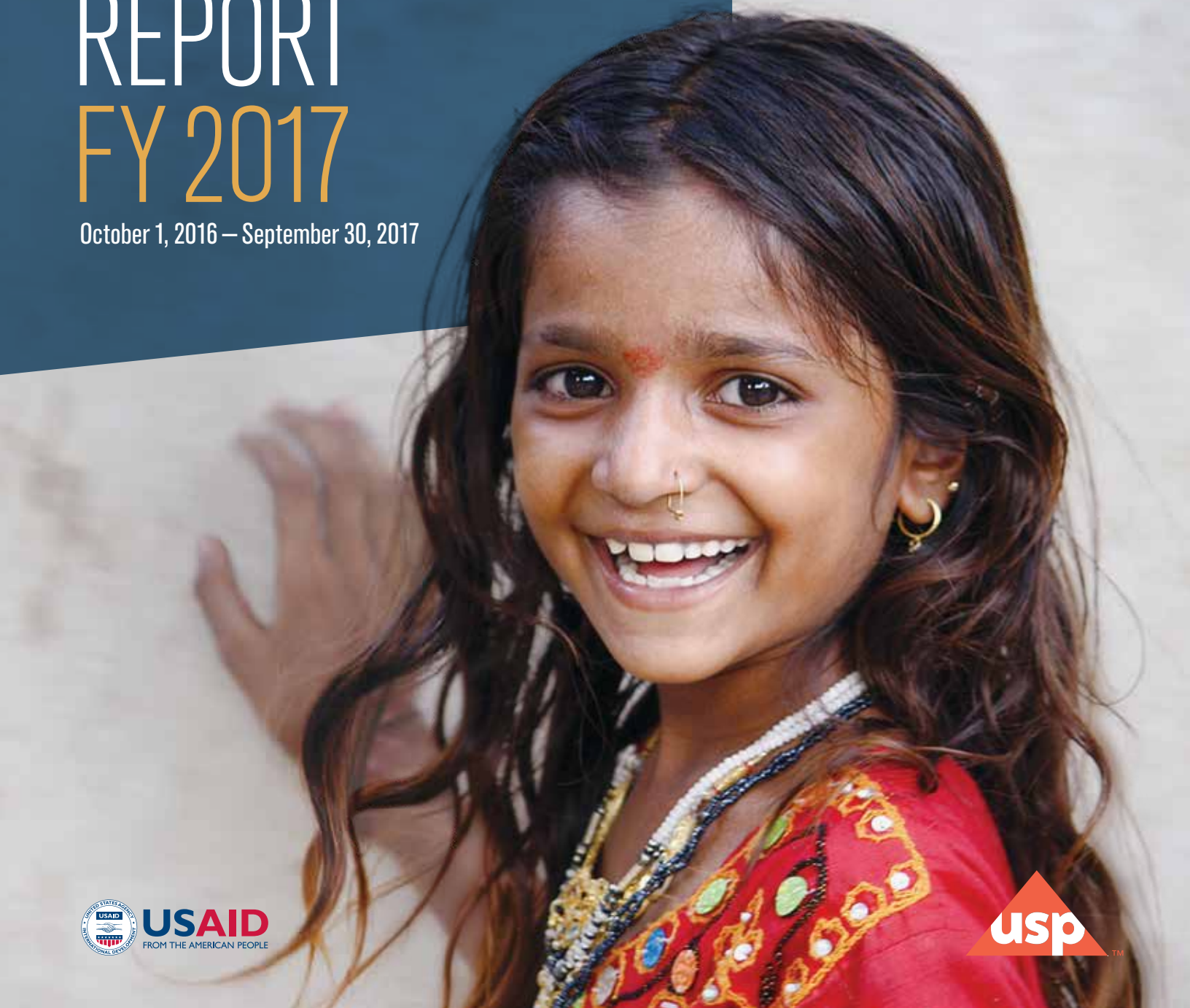
PQM Promoting the Quality of Medicines

ANNUAL PERFORMANCE REPORT FY 2017

October 1, 2016 – September 30, 2017



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Contents

Note from the Director

The Promoting the Quality of Medicines (PQM) program is funded by the U.S. Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention (USP). The PQM program provides technical assistance to strengthen medicines regulatory authorities and quality assurance systems and supports manufacturing of quality-assured priority medicines. This year we celebrate the 8th anniversary of the PQM program as well as the noteworthy progress made by countries and institutions with PQM support. I am pleased to present our 2017 Annual Performance Report, which documents the major accomplishments this year from the three intermediate result areas.

Of the many highlights in each result area, I'd like to share just a few to illustrate our work throughout the year. Our teams in Mozambique and Guinea provided technical assistance for the development of national-level regulations that will have lasting effects on quality assurance of medicines. In an effort to increase the supply of quality-assured priority medicines globally, our team working on good manufacturing practices supported the prequalification or approval of three active pharmaceutical ingredients and four finished pharmaceutical products for tuberculosis, neglected tropical diseases, and maternal and child health. At the local level, good manufacturing practices were improved for manufacturers in Pakistan, leading the first locally produced, affordable, and quality-assured chlorhexidine, essential for preventing umbilical cord infections in newborns, in the country. Quality-assured oxytocin, a key maternal health product, is also a challenge across many low- and middle-income countries. In Nigeria a survey indicated that 74 percent of samples tested failed. As a result, PQM facilitated a workshop on good storage and distribution practices for marketing authorization holders of the product, and the regulatory authority outlined that marketing authorization will not be approved to those without suitable storage facilities and that temperature tracking and trending should be done to ensure optimal efficacy. Also this year, PQM-supported Sanbe Farma in Indonesia produced the first generic oxytocin prequalified by the World Health Organization, leading to an increase in supply of this key product on the global market. Lastly, our work to increase the capacity of countries to use medical product quality information for decision-making resulted in 35 regulatory actions against substandard and falsified products across six countries.

Our team working on good manufacturing practices supported the prequalification or approval of three active pharmaceutical ingredients and four finished pharmaceutical products for tuberculosis, neglected tropical diseases, and maternal and child health.

As we transition to FY 2018, PQM remains dedicated to its goal of strengthening quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health. There is still work to be done, but we look forward to expanding on the accomplishments of this year.

It is a great honor to do the work we do, and to have the opportunity to collaborate with committed partners at the global, regional, and local levels. Please continue to follow our progress toward ensuring that quality-assured medicines are available to those who need them most around the world.

Jude I. Nwokike
Director, PQM Program

About the PQM Program

USAID Funding Sources	Bureau for Global Health, Office of Health Systems, Office of Infectious Disease, Office of Maternal/Child Health and Nutrition, USAID Country Missions
Name of Implementing Partner	Promoting the Quality of Medicines Implemented by the U.S. Pharmacopeial Convention
Cooperative Agreement Number	GHS-A-00-09-00003-00
Period of Performance	September 18, 2009, to September 17, 2019
Agreement Officer's Representative Team	Mr. Bob Emrey, Lead Health Systems Specialist Ms. Elisabeth Ludeman, Senior Pharmaceutical Management Advisor Ms. Tobey Busch, Senior Pharmaceutical Management Advisor
PQM Responsible Staff	Mr. Jude Nwokike, Director

The Promoting the Quality of Medicines (PQM) program is a Cooperative Agreement between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP). Since 1992, USP has worked with USAID to address critical pharmaceutical management challenges in low- and middle-income countries. The earliest program, the Rational Pharmaceutical Management Project, implemented and evaluated country-specific drug information resource programs in selected developing countries. Subsequently, the Drug Quality and Information program focused on medicines quality control and quality assurance systems. The PQM program (2009–2019) provides technical assistance to strengthen medicines regulatory authorities and quality assurance systems and supports manufacturing of quality-assured priority medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

As of September 2017, USAID supports PQM's work in 20 countries, two Regional Missions, one Cross Bureau program, and four core health programs.

Promoting the Quality of Medicines. 2017. Promoting the Quality of Medicines Program Annual Performance Report: Fiscal Year 2017, October 1, 2016–September 30, 2017. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, MD: United States Pharmacopeial Convention (USP).

