

Annual Performance Report **FY 2018**

October 1, 2017–September 30, 2018



Promoting
the Quality of medicines



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Note from the Director



In FY 2018, the U.S. Agency for International Development and the U.S. Pharmacopeial Convention celebrated their ninth year of partnership on the Promoting the Quality of Medicines (PQM) program. As PQM looks to its final year of implementation in 2019, this Annual

Performance Report not only demonstrates how countries and institutions have used our program's technical support to continue expanding access to quality-assured medicines; it also demonstrates the importance of planning a sustainable future for quality-assured medicines programming at the national and international levels.

The PQM program's objectives or Intermediate Results cover three areas that create a holistic approach to improving the quality of medical products in low- and middle-income countries: systems, supplies, and information. As a lead-in to this report, I am proud to highlight key achievements in each of these areas.

In Ethiopia, PQM's country team provided systems-level support for the development of specialized registration guidelines, paving the way for timelier access to critically needed vaccines and biological products on the domestic market. In an effort to increase the global supply of amikacin solution for injection, a medicine recommended by WHO for treatment of Multi-Drug Resistant TB (MDR-TB), our team of good manufacturing practices experts worked with Qilu Pharmaceutical Co. Ltd. to attain the

first-ever World Health Organization prequalification for this product. PQM also strengthened good manufacturing practices for local manufacturers of oxytocin and magnesium sulfate in Nigeria, leading to market authorization for these essential medicines for preventing postpartum hemorrhage and preclampsia/eclampsia, thereby directly targeting the country's alarming rate of maternal mortality. Our work to increase the capacity of countries to use quality information on medical products for decision-making resulted in 31 regulatory actions against substandard and falsified products across 6 countries. The PQM program also launched *Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries*, a resource to help countries monitor medicines through an approach that tailors activities according to local needs, optimizes limited resources, and focuses efforts on areas that present the greatest risks to public health.

PQM remains dedicated to its goal of strengthening quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health. There is still work to be done, so we are eager to expand on this year's accomplishments.

It is a great honor to do the work we do, and to have the opportunity to collaborate with 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.

A handwritten signature in black ink, appearing to read 'Jude I. Nwokike', written over a light grey background.

Jude I. Nwokike
Senior Director, PQM Program



Our work... resulted in
31 regulatory actions
against substandard
and falsified products
across **6 countries**



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, Senior 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 medicines information and quality 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 2018, USAID supports PQM's work in 18 countries, 1 regional mission, 1 Cross Bureau program, and 3 core health programs.

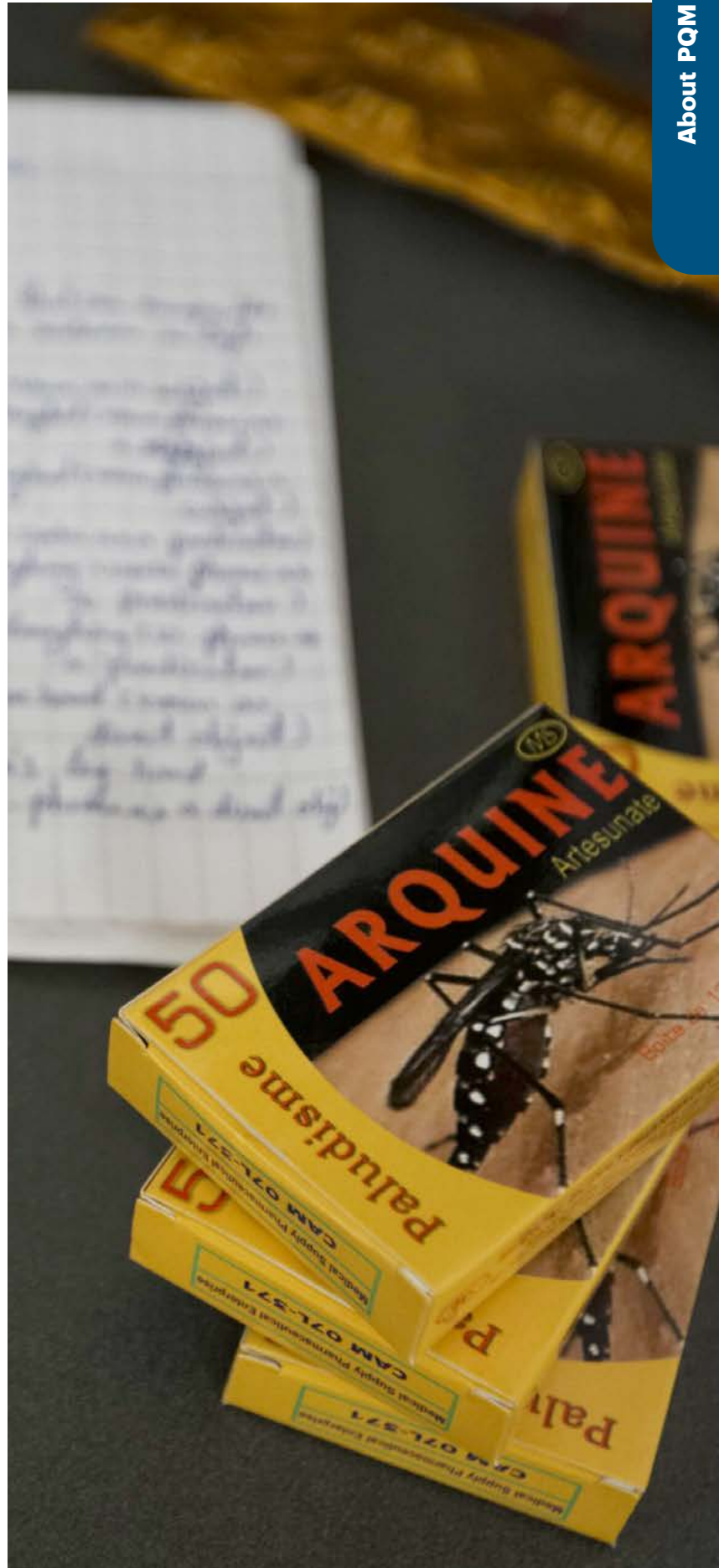
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Acronyms

API	active pharmaceutical ingredient
BE	bioequivalence
CAPA	corrective and preventive action
CRO	clinical research organization
CTD	Common Technical Document
ERP	expert review panel
FDA	Food and Drug Administration
FPP	finished pharmaceutical product
GMP	good manufacturing practices
IEC	International Electrotechnical Commission
IR	Intermediate Result
ISO	International Organization for Standardization
LMIC	low- and middle-income country
MDR-TB	multidrug-resistant tuberculosis
MNCH	maternal, neonatal, and child health
MRA	medicines regulatory authority
NQCL	national quality control laboratory
NTD	neglected tropical diseases
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMI	U.S. President's Malaria Initiative
PMS	post-marketing surveillance
PQ	prequalification
PQM	Promoting the Quality of Medicines
QA	quality assurance
QC	quality control
QMS	quality management system
RB-PMS	risk-based post-marketing surveillance
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

