



 **Spotlight**



Pakistan streamlines process to bring quality medical products to market

The Drug Regulatory Authority of Pakistan and USAID recently launched the Pakistan Integrated Regulatory Information Management System (PIRIMS). PIRIMS integrates data and

documentation for the registration, inspection, and licensing of medicines and the facilities in the supply chain that handle them. Now, regulators can more efficiently monitor the quality of medicines from their development to the last step in the supply chain. Pharmaceutical companies also have a more streamlined process for seeking market authorization for a medicine. And PIRIMS makes it easier to report poor-quality medical products, enabling regulatory authorities to act swiftly. PIRIMS was developed with technical assistance from USAID's PQM+ and PQM programs.

[Learn more](#)

 **Learning**

Unpacking medical product regulatory systems

Regulatory systems, which include quality assurance systems, are inherently complex. Their ability to ensure medical product quality underpins the success of country and USAID health programs. In PQM+'s first webinar, experts used real-world examples to explain the role that medicines regulatory systems play in protecting global health. More than 130 people joined from around the world. **PQM+'s next webinar will be in March.**

Impact

Reports capture progress, impact

PQM+'s first annual report highlights the progress in supporting LMICs to sustainably strengthen quality assurance systems to ensure access to quality-assured medical products for malaria, NTDs, TB, infectious diseases like COVID-19, as well as reproductive, maternal, newborn, and child health. Also, final program report of Promoting the Quality of Medicines captures the global impact of PQM+'s predecessor program – improving 91 quality control laboratories in 33 countries and building the capacity of 45 manufacturers in 12 countries to produce quality essential medicines.



Read the PQM+ Annual Report

Health Elements



Fight against malaria

Learn how PQM+ works with countries across Africa and Asia to ensure the quality of medicines and medical products in the global fight against malaria.

Fact sheet

Global Highlights

Supporting COVID-19 response in partner countries

PQM+ is working with **Bangladesh and Pakistan** to ensure the production of quality personal protective



equipment (PPE) and medical products used to prevent and treat **COVID-19**. Pakistan has granted emergency use authorization for both a real-time polymerase chain reaction (PCR) in vitro diagnostic test and an antigen testing kit.

Kenya

Kenya established a **pharmacovigilance and post-marketing surveillance** technical working group to provide strategic assistance and coordination for these important regulatory functions. The Ministry of Health presided over the virtual inauguration, which included 41 participants from local government agencies, the World Health Organization Kenya, and Kenya's Pharmacy and Poisons Board.



Mali

To support Mali's **National Health Laboratory** achieve **ISO/IEC 17025 accreditation**, PQM+ coordinated a series of virtual trainings to prepare local staff to conduct the key quality control (QC) testing techniques. PQM+ developed seven videos that demonstrate the techniques in the laboratory's proposed ISO/IEC 17025 accreditation scope – from sample preparation to data analysis. This type of accreditation assures calibration and testing laboratories are delivering good services and consistent data.

Nepal

PQM+'s team conducted a rapid assessment of the **Department of Drug Administration's** post-marketing surveillance, inspection, and quality control testing systems to look at workforce capacity and identify human resource needs for these critical regulatory functions.



Nigeria

PQM+ is strengthening the capacity of seven **Nigerian pharmaceutical manufacturers** to produce quality-assured priority medical products, especially maternal and child health and malaria medicines, by addressing Good Manufacturing Practices and other quality challenges. One of the manufacturers of chlorhexidine digluconate 7.1%, which is used to prevent infection in newborns'

umbilical cord stumps, won approval from the West African Health Organization. This will expedite the product's registration in all 15 member countries of the Economic Community of West African States.



Jude Nwokike, PQM+ Program Director, outlines strategies to tap into Africa's underutilized capacity to locally produce quality-assured, essential medical products in his recent Council on Foreign Relations blog, *Scaling Up African Pharmaceutical Manufacturing in a Time of COVID-19*.

Local manufacturers can help to address the shortage of medical products in Africa and also reduce the proliferation of falsified products, explains Lawrence Evans III, PQM+ Technical Director, in *African Leadership Magazine*.

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