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Acronyms

API	Active pharmaceutical ingredient
BE	Bioequivalence
CEP	Certificate of Suitability
CLM	Collaborative Learning Model
CRO	Clinical research organization
CTD	Common Technical Document
DT	Dispersible tablet
ERP	Expert Review Panel
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
IEC	International Electrotechnical Commission
IR	Intermediate Result
ISO	International Standardization Organization
M&E	Monitoring and evaluation
MNCH	Maternal, newborn, and child health
MRA	Medicines regulatory authority
NMCP	National Malaria Control Program
NTD	Neglected tropical diseases
PMS	Post-marketing surveillance
PQ	Prequalification
PQM	Promoting the Quality of Medicines
QA	Quality assurance
QC	Quality control
QMS	Quality management system
SOP	Standard operating procedure
TB	Tuberculosis
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeial Convention
WHO	World Health Organization
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USP	United States Pharmacopeial Convention
WHO	World Health Organization

Background

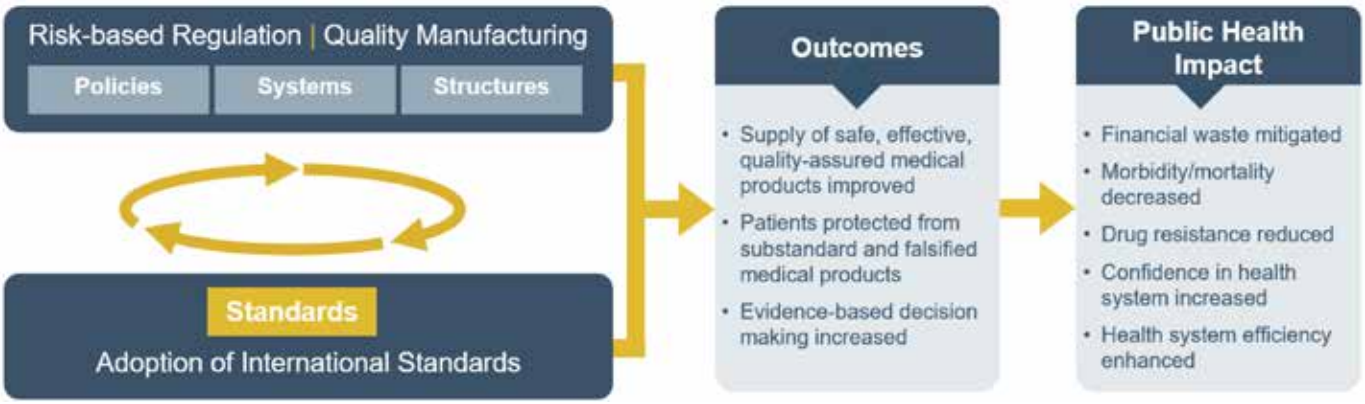
Each year, tens of thousands of deaths globally are attributed to falsified and substandard medical products. Some medicines are intentionally falsified to generate profit, while others are produced under conditions that result in less than optimal quality, degrade under poor storage conditions, or are adulterated somewhere along the supply chain under weak regulations. The effects of poor-quality medicines expand beyond loss of life—increased drug resistance, loss of labor productivity, wasted resources, and lost confidence in the health system are all unfortunate byproducts. The impact of poor-quality medicines is hardest felt in low- and middle-income countries, which may be more vulnerable to weak regulatory oversight compounded by limited resources, porous borders, and inadequate legislation and means to prosecute offenders.

Any sustainable solution must be based on a system strengthening approach at the national and local levels that focuses on streamlining the regulatory process and increasing the supply of quality-assured medicines. Building on a foundation of recognized standards is paramount to achieving Risk-based Regulation and Quality Manufacturing. In addition, appropriate attention needs to be placed on effective policies, systems, and procedures as they are interconnected. The Medicine Quality Assurance Framework below depicts the areas that are critical to achieving expected outcomes and positive health impact towards a resilient health system.

The Promoting the Quality of Medicines (PQM) program is a cooperative agreement between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP). Since 1992, USP has worked with USAID to support low- and middle-income countries in addressing critical issues related to medicines information and quality. The PQM program provides technical assistance to build the capacity of medicines regulatory authorities and quality assurance systems in countries with weak health systems. PQM also provides technical support to manufacturers of quality-assured priority medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

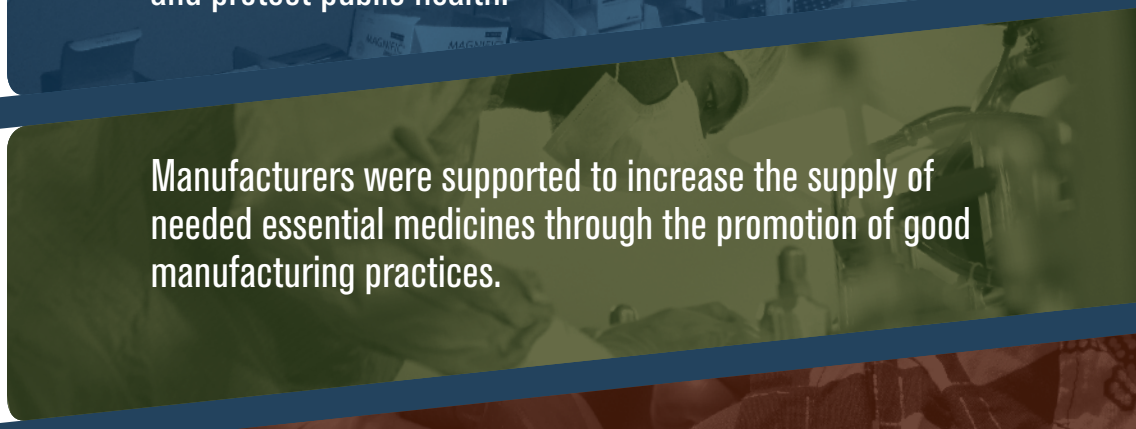
During FY 2017, PQM implemented projects in with support from 20 USAID country Missions, 2 Regional Missions, 1 Cross Bureau program, and 4 core health programs.

Medicine Quality Assurance Framework



FY17 Key Achievements and Successes

124 Regulatory actions were taken in 6 countries to identify falsified and substandard medicines along the supply chain, remove them from the market, and protect public health.



62 Manufacturers were supported to increase the supply of needed essential medicines through the promotion of good manufacturing practices.

66 Medicine quality control laboratories in 8 countries were supported toward improving their standard of practice.

7 Priority medicines were successfully prequalified or stringent regulatory authority approved, helping to avert potential shortages.

4 National quality control laboratories in Africa and Asia achieved ISO 17025:2005 accreditation or WHO prequalification, certifying laboratory competency against stringent international standards.

Technical Approach

Our Approach

The PQM approach reflects a holistic view of medicines quality assurance—seeking to address quality-related aspects of medicine production, patient use, and everything in between—to strengthen and improve the systems, structures, and processes that promote product quality. This approach recognizes the dynamic and cross-cutting relationships among different components of the health system, and therefore seeks to address product quality issues in a sustainable manner using systems-based thinking and solutions. The framework below serves as a visual guide for how we build quality assurance systems for medicines by working with key stakeholders in the areas of quality manufacturing and risk-based regulation to achieve critical public health outcomes.

Strengthening Regulatory Systems

To improve the availability of safe, effective, and quality-assured medicines in low- and middle-income countries, PQM partners with regional and national regulatory authorities, national quality control laboratories, academic institutions, and other international organizations to strengthen local capacity to carry out key quality assurance functions, including product registration, inspections of medicine producers and distributors, and post-marketing surveillance. Spanning multiple aspects of the health system, we work to support the adoption of effective and enforceable policies and legislation, bolster human resource capacity to effectively manage product quality, and harness information to facilitate transparent, accountable, and evidence-based decision-making at all levels.

An important component of our work is collaborating with regulatory authorities to design and implement technically sound and sustainable risk-based medicines surveillance programs that are responsive to unique country contexts and needs. Moving from intermittent medicines quality monitoring to risk-based post-marketing surveillance programs is critical to ensure the quality of medicines. This risk-based approach optimizes the use of resources and enables countries to transition from donor-supported sampling and testing activities to locally funded and sustainable post-marketing surveillance programs.

As part of these efforts, we work with national quality control laboratories to strengthen systems that enable them to accurately and reliably test the quality of medicines.

Technical Areas of Expertise

Regulatory	Quality Control Laboratories	Manufacturing
• Laws, policies, regulation • Quality assurance guidelines • Dossier evaluation • Product registration • Inspections • Integrated information management • Post-marketing surveillance • Bioequivalence studies	• Quality management systems • Analytical instrumentation support • Support for WHO/ISO accreditation • Analytical testing • Self-inspection	• Good manufacturing practices • Chemistry, manufacturing, and controls • Product and process development • Support for WHO/ISO accreditation • Common Technical Document (CTD) dossier compilation

Workforce development | Information management | Decision-making tools | Curriculum development

Through this support, the laboratories we work with pursue and achieve compliance with international standards, such as ISO/IEC 17025:2005 and the World Health Organization (WHO) prequalification program.

Increasing the Supply of Quality-Assured Medicines

To increase the supply of quality-assured essential medicines, PQM works to identify and support local and international manufacturers in producing priority medicines that meet internationally recognized good manufacturing practices (GMP) and standards set by the WHO prequalification program and/or regulatory authorities from countries with stringent standards. These efforts have helped to avert shortages of essential medicines and, in some cases, resulted in a substantial reduction in price.

PQM Principles

Risk-based and pragmatic solutions

Assessing local risks to public health helps prioritize interventions and direct human and financial resources where they are most needed.

Internationally recognized standards and best practices

PQM assists countries to build on existing systems to achieve international standards such as WHO prequalification and ISO 17025:2005.

Regional harmonization

Harmonization at the regional level helps leverage resources to address regulatory needs across multiple countries and encourages South–South collaboration.

Complementarity and partnership

PQM works with other implementing partners, multilateral organizations, government agencies, and academic institutions to coordinate efforts and maximize results.

Resilience and sustainability

We seek to improve the quality of medicines by addressing cross-cutting quality assurance issues that influence quality through systems-based approaches and solutions.

Innovation into Action: Approaches

Traditional laboratory training approaches follow a one-to-one or mentorship modeling method. In this approach to laboratory strengthening, laboratory staff are trained by foreign experts who provide short-term, in-country technical assistance. However, due to attrition and a lack of sustained local support, this model often prevents countries from effectively achieving scale.

The PQM Collaborative Learning Model (CLM) for laboratory strengthening consolidates and standardizes the training of multiple laboratories within a country. This approach promotes ownership and collaboration among the laboratory staff in the country, and reduces costs typically associated with decentralized training. In addition, if one laboratory experiences a high rate of attrition, new staff can be mentored by previously trained, tenured colleagues from neighboring laboratories, rather than relying on foreign assistance again.