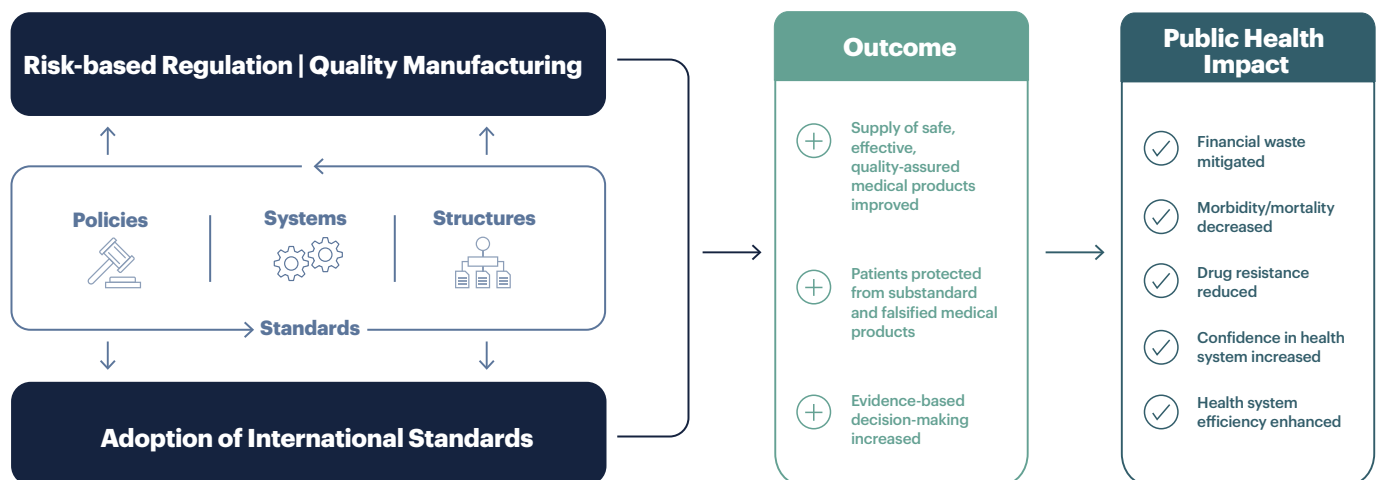


Background

Each year, tens of thousands of deaths globally are attributed to substandard and falsified 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 LMICs, 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 toward a resilient health system.

Medicine Quality Assurance Framework





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.
- **Complementarity and partnership:** PQM works with other implementing partners, multilateral organizations, government agencies, and academic institutions to coordinate efforts and maximize results.
- **Internationally recognized standards and best practices:** PQM assists countries to build on existing systems to achieve international standards such as WHO prequalification and ISO/IEC 17025.
- **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.
- **Regional harmonization:** Harmonization at the regional level helps leverage resources to address regulatory needs across multiple countries and encourages South-to-South collaboration.

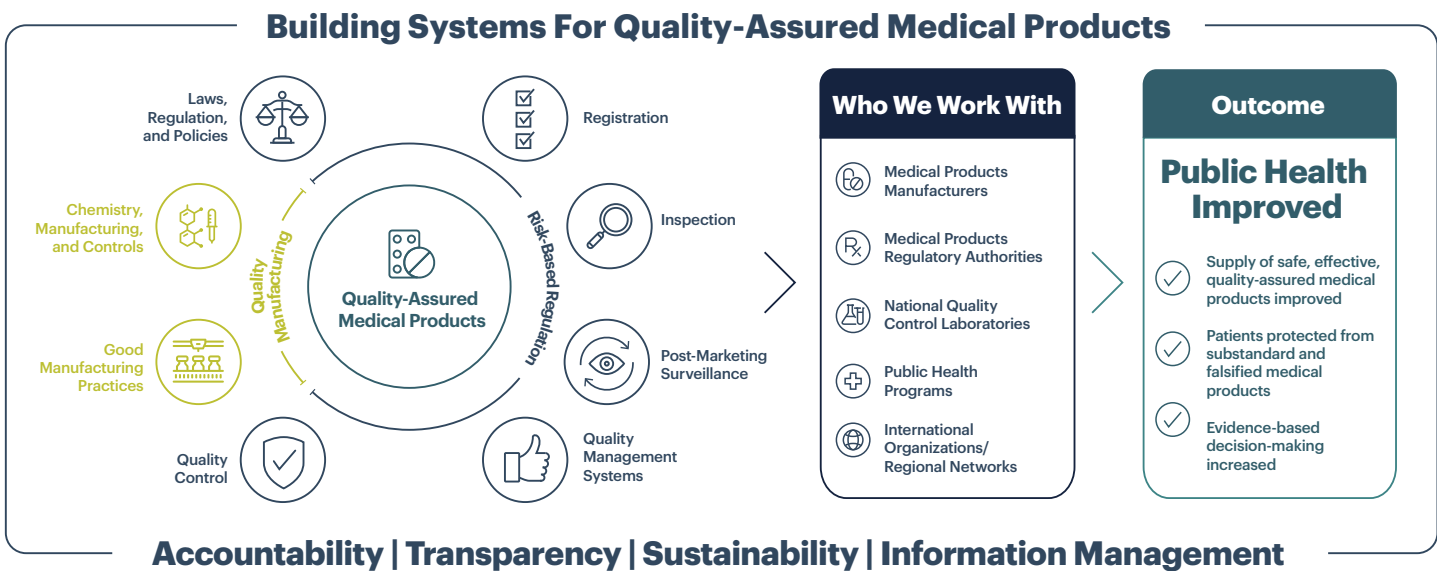


Technical Approach

Strengthening Regulatory Systems

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.

PQM Technical Framework



Technical Areas of Expertise

Regulatory	Quality Control Laboratories	Manufacturing
<ul style="list-style-type: none"> • Laws, policies, regulations • Quality assurance guidelines • Dossier evaluation • Product registration • Inspections • Integrated information management • Post-marketing surveillance • Bioequivalence studies 	<ul style="list-style-type: none"> • Quality management systems • Analytical instrumentation support • Support for WHO/ISO accreditation • Analytical testing • Self-inspection 	<ul style="list-style-type: none"> • 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

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 (NQCLs), 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 (PMS). 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 (RB-PMS) programs is critical to ensuring 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 PMS programs.

As part of these efforts, we work with NQCLs to strengthen systems that enable laboratories to accurately and reliably test the quality of medicines. Through this support, the laboratories we work with pursue and achieve compliance with international standards, such as ISO/IEC 17025 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 avert shortages of essential medicines and in some cases have resulted in a substantial reduction in price.

Innovation into Action

Risk-based regulation of medical products

Regulatory authorities in LMICs sometimes spend a bulk of their financial resources on aspects of quality assurance that may not necessarily yield the greatest benefit to public health. For example, some medicines regulatory authorities (MRAs) spend a disproportionate amount of resources on dossier review, evaluating current GMP, PMS, and quality testing. In the case of PMS, although resources may be devoted to this function, activities are often undertaken in an ad hoc or non-strategic manner, or they may not be based on existing data or indicators of risk. Additionally, the lack of rigor in the methodology means that although significant resources may be used for surveillance purposes, ultimately the results may not be reliable enough to use for decision-making purposes.

