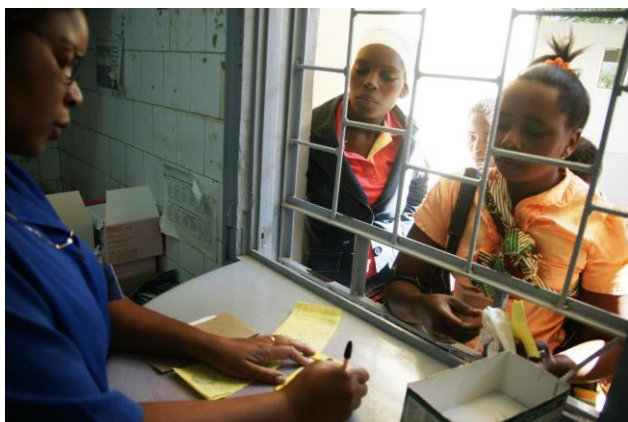


Protecting Patients from Poor-Quality Medicines in Mozambique

Conducting medicines quality monitoring as part of a comprehensive post-marketing surveillance program



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A pharmacist in Chokwe, Mozambique, dispenses Coartem, an antimalarial medication. Sustained capacity to detect falsified and substandard medicines is vital to protecting patients and maintaining their confidence in the health system.

The Promoting the Quality of Medicines (PQM) program began providing technical assistance to Mozambique in 2011 to strengthen the country's pharmaceutical regulatory system, particularly targeting the national laboratory quality management system, medicines quality surveillance, and medicines quality control.

Mozambique relies on foreign manufacturers for nearly all its medicines needs. This creates a lengthy health commodity supply chain and thus increases vulnerability to infiltration by poor-quality medicines. In 2011, the Ministry of Health began collaborating with the Promoting Quality of Medicines (PQM) program, which is funded by the U.S. Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention, to introduce country-wide medicines quality monitoring (MQM). The activity has been a continuous source of essential information, helping identify substandard and falsified medical products and providing evidence to inform regulatory decisions and actions.

Working initially with the Ministry of Health's Pharmaceutical Department and then with its successor, the National Directorate of Pharmacy (DNF), PQM helped establish 14 MQM sites for regularly collecting and testing samples of priority medicines, such as antiretrovirals, antimalarials, anti-tuberculosis medicines, antibiotics, and commodities for maternal and child health. PQM's support focused on developing screening protocols, procuring required equipment, and providing associated training to DNF staff.

At the MQM sites, two levels of screening are conducted on samples: (level 1) visual inspection of packaging to verify the accuracy of printed information and detect any damage; and (level 2) analytical screening utilizing mobile technologies like GPH-Minilab™ to assess whether a product's active ingredient is present and in the right amount. Samples failing either level of testing are submitted to the National Laboratory for Medicines Quality Control (LNCQM) in Maputo for comprehensive compendial (pharmacopeial) testing. Notably, PQM was also Mozambique's partner for relaunching the LNCQM in 2011, almost three years after a fire destroyed the facility and halted medicines testing in the country.

MQM is part of a comprehensive post-marketing surveillance (PMS) program, which encompasses: systematic planning, sampling site selection, medicines collection, analytical testing, data analysis, public reporting, and regulatory action in response to products that are non-compliant with quality standards. Faced with competing health priorities and limited resources to address them, Mozambique and other lower- and middle-income countries have worked with PQM to introduce risk-based approaches into PMS activities. This means using risk-analysis to select the type of medicines to be collected and the locations most likely to have poor quality products.

Mozambique's efficient PMS program provides a clear deterrent to anyone attempting to bring illegal pharmaceuticals into the country and is a vital tool for detecting falsified and substandard medicines.