PQM supports medicines regulatory authorities (MRAs) to implement risk-based approaches that help prioritize scarce resources toward activities that provide the greatest public health benefit. PQM guides MRAs to focus their resources on those pre-market activities that only the MRA itself can do but to rely on stringent regulatory authorities for regulatory information.

PQM also collaborates with MRAs to design and implement technically sound and sustainable risk-based post-marketing surveillance programs appropriate to unique country contexts. Moving from intermittent or ad hoc medicines quality monitoring to institutionalized risk-based post-marketing surveillance is critical to ensuring that MRAs focus sampling and testing efforts where the risk to the population is greatest. The risk-based approach maximizes use of scarce resources, creates efficiencies, and helps support countries to transition from donor-supported sampling and testing activities to locally funded and sustainable post-marketing surveillance.

Progress by Result Area: Highlights

PQM Goal > Quality assurance systems strengthened to sustainably ensure quality and safety of medical products and protect public health

Intermediate Result 1 (IR1) Medical products quality assurance systems strengthened

1.1 Quality assurance policies, legislation, guidelines, and procedures improved

Mozambique's parliament passes a bill to improve regulation of medical products

1.2 Registration, inspection, and licensing functions of medicine regulatory agencies sustainably improved (pre-market)

1.3 Standard of practice at national quality control laboratories sustainably improved

Agulu and Kaduna Zonal Laboratories in Nigeria both receive ISO 17025 accreditation

1.4 Institutional capacity for medical product quality assurance workforce sustainably improved

1.5 Capacity for post-marketing surveillance of medical products sustainably improved

A Workshop for Joint Sampling and Testing of TB and HIV Medicines is convened in Indonesia

IR2 Supply of quality-assured priority medicines increased

2.1 Supply of quality-assured priority medicines produced locally increased

Pakistan brings locally produced, affordable, quality-assured chlorhexidine to market

2.2 Supply of quality-assured priority medicines produced locally increased

Manufacturers achieve WHO PQ, CEP, or ERP approval for 8 TB, NTD, and MNCH products

2.3 Clinical research organizations compliance with good clinical practices and good laboratory practices increased

2.4 Sources of quality-assured API and FPP diversified and supply secured

IR3 Utilization of medical product quality information for decision-making increased

3.1 Availability of information related to quality of medical products increased

3.2 Enforcement actions against falsified, substandard, and unapproved medical products increased

Antimalarial products removed from circulation in Liberia

3.3 Information on quality assurance of medical products used for advocacy increased

IR1

PROGRESS BY
RESULT AREA

Medical products quality assurance systems strengthened

Medical products are instrumental to any health system, but only if they are safe, effective, and quality-assured. Quality, in particular, is paramount to ensuring that the safety and efficacy of medicines and medical products are maintained from the moment a product is manufactured, across the entire supply chain, until it reaches the patient.

By strengthening systems that help ensure quality—from developing effective and enforceable legislation, policies, and workforce capacity to helping implement regulations, guidelines, and operational procedures—the PQM program aims to address the end-to-end challenges that affect medicines quality. The ultimate goal is to reduce and eliminate substandard and falsified products that pose serious risks to the health of patients and undermine global health and development efforts.

1.1 Quality assurance policies, legislation, guidelines, and procedures improved

National medicines policies define the requirements that help ensure medicine access, quality, and rational use. A medicines policy also serves as the framework for developing sound pharmaceutical law, which provides the legal mandate for the creation of a national medicines regulatory authority (MRA). Working with in-country stakeholders at all levels, PQM helps to develop or revise policies, legislation and regulations, and guidelines by providing technical assistance to MRAs to ensure quality assurance topics are adequately covered and that the overarching regulatory framework is appropriate to their context and of internationally accepted standards.

This year, a key accomplishment within this result area can be seen in Mozambique, where the parliament unanimously passed a bill on Medicines, Vaccines, Biological and Health Products for Human Use. The bill amends the original law from 1998, which lacked key regulatory provisions. The groundbreaking bill gives the Pharmaceutical Department (PD) authority to improve regulation of the medical products in the country to ensure their quality, safety, and efficacy. To accomplish this important milestone, PQM collaborated with the PD and key partners and stakeholders to establish a technical working group that advocated for law revisions that would ensure critical quality assurance components were introduced and authorize the PD to perform key regulatory functions. Once signed by the president, this landmark bill and its application by the PD will create an environment that promotes medical products quality and protects patients.

Similarly in Guinea, PQM contributed to the revision of the pharmaceutical law through participation in a commission appointed by the Minister of Health to finalize the law revision. With PQM's support, the new draft law introduced clear and updated rules for licensing, registration, inspection, and post-marketing surveillance. The final text "Preliminary Draft Law on Medicines, Other Health Products and Pharmaceutical Exercise" was submitted to the Minister of Health and will subsequently be poised for adoption by the Council of Ministers and the National Assembly.

Mozambique's groundbreaking bill gives the Pharmaceutical Department authority to improve regulation of medical products to ensure their quality, safety, and efficacy.

PQM also supported the Ethiopian regulatory authority to develop a Pharmaceutical Manufacturer GMP Inspection Directive that was approved and issued, setting a legal binding framework on GMP inspection. This directive provides clear direction on how to process and access applications, handle complaints, and set responsibilities for inspectors. The directive also lays foundations for essential elements of GMP inspection to improve transparency, accountability, traceability, and competence of inspectors

in the process of enforcing requirements to conduct local and foreign GMP inspections by the authority. The improvement in the manufacturers' inspection process helps ensure that quality is built into the product and helps process timely marketing authorization for those meeting GMP requirements.

1.2 Registration, inspection, and licensing functions of medicine regulatory agencies sustainably improved (pre-market)

Among the key functions of an MRA, the registration or approval of medical products and the inspection and licensing of manufacturing facilities are crucial processes designed to ensure that only quality-assured products enter the market. PQM works with MRAs to build strong institutional capacity and support registration and licensing through hands-on training and technical assistance. By helping MRAs prioritize key issues through risk-based approaches, PQM guides regulatory agencies to focus their pre-market resources toward solutions that add value and will result in high-impact and sustainable health outcomes.

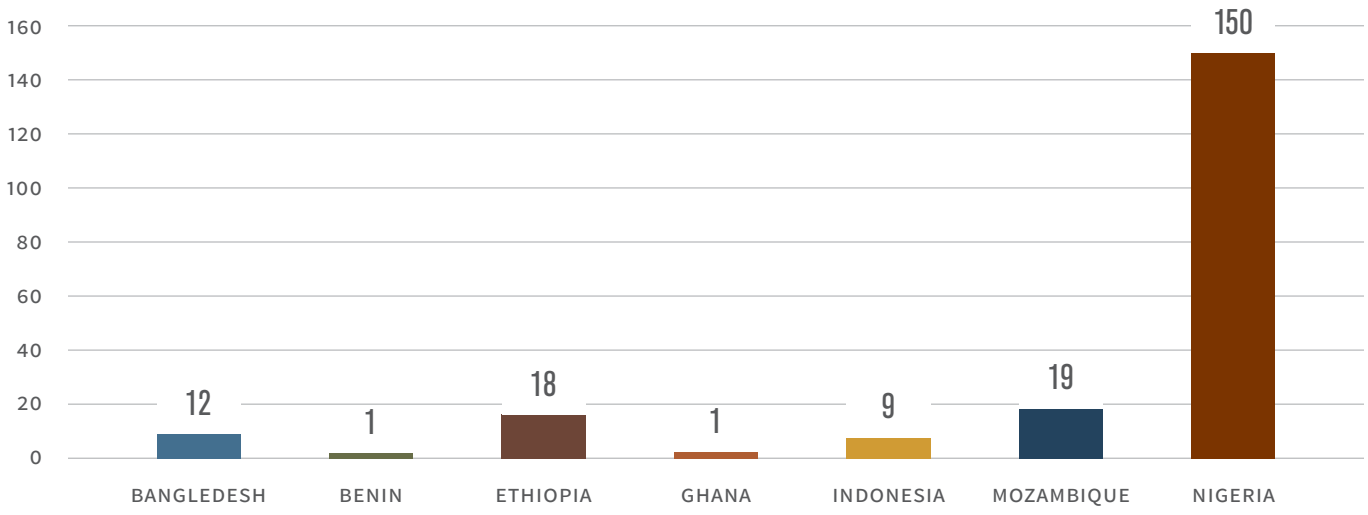
In tandem with the Pharmaceutical Manufacturer GMP Inspection Directive in Ethiopia, PQM provided technical assistance to the MRA (EFMHACA) to streamline the review process of 170 applications for marketing authorization approval. PQM supported EFMHACA to solve pending issues that delayed actual approval of dossiers after the primary review by facilitating and participating in discussions with a group of relevant technical staff. These discussions resulted in the issuance of market authorizations for 170 out of 190 applications (which had been on hold for various reasons), resulting in the timely availability of critical essential medicines, including antiretrovirals and products for opportunistic infections and maternal and child health. The remaining 20 were noted as having deficiencies that need to be corrected prior to approval.

PQM also provided technical assistance to EFMHACA to strengthen its inspection practices through capacity-building and mentorship. EFMHACA inspected 76 foreign manufacturers using a GMP inspection checklist developed with PQM support. Results from the first round of inspections showed that 13 manufacturers fully met the GMP requirements for market authorization, 15 partially met the requirements, and 15 did not meet the requirements and were rejected.

