



Strengthening Medical Product Quality Assurance Systems in Ethiopia: Progress on the Path to Self-Reliance

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Background



Ethiopia is currently in the midst of a major public health transformation. Working with development partners, the country has made remarkable progress in improving public health outcomes and decreasing morbidity and mortality caused by infectious diseases such as malaria, tuberculosis, and HIV/AIDS. In addition, Ethiopia has reduced its maternal mortality rate by 70 percent since 1990 and decreased its under-5 mortality rate by more than 50 percent.¹

Underlying and essential to these gains are major investments and coordinated efforts from the Ethiopian government, development partners, and donors to strengthen local health systems—including those that assure the quality of medical products—to increase system efficiencies, population coverage, and performance. Ultimately, continued efforts to create robust, resilient, and self-reliant health systems will be the foundation for ensuring long-term and sustainable advancement of health in Ethiopia. Despite the dramatic progress made in these areas, nearly 60 percent of the population is at risk of contracting malaria, which remains one of the leading causes of morbidity in the country.^{2,3} In addition, antimicrobial resistance to commonly used antibiotics and the continued availability of poor-quality medical products threaten to undermine progress to date.

Robust and effective regulatory and quality assurance systems help to detect poor-quality medicines and enable national medicines regulatory authorities to take evidence-based regulatory actions to protect local populations. To help fulfill this mandate and respond to the changing needs of the pharmaceutical sector, the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) has been working with the Promoting the Quality of Medicines (PQM) program (funded by the U.S. President's Malaria Initiative and U.S. Agency for International Development and implemented by the U.S. Pharmacopeial Convention) since 2009 to strengthen in-country medical product quality assurance systems.



Women wait outside a district hospital in Kombolcha, Ethiopia. Photo credit: Ed Scholl, Courtesy of Photoshare.

Strategic Approach

When work began with EFMHACA in 2009, PQM sought to better understand the challenges facing the regulatory authority. PQM conducted a rapid gap analysis that helped to identify critical areas of deficiency in the medical product quality assurance system. This gap analysis identified several opportunities for improvement, including inadequate laboratory infrastructure, weak quality management systems, absence of regular equipment maintenance and calibration services, absence of proficiency testing or inter-laboratory comparison schemes, lack of internal and external auditing systems, and a shortage of personnel with appropriate competencies. These challenges hindered the confidence and trust that external stakeholders had in EFMHACA's decisions and the test results being generated from its national quality control laboratory (NQCL).

Following the gap analysis, PQM acted to create consensus on the way forward and began working with EFMHACA management and laboratory staff to design and implement interventions that would build EFMHACA's capacity. The goal was to enable EFMHACA to fulfill its mandate of protecting public health by applying internationally recognized best practices.

In particular, PQM worked with EFMHACA's NQCL to address immediate constraints related to space and facilities and supported EFMHACA in relocating the laboratory to a new building. PQM provided technical expertise to optimize and align the design and arrangement of equipment and operations at the new laboratory space with internationally recognized standards. PQM also helped to implement protocols for the transfer, installation, and requalification of equipment in accordance with the requirements of good laboratory practices.

To build longer-term technical and managerial capacity for medical product quality assurance, PQM took a holistic approach to strengthening the processes, structures, and systems of EFMHACA and the NQCL. PQM worked collaboratively to implement the following interventions:

- Targeted trainings, hands-on support, and supervision to staff for analytical testing techniques and quality management systems. Quality management systems are the foundation for ensuring that an organization is performing at a high level that meets customer and regulatory requirements.
- Staff exchange opportunities with other ISO 17025:2005 accredited laboratories outside of Ethiopia. Staff then applied the lessons from more advanced laboratories in the EFMHACA NQCL.



A health worker in Ethiopia holds antimalarial medication. Photo credit: Bonnie Gillespie, Courtesy of Photoshare.

