
Worked with two new manufacturers of WHO PQ TB medicines (Lupin and Svizera) to register their products in Tajikistan.								
Uzbekistan	0	1	1	1	0	0	0	1
PQM+ helped strengthen the Association of Domestic Manufacturers (conducted Quality Club meeting with Agency, Agency's staff board, and association)								
Total CC.PPP.a				**6**	**14**	**5**	**3**	**28**

Annex 1A. RB-PMS Results Concluded in PY3, by Country

Country	Regions sampled	Medicines sampled	No. of samples collected/tested	Results from PMS concluded in PY3
Burkina Faso, round 1, 2021-2022	7 regions (Central, Central-East, Central-North, East, Haut-Bassins, North, and Plateau Central) (Facilities randomized by risk of geographic area)	Anti-malarials—artesunate, artemether, and quinine injections and sulfadoxine/ pyrimethamine tablets	320 samples	▪ No samples failed ▪ 68% of samples unregistered ▪ Results not nationally representative
DRC, round 1, 2021-2022	3 of 26 provinces: Kinshasa, Maniema, Tshopo (Facilities randomized by risk of geographic area)	Anti-malarials—artemether injection, artemether/ lumefantrine compressed dispersible tablet and suspension powder, artesunate powder for injection and suppository, dihydroartemisinine/ piperaquine phosphate compressed dispersible tablet and suspension powder, quinine sulfate compressed, quinine liquid oral drop solution, quinine bichlorhydrate injection, and sulfadoxine/ pyrimethamine compressed	303 samples	▪ 3% of samples failed—quinine sulfate tablets, quinine oral solution (drops), artemether injection ▪ 22% of samples unregistered ▪ Results not nationally representative ▪ DPM has outlined steps to determine the source of SF and unregistered medicines and to learn how they reach market to help determine appropriate regulatory action.
Ethiopia, round 1, 2021-2022	7 regions (Afar, Amhara, Diredawa, Gambela, Oromia, SNNP, Somali) (Facilities randomized by risk of geographic area)	Anti-malarials—artesunate injection 60mg/30mg, artemether injection, primaquine phosphate tablet, and quinine sulfate tablet MNCH—oxytocin injection	270 samples were supposed to be collected but, because of security issues and a shortage of medicines at the time of collection, only 70 (53 anti-malarial, 17 oxytocin) samples could be collected and tested.	▪ 5.9% (1 oxytocin sample) ▪ All anti-malarials passed ▪ Results not nationally representative
Ghana round 1, 2021-2022	5 of 10 original regions (Ashanti, the former Brong-Ahafo, central, eastern, and greater-Accra regions) (Facilities randomized by risk of geographic area)	Anti-malarials—artesunate injection, artemether injection, and artemether/ lumefantrine dispersible tablet MNCH—oxytocin injection and misoprostol tablets	378 samples	▪ 11% of samples (42) failed. Failure rates for specific medicines were: 45% oxytocin, 6% misoprostol, 0.6% antimalarials ▪ 35% of samples unregistered (12 anti-malarials, 7 oxytocin brands) ▪ Results not nationally representative

Country	Regions sampled	Medicines sampled	No. of samples collected/tested	Results from PMS concluded in PY3
				▪ Products seized—artesunate injection (5,476+ vials), artemether injection (2 ampoules), oxytocin (342 ampoules), and misoprostol (4 packs & 150 tablets). Also fines to the tune of GHS 350,000 were issued to two regions.
Kenya, round 1, 2021-2022	17 counties across the country (Facilities randomized by risk of geographic area)	Anti-malarials—artesunate injection 60mg/30mg and artemether 20 mg + lumefantrine 120mg tab(6s) MNCH—oxytocin injection 10IU/5IU/mL ampoules and gentamycin 20 mg/2mL injection	285 samples	▪ 0% failed ▪ Results not nationally representative ▪ PPB wrote to the manufacturer of artemether lumefantrine to update the labelling of products per the product's registration requirements. Labelling should include the complete address of the manufacturing site.
Liberia, round 1, 2021-2022	5 of 15 regions: Nimba, Gbarpolu, Lofa, Gand Gedeh, Sinoe (Facilities randomized by risk of geographic area)	Anti-malarials—artesunate 60mg/mL injection, artemether 20mg/80mg/mL injection, artemether 20mg/120mg lumefantrine suspension, and quinine dihydrochloride 600mg/2mL injection MNCH medicines—oxytocin injection, magnesium sulfate injection, and ergometrine maleate tablet	303 malaria & MNCH samples	▪ 29% (46 malaria and 41 MNCH samples) failed ▪ 57% of samples unregistered ▪ Results nationally representative ▪ In Q1, LMHRA seized 36 cartons of quinine injections (batch #200531) and 34 boxes of quinine injections (batch #190841) ▪ In Q2, LMHRA confiscated 750 pieces of quinine tablets and 28 boxes of amoxicillin from 2 pharmacies in Monrovia; and 25 boxes of quinine from a leading importer of pharmaceutical products in Liberia
Mali, round 2, 2021-2022	5 regions: Bamako, Kayes, Koulikoro, Sikasso, Segou (Facilities randomized by risk of geographic area)	Anti-malarials—artesunate injectable, artemether+lumefantrine, quinine injectable, artemether injectable MNCH medicines—oxytocin injection, diazepam injection, magnesium sulfate injection, and tranexamic acid injection	320 samples (225 antimalarials, 95 MNCH)	▪ 4% failed (1% antimalarials, 4% MNCH medicines [diazepam injection]) ▪ 74% of samples unregistered ▪ Results not nationally representative ▪ 4 lots diazepam, 1 lot of combiart recalled
Nigeria, round 1, 2021-2022	11 PMI priority states plus FCT	Anti-malarials—artesunate/amodiaquine, SP, quinine sulfate, artemether injection, artesunate injection, and dihydroartemisin/piperaquine phosphate) MNCH—misoprostol, oxytocin	448 samples	▪ 5.1% failed (7.5% artesunate/amodiaquine, 9.2% artemether/ lumefantrine, 10.1% sulfadoxine/ pyrimethamine) ▪ Results not nationally representative

