Spotlight

WHO prequalifies manufacturing of two essential medicines in Nigeria and India

PQM+ commends the World Health Organization's decision to prequalify two essential medicines: sulfadoxine-pyrimethamine (SP) 500mg/25mg tablet for malaria, developed by Nigeria-based Swiss Pharma Nigeria Ltd. (Swipha), and chewable albendazole 400mg tablet for treating intestinal parasites by India-based Mepro Pharmaceuticals. The prequalification of both medicines marks a

significant milestone in the global fight against infectious diseases.

Mepro and Swipha received extensive technical support from USAID's PQM+ program, including improving compliance with good manufacturing practices to ensure the medicines are produced consistently according to quality standards. PQM+ also provided comprehensive technical assistance to the manufacturers to develop the products, manage the necessary studies, develop their dossiers, respond to questions about the dossiers from the WHO PQ team, and prepare for the WHO team's audit, which ultimately led to these products receiving WHO prequalification. This achievement could significantly increase the availability of essential medicines for millions affected by malaria, especially in pregnant women, and neglected tropical diseases (NTDs). Read the press release to learn more.

Learn more

Global Highlights

Ensuring quality medical devices in Nepal and South Asia

Manufacturing medical devices and authorizing their use often depend on the capacity of both the local manufacturer to comply with good manufacturing practices and the national regulator to evaluate the safety, efficacy, and quality of the product. PQM+ is working with manufacturers and regulators in Nepal, Bangladesh, and Pakistan to ensure the quality of medical devices, with an aim to strengthen their quality systems and improve the availability of locally produced, quality-assured medical devices. Explore our latest interactive story to learn more.

Read the story

Substandard and Falsified Medicines Burden Model webinar

PQM+ hosted the latest USAID Office of Health Systems Strengthening Learning Series webinar on the Substandard and Falsified (SF) Medicines Burden Model, developed by PQM+. The webinar introduced the SF medicines burden model and reviewed results for two major maternal, newborn, and child health (MNCH) products - oxytocin and amoxicillin. It explored a pilot of the model using SF oxytocin in Kenya, provided estimated results for the burden of SF oxytocin and amoxicillin in Africa and Asia, and explained how country-specific results can be readily calculated. Access the recording of the webinar and presentation slides, including a downloadable version of the model and resource documents on modeling the burden of substandard and falsified oxytocin and amoxicillin.

Watch the webinar

eCTD and eQMS software solutions webinars

Developing strong product dossiers for quality-assured medical products and ensuring swift and effective review are critical factors that help increase access to quality-assured medicines for millions of patients in low- and middle-income countries. PQM+ recently hosted two webinars to introduce current eCTD and eQMS software on the market and aid regulatory authorities and pharmaceutical industry professionals in selecting software solutions appropriate for their needs. Access the webinar recordings and resources documents to learn more.

Watch the webinars

Ghana gears up for local vaccine production

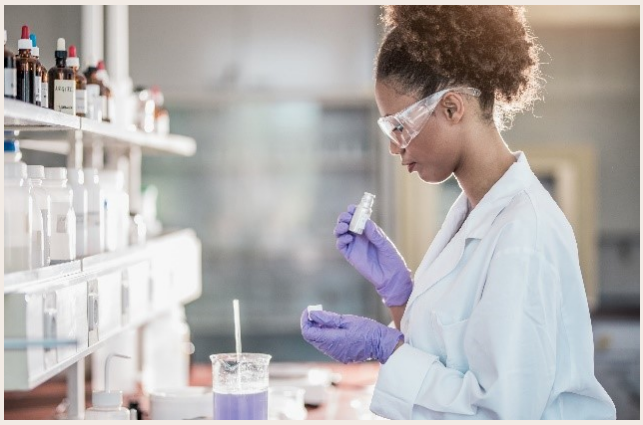
At the height of the COVID-19 pandemic, PQM+ partnered with the Food and Drugs Authority in

Ghana to develop the country's capacity as a local vaccine manufacturing center through the U.S. Government's Initiative for Global Vaccine Access (Global VAX). Today, Ghana is the first country in West Africa with a WHO-prequalified national medicines quality control laboratory. The program's support was instrumental in strengthening Ghana's regulatory and quality control capabilities, information management systems, and lab testing capacity, including independent lot release testing. Learn more about this work to ensure the quality of vaccines and other medical products.

Read the factsheet

News

Lesotho takes a step toward stronger pharmacovigilance



Lesotho is the newest member of the WHO Programme for International Drug Monitoring (PIDM), an international collaboration with the goal of ensuring identification of safety problems in medicinal products. Thanks in part to support from USAID's PQM+ program, Lesotho is working to share insights and data to improve patient safety both nationwide and globally to advance pharmacovigilance. Learn more about how safety monitoring of medicines and vaccines protects patients.

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