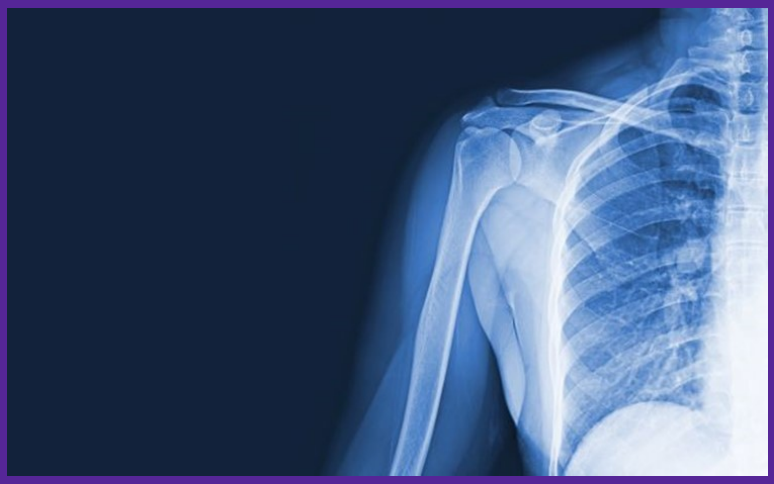
Spotlight

Ensuring a reliable supply of quality-assured tuberculosis medicines



Amid a spotlight on tuberculosis (TB) as the World Conference on Lung Health convenes in Paris this month, USAID is celebrating its September **launch of the Global Accelerator to End TB Plus**. This $23 million package of interventions, USAID notes, "will accelerate the development of strategies to achieve a more accountable, responsible, and inclusive TB response." The effort will drive progress to end TB by 2030 and includes support for widescale interventions to screen for and detect TB, increased support for TB in conflict settings, a commitment to allocating a majority of TB funding to local partners, a preventive treatment program, and clinical trial research. To contribute to these efforts, PQM+ collaborated with a US-based partner to develop an alternative manufacturing process to efficiently produce pure rifapentine active pharmaceutical ingredient (API). The final manufacturing process has been documented and is awaiting technology transfer to a manufacturer in Africa. This should help reduce costs of rifapentine products and contribute to ensuring a reliable supply of quality-assured TB medicines.

Global Highlights

Bangladesh passes Drugs and Cosmetics Act

Bangladesh's parliament recently passed the Drugs and Cosmetics Act of 2023, replacing the 1940 Drugs Act and 1982 Drugs Ordinance. In tandem, PQM+ coordinated with Bangladesh's Directorate General of Drug Administration (DGDA) to update and finalize the country's regulatory framework document and align it with the new legislation. The passage of the Drugs and Cosmetics Act required several years of dedicated support from several partners, including PQM+ and its predecessor program, Promoting the Quality of Medicines (PQM). USAID, through PQM and PQM+ helped strengthen the act by adding two provisions. The first further defined good practices to reflect the content and the intent of the law more accurately, and the second included a product recall provision for substandard and falsified (SF) products distributed on the market. This legal framework will be essential for regulating and enforcing drugs and cosmetics product quality.

Growth of the African National Control Laboratories-Reliance Network

PQM+ strives to foster local ownership. Our assistance toward the operationalization of the African Medicines Agency demonstrates the benefit of regional initiatives. In 2009, the predecessor PQM program helped strengthen individual national quality control laboratories (NQCLs) and helped establish the Network of National Official Medicines Quality Control Laboratories with USAID investment. This small laboratory network evolved into a locally led continental network called the African Medicines Quality Forum. In 2022, PQM+ began supporting the African Medicines Regulatory Harmonization program to develop a vaccine laboratory network for Africa. As a part of its support for a collaborative process to conceive and design the African National Control Laboratories–Reliance Network (ANCL RN), PQM+ submitted a package of plans and resources to the African Union Development Agency–New Partnership for Africa's Development (AUDA NEPAD).

Nepal expands campaign to increase awareness of substandard and falsified medicines

Ghana manufacturers transition to electronic document submissions

In Ghana, PQM+ is building the capacity of potential vaccine manufacturers to

In Nepal, PQM+ is ramping up efforts to educate pharmacy staff and the public about the dangers of SF medicines. In collaboration with Nepal's Department of Drug Administration (DDA), PQM+ designed infographic stickers and is now assisting with printing and distributing these products to pharmacies and health facilities. During the pandemic, PQM+ worked with DDA to distribute and display approximately 3,000 Nepalese-language posters to pharmacies throughout the country. The team also aired jingles about quality-assured medicines for three months on national and local radio stations. These efforts aim to spur widespread consumer demand for high-quality medical products. PQM+ continues to collaborate with the Nepal Health Research Council and similar organizations to raise awareness about the dangers of SF medicines.

submit applications to register their vaccines and related documents electronically. Currently, applications (known as dossiers) are submitted in the common technical document (CTD) format, but as African regulatory agencies such as the Ghana FDA shift to electronic regulatory information management systems (RIMS), manufacturers will need to submit dossiers electronically in the eCTD format. PQM+ recently hosted a workshop to train representatives from local pharmaceutical manufacturers on how to prepare and submit eCTD dossier files and use electronic regulatory submission software tools. PQM+ is also supporting FDA Ghana to install an integrated RIMS through which it can accept eCTD dossiers. These changes will build efficiency in the health system as they decrease the time and resources needed to get medicines approved for manufacturing.

Nigeria builds capacity to encourage PPMV registration

Patent and proprietary medicine vendors (PPMVs) are an integral part of Nigeria's health care system, especially in rural and semi-urban regions. PPMVs are required to register with the Pharmacy Council of Nigeria (PCN), but a lack of enforcement means many operate without registration. Customers – many of whom are marginalized – of these unregulated medical product retail outlets are vulnerable to the dangers of SF medicines. To reduce the risks, PQM+ is working with the Association of Community Pharmacists of Nigeria and the National Association of Patent and Proprietary Medicine Dealers to build capacity to boost registration rates. The associations and PQM+ collaborated to

Mali strengthens surveillance of medical products

Mali has taken steps to ensure the quality of medical products circulating in the country, including recalling SF products, enforcing recalls, and monitoring efforts to strengthen the regulation of imported medical products. The National Health Laboratory and the Mali Directorate of Pharmacies and Medicines adopted a risk-based approach to post-marketing surveillance (RB-PMS) of medicines quality, relying on a streamlined strategy for sampling and testing that could identify unregistered and poor-quality medicines at a lower cost. In essence, RB-PMS channels precious resources toward medicines and locations with the highest risks to patients. Read more **here**.

share data on regions with the greatest threat of SF medicines. This evidence will guide PCN's inspections and enforcement activities.

News

COVID-19 test-to-treat resource now available

USAID recently introduced COVID-19 **test-to-treat (T2T) programming** in priority countries whose populations have a high risk of severe illness from the virus. As part of this work, PQM+ prepared a scientific and technical information package to assist national medicines regulatory authorities in low- and middle-income countries to make informed decisions on market authorization of COVID-19 antivirals, namely nirmatrelvir (co-packaged with ritonavir) and molnupiravir. Both medicines may prevent serious disease and death in high-risk populations when administered early in a COVID-19 infection. Check out the full compilation of relevant data and scientific recommendations concerning the safety, efficacy, and use of these two antiviral products **here**.

To learn more about the PQM+ program, visit **www.usp-pqmplus.org**