Risk-based regulation of medical products incorporates risk management principles to ensure regulatory resources are used in ways that provide the maximum benefit to the public and that regulatory functions are carried out as efficiently as possible and established on evidence-based risks to public health. Pharmaceutical quality assurance systems should therefore include risk-based strategies to detect and respond to the presence of substandard and falsified medicines, address vulnerabilities in the quality assurance system, and inform the allocation of resources to effectively carry out essential regulatory functions.

This year, PQM developed resources to support regulatory authorities in LMICs as they move toward risk-based regulation of medical products:

- ▶ [“A Risk-Based Resource Allocation Framework for Pharmaceutical Quality Assurance for Medicines Regulatory Authorities in Low- and Middle-Income Countries”](#)
- ▶ [“Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries”](#)







FY18 **key** Achievements

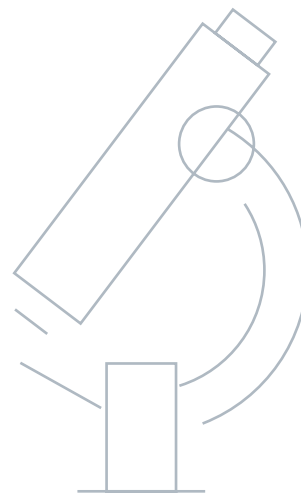
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National quality assurance policies, regulations, and legislations were developed or updated and submitted for adoption, providing legal mandates that will help ensure medicines' access, quality, and rational use.



7

National quality control laboratories in Africa and Asia achieved or maintained ISO 17025 accreditation or, certifying laboratory competency against stringent international standards.





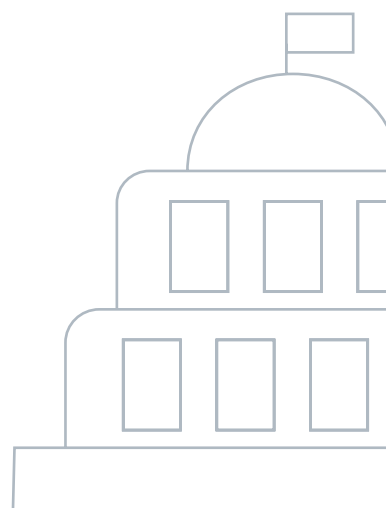
1

Priority medicine achieved WHO prequalification, becoming the first quality-assured source of the product on the global public health market.



31

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



Progress by Result area



PQM GOAL

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



Highlights

IR1

Medical products
quality assurance
systems strengthened



IR1.1

Quality assurance policies, legislation, guidelines, and procedures improved



Ethiopia develops specialized guidelines to help facilitate registration of vaccines and biological products



IR1.2

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



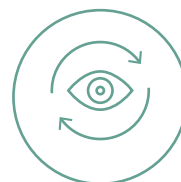
IR1.3

Standard of practices at national quality control laboratories sustainably improved



IR1.4

Institutional capacity for regulatory workforce sustainably improved



IR1.5

Capacity for post-marketing surveillance of medical products sustainably improved

IR2

Supply of quality-assured priority medicines increased



IR2.1

Quality-assured priority medicines produced locally increased



Nigeria issues market authorization approval for oxytocin and magnesium sulfate injections produced by a local manufacturer



IR2.2

Quality-assured priority medicines produced globally increased

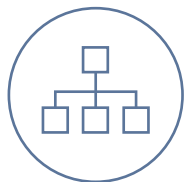


PQM-supported manufacturer achieves the first WHO prequalification of amikacin sulfate solution for injection to treat multidrug-resistant tuberculosis (MDR-TB)



IR2.3

CROs' compliance with good clinical practices and good laboratory practices increased



IR2.4

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

IR3

Utilization of medical product quality information for decision-making increased



IR3.1

Availability of information related to quality of medical products increased



PQM launches "Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries"



IR3.2

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



Senegal confiscates poor-quality medicines, including antimalarials, worth over \$2.4 million USD



IR3.3

Information on quality assurance of medical products used for advocacy increased



IR1

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 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 meets internationally accepted standards.

This year, a key accomplishment within this result area can be seen in Ethiopia, where PQM supported the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) to develop three guidelines: Guidelines for Registration of Vaccines, Guidelines for Registration of Similar Biotherapeutics Products, and Guidelines for Registration of Biotherapeutic Protein Products Prepared by Recombinant DNA Technology. The guidelines will help facilitate registration of specialized priority medicines, including vaccines and other biological products, and is expected to increase access to new and innovative medicines that better address existing and emerging diseases. In addition to their contribution to the alignment with international best practices, these guidelines will help in the review of dossiers for these types of products.

PQM also worked with EFMHACA to develop a Recall Directive. Serving as a legally binding enforcement tool, this directive will impact the recall process whenever

a poor-quality medicine is detected after distribution in the country. In addition, it will help improve compliance of responsible stakeholders with regulatory requirements during the removal of poor-quality medicines from the market.

*Medical products are instrumental to any health system, **but only if they are safe, effective, and quality assured***

In Guinea, a revision of the pharmaceutical law was adopted by the National Assembly and signed by the president this year. PQM supported the National Directorate of Pharmacy and Medicine (DNPM) throughout the revision process. The enactment of the revised law will also require the establishment of regulations that will strengthen the pivotal functions of DNPM, such as registration and PMS activities, to reduce the exposure of the public to poor-quality medicines circulating in the market.



Bangladesh's medicines regulatory system has been developed through several pieces of legislation promulgated over the years, beginning with enactment in the 1940s and subsequent amendments. Relative to current standards, it is necessary to modernize the legislation to respond to changes and new challenges, as well as to build capacity to meet the new and growing need for regulation to ensure medicines quality, safety, and efficacy. In 2017, a draft revision to the outdated legislation was developed; although it was a vast improvement, it was found to lack key provisions to address pharmaceutical supply chain issues, medicines quality, and the use of good practices that are critical to regulate pharmaceutical activities in the country. This year, PQM worked to review the proposed legislation and recommended a number of new provisions, including one for the recall of substandard and falsified medicines.

1.2 Registration, inspection, and licensing functions of medicines 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 the previous fiscal year, PQM supported EFMHACA to develop a Pharmaceutical Manufacturer GMP Inspection Directive that laid the foundation for essential elements of GMP inspections to improve transparency, accountability, traceability, and competence of inspectors. This year, PQM and EFMHACA built upon the directive to develop a GMP Inspection Manual. The Inspection Manual adopts

a strategy to improve the effectiveness of inspections conducted by EFMHACA and regional regulatory bodies on medicine distribution channels and retail outlets.

