

PQM Activities in Sub-Saharan Africa

Medicines quality assurance problems are rife in sub-Saharan Africa. The Promoting the Quality of Medicines (PQM) program—funded through the U.S. Agency for International Development and implemented by the U. S. Pharmacopeial Convention (USP)—is tasked with providing technical assistance to developing countries to strengthen the quality assurance and quality control (QA/QC) of their medicines. PQM currently supports activities in 13 African countries—Angola, Burundi, Ethiopia, Ghana, Guinea, Kenya, Liberia, Mali, Mozambique, Nigeria, Senegal, Tanzania, Zimbabwe—that continue to build their capacity to safeguard medicines.

Many of the activities conducted in sub-Saharan Africa are funded by the President's Malaria Initiative (PMI), where the focus is primarily on activities contributing to antimalarial medicines quality. As those activities result in strengthening the country's health systems overall, particularly for medicines quality assurance, they ultimately benefit all essential medicines. The President's Emergency Plan for AIDS Relief (PEPFAR) also contributes to strengthening systems in three countries—Burundi, Ethiopia and Senegal—to better ensure the quality of antiretroviral medicines used in the treatment of HIV/AIDS.

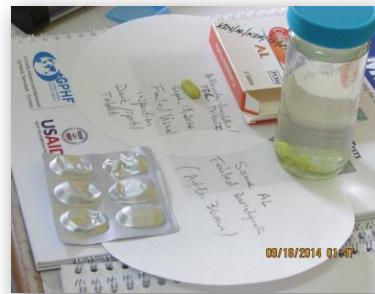
The main thrust of PQM activities centers on strengthening medicines regulatory authorities (MRAs) and their national quality control laboratories (NQCLs) to maintain the quality control of medicines from registration to distribution and sales. PQM trains health control program staff and regulatory authorities on sampling and testing techniques in the marketplace and analytical testing in the laboratory to detect counterfeit and substandard medicines. MRAs learn how to use the data collected to enforce regulatory actions against violators and to raise awareness among the populace about the dangers of using unregulated medicines.



Medicines Quality Monitoring

In many developing countries, data about the quality of medicines is limited, outdated, or nonexistent. PQM assesses a country's existing QA/QC systems; identifies gaps in the systems; and, then, collaborates with the medicines regulatory authority and national health programs to establish (or fortify) a system to regularly examine the quality of medicines circulating in the country. PQM has worked with national and local stakeholders in 10 African countries, to date, to help establish a total of 72 sentinel sites for screening medicines quality. Together with regulators, disease control programs, and other partners, PQM develops an appropriate protocol for sampling and testing, determines where to locate sentinel sites, provides each site with a Minilab® (a portable laboratory) and necessary supplies, and trains field staff in sampling techniques, basic Minilab® testing, and data reporting. The staff of the NQCL in each country receives additional training in advanced testing methods and data analysis. PQM encourages countries to build these quality control measures into their national malaria, tuberculosis, and HIV/AIDS control programs and to use test results to guide regulatory actions.

MQM programs have identified counterfeit and/or substandard medicines in each of PQM's participating countries during the past five years, providing authorities with the evidence needed to take enforcement actions. In 2014, one day of sample collection in Kenya revealed five counterfeit/substandard antimalarial medicines in Kericho County; the authorities took swift regulatory action, notifying sellers to quarantine the medicines until further notice. Liberia recently charged a local importer and wholesaler US\$ 6,000 in fines and fees for marketing unregistered and poor quality medicines. A Minilab® training in Mozambique detected degradants in pediatric Paracetamol. The Ghana FDA banned quantities of unregistered, fake, and substandard medicines supplied to hospitals and pharmacies when MQM found more than 60 percent of the uterotonic available did not meet required standards.