1.3 Standard of practice at national quality control laboratories sustainably improved

MRAs, national procurement agencies, and international donors require reliable and accurate data from quality control labs during the medicines registration process, when implementing corrective actions for poor-quality medicines identified following post-marketing surveillance (PMS), and to ensure that procured and donated products meet quality requirements. To help guarantee consistently reliable and accurate data, PQM builds the capacity of national quality control laboratories to improve their standards through assessments, hands-on training, and technical assistance. PQM places particular emphasis on strengthening quality management systems to help

Number of Quality Assurace Guidelines or Procedures Developed or Updated and Submitted for Adoption: Oct 2016 – Sept 2017



laboratories attain certifications of compliance with internationally recognized standards, such as ISO/IEC 17025:2005 and/or WHO prequalification (PQ).

In FY 2017, PQM supported 66 laboratories, including 32 provincial laboratories in Indonesia. With technical assistance from PQM, four laboratories in Nigeria, Burma, and Vietnam attained ISO/IEC 17025:2005 accreditation or WHO prequalification for the first time, and two laboratories in Kenya and Nigeria maintained their existing ISO accreditation or WHO prequalification.

A critical step toward improving standards of practice at laboratories and attaining ISO accreditation or WHO prequalification is the adoption of standard operating procedures (SOPs). This year, PQM supported national quality control laboratories to develop or update 225 guidelines and procedures. The adoption and use of well-developed SOPs ensure consistent laboratory practices, results that are reliable and trusted, and progress in meeting or maintaining international accreditation.

Key milestones this year were seen in Burma, Nigeria, and Indonesia. The Department of Food and Drug Administration Laboratory in Nay Pyi Taw, Burma received ISO 17025 accreditation six months ahead of schedule, the Agulu and Kaduna Zonal Laboratories in Nigeria both received ISO 17025 accreditation, and the PTBB National QC Laboratory in Indonesia submitted a Laboratory Information File and related documents to WHO to begin the process for Prequalification. ISO 17025 accreditation and WHO Prequalification certifies the laboratories' ability to effectively test medicines for malaria, tuberculosis, and other diseases, creates opportunities for economic growth, and contributes to quality assurance of medicines regionally.

With technical assistance from PQM, four laboratories in Nigeria, Burma, and Vietnam attained ISO/IEC 17025:2005 accreditation or WHO prequalification for the first time.

Nigeria's Central Drug Control Laboratory in Yaba, Lagos, was also listed this year as an African Regional Center of Regulatory Excellence by the New Partnership for Africa's Development (NEPAD). NEPAD is an economic development program of the African Union, and selection of the laboratory demonstrates its capacity as a center of excellence for the entire continent of Africa. This designation provides an opportunity for the laboratory to play a major regional role in the support of monitoring and testing medicines quality across countries in West Africa.

IR1

SUCCESS STORY

Poor-quality medicines for diseases like malaria and tuberculosis can lead to treatment failure and the development of antimicrobial resistance. Internationally recognized quality control laboratories are essential for any MRA to ensure the safety and effectiveness of medical products.

In FY 2016, PQM provided technical assistance to Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) Central Drug Control Laboratory in Yaba, Lagos, to become ISO/IEC 17025:2005 accredited. This year, PQM used the Collaborative Learning Model (CLM) to support two zonal laboratories in also obtaining international accreditation. The CLM reduces training costs and promotes country ownership and collaboration among laboratory staff.

The Zonal Laboratories in Agulu and Kaduna initially lacked adequate capacity and competency to meet quality control testing needs in eastern and northern Nigeria. This left NAFDAC without the means to fulfill its full mandate to help address serious health threats, including those posed by informal markets located in those regions.

To address this problem, PQM worked with NAFDAC to first help build the Agulu Zonal Laboratory's infrastructure and strengthen its capabilities. PQM assessed the gaps and collaborated with NAFDAC and Agulu leadership to develop a capacity-building plan that included hands-on training and demonstrations. The training was supplemented with follow-up technical assistance and additional support to improve quality management and control processes. In December 2016, after just 1 year, the Agulu Zonal Laboratory received ISO/IEC 17025:2005 accreditation.

Following the Agulu accreditation, PQM's CLM was applied to trainings for the Kaduna Laboratory staff. Trainings were conducted at the Agulu Laboratory, and the Kaduna team was able to apply lessons learned back to their laboratory. In June 2017, only 7 months later, the Kaduna Zonal Laboratory also received ISO/IEC 17025:2005 accreditation.

With this achievement, 100 percent of medicines quality tests performed in Nigeria will now be conducted across three ISO-accredited laboratories. These laboratories have increased capacity to:

- Reliably assess the quality of essential medicines.
- Provide evidence to stop poor-quality medicines from entering Nigeria and remove them from the market through surveillance activities.
- Safeguard Nigerians from the effects of poor-quality medicines, which can lead to treatment failures, the spread of harmful diseases, and antimicrobial resistance.

1.4 Institutional capacity for medical product quality assurance workforce sustainably improved

Building workforce capacity at central and decentralized institutions and facilities involved in maintaining operationally effective quality assurance systems is a core component of PQM's approach. PQM's experts work in collaboration with WHO's global, regional, and national offices to provide hands-on trainings focused on a wide range of good practice guidelines, particularly bioequivalence aspects of good clinical practices, good manufacturing practices, and good laboratory practices, including quality control testing procedures and laboratory equipment maintenance.

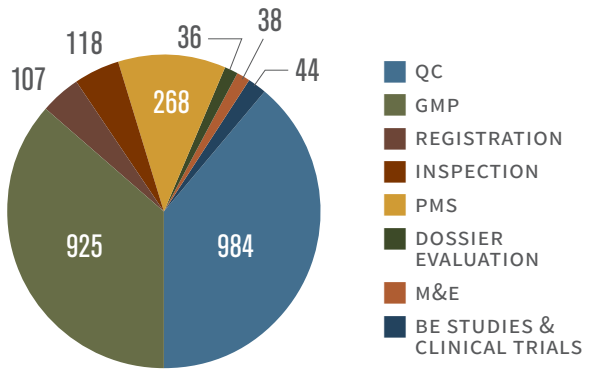
PQM's in-service training programs, CLM application, train-the-trainers approach, and hands-on support facilitate the transformation of knowledge into practice. PQM also supports the strengthening of quality assurance topics in preservice programs in academic institutions as a critical part of the long-term solution for workforce development. By combining preservice and in-service training interventions and the development of structures and processes necessary for effective quality management systems (QMS), PQM builds a sustainable in-country regulatory and quality assurance workforce.

This year, PQM provided training to 2,533 individuals in 8 different technical areas.

In FY 2017, the Drug Regulatory Authority of Pakistan (DRAP) moved to replace the existing template for medicines registration applications with the Common Technical Document (CTD), based on recommendations from PQM. The CTD format will improve dossier review and enhance efficiencies in product registrations in the country; however, this change meant that both regulators and the manufacturing industry would need training on CTD. Over the course of only 2 months, PQM collaborated with DRAP to deliver training on CTD use, adoption, and requirements to 497 regulators and technical staff from industry in 3 different geographic locations.

In Ethiopia, the regulatory authority (EFMHACA) must periodically calibrate its instrumentation in the national quality control laboratory to produce reliable results and maintain ISO 17025:2005 accreditation. In the past, EFMHACA outsourced this calibration to costly international contractors because there were no local accredited providers. This year, PQM provided tailored technical assistance and training to

Number of Individuals that Completed Training in Key QA/QC Related Technical Areas: Oct 2016 – Sept 2017



the National Metrology Institute of Ethiopia to expand the Institute's scope of services to include accreditation for the calibration of pressure and temperature instrumentation. To date, this expanded capacity has decreased EFMHACA's use of international contract service providers by two-thirds and reduced annual calibration costs by 58 percent.

In support of preservice training, PQM provided support to Ethiopia's Addis Ababa University School of Pharmacy to identify and recruit "fly-in professors" to provide a course on Clinical Pharmacy, Fundamentals of Regulatory Affairs, and Quality Management Systems to students enrolled in the post-graduate program on regulatory affairs. In discussions with the School, the types of modules to be developed for the regulatory affairs program were identified, and PQM agreed to provide technical assistance for the development of a modular course curriculum for QMS. This is important because the graduates from the program will be able to champion the adoption of QMS for both local industry and EFMHACA upon entering the workforce. Once the module is approved, the school will use its own local staff to provide the training instead of relying on professors from overseas, which will ensure the sustainability of the program in the absence of external support in the future.

1.5 Capacity for post-marketing surveillance of medical products sustainably improved

Ensuring the quality of medical products throughout the supply chain presents challenges that extend beyond the registration and procurement processes. Substandard medicines may occur due to poor manufacturing practices or as a result of poor storage conditions or practices. In addition, weak regulatory systems leading to unregulated distribution and sale of medicines and porous country

28 percent of PQM-supported sentinel sites have completely transitioned to government funded, owned, and sustained programs through support from PQM in developing sustainability plans.

borders facilitate the introduction of substandard, falsified, and unapproved medicines. To help address these challenges, PQM collaborates with MRAs to establish and strengthen PMS programs that regularly examine the quality of medicines throughout the supply chain.

PQM's support to MRAs includes implementation of risk-based approaches that help prioritize scarce human and financial resources, assistance in strategic planning, and targeted sampling for products and locations where surveillance is most needed. PQM also provides training to field staff in sampling procedures, use of field screening tools and technologies (such as GPHF Minilab™), data management, and reporting. Field testing with screening methods and laboratory testing with complex and comprehensive compendial methodologies are integrated within the implementation of a risk-based framework for PMS.