The Inspection Manual outlines appropriate steps to be followed for auditing medicine retail outlets and distributors with respect to good dispensing, good storage, and good distribution practices. It also requires inspectors to crosscheck whether establishments are authorized to handle the products found within their establishments and whether the products are obtained

*It is necessary to modernize legislation to **respond to changes and new challenges***

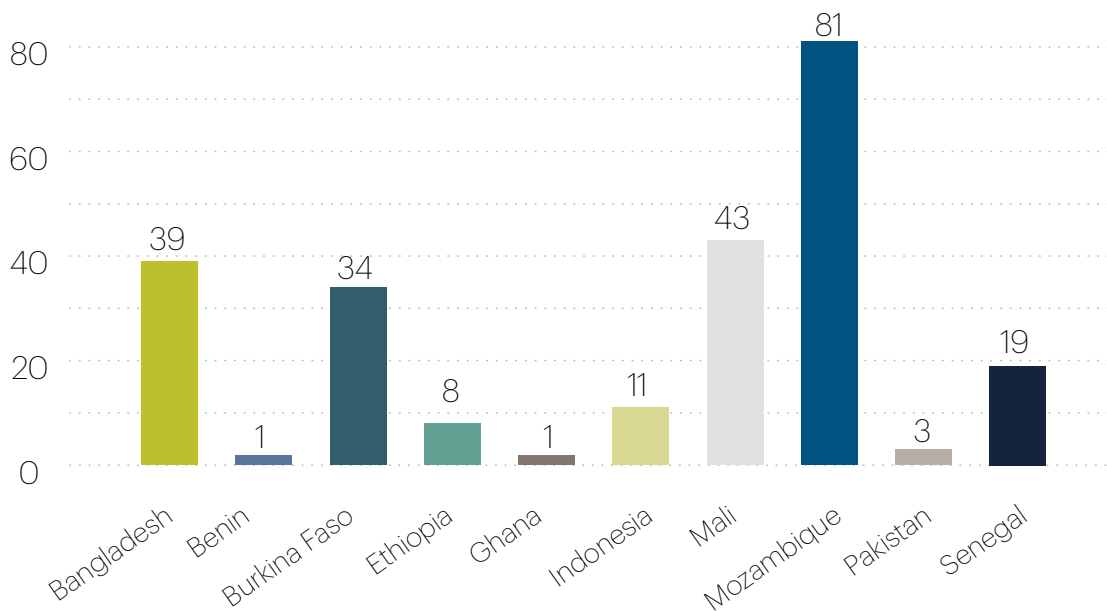


from legal sources. This rigorous process of auditing during inspection is expected to boost the capacity of EFMHACA and regional regulators to detect and prevent the circulation of poor-quality medicines, thereby helping to ensure the safety, quality, and effective use of medicines circulating in Ethiopia's market.

1.3 Standard of practices at national quality control laboratories sustainably improved

MRAs, national procurement agencies, and international donors require reliable and accurate data from quality control laboratories during the medicines registration process, when implementing corrective actions for poor-quality medicines identified following 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 NQCLs to improve laboratory standards through assessments, hands-on training, and

Number of Quality Assurance Guidelines or Procedures Developed or Updated and Submitted for Adoption *(October 2017–September 2018)*



technical assistance. PQM places particular emphasis on strengthening quality management systems to help laboratories attain certifications of compliance with internationally recognized standards, such as ISO/IEC 17025 accreditation and/or WHO prequalification.


In FY 2018, PQM supported 63 laboratories, including 31 provincial laboratories in Indonesia. With technical assistance from PQM, one laboratory in Nigeria attained ISO/IEC 17025 accreditation for the first time, and six laboratories in Ethiopia, Ghana, Nigeria, and Myanmar maintained their existing ISO accreditation through the internationally recognized ANSI-ASQ National Accreditation Board.

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 NQCLs to develop or update 240 guidelines and procedures. The adoption and use of well-developed SOPs ensure consistent laboratory practices, results that are reliable and trusted, and progress in attaining or maintaining international accreditation.

Key milestones were seen this year in Nigeria, where three laboratories were able to maintain their accreditation status. The National Agency for Food and Drug Administration and Control (NAFDAC) Yaba, Agulu, and Kaduna laboratories maintained their ISO/IEC 17025 accreditation for existing test methods and also expanded their scopes to include microbiology, giving all three laboratories the ability to perform key quality control tests required for injectable medicines.

Additionally as a result of PQM's technical assistance, Nigeria's National Institute for Pharmaceutical Research and Development (NIPRD) attained ISO/IEC 17025 accreditation for the first time. The accreditation of NIPRD better positions the advancement of local pharmaceutical research and development, increases interaction with local manufacturers, and supports third-party testing of locally manufactured medical products in Nigeria.

PQM also began working with NAFDAC this year to support its National Control Laboratory for Biologics (NCLB). NCLB is the only laboratory in the country responsible for the quality control of vaccines and

PQM supported
more than **1,800** 
**individuals to
complete training in
key technical areas**

biologics in Nigeria. When accredited, the laboratory will provide ensured quality testing for vaccines developed and imported into the country.

In Pakistan this year, PQM's technical assistance helped three Drug Testing Laboratories (DTLs) in Lahore, Multan, and Faisalabad attain local ISO 17025 accreditation through the Pakistan National Accreditation Council. PQM continues to work with DTL Lahore specifically in providing support for the laboratory to prepare for WHO prequalification. This will not only help DTL Lahore meet internationally recognized standards but will also ensure the accuracy of test results and reliability of the laboratory in the surveillance of medicines quality after market authorization.

1.4 Institutional capacity for regulatory 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 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, GMP, and good laboratory practices, including quality control testing procedures and laboratory equipment maintenance.

PQM's in-service training programs, application of the Collaborative Learning Model, train-the-trainers

approach, and hands-on support facilitate the turning of knowledge into practice. PQM 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. Adopting a Collaborative Learning Model, PQM first gathers staff from multiple laboratories within each country and provides consolidated trainings to them. This ensures that the material delivered is consistent, reduces costs typically incurred from decentralized training operations, and promotes country ownership and collaboration among laboratory staff. 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. By combining preservice and in-service training interventions and the development of structures and processes necessary for effective quality management systems, PQM builds a sustainable in-country regulatory and quality assurance workforce.

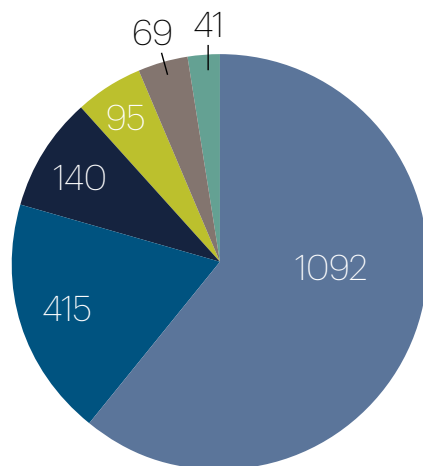
This year, PQM supported more than 1,800 individuals to complete training in key quality assurance/quality control-related technical areas.