- Development or revision of 7 quality manuals and more than 100 standard operating procedures. These documents are essential in assuring that the NQCL's activities are carried out in a consistent and reliable manner that ensures accuracy and quality.
- Preparation for ISO 17025:2005 accreditation by instituting required prerequisites. This included supporting the NQCL to participate in proficiency testing at the international level, which helps assess the accuracy of its test results by comparing them with those from other high-performing laboratories.
- Capacity-building for EFHMACA and the National Metrology Institute to effectively maintain and calibrate equipment at the NQCL. This was a critical gap identified during the initial gap assessment that previously led to equipment downtime and delays in issuing test results.
- Assessment of and technical support to four branch laboratories. Drawing on PQM's Collaborative Learning Model (CLM), staff from multiple laboratories were trained together to reinforce capacity and share lessons learned across branch laboratories. The CLM facilitates trainees to become trainers after technical and managerial competencies have been built.
- Development and launch of a new master's program in regulatory affairs with Addis Ababa University to increase the number of qualified candidates entering the regulatory workforce.

Progress on the Path to Self-Reliance

Strengthening quality control laboratories can help countries like Ethiopia become more self-reliant in conducting post-marketing surveillance, harmonizing with other regulators, and ensuring the quality of medical products. The graphic below shows how incremental progress can help move in-country medical product quality assurance systems toward self-reliance.



Results

A Firm Foundation: Strengthened Capacity to Test for Quality

After 2 years of continued technical assistance, in 2011 the NQCL was accredited for ISO 17025:2005 in seven physicochemical test methods. The scope of accreditation was then expanded to medical devices (condom) in 2014. Following accreditation, PQM continued to provide technical assistance in maintaining the status of accreditation, expanding its scope, and continuing participation in regular proficiency testing. By 2018, the NQCL had successfully expanded its scope of accreditation to 16 different test methods—an achievement that confirms the robust testing capacity that the laboratory has attained.

Following PQM support, EFMHACA's four branch laboratories are now fully capable of testing medicines quality by using key analytical quality control techniques. These laboratories now support national efforts to monitor the quality of medical products and participate in routine post-marketing surveillance activities. Thus far, the 4 laboratories have tested more than 1,000 medicine samples to support risk-based post-marketing surveillance and are eagerly working with EFMHACA to attain ISO 17025 accreditation.

In response to the growing need for instrument maintenance capacity, and as a result of continued advocacy and technical support provided by PQM, a strategic plan was developed that supported the establishment of a new Laboratory Equipment Maintenance Unit and the hiring of dedicated staff who are fully managed by EFMHACA. At the same time, PQM's support to the National Metrology Institute led to the successful expansion of its certified calibration capacity to cover the full range of equipment available at EFMHACA. As of 2019, the National Metrology Institute is providing the full range of calibration services to EFMHACA, reducing the cost of calibration by an estimated 80 percent.



Malaria medicines on a shelf at a rural health clinic in Ethiopia. Photo credit: Cameron Taylor, Courtesy of Photoshare.

Before 2015, EFMHACA's branch laboratories were unable to test medicines quality. As a result of PQM's capacitybuilding efforts, the branch laboratories have successfully tested more than 1,000 medicine samples as of 2019.

Making Strides in Quality Assurance through Routine Post-Marketing Surveillance

Together, these interventions have led to significant improvements in EFMHACA's ability to detect substandard and falsified medical products. As a result, EFMHACA is now able to routinely carry out post-marketing surveillance to assess the quality of medical products, and the number of samples it tests every year has increased dramatically.

Between 2009 and 2019, 10 rounds of post-marketing surveillance were conducted, and 3,455 medical product samples were tested. Overall, a total of 25 million condoms in 2015 and 69 million condoms in 2016 that were found to be of poor quality were recalled and/or prevented from entering the market.

Encouragingly, progress is being made to ensure the quality of antimalarials. According to EFMHACA's annual post-marketing surveillance report, the failure rate of antimalarial medicines decreased from 12.6 percent in 2009 to 0 percent in 2019, with an average failure rate of 6.3 percent per year (ranging from 17.2% to 0%). Based on the results from quality surveillance, EFMHACA has taken a total of 114 regulatory actions, 92 percent of which involved recalling or withdrawing medical products from the market—actions that directly protected the public from potentially harmful poor-quality products.