Annex 1B. List of laboratories pursuing new accreditations, by type of accreditation and year obtained (where relevant)

NQCLs (except where indicated)	ISO 17025:2017	WHO PQ	ISO 15189	ISO 17043	ISO 13485
Bangladesh Central Drug Testing Laboratory	x				
Bangladesh Microbiology Laboratory		x			
Bangladesh Plasma Plus Application & Research Testing Lab (private)	x	x			
Bangladesh Physiochemical Laboratory		2020 (10 methods)			
Bangladesh Vaccine Chemical Laboratory		x			
Benin ANCQ	x				
Burkina Faso LNSP	x				
Burma YSI Pharmaceuticals QCL (private)	x				
DRC LNCQ-LAPHAKI	x				
Ethiopia FDA branch laboratory Diredawa	x				
Guinea LNCQM	x				
Kazakhstan Almaty		x			
Kazakhstan Karaganda		2020			
Liberia LMHRA QCL	x				
Liberia National Standards Lab	x				
Madagascar LNCQM	x				
Mali LNS	x				
Mali Microbiology Laboratory	x				
Mali Medical Devices Laboratory					x
Mozambique DCQ	x				
Nepal NML	x				
Nigeria NAFDAC Yaba (in vitro diagnostics)	x				
Nigeria NAFDAC Agulu (medical devices)	x				
Nigeria Vaccines and Biologics Laboratory					x
Pakistan Appellate Lab	x				
Pakistan CDL, Karachi		x			
Pakistan DTL, Punjab, Bahawalpur		x			
Pakistan DTL, Punjab, Lahore (calibration)	x	x			
Pakistan DTL, Punjab, Multan		x		x	
Pakistan DTL, Punjab, Rawalpindi		x			
Pakistan IPH Diagnostic Laboratory, Lahore			2022		
Pakistan Institute of Medical Sciences Diagnostic Laboratory			x		
Rwanda QCL	x				
Senegal LNCM	x				

NQCLs (except where indicated)	ISO 17025:2017	WHO PQ	ISO 15189	ISO 17043	ISO 13485
Tajikistan Dushanbe	2022				
Uzbekistan Andijan		x			
Uzbekistan Tashkent		x			

Annex 1C. Accreditations, pre-qualifications, re-accreditations, and re-qualifications under PQM+

NQCLs	Baseline	ISO 17025:2017	WHO PQ
Bangladesh Physiochemical Laboratory	▪ ISO 17025:2017 (10 methods), 2018 PQM	Re-accredited 2020 and 2021 (12 methods)	Re-qualified 2021 (16 methods)
Burma Nay Pi Taw	▪ ISO 17025:2005 (10 methods), 2016, re-accredited 2017, PQM ▪ ISO 17025:2017 re-accredited 2018, 2019 PQM	Re-accredited 2020, 2021, 2022 (10 methods)	
Kazakhstan Almaty	▪ ISO 17025:2017 re-accredited/EDQM 2019 PQM	National re-accreditation 2020	
Kazakhstan Karaganda			2020
Ethiopia PQAD	• ISO 17025:2017 re-accredited 2019 PQM	Re-accredited 2021, 2022	
Nigeria Agulu	• ISO 17025:2017, 2019 PQM (7 methods)	Re-accredited 2020, 2021, 2022 (7, 16, 16 methods)	
Nigeria Kaduna	• ISO 17025:2017, 2019 PQM (7 methods)	Re-accredited 2020, 2021, 2022 (7, 16, 16 methods)	
Nigeria Yaba	• ISO 17025:2017, 2019 PQM (7 methods)	Re-accredited 2020, 2021, 2022 (7, 17, 17 methods)	
Nigeria Vaccines & Biologics Laboratory	• ISO 17025:2017, 2019 PQM (10 methods)	Re-accredited 2020, 2021, 2022 (10, 14, 23 methods)	
Nigeria NIPRD	• ISO 17025:2017, 2019 PQM (6 methods)	Re-accredited 2020, 2022 (6, 6 methods)	
Uzbekistan Andijan	National recertification 2019	National 2021	
Uzbekistan Tashkent	National recertification 2019	National 2020, 2021	