In Ethiopia, PQM supported EFMHACA's specialized training needs by providing training to 30 EFMHACA inspectors on GMP inspection of sterile product manufacturers. Building the inspectors' capacity on GMP requirements for sterile products will help deter the entrance of poor-quality sterile products, including injectables (e.g., gentamicin and oxytocin), infusions, and blood products, into the country. It will also help to speed up inspection of manufacturers that have product registration applications with EFMHACA.

To continue strengthening PMS capacity in Mali, PQM supported the National Laboratory of Health (LNS) to procure a handheld NanoRam® Raman spectrometer and trained four laboratory staff on its use in the detection of falsified medicines. The training included an overview of

Number of Individuals Who Completed Training in Key Quality Assurance/Quality Control-Related Technical Areas

(October 2017–September 2018)



*Includes individuals who may have been trained more than once

Raman spectroscopy and the NanoRam® device, as well as hands-on training for testing antimalarial medicines. The overview part of the training was also open to two pharmacy students who were receiving training in medicines quality control at LNS. PQM designed the hands-on training as a “training of trainers,” and by the fourth day of training, one trained trainer successfully provided training to an additional laboratory staff member. Trained staff were also able to develop methods for screening medicines other than antimalarials, including select antibiotics. LNS staff subsequently used the handheld NanoRam® to screen antimalarial medicines samples collected as part of post-marketing surveillance activities facilitated by PQM.

PQM also worked to support preservice programs in academic institutions in Bangladesh, Ethiopia, and

Nigeria this year. In Bangladesh, PQM conducted a gap assessment of existing curricula from 21 of the 39 universities in the country that provide bachelors and masters degrees in pharmacy. A consultative workshop was held to share recommendations on changes in the curricula of pharmacy schools in the country that would ultimately create more competent graduates to be recruited by the MRA and other health service providers for Bangladesh’s workforce.

Similarly in Ethiopia, PQM supported a consultative meeting organized by the Ethiopian Pharmacists Association and Addis Ababa University (AAU) to discuss and propose a potential new curriculum for the pharmacy workforce with a special emphasis on preservice training. This curriculum addresses the current challenges related to the quality of professionals and responds to the emerging needs of professionals tailored to specific pharmaceutical sectors, such as the booming pharmaceutical industry in Ethiopia. PQM also aided in the development of two teaching modules for the AAU School of Pharmacy’s regulatory affairs post-graduate program. The modules for Product Registration and Inspection and Regulatory Science and Compliance will help utilize existing faculty to teach the courses and not rely in the long term on professors from overseas.

In 2016, PQM collaborated with the Pharmacists Council of Nigeria to convene a committee to review and revise the university undergraduate and graduate pharmaceutical quality assurance system curriculum. This year, PQM built upon the curriculum revision work by rolling out a pilot implementation of the curriculum with Nnamdi Azikwe University School of Pharmacy through teaching of the curriculum modules and tailored mentoring support to 25 lecturers and 202 students. These teaching modules will subsequently be rolled out to additional universities in other geopolitical zones to build capacity in pharmaceutical quality assurance and contribute toward a sustainable pipeline of skilled professionals for the pharmaceutical sector in Nigeria.

FY18 Success Stories



Using Mobile Technologies to Detect Poor-Quality Medicines in Benin

As one of Africa's most frequent points of entry for falsified medicines, Benin requires a rapid and cost-effective way of finding poor-quality medicines before they reach patients.¹ Since 2017, the country has been using two mobile tools, the suitcase-sized GPHF-Minilab™ and the hand-held Raman spectrometer, to screen suspicious pharmaceuticals in the country's commodity pipeline. Technologies like these not only enable quick screening of products in the field, but also lessen the burden on national quality assurance laboratories by ensuring that only samples that fail screening will be subject to more complex (and costly) testing.

From 2015 to 2017, PQM trained staff members at Benin's National Laboratory for the Quality Control of Medicines and Medical Consumables (LNCQ) in Minilab™ and Raman spectrometer use as part of a larger effort to build the laboratory's capacity in analytical quality control methods. In FY 2018, the LNCQ team provided follow-on training to 13 students from local public and private universities on the mobile technologies, expanding the number of analysts and fulfilling an organizational mandate to collaborate with the education sector.

The payoff for mobile medicines screening in Benin was nearly immediate. The LNCQ conducted Minilab™ or spectrometry screening on 156 samples in 2017. In a high-profile example of regulatory action early in 2018, the Benin Customs Authority seized and destroyed several dubious-looking medicines parcels at the Cotonou Cadjehoun Airport after mobile screening revealed they were falsified antimalarials.

LNCQ's Director, Dr. Parfait Adjakidje, emphasizes that while mobile technologies can help significantly streamline medicines quality surveillance, they are not a replacement for laboratory testing. "No single tool can be used to analyze all medicines," he advised. "Mobile screening allows us to detect when the active ingredient in a medicine is either missing or weakened, and laboratory testing then defines the product's exact composition."

As Benin uses mobile screening to expand its ability to find and remove substandard and falsified medicines from the market, it is protecting patients from often lethal consequences and contributing to renewed confidence in the national health system.

¹ Aminu N, Sha'aban A, Abubakar A, Gwarzo MS. Unveiling the peril of substandard and falsified medicines to public health and safety in Africa: need for all-out war to end the menace. MA@PoC. 2017 Dec 23 [cited 2018 Oct 15];1(1)e145–e154. Available from <http://journals.sagepub.com/doi/full/10.5301/maapoc.0000023#articleCitationDownloadContainer>.

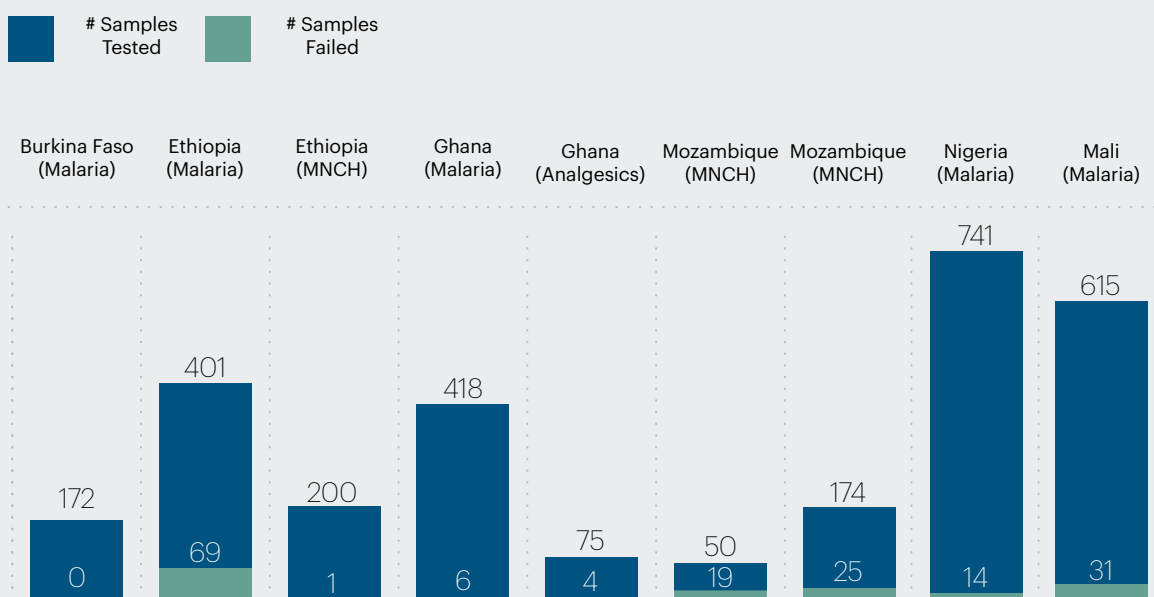
1.5 Capacity for post-marketing surveillance of medical products sustainably improved

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 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 the 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 2018, PQM supported 6 countries to generate medicines quality test results for over 2,800 samples tested for key public health medicines, including those for malaria and maternal, newborn, and child health.