In FY 2017, PQM supported 6 countries to generate medicines quality test results for over 2,150 medicine samples collected for key public health medicines, including for malaria, tuberculosis (TB), and HIV/AIDS. Through PQM's building of capacity and skills of countries to carry out medicines quality surveillance, currently 28 percent of the PQM-supported sentinel sites have completely transitioned to government-funded, owned, and sustained programs.

Country & Product Type	# of Samples Tested	# of Samples Failed
Benin (Malaria)	8	1
Ethiopia (MNCH)	180	0
Ethiopia (Malaria)	163	3
Ethiopia (Opportunistic Infections)	158	0
Ghana (MNCH)	50	7
Guinea (Malaria)	7	1
Guinea (TB)	2	1
Guinea (HIV)	2	1
Guinea (Opportunistic Infections)	5	0
Nigeria (Malaria)	897	14
Nigeria (MNCH)	636	188
Philippines (TB)	51	0

One of the most alarming results from medicines quality surveillance this year was seen in Nigeria, where a comprehensive final laboratory analysis report for oxytocin, completed by the recently ISO 17025-accredited Agulu Zonal Laboratory, showed that 74 percent of the samples failed quality control tests. Oxytocin is a key priority medicine used to prevent and treat postpartum hemorrhage to reduce maternal mortality. While the sampling results are not necessarily representative of the burden of poor-quality oxytocin in the country, they indicate the potential size of the problem with the quality of oxytocin. In a swift reaction, NAFDAC organized a meeting to discuss the cause of these findings and implement interventions to ensure the quality of oxytocin.

In Liberia, PQM proposed the idea to the National Malaria Control Program (NMCP) of incorporating quality into the national malaria monitoring and evaluation (M&E) strategy. The idea was accepted in April 2017 by the Liberia Medicines and Health Product Regulatory Authority (LMHRA) and NMCP and was included in the 2016–2020 M&E plan. For the first time, NMCP's M&E strategy will account for the quality of malarial medicines distributed to public health facilities throughout Liberia. Under the new arrangement, LMHRA will be charged with the responsibility of performing PMS activities in accordance with established protocols developed in collaboration with PQM. PQM will continue to support the strengthening of LMHRA's PMS capacity. Future PMS activities will be conducted at NMCP's five surveillance sites.

Also this year, PQM convened a planning workshop in Indonesia with the National TB Program and 11 provincial health offices and laboratories on the "Joint Sampling and Testing of TB and HIV Medicines." This activity involved identifying the medicines to be sampled and tested, as well as the provincial and district warehouses from which samples would be taken. This is a joint activity between the Ministry of Health and the regulatory authority (BPOM) to encourage rapid implementation of the Permenkes 75/2016 regulation on ensuring medicines quality control activities in government-sector programs. A key outcome of these activities for joint sampling is to successfully implement the regulation on the quality control of medicines in the government sector, including dissemination of quality testing data to relevant Ministry of Health partners in a timely manner, which is a crucial step toward a robust quality control system in Indonesia.

IR2

PROGRESS BY
RESULT AREA

Supply of quality-assured priority medicines increased

A continuous supply of quality-assured products—particularly for priority medicines for tuberculosis; neglected tropical diseases; and maternal, newborn, and child health—are necessary to address national health priorities and plans. However, the limited number of manufacturers weakens supply security and increases the vulnerability of supply chains to shortages, stock-outs, and poor-quality medicines. Further exacerbating supply challenges is the lack of economic incentives for manufacturers to produce essential medicines. PQM works with manufacturers to improve compliance with international quality standards to meet local and global demand for quality-assured medicines. PQM assistance ensures a steady supply of essential medicines of assured quality, safety, and efficacy, thus strengthening countries' health systems to improve health outcomes.

2.1 Supply of quality-assured priority medicines produced locally increased

In support of key USAID priority health programs, PQM provides technical assistance and guidance to manufacturers for the local production of priority medicines, including those used to treat newborn infections and child and maternal health products. Local production may decrease reliance on international donation and help establish a sustainable local supply. In addition, developing local manufacturing capacity, where feasible and appropriate, and enhancing regulatory oversight can improve both national and regional capabilities for sustainable sourcing of quality-assured medicines.

In FY 2017, PQM supported 25 manufacturers in 6 countries toward production of quality-assured products for local markets. Most notable are chlorhexidine gel in Pakistan, which received government authorization for local production, and oxytocin injection and amoxicillin dispersible tablet (DT) in Indonesia, which achieved WHO prequalification and Expert Review Panel (ERP) approval, respectively. While WHO prequalification and ERP act as mechanisms for global procurement, they also serve as an indication that production of these two products for the local market will be quality assured.

2.2 Supply of quality-assured priority medicines produced globally increased

To address the global need for essential medicines, PQM works with manufacturers to help them develop and submit dossiers for certification by the WHO PQ of Medicines Program for tuberculosis, malaria, and neglected tropical disease medicines. Both WHO prequalification and stringent regulatory authority approval confirm that these medicines meet acceptable international standards for quality, safety, and efficacy, and can be purchased by international procurement agencies. In addition, by increasing

Country	Number of local manufactures receiving technical assistance	Product types
Ethiopia	4	ethambutol FPP, ciprofloxacine FPP, zinc sulfate FPP, doxycycline FPP, chlorhexidine gel FPP
Nigeria	11	amoxicllin DT FPP, oxytocin FPP, magnesuim sulfate FPP, zinc sulfate FPP, chlorhexidine gel FPP, arthemether lumefertrine FPP, ready-to-use therapuetic foods
Indonesia	4	levofloxicin FPP, oxytocin injection FPP, amoxicillin DT FPP
Pakistan	4	chlorhexidine gel FPP
Kazakhstan	1	levofloxacin FPP, moxifloxacin FPP
Uzbekistan	1	levofloxacin FPP, moxifloxacin FPP

IR2

SUCCESS STORY

Globally, 2.7 million babies die during their first month of life—16 percent of these deaths are from sepsis, meningitis, or tetanus.[1]

Despite this dire statistic, preventive medicine can significantly reduce newborn mortality when it is affordable and available. Chlorhexidine, an antiseptic used to clean umbilical cords, can reduce the risk of newborn death by 23 percent.[2] Quality-assured chlorhexidine, when produced locally, costs pennies per patient—but without a local supply, countries are vulnerable to fluctuations in foreign pricing and availability.

Recognizing the high rate of newborn mortality in Pakistan, PQM began work in late 2015 to identify Pakistan-based manufacturers that could produce quality-assured chlorhexidine.

PQM helped to conduct gap analyses of manufacturers and, this year, instituted corrective and preventive actions of the findings, trained local staff, standardized testing techniques and protocols, and helped the manufacturers apply for government approval to produce chlorhexidine. PQM is also building the capacity of the Drug Regulatory Authority of Pakistan and the Ministry of National Health Services, Regulations & Coordination—efforts intended to help expedite the medicines registration process and establish a fair price for medicines like chlorhexidine. PQM's work paid off: four manufacturers—ATCO Laboratories Ltd., Aspin Pharma Ltd., Akhai Pharmaceutical, and Zafa Laboratories—became the first ever in Pakistan to receive government authorization to produce chlorhexidine. With this authorization, a dose of chlorhexidine now costs just 14 cents—one-third the price of chlorhexidine in neighboring Nepal.

In October 2017, ATCO Laboratories Ltd. saw the first commercial launch of the chlorhexidine 7.1% gel product. The other manufacturers are expected to follow suit, and in a matter of months, locally produced, affordable, quality-assured chlorhexidine is expected to reach health facilities across the country, dramatically expanding chlorhexidine's availability and reducing the price of an essential medicine for newborns. This USAID investment through the PQM program has the potential to save thousands of newborn lives every year.

1. Liu, L., et al. (2016). Global, regional, and national causes of under-5 mortality in 2000-15: An updated systematic analysis with implications for the Sustainable Development Goals. The Lancet, 388, 3027–3035. http://dx.doi.org/10.1016/S0140-6736(16)31593-8

2. Imdad, A., et al. (2013). The effect of umbilical cord cleansing with chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: A meta-analysis. BMC Public Health, 13(Suppl. 3):s15. http://dx.doi.org/10.1186/1471-2458-13-S3-S15

the number of suppliers and creating a competitive environment, PQM helps shape the market for essential medicines and contributes to reducing the price of these essential products.

In one of the most successful years to date, PQM's support led to WHO prequalification or Certificate of Suitability (CEP) approval of 2 neglected tropical diseases (NTD) products, 3 TB products, and 1 maternal, newborn, and child health (MNCH) product.