Building Capacity of Medicines Quality Control Laboratories

A country's NQCL plays a critical role in building a strong national quality assurance system and in providing support to the MRA to ensure the quality of medicines in the country. PQM offers technical assistance that addresses an NQCL's needs for appropriately testing medicines quality. After assessing an NQCL, PQM identifies any deficiencies and provides recommendations regarding equipment needs, personnel training, and improvement of operating standards. Through national and regional training, PQM helps improve an NQCL's basic and advanced analytical techniques, emphasizing Good Laboratory Practices, and its capabilities to perform testing according to compendial methods. It also assists the NQCL to develop a sound quality management system encompassing all aspects of organizational structure, human resources, processes, and procedures.



Building capacity in individual labs also advances the overall regional capabilities. PQM helped establish inter-laboratory testing among many NQCLs in Africa to support them in improving their proficiency and launched the Network of Official Medicines Control Laboratories (NOMCoL-Africa) to strengthen south-south collaboration. The 16 NQCLs participating in NOMCoL-Africa conduct both proficiency testing and inter-laboratory testing that helps build their capabilities to ensure that the data they produce is accurate, valid, and trustworthy.



Successful participation in proficiency and inter-laboratory testing schemes is a key component in obtaining ISO/IEC 17025:2005 accreditation and World Health Organization (WHO) Prequalification. PQM provides interested NQCLs technical assistance throughout the process of a lab becoming accredited or certified. The willingness of an NQCL to work toward those goals shows the commitment to excellence of the laboratory management, personnel, and analysts. Thus far, three NQCLs—Ethiopia, Ghana, and Nigeria—have reached ISO 17025 accreditation with PQM assistance, and continue to work

toward WHO Prequalification; one, Kenya, has been recommended for accreditation; and two, Liberia and Senegal, are making progress on the same goal.

Raising Awareness about the Dangers of Counterfeit and Substandard Medicines



Counterfeit and substandard medicines pose a grave threat to patients, especially in developing countries where quality control can be lax. PQM develops a workplan with each participating country that includes a component to raise awareness among authorities, healthcare workers, and the general public about the danger of using medicines from any source other than a regulated outlet. PQM uses a variety of methods to raise awareness about the potential dangers—trade bulletins, journal articles, conference exhibits, videos, and public service announcements—each tailored to best reach the individual audience. A communications campaign in Senegal, for example, used political,

administrative, and religious leaders to educate health professionals and the public about the importance of buying medicines from authorized retailers and to alert illicit vendors of the penalties for continuing criminal activities. As a result, authorities closed a major illicit market in Dakar and established an inter-Ministerial committee to fight counterfeit and substandard medical products. Similar campaigns held in Ethiopia and Liberia used regional music, caravans, educational workshops, and radio/TV messages to inform local healthcare workers and the public about measures they were taking to control the illegal trade of medicines and the consequences for not cooperating.

In addition, PQM has developed a free, internet-accessible database that reports MQM results from many of the countries in Africa, Southeast Asia, and Latin America. Making this data publicly available helps raise awareness about medicines quality issues in the region.



Manufacturers and Good Manufacturing Practices

A priority of the PQM program is increasing the supply of good quality medicines by providing local pharmaceutical manufacturers the technical assistance needed to comply with internationally accepted good manufacturing practices (GMP). Not only does PQM work with MRAs to train their teams on GMP inspection methods, PQM's specialists assess manufacturers for compliance with GMP requirements and evaluate their staff's skills, facilities, equipment, procedures, and quality systems. After reviewing the results with the manufacturer, together they define gaps, and set priorities to address them. For manufacturers wishing to pursue WHO Prequalification, PQM provides guidance in preparing product dossiers for submission and works with them throughout the process to comply with WHO requirements. Currently, PQM delivers technical assistance to local manufacturers in Ghana and Zimbabwe for anti-tuberculosis medicines and in Ethiopia, Ghana, Kenya, and Nigeria on medicines for maternal, newborn, and child health (zinc, oral rehydration salts, uterotonic, and amoxicillin dispersible tablets). With PQM technical assistance, Nigeria's Drugfield Pharmaceutical became the first African manufacturer to produce chlorhexidine gel for newborn umbilical cord care.

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