In addition, EFMHACA joined with PQM to organize 10 public awareness and advocacy workshops to disseminate and share information with partners, stakeholders, and community and religious leaders so that they could engage and collaborate with EFMHACA in the fight against substandard and falsified medicines.

Failure Rate of Antimalarial Medicines



The impact EFMHACA's post-marketing surveillance capacity extends beyond the borders of Ethiopia. For example, in 2013, a falsified quinine product identified by EFMHACA was shared with the World Health Organization (WHO) and disseminated through the WHO Alert system, which limited the product's distribution in multiple other countries. When a defective condom product was detected in Ethiopia in 2016, the results were shared with other regulators at the 2016 International Conference of Drug Regulatory Authorities, which prompted the banning of the product in neighboring countries such as Uganda. Importantly, EFMHACA is now actively pioneering efforts to enhance regional harmonization and information exchange and contributed to the establishment of a joint forum for regulators in the Intergovernmental Authority on Development (IGAD) in 2015. Since its establishment, the joint forum has become progressively stronger, issuing a 5-year strategic plan and now articulating areas of harmonization across Member State regulatory authorities. EFMHACA recently held responsibility for testing the quality of medical product samples collected during a first-of-its-kind cross-border post-marketing surveillance activity. The results from EFMHACA's laboratory were accepted by all IGAD Member State regulatory authorities.

Looking Forward



With its newly strengthened capacities in quality control testing, equipment maintenance, and post-marketing surveillance, EFMHACA has catapulted its regulatory maturity to new levels and is now a regulatory leader in the region. However, as is the case for even the most advanced regulatory authorities, EFMHACA faces continued challenges related to limited financial and human resources, the increasingly globalized nature of supply chains, more complex pharmaceutical products, and the ever-evolving tactics of bad actors to gain market access.

To effectively respond to these challenges and achieve self-reliance, EFMHACA will need to continue its efforts to strengthen the nation's medical product quality assurance system by mainstreaming risk-based approaches for post-marketing surveillance, inspections, marketing authorization, and other regulatory functions; supporting the NQCL for additional analytical methods; closing the loop from pre-market review of medical products to post-market quality and safety surveillance; regulating post-approval bioequivalence studies and clinical trials; incorporating serialization and "track and trace" guidelines; and integrating regulatory information for more rapid sharing and dissemination of information.



Anti-malarials in a rural health clinic in Ethiopia. Photo credit: Cameron Taylor, Courtesy of Photoshare.

Endnotes

- 1 World Health Organization. 2018. Country Cooperation Strategy: at a glance. Available at: <u>https://apps.who.int/iris/bitstream/</u> <u>handle/10665/137170/ccsbrief_eth_en.pdf;jsessionid=B85A7D32BC6C1174DFD74F93B5951795?sequence=1</u>. Accessed on: 6 August 2019.
- 2 President's Malaria Initiative. 2019. [Web Page] Ethiopia. Available at: https://www.pmi.gov/where-we-work/ethiopia. Accessed on: 6 August 2019.
- 3 President's Malaria Initiative. 2018. [Fact Sheet] Ethiopia Country Profile. Available at: <u>https://www.pmi.gov/docs/default-source/default-docu-ment-library/country-profiles/ethiopia_profile.pdf?sfvrsn=20</u>. Accessed: 6 August 2019.

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About PQM

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). PQM helps to strengthen medicines regulatory authorities and quality assurance systems and supports manufacturing of quality-assured priority essential medicines for malaria, HIV/AIDS, tuberculosis, neglected tropical diseases, and maternal and child health.

Photo credits: Photos are courtesy of the PQM program unless otherwise noted. Cover photo - A woman in northern Ethiopia holds an infant under a bed net. ©2007 Bonnie Gillespie, Courtesy of Photoshare.

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