

# Promoting the Quality of Medicines Plus (PQM+)



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## Spotlight

### Mali Adopts Risk-Based Sampling Approach to Assess the Quality of Medical Products

Poor-quality medical products can undermine national health programs. Continuous monitoring across the supply chain is critical to ensure the safety and quality of medical products circulating in countries. In Mali, Promoting the Quality of Medicines Plus (PQM+) is collaborating with the National Health Laboratory (*Laboratoire National de Santé*) and the Directorate of Pharmacy (*Direction de la Pharmacie et du Médicament*) to adopt a new risk-based approach to post-marketing surveillance (RB-PMS). RB-PMS channels limited resources toward medicines and locations that present the highest risks to patients.



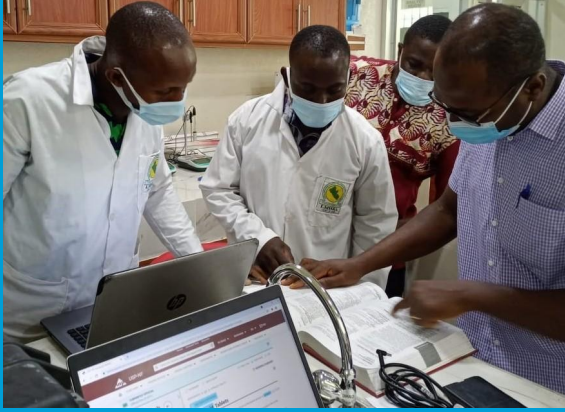
The country's first RB-PMS survey found 69% of medical products, many antimalarials, were unregistered or unapproved. In addition, 4% of medicine samples failed quality control tests, indicating they were either substandard - lacking sufficient active pharmaceutical ingredients or APIs - or falsified (SF). "In view of the scarcity of resources and its scientific nature, this technique must be continued, optimized, and sustained to safeguard health and guarantee access to quality medicines," said Dr. Ousmane Dembélé, president of Mali's national PMS technical working group.



## Impact

### Liberian Regulatory Agency Finalizes Strategic Plan

Liberia's Medicines and Health Regulatory Authority (LMHRA) developed a Five-Year Strategic Plan (2021-2025) to strengthen the



governance of the medical product quality assurance system. The board of directors, representing the Ministry of Health, School of Pharmacy, Ministry of Justice, Ministry of Commerce, and the Consumers Groups Association, validated the plan. It includes six goals: establish an effective, efficient regulatory system; create a quality management system; develop and implement an effective information management system; promote partnership, cooperation, collaboration, and decentralization;

maintain adequate human resources capacity; and mobilize technical and financial resources to implement regulatory functions.



## Global Highlights

In many countries, COVID-19 travel restrictions make it impossible to conduct on-site Good Manufacturing Practices (GMP) inspections of manufacturers. This can delay the market authorization of medical products. Adapting to the pandemic, **Kazakhstan's** Pharmaceutical Inspectorate successfully conducted its **first remote assessment of a pharmaceutical manufacturer**, which is based in India. PQM+'s team trained Inspectorate staff to conduct the remote GMP assessment and also developed key checklists and questionnaires. To share lessons learned, the Inspectorate and PQM+ recently held a webinar for 22 pharmaceutical Inspectorate representatives from Kazakhstan and Uzbekistan.



Government officials in **Pakistan** can now better evaluate the dossiers of **in vitro diagnostic medical devices** thanks to a recent training conducted by PQM+ and a U.S.-based diagnostic equipment provider. Staff of the Drug Regulatory Authority of Pakistan (DRAP) learned how to apply international best practices to assess product dossiers, which include products' technical data. Dossier assessment helps ensure that products registered or released under emergency use authorization, such as during the COVID-19

pandemic, are safe and of acceptable quality.

In **Bangladesh**, the Directorate General of Drug Administration (DGDA) is making significant progress toward achieving **Maturity Level 3** — as measured by WHO's Global Benchmarking Tool (GBT) — for its market surveillance and control, laboratory testing, lot release, clinical trial, and marketing authorization regulatory functions. Maturity Level 3 signifies a stable, well-functioning, and integrated regulatory system. To that end, PQM+ has supported DGDA in 10 functional areas to comply with the many indicators required by WHO. For instance, the program supported DGDA to conduct an internal audit, a mock audit, and a self-assessment as well as to update its Institutional Development Plan, generate evidence documents, and link with the GBT tool.



PQM+ will collaborate with the Government of **Mozambique**



Photo courtesy of the National Institute of Allergy and Infectious Diseases (NIAID) via Flickr.com

in assessing the **quality of anti-retroviral medicines (ARVs)** with resources from the President's Emergency Plan for AIDS Relief (PEPFAR). PQM+ will work to support post-marketing surveillance of ARVs in the nation, where the HIV prevalence was estimated at 13.2% of the adult population, or about 2.3 million people, as of 2020. Of those, about 1.34 million are on anti-retroviral therapy, according to PEPFAR's Mozambique Country Operational Plan.



## Health Elements

### New MNCH Resources Developed to Support Product Registration and Post-Marketing Surveillance

The widespread circulation of SF maternal, newborn, and child health (MNCH) medical products in country and global markets compromises efforts to reduce the morbidity and mortality of mothers and their babies. To help expand access to quality-assured medical products, PQM+ created new resources - or job aids - for regulators and lab staff to ensure the quality of critical medical products as well as a new guidance document on risk-based post-marketing surveillance (RB-PMS) of such products. These free resources, in both French and English, are available on [the PQM+ site](#).

Learn more about PQM+'s work in a [new MNCH fact sheet](#).



## Learning

### USP Toolkits Now Available to Check COVID-19 Vaccine Quality

As COVID-19 vaccines roll out globally, the detection and removal of SF products is critical. USP has developed free [new toolkits](#) to help regulators and national control labs assess vaccine quality. Recently, PQM+ convened several regional webinars, drawing more than 600 attendees from around the globe, to explain how to use the toolkits to help safeguard countries' vaccine supply chains. A [recording of the webinar](#) is available for viewing.

### Webinar Explores Quality, Cost Perceptions of Generic Products

Kenya's Ecumenical Pharmaceutical Network and PQM+ held a [webinar on generic medicines](#) to boost awareness about affordable, quality-assured essential generic medicines. Aimed at hospital administrators, pharmaceutical services heads, Ministry of Health representatives, and regulatory agencies, experts discussed the importance of generics, the sustainability of the local quality-assured medicines supply, and managerial and regulatory strategies, among other topics. PQM+ speakers included Program Director Jude Nwokike and technical advisors Daniel Karimi and Teferi Bedane.

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