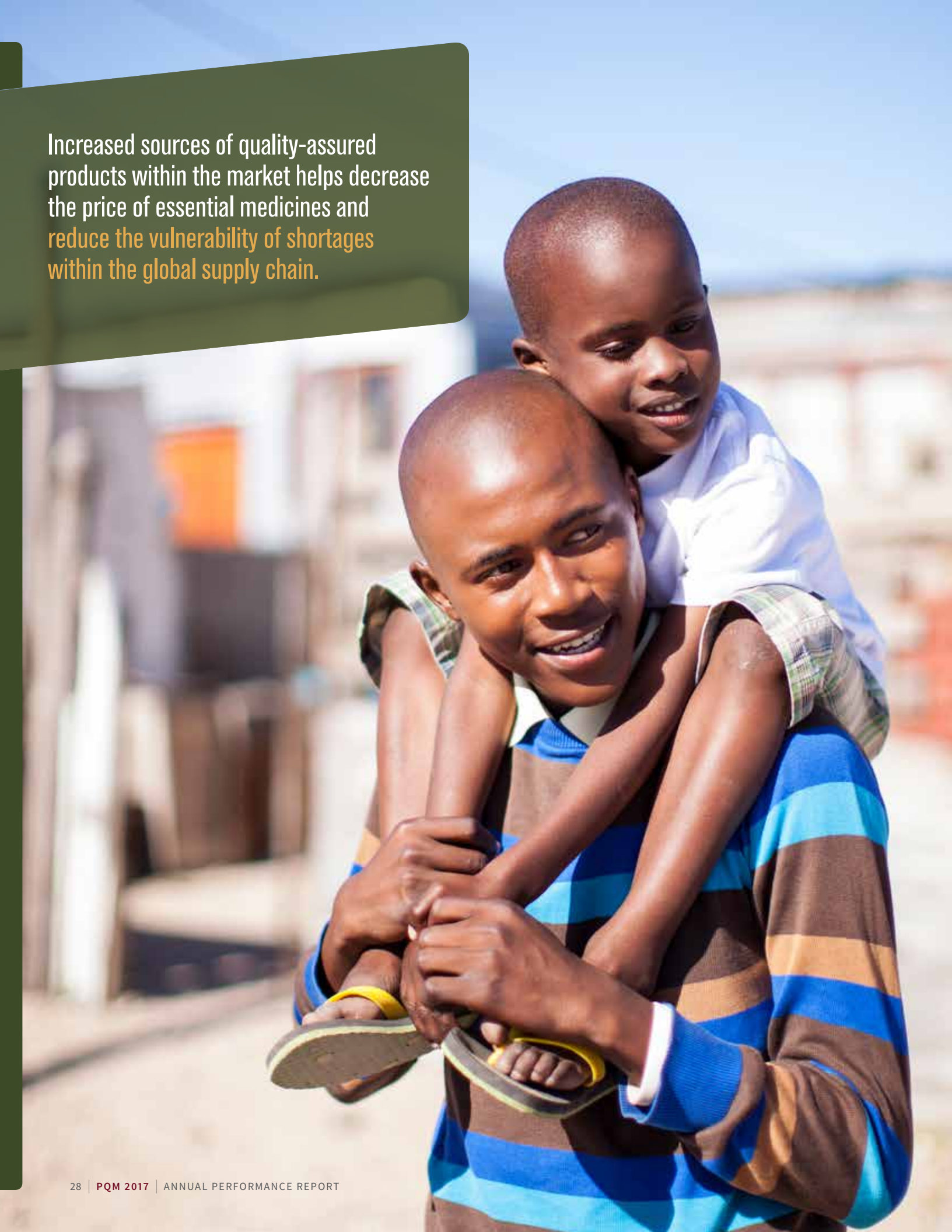
Name of Product	Approval body	Product Type
oxytocin injection FPP	WHO	MNCH
amoxicillin FPP	ERP	MNCH
praziqauntel API	CEP	NTD
praziquantel API	WHO	NTD
cycloserine API	WHO	TB
streptomycin FPP	WHO	TB
capreomycin FPP	WHO	TB

A local medicines manufacturer in Indonesia that receives technical assistance from PQM, Sanbe Farma/Caprifarmindo, achieved WHO prequalification for oxytocin injection and ERP approval for amoxicillin 250mg dispersible tablets, to be procured by the United Nations Children's Fund (UNICEF). PQM was essential in assisting to build the overall quality control systems for Sanbe Farma/Caprifarmindo, as well as in providing GMP support, which helped the company attain WHO prequalification and ERP approval for the products. These two priority products will lead to an increased supply of quality-assured products for maternal and child health on the global market.

Praziquantel is an important medicine for treating NTDs, and having a quality-assured active pharmaceutical ingredient (API) source is vital for the production of quality finished products. Shanghai Jiayi Pharma received CEP approval for praziquantel API. CEP-approved API suppliers may be used by finished pharmaceutical product (FPP) manufacturers interested in WHO prequalification or other stringent regulatory authority approval for praziquantel. In addition, Hisun Pharma obtained WHO prequalification for praziquantel API. Hisun Pharma is the first manufacturer to reach WHO prequalification status for praziquantel API. With these products receiving CEP approval and WHO prequalification, there are now two sources of quality-assured praziquantel API that can be used for production of quality-assured praziquantel FPP. This could potentially increase the supply of needed quality-assured praziquantel FPP on the global market.

As a result of the continued technical assistance provided by PQM, Dong-A ST pharmaceutical company was able to submit its API Master File for clofazimine API to WHO for prequalification on February 15, 2017. Upon submission, it was accepted for review. Clofazimine is one of the highest priority products for USAID, as it is a key medicine for the shortened regiment for multidrug-resistant-TB treatment, as recommended by WHO. Availability of quality-assured API on the global market would support the availability of manufacturing and increase availability of quality-assured clofazimine finished product for multidrug-resistant-TB patients.

In June 2017, NCPC received WHO prequalification for streptomycin FPP, the first for this product. Streptomycin is an important anti-TB medicine, and these steps are expected to result in an increased supply of quality-assured products at affordable prices on the global market, potentially being supplied to low- and middle-income countries through the Global Drug Facility. A few months later in September 2017, NCPC also received WHO prequalification for capreomycin FPP. It became the fourth manufacturer to receive WHO prequalification for capreomycin FPP, and with its own API source, there is potential for a drop in price. This is another example of how the initial work that PQM conducts in providing technical assistance to a manufacturer can be applied to multiple products for the manufacturer—another sustainability success.



Increased sources of quality-assured products within the market helps decrease the price of essential medicines and reduce the vulnerability of shortages within the global supply chain.

2.3 CROs compliance with Good Clinical Practices and Good Laboratory Practices increased

In the process of submitting an application to the WHO PQ Medicines Program or other stringent regulatory authority, manufacturers require access to clinical research organizations (CRO) to conduct bioequivalence (BE) studies when indicated. PQM engagement with CROs helps them to address compliance issues and timeliness and improve the cost-effectiveness of the services they provide in the approval process for priority medicines. PQM engagement aims to decrease the time needed for product approval as well as the actual cost of BE studies. PQM prioritizes support to CROs that can provide reliable data for timely approval of priority medicines.

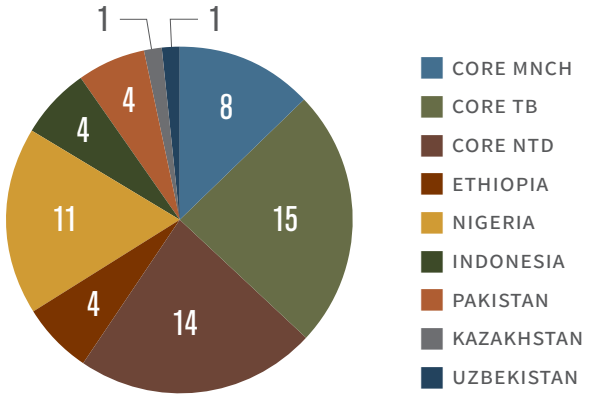
This year, PQM collaborated with partners in supporting the Regional Bioequivalence Center (RBEC) in Ethiopia. The presence of a strong BE center that complies with good clinical and good laboratory practices is critical in developing local capacity for bioequivalence studies at lower costs. It provides a platform to enforce regulatory requirements for market authorization of locally produced generic medicines. It also represents a key step forward to ensure the quality and safety of medicines manufactured in the region, including medicines for priority health programs such as malaria, MNCH, HIV/AIDS, and TB. PQM has built the capacity and expertise of staff in the center on advanced BE studies and clinical trial principles. PQM also strengthened the RBEC's laboratory toward good laboratory standards of practice.

2.4 Sources for quality-assured API/FPP diversified and supply secured

For some health products that are of critical public health importance, there is only one source of quality-assured essential medicine to supply the global market. This makes the medicine vulnerable to substantial price increases for both procurement agencies and countries purchasing the product. It also increases the risk for potential disruptions in supply if the manufacturer sustains any operational setbacks during production. PQM has observed companies that manufacture both the API and the FPP become the sole source of a quality-assured product on the market. Additionally, when there is only one or a few manufacturers of the API, interrupting the supply of the API to other FPP manufacturers allows for price increases in a monopolized FPP market downstream. To help avoid these challenges related to the supply of priority medicines, PQM works to identify API manufacturers that can help ensure the API supply to multiple FPP manufacturers. This increases sources and competition within the market and helps reduce the price of essential medicines. Additionally, by developing multiple sources of quality-assured FPPs, the risk of price gouging is averted and the vulnerability of the global supply chain to shortages is greatly reduced.

In total this year, PQM contributed to increasing the supply of priority public health medicines through technical support provided to 62 manufacturers (37 manufacturers supported by core health elements and 25 by country missions). PQM works to build manufacturer capacity to attain international standards for GMP.