PQM supported 6 countries to generate medicines quality test results for over 2,800 samples





A successful example of quality surveillance was seen this year in Ethiopia, where routine PMS indicated that 55 out of 58 quinine sulfate tablet samples tested did not meet quality requirements. A large number of these failed samples came from a single manufacturer and were imported by a single importer. EFMHACA promptly removed the recalled products from the market, conducted further investigative inspections, and took regulatory actions against the manufacturer.

Similarly in Ghana, PMS of antimalarial and analgesic medicines included 422 antimalarial samples

and 75 analgesic samples collected from all 10 regions of the country. Of these, 418 antimalarials were tested, and 6 (1.4%) were found to be substandard. Four samples were chloroquine, an oral monotherapy, which were excluded from testing, as the product is banned in the country. For the analgesic samples, a total of 75 samples were collected, and 4 samples (5.3%) failed to meet quality specifications. The Ghana FDA took regulatory actions to remove the substandard medicines from the market.

In Indonesia, Minilab™ screening was officially adopted within the Drug and Food Control Agency's (BPOM)

routine sampling guideline for PMS in nine provincial BPOM institutions. In these provinces, plans are underway to procure equipment and train staff for Minilab™ screening through a cooperative activity between PQM and the KNCV Tuberculosis Foundation's Challenge TB program. PQM will also conduct focus-group discussions and assessments of the trainees from the Ministry of Health and BPOM on the effectiveness of this type of collaboration and the best way forward for data sharing and joint enforcement actions when out-of-specification products are identified.



IR2

Supply of quality-assured priority medicines increased

A continuous supply of quality-assured products—particularly for essential priority medicines for tuberculosis (TB), neglected tropical diseases, and maternal 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's assistance helps ensure a steady supply of essential medicines of assured quality, safety, and efficacy, thus strengthening countries' health systems to improve health outcomes.

2.1 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 essential medicines, including those used to treat newborn infections and maternal and child health products. Local production may decrease reliance on international donations 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 2018, PQM supported 26 manufacturers in 8 countries toward production of quality-assured products. Notable achievements were seen in Nigeria, where NAFDAC issued market authorization approval to Juhel Pharmaceuticals for oxytocin and magnesium sulfate injections.

PQM provided technical assistance to the manufacturer for the products, and the approval for Juhel Pharmaceuticals marked the first approval of both medicines produced by a local manufacturer in West Africa. This achievement will increase the availability of quality-assured oxytocin and magnesium sulfate injections. Having a local supply closer to the last mile of the supply chain can help reduce supply issues and lessen environmental exposure during transit that may impact product quality.

Building on the success of FY 2017, Pakistan saw the first commercial batches of quality-assured chlorhexidine 7.1% gel reach the local market this year. Four manufacturers now make the product, and it is available in all provinces and regions of Pakistan as an over-the-counter medicine, readily accessible by the general public. The products are also now available for procurement by provincial governments, where they are already included in the list of essential medicines for lady health workers working under the Prime Minister's Program for Family Planning and Primary Health Care.

Country	Number of local manufactures receiving technical assistance	Products
Bangladesh	1	chlorhexidine solution
Ethiopia	1	ethambutol tablets
Ghana	1	artemether–lumefantrine tablets
Indonesia	4	levofloxacin tablets, rifampicin–isoniazid tablets
Kazakhstan	1	levofloxacin tablets
Nigeria	10	oxytocin injection, magnesium sulfate injection, sulfadoxine–pyrimethamine tablets, amoxicillin dispersible tablets, chlorhexidine gel, artemether–lumefantrine tablets, zinc sulfate dispersible tablets, ready-to-use therapeutic foods
Pakistan	7	amoxicillin dispersible tablets, chlorhexidine gel, zinc sulfate dispersible tablets
Uzbekistan	1	levofloxacin tablets



2.2 Quality-assured priority medicines produced globally increased

To address global needs for essential medicines, PQM works with manufacturers to help them develop and submit dossiers for certification by the WHO Prequalification of Medicines Programme for medicines to treat tuberculosis, malaria, maternal and child health, and neglected tropical diseases. Both WHO prequalification and stringent regulatory authority approval confirm that these medicines meet acceptable international standards for quality, safety, and efficacy and that they can be purchased by international procurement agencies. In addition, by increasing 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 medical products.

This year, PQM worked with the manufacturer Qilu Pharma to see the first WHO prequalification of amikacin solution for injection for the global public health market. Amikacin is a key product used for treating MDR-TB, and having a quality-assured product available for procurement agencies is vital for the supply of this medicine in LMICs.

Another major accomplishment was Indonesian manufacturer Kalbe Farma's levofloxacin 500 mg tablet product dossier being accepted for review by the WHO prequalification team, as well as WHO finding the manufacturer to be working at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products. This is the first oral solid dosage form submission to WHO for prequalification in Indonesia, and marks a major achievement for PQM in Indonesia in building overall quality and GMP compliance.

Having **a quality-assured product** available for procurement agencies is **vital** ”



2.3 CROs' compliance with good clinical practices and good laboratory practices increased

In the process of submitting an application to the WHO Prequalification of Medicines Programme or other stringent regulatory authority, manufacturers require access to clinical research organizations (CROs) to conduct bioequivalence 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 bioequivalence studies. PQM prioritizes support to CROs that can provide reliable data for timely approval of priority essential medicines.

With technical assistance from PQM, a manufacturer of praziquantel tablets, an essential product to treat neglected tropical diseases, obtained approval from the local regulatory agency and the ethics committee on its bioequivalence protocol. By receiving this approval, the manufacturer and CRO can now prepare for the enrollment of subjects in the bioequivalence study. This is a key step in getting the product ready for WHO prequalification so that it can become a quality-assured source of the neglected tropical diseases medicine for the global public health market.

