Promoting the Quality of Medicines Plus (PQM+)

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Spotlight

Pharmaceutical companies earn WHO prequalification for essential medicine

As a result of USAID support through PQM+ and its predecessor PQM program, pharmaceutical companies in Nigeria and Pakistan recently achieved international recognition for their zinc sulfate products. Zinc sulfate is one of WHO's essential medicines for newborn and child health.

In an important step in the development of pharmaceutical manufacturing capacity on the African continent, the World Health Organization's Prequalification (PQ) Unit approved zinc sulfate in the form of 20 mg dispersible tablet for manufacturing by Swiss Pharma Nigeria Limited (SWIPHA) in June. PQM+ helped SWIPHA, headquartered in Lagos, Nigeria, to develop this product, complete the necessary studies, develop the dossier, and pass WHO's facility inspection. This **milestone achievement** marks the first time a pharmaceutical company in West Africa has achieved WHO prequalification for a medical product.

On July 12, the World Health Organization's Prequalification Unit also approved PharmEvo's dispersible **zinc tablet** and oral **zinc solution**. PharmEvo's head office is based in Karachi, Pakistan. PQM+ provided technical support to PharmEvo throughout the duration of the PQ process, helping to accelerate the timeline and reduce costs. This WHO recognition makes Pakistan the first country in the world to have PQ for zinc sulfate oral solution and the fourth LMIC to have a manufacturer prequalified to produce pediatric zinc sulfate dispersible tablets.

Zinc sulfate in concert with oral rehydration therapy is widely used to treat diarrhea to make episodes less severe, particularly **in children**. WHO's approval signals confidence in the quality of the medicines manufactured by both countries, making them eligible, in principle, for procurement by United Nations agencies and donor organizations.

Global Highlights

Ghana's national lab receives global recognition

Ghana's Drug Physicochemical Laboratory became the first WHO-prequalified (WHO PQ) national medicines quality control laboratory **in West Africa.** This milestone marks a **critical step for Ghana** and the African continent. The lab is positioned to serve as a regional center of excellence to provide training to other medicines regulatory authorities and national quality control labs in Africa. FDA Ghana can now participate in international bids to analyze medicines procured by U.N. agencies, which could boost its financial independence. **Read more.**

Ethiopia's medical device lab achieves accreditation

PQM+ collaborates with the Ethiopian Food and Drug Authority (EFDA) to build the skills and capacity of their lab staff to meet international standards for quality, competency, and consistency. Recently, Ethiopia's medical devices laboratory achieved ISO/IEC 17025:2017 accreditation for glove testing. Ethiopia's progress demonstrates how USAID's long-term investment in the country's health system strengthens national labs and improves the quality of medical products. **Read more.**

Our team in Ethiopia joined the Ethiopian Metrology Institute (EMI) to celebrate World Metrology Day this spring. PQM+'s predecessor project, PQM, helped strengthen EMI so that it could calibrate equipment, including equipment used