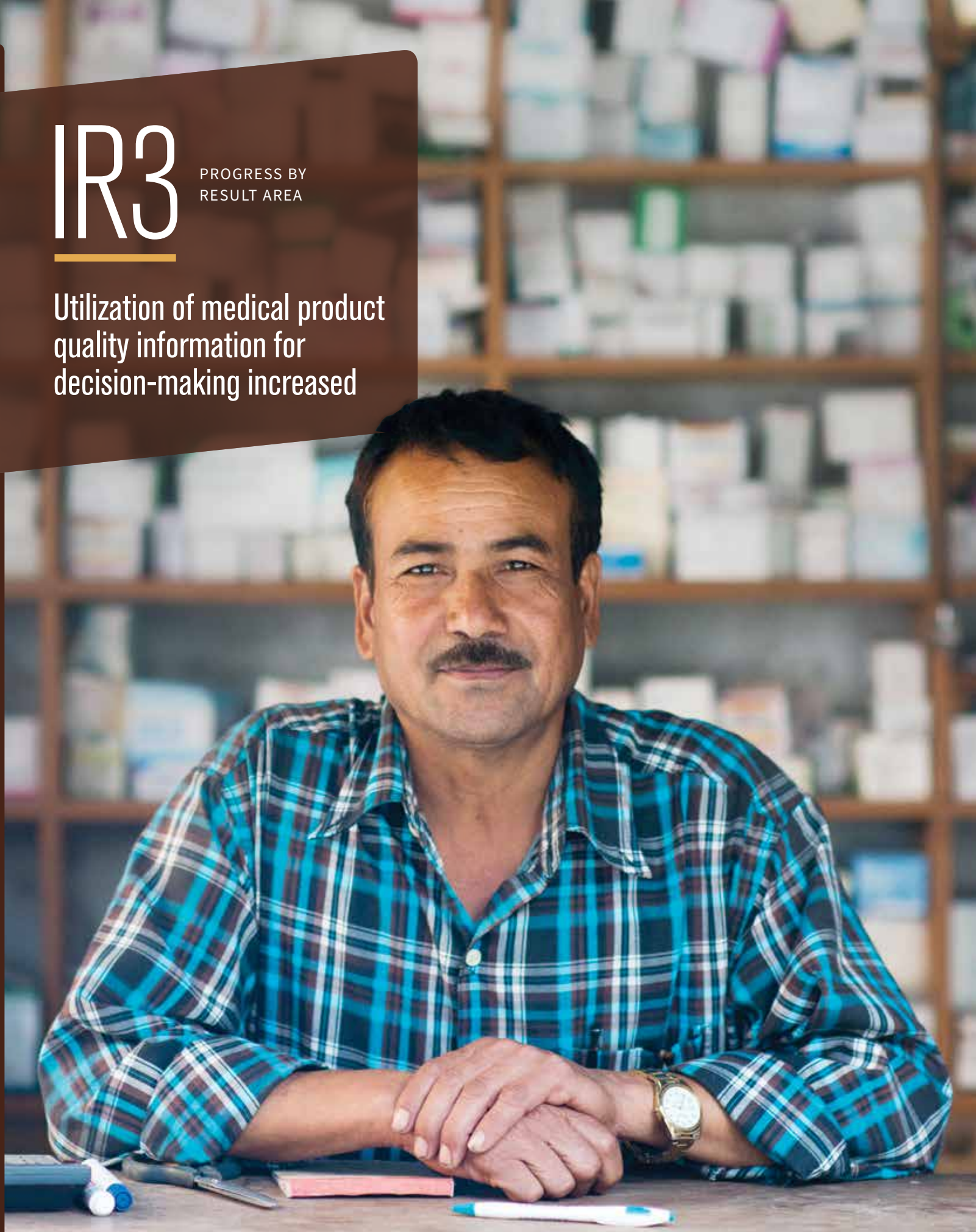
Number of Manufacturers that Received PQM Technical Assistance: Oct 2016 – Sept 2017



IR3

PROGRESS BY
RESULT AREA

Utilization of medical product quality information for decision-making increased



The collection, analysis, and use of data on medical products evaluation, inspection, and post-approval surveillance support evidence-based decision-making critical for promoting access to quality-assured products and for reducing and eliminating substandard and falsified products. PQM supports the adoption of data standards and integrated regulatory information management to ensure that accurate, up-to-date, and reliable data inform regulatory actions and are disseminated to all stakeholders. By working with local, national, and international partners, PQM helps to bring awareness on the use of data to improve transparency and accountability in the pharmaceutical sector, inform decision-making, shape public policies on pharmaceuticals, and support the attainment of public health objectives.

3.1 Availability of information related to quality of medical products increased

PQM assists national stakeholders with implementing medicines quality monitoring to generate data on the quality of pharmaceuticals circulating in country. To sustain such a critically protective public health activity, PQM supports countries to develop or strengthen post-marketing surveillance as a regulatory function. PQM also supports countries to increase the body of knowledge generated on the quality of priority medicines used in public health programs, particularly medicines used for maternal, newborn, and child health; HIV/AIDS; and tuberculosis.

In Nigeria, as part of a multipronged approach to address the challenge of storage conditions of oxytocin, PQM facilitated a workshop on good storage and distribution practices for marketing authorization holders of oxytocin injection. Key outcomes of the meeting included that prospective market authorization holders without suitable storage facilities will not be given marketing authorization of oxytocin in Nigeria, and that temperature tracking and trending should be done for sensitive products to ensure that they are maintained at the recommended temperature for optimal efficacy. NAFDAC will also increase collaboration with the Nigeria customs service to ensure cold chain pharmaceutical products are fast-tracked, including speedy clearance from ports, different storage processes for sensitive and nonsensitive products, and adoption of direct marketing of sensitive products.

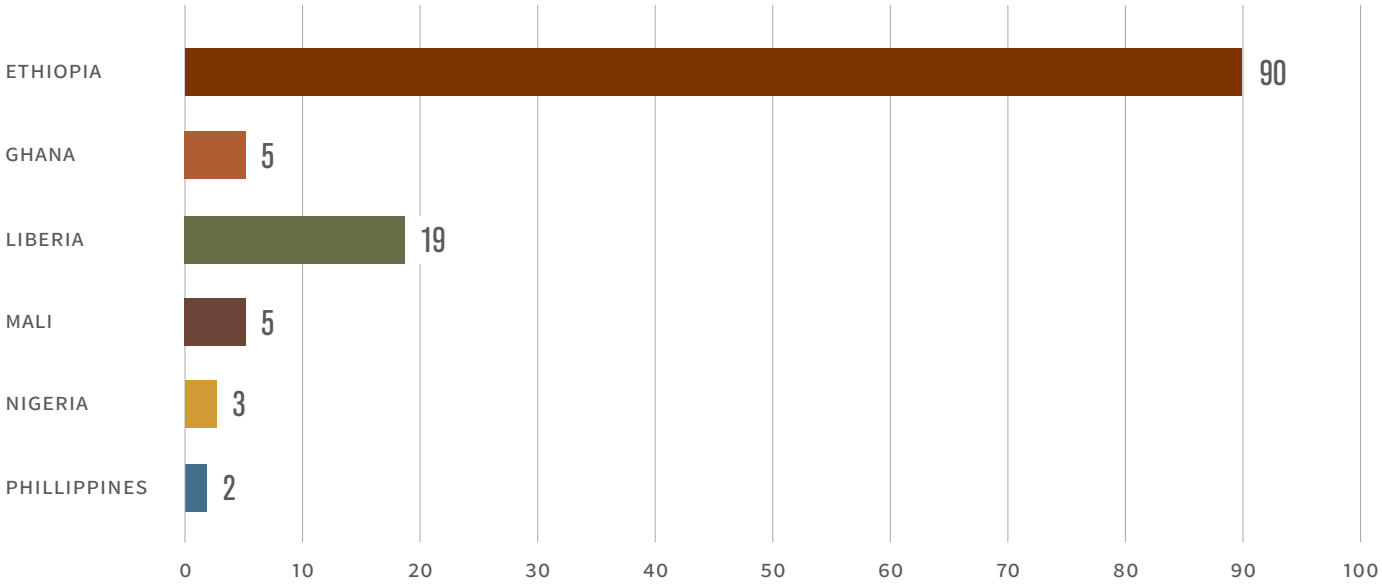
Also this year, PQM developed a framework and guidelines for implementing a risk-based approach for medicine quality sampling and testing. The guidelines provide detailed criteria to consider for keeping interventions focused and effective when resources are limited. This new framework was recently piloted in the Philippines with the country's Food and Drug Administration and was found to be acceptable also for incorporating a risk-based decision tree in the development and implementation of the PMS guideline. Forthcoming, Senegal and Burkina Faso are also planning to implement risk-based PMS.

3.2 Enforcement actions against falsified, substandard, and unapproved medical products increased

PQM works with in-country partners to detect and support action against cases of substandard and falsified medicines. When poor-quality medicines are detected, PQM collaborates with MRAs to facilitate compliance and enforcement actions and remove these medicines from the market. PQM also shares information to alert stakeholders and the public about the issue. By creating and supporting regional networks for sharing information, PQM also facilitates implementation of corrective actions in neighboring countries on poor-quality medical products sourced from the same manufacturers.

IR3

Number of Regulatory Actions Made by MRAs: Oct 2016 – Sept 2017



In FY 2017, a total of 124 regulatory actions were made by six MRAs supported by PQM.

In Nigeria, after a workshop on good storage and distribution practices for marketing authorization holders of oxytocin injection, poor-quality medicine batch collection commenced from all affected health facilities and markets to ensure that ineffective products cannot be accessed and used. In a testament to NAFDAC's successful regulatory action implementation, a total of 1,183 ampoules of poor-quality oxytocin were confiscated from the market.