Additionally in Indonesia this year, PQM initiated collaboration with key in-country universities and Centers of Excellence that provide bioequivalence expertise to the regulatory authority (BPOM) on developing a sustainable mechanism for high-quality technical assistance. PQM has shifted its focus from providing support to the Centers of Excellence to providing support for the Bioavailability/Bioequivalence



56

Manufacturers received technical assistance from PQM to contribute toward **increasing the supply of quality-assured priority public health medicines**

Forum, a communication forum for CROs working in bioequivalence (in both the academic and private sectors) that builds capacity in Indonesia and regularly conducts training workshops for members. PQM plans to develop a training of trainers methodology that will establish a pool of experts for providing bioavailability/bioequivalence trainings for CROs, as well as supporting BPOM.

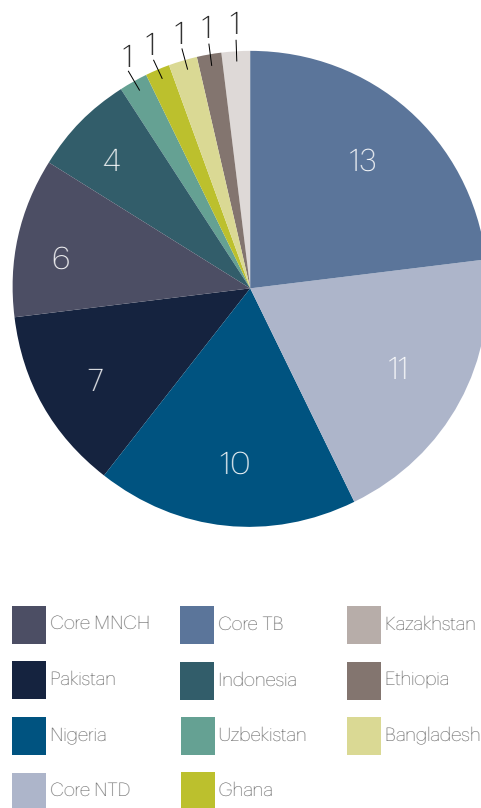
2.4 Sources of quality-assured API and FPP diversified and supply secured

In some instances, there is only one source of a quality-assured essential medicine to supply the global public health 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 witnessed companies that manufacture both the active pharmaceutical ingredient (API) and the finished pharmaceutical product (FPP) become the sole source of a quality-assured product on the market. Interrupting the supply of APIs to other FPP manufacturers allows for price increases in a monopolized FPP market. To prevent this, PQM works to identify API manufacturers that can supply APIs to multiple FPP manufacturers. This increases sources and competition within the market and helps reduce the prices 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.

PQM contributed to increasing the supply of priority public health medicines through technical assistance provided to 56 manufacturers this year (30 manufacturers supported by Core health elements and 26 by Missions). PQM works to build manufacturers' capacity to attain international standards for GMP.

Number of Manufacturers that Received PQM Technical Assistance

(October 2017–September 2018)



This year, PQM-supported manufacturers had dossiers accepted for review by WHO prequalification for the following products creating increased sources within the global public health market:

- ▶ Magnesium sulfate injection, MNCH product
- ▶ Clofazimine capsules, MDR-TB product

The clofazimine dossier acceptance is particularly important, as the product is one of the essential medicines for treatment of MDR-TB, and currently there is only one other quality-assured source on the market. With an additional source of the product approved by WHO, the market for quality-assured clofazimine will be more secure.



IR3

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 that is 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 bring awareness to 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 PMS as a regulatory function. PQM also supports countries to increase the body of knowledge generated on the quality of priority essential medicines used in public health programs, particularly medicines used for maternal and child health, HIV/AIDS, and tuberculosis. PQM is undertaking a series of additional initiatives to increase the availability of data related to the quality of medical products, including working across regulatory functional areas; registration, licensing, and inspection; and PMS to harness opportunities for data capture and sharing.

In an effort to increase information in the public domain related to the manufacture of quality-assured medicines, PQM finalized and made available on PQM's website the first publication of Product Information Reports (PIRs) for amoxicillin and rifapentine, key child health and anti-TB medicines. The PIRs are documents that have been developed to provide critical technical information and guidance related to the manufacture of medicines that are of global public health importance. Each PIR synthesizes available physicochemical, pharmacokinetic, toxicological, and other information for a given product and analyzes key manufacturing challenges.

PIRs are intended to support informed decision-making regarding product development, scale-up, and manufacturing by proactively identifying and addressing potential manufacturing issues. The PIRs may also be used by stakeholders concerned with expanding the supply of and access to essential medicines to develop an understanding of how product development and manufacturing challenges impact the availability of these products.

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

PQM works with in-country partners to detect and support actions 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.

*This year, **31** regulatory actions were made by 6 MRAs supported by PQM* 

This year, 31 regulatory actions were made by 6 MRAs supported by PQM, including 20 actions for antimalarials, 4 for analgesics, 4 for MNCH products, and 3 for other products.

In Senegal, the medicines regulatory authority (DPM) and local law enforcement agencies confiscated a vast amount of poor-quality medicines. In 2014, the Ministry of Health established the Inter-Ministerial Committee (IMC) Act with the main objective of collaboration among DPM and enforcement agencies to combat the sale and/or import of poor-quality medicines. The establishment of the IMC Act was one of the main outcomes following communication and education campaigns conducted by PQM in 2009 and 2011. With the establishment of this IMC among DPM and enforcement agencies, DPM



FY18 Success Stories

PQM Launches Risk-Based Post-Marketing Surveillance Guidelines

Through PQM's Cross Bureau project, the "Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries" document was launched this year. Building on WHO guidelines for conducting quality of medicines surveys and medicines testing, as well as more than 15 years of PQM experience in supporting LMICs to establish and implement medicines quality monitoring activities, these guidelines aim to help regulatory agencies implement technically sound, cost-effective, and sustainable national PMS programs. For this, PQM introduced risk-based elements for both the sampling process (e.g., medicines characteristics, geographical location, types of facilities) and for testing (e.g., multilevel testing approach for both field and laboratory quality control). Implementation of these risk-based approaches will help countries allocate limited human and financial resources for continuous monitoring of the quality of medicines in the market to help ensure their efficacy and safety when they reach patients.

Developing and implementing an RB-PMS program is an iterative process meant to revert back to regular

prioritization and planning informed by lessons from previous cycles of surveillance. Assessment of a pharmaceutical sector informs development of a PMS program and provides insights on objectives and potential priority areas. PMS and the associated sampling and testing activities should be coordinated and owned by the MRA and designed to address predefined objectives through the establishment of a rigorous and agreed-upon methodology. Using a risk-based methodology to guide both sampling and testing activities ensures that each contributes to program objectives, makes the most of resources, and generates quality data that can be used to drive effective decision-making. The application of risk-based approaches offers an opportunity for LMICs to establish effective, affordable, and sustainable medicines PMS systems.

PQM has begun working with selected countries for the prompt use of these guidelines when establishing their national PMS programs. In FY 2018, trainings and workshops on PQM's approach to RB-PMS were held in Bangladesh, Myanmar, Ghana, Guinea, Mali, and Mozambique, as well as in Uganda through the Intergovernmental Authority on Development-Medicine Regulatory Harmonization (IGAD-MRH) initiative.

was able to take regulatory actions in its fight against the sale of medicines in nonregulated pharmacies and informal markets. On November 13, 2017, this joint effort led to the confiscation of two trucks full of poor-quality medicines before they entered Touba City. The confiscated medicines, which included antimalarials, were worth approximately 1,355,160,000 CFA, the equivalent of \$2,419,928 USD.

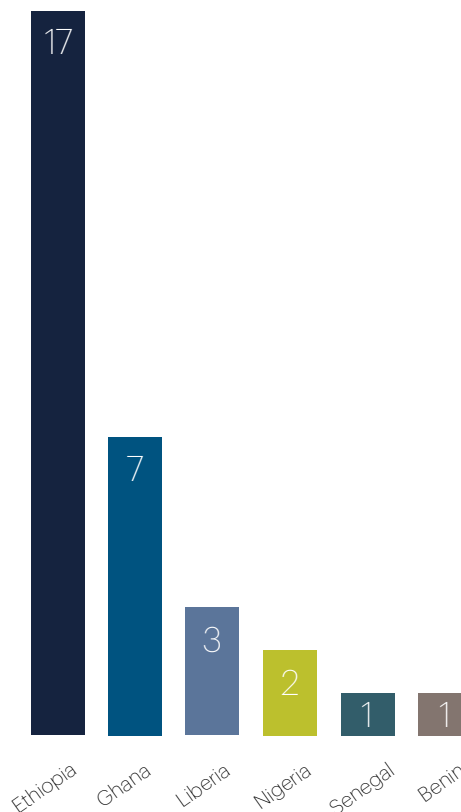
Ethiopia's regulatory authority (EFMHACA) took regulatory actions this year on failed samples following quality testing of products collected during routine PMS. Based on EFMHACA's directives, the failed samples of quinine sulfate tablet were removed from the market by the importer of the product. An EFMHACA recall letter resulting from PMS findings led to several other poor-quality products being removed from the market, including primaquine tablets, zinc sulfate dispersible tablets, and artemether injection. Additionally, analysis of product defect reports received through the adverse drug reaction reporting system led to the recall of iodine tincture and lidocaine solution for injection, as further investigation on these products confirmed them to be of poor quality. All of these medicines are in high demand in day-to-day clinical practice and could have endangered the lives of many, had they not been detected and withdrawn from the supply chain system in time.

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

Number of Regulatory Actions Made by MRAs

(October 2017–September 2018)



share information with the global community, PQM participates in regional and international meetings and develops printed and digital media materials to increase advocacy on matters related to medical products quality.

PQM provided technical leadership at the local level and made presentations at a national workshop in Nigeria themed "Oxytocin Injection Quality Audit: Results from the Clinical Experience Study." The workshop came out of the PMS results of critical maternal health products in the country, which revealed that over 70 percent of oxytocin samples analyzed at NAFDAC's ISO accredited laboratories failed quality control tests. Oxytocin injection is used to begin or improve contractions during labor and reduce bleeding after childbirth. Subsequent to the findings, USP provided supplemental funding through PQM to support researchers at the



Lagos University Teaching Hospital to study whether there is any correlation between the PMS results and clinical experiences of healthcare providers in Lagos state in the use of oxytocin for postpartum hemorrhage treatment. PQM made presentations at a webinar session titled “Quality Oxytocin: Nigeria” organized by the Maternal Health Supplies Caucus. The combination of both presentations on results from the oxytocin injection quality audit and clinical experience study demonstrated the connection between PMS of medicines and patients and healthcare providers’ experiences.

At the regional level, PQM began working this year on a regional work plan supporting priorities of the IGAD-MRH and funded by USAID/East Africa. PQM supported the regional body through establishment of an expert working group to identify PMS/pharmacovigilance document gaps, provide recommendations for implementation of PMS/pharmacovigilance activities

in the region, and facilitate a survey to determine the prevalence of substandard and falsified medicines at selected cross-border sites to inform future interventions. This work is particularly important given the cross-border challenges that the region faces.

At the global level, PQM presented at major conferences on medicines quality assurance, including the following:

- ▶ 48th Union World Conference on Lung Health, presenting on “Supporting TB drugs manufacturers to increase the supply of a life-saving anti-TB medicine: USP PQM technical approach”
- ▶ Pre-International Conference of Drug Regulatory Authorities, presenting on “Changing procurement models: maintaining safety and quality of medical products”

Sustainability

This year, Ethiopia's National Metrology Institute (NMI) confirmed its capability to calibrate all of EFMHACA's laboratory equipment. Going forward, EFMHACA will no longer need to contract a foreign institute to calibrate any of its equipment. PQM has long been supporting EFMHACA in equipment maintenance and calibration as part of building the capacity of the quality control laboratory and attaining/maintaining international accreditation. While equipment maintenance was transferred to EFMHACA about 2 years ago, providing technical assistance on equipment calibration continued as part of PQM's support. PQM explored various options to build local capacity of third-party providers to EFMHACA to promote sustainability. Equipment calibration was identified as one of the more important areas to support because it is a mandatory requirement for maintaining the current ISO accreditation of EFMHACA.

Technical support to NMI began in FY 2017 when PQM identified the institute as a key partner and initiated building its capacity. PQM identified key gaps that could help NMI expand the scope of its calibration services to include equipment at EFMHACA. This strategy started bearing fruit in early FY 2018, when NMI was able to calibrate more than 70 percent of EFMHACA's laboratory equipment. EFMHACA was able to cover all the local costs paid to NMI, resulting in a substantial reduction in USAID's investments. PQM continued working with NMI in late FY 2018 to fill the remaining few gaps, and by the end of the year, it was reassured that NMI would be able to cover all of EFMHACA's needs in FY 2019 (100% coverage). As PQM approaches the end of its period of performance, this is a major success and milestone in terms of ensuring sustainability and transitioning years of technical assistance in a highly technical area.

In terms of laboratory reaccreditation, PQM has worked closely with regulatory authorities in Nigeria and Ghana to foster sustainability. As part of NAFDAC's commitment to sustainability, all costs associated with equipment calibration, proficiency tests, and other laboratory supplies required for reaccreditation of the Yaba, Agulu, and Kaduna laboratories this year were paid for by NAFDAC. Minimal technical assistance was provided by PQM during the preparation for the surveillance audits that led to scope expansion, as the laboratory staff exhibited technical competency and took the lead during the process.

PQM identified key gaps that could help NMI
expand the scope of its calibration services



In Ghana, FY 2018 marked the second year that the Ghana FDA (GFDA) demonstrated technical capacity for maintaining its laboratory accreditation with little technical involvement from PQM experts. This continues to demonstrate that PQM's efforts have built technical capacity for maintaining ISO 17025 accreditation status within the laboratory. It is also noteworthy that this year also marks the first time GFDA contributed 50 percent of the cost of the ISO 17025 accreditation reassessment in line with ongoing commitment by GFDA leadership for sustainability.

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