Separately this year in Ghana, PMS results indicated that 7 out of 50 zinc sulfate tablets (14%) sampled from the Greater Accra region at the time failed disintegration testing. One of the batches that failed the disintegration test also failed the assay test. Following the issuance of the surveillance data, the Ghana Food and Drug Administration instituted regulatory actions, and the manufacturer recalled all failed batches from the market. Additionally, the manufacturer agreed to start checking control samples of all batches monthly for hardness testing and to ensure uniformity, and will also conduct stability studies on a reformulated batch of the product that contains an extra quantity of a disintegrant.

In Liberia in early FY 2017, PQM participated in a 3-day joint PMS exercise with the National Malaria Control Program (NMCP) and regulatory authority (LMHRA) in two counties where four different falsified artemether injections were identified. As a result, over 200 packs of the falsified product were confiscated. LMHRA used the documented details to inform the public via electronic and print media about the danger of using falsified products.

Later in the year, PQM supported LMHRA to conduct an exercise to remove selected antimalarial monotherapies from circulation. While Liberia is 1 of the 49 countries that has taken steps to ban the use of oral artemisinin-based monotherapy, medicines quality surveillance reports have consistently demonstrated the widespread use of amodiaquine monotherapy for the treatment and management of malaria in Liberia. WHO recommends combination therapy to treat malaria and discourages artemisinin-based monotherapies.

The exercise resulted in 27,600 packs of amodiaquine monotherapy (of 3 tablets each) removed from the market. Additionally, 143 cartons of medicines (over 100,000 pieces of assorted unregistered and falsified quinine tablet, artemether injection, and other products) were also removed from the inspected facilities. In total, the confiscated products were worth an estimated $68,000 USD (over 8 million Liberian dollars), and LMHRA issued citations for five major violators to an administrative hearing. Meanwhile, a stakeholders' meeting was held, and 34 awareness campaigns on the danger of using antimalarial monotherapy to treat malaria were conducted in cities, towns, and villages.

In total, the confiscated products were worth an estimated $68,000 USD (over 8 million Liberian dollars), and LMHRA issued citations for five major violators to an administrative hearing.

3.3 Information on quality assurance of medical products used for advocacy increased

PQM raises awareness about the dangers of substandard and falsified medicines—providing information to the public and government stakeholders by supporting local, regional, and global initiatives on medicines quality. Activities often include hosting and attending partner meetings, developing regional databases and alert systems, advocating for the allocation of resources to improve pharmaceutical quality systems, and encouraging collaboration among stakeholders. To share information with the global community, PQM participates in regional and international meetings, then develops printed and digital media materials to increase advocacy on matters related to medical products quality.

At the local level, PQM participated in World Malaria Day this year in Liberia and Nigeria. At these events, PQM engaged the public and civil society by highlighting the importance of quality. Samples of poor-quality antimalarial medicines were displayed, and explanations on how to detect substandard and falsified medicines by simple visual inspection or using screening tools followed. This opportunity was also used to raise public awareness about the importance of monitoring products to identify and remove substandard and falsified medicines circulating in local markets.

At the regional level, PQM supported the East African Community (EAC) Medicines Registration Harmonization (MRH) initiative to strengthen the capacity of member states' MRAs to carry out key regulatory functions and register medicines through a joint dossier evaluation. In particular, PQM hosted a Regional Workshop on Advanced Good Manufacturing Practice Aspects in support of the EAC-MRH and also provided technical guidance during the EAC-MRH 5th Joint Dossier Assessment Meeting and 4th Meeting of the Expert Working Group on Good Manufacturing Practices.

At the global level, PQM presented at 11 major fora for medicines quality assurance, including the following:

- 2017 Consortium of Universities for Global Public Health Conference on multi-country experience supporting MRAs in low- and middle-income countries to keep falsified medicines—including antimalarials, maternal and child health products, and family planning products—from circulating in their markets
- 47th Union World Conference on Lung Health and presented a poster presentation on "Strengthening Quality Assurance Systems of Pharmaceutical Manufacturers to Ensure Availability of Affordable TB Medicines on the Global Market"
- American Society of Tropical Medicine and Hygiene (ASTMH) 2016 Annual on "Surveillance of Medicines Quality in Select African Countries: Challenges and Opportunities"

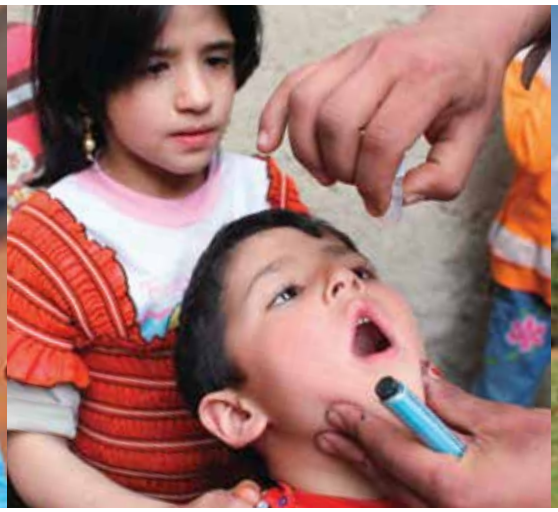
Sustainability and Lessons Learned

Sustainability

In Ghana, three quality control laboratories (physical chemistry, pharmaceutical microbiology, and medical devices) were visited by the ANSI-ASQ National Accreditation Board (ANAB) for an audit inspection to reaccredit them for ISO 17025. The Ghana Food and Drug Administration (GFDA) prepared for the audit visit with minimal support from PQM. Building on PQM technical support toward accreditation maintenance, GFDA also took the initiative, leveraging funds from another donor, the United Nations Industrial Development Organization (UNIDO), to expand the scope of accreditation to also include food microbiology. ANAB awarded the scope expansion accreditation in August 2017. This activity demonstrates that PQM support to GFDA over the years is yielding positive returns that will help ensure sustained operations and implementation by GFDA. It also demonstrates that GFDA has improved its technical capacity and is taking complete ownership of its ISO 17025 accreditation maintenance for its laboratories and also testifies to PQM's success in building the capacity and skills required to carry out this function effectively.

PQM has previously provided support to improve EFMHACA's quality assurance systems through building staff capacity, providing essential materials to the laboratory, and supporting participation in proficiency testing. Proficiency testing determines the performance of individual laboratories for specific tests or measurements and is used to monitor their ongoing performance. Through continued PQM support this year, 4 EFMHACA branch laboratories collected 200 samples for routine PMS, which they also tested using compendial methods. This is evidence that the knowledge and skills transfer by PQM to branch laboratory staff in quality control testing was effective. The branch laboratories took full ownership of the process, including procurement of chemicals, while PQM provided reference standards required for the tests.

EFMHACA also took appropriate regulatory measures to address the problem of falsified quinine sulfate, which was identified following PQM-supported PMS. This finding was reported to the WHO Rapid Alert system, and EFMHACA conducted further investigations to identify the route through which the product came into the country. To further strengthen PMS in Ethiopia, EFMHACA instituted a new strategy to require importers to cover the PMS-related costs for their products. This measure will help EFMHACA conduct PMS on a more routine basis, reduce some of the financial constraints experienced in the past, and ultimately contribute to its sustainability in Ethiopia.



In Ethiopia and Bangladesh, PQM supported trainings to improve local capacity for calibration and maintenance of laboratory instrumentation. Ensuring that equipment is properly calibrated to test medical products—and with less reliance on external service providers for this essential laboratory function—is estimated to benefit the national quality control laboratories with cost savings as high as $15,000 and $17,000 annually, respectively.

Lastly, in Ethiopia as well as in Bangladesh, PQM supported trainings to improve local capacity for calibration and maintenance of laboratory instrumentation. Ensuring that equipment is properly calibrated to test medical products—and with less reliance on external service providers for this essential laboratory function—is estimated to benefit the national quality control laboratories with cost savings as high as $15,000 and $17,000 annually, respectively. In addition to the annual cost savings , there is long-term sustaining value added through the creation of in-country capacity to ensure availability of on-time and affordable support that may also help satisfy existing calibration needs from local pharmaceutical industries.

Lessons Learned

A fire completely destroyed the national quality control laboratory of the Liberian regulatory authority (LMHRA) in May 2017. Despite the total loss of the laboratory facility and equipment, LMHRA is attempting to make rapid adjustments that will enable it to use Minilab™ where possible as a screening tool to resume testing of samples from importers of pharmaceutical and health products. However, as Minilab™ is not a sufficient tool to fully assess the quality of medicines, LMHRA will need to identify a third-party laboratory to support routine quality control testing. In the interim, USP is providing compendial testing services. The fire that led to the destruction of the laboratory building and critical equipment, as well as the loss of quality data, have underscored the importance of ensuring that laboratories have safety measures in place that prevent such unexpected situations.

In Ethiopia, EFMHACA noted this year that the existing regulatory guidelines need to be utilized by stakeholders and that some of the guidelines must be supported by legal authority for enforcement through development and issuance of corresponding regulations in the form of legally binding directives. As a result, efforts to create awareness about some of the regulatory tools, such as good documentation practice and good storage practice guidelines were required. PQM was instrumental in the advocacy of the regulatory tools and will apply this lesson learned to other countries with similar experiences.



"It is a great honor to do the work we do, and to have the opportunity to collaborate with committed partners at the global, regional, and local levels. Please continue to follow our progress toward ensuring that quality-assured medicines are available to those who need them most around the world."

Jude I. Nwokike
Director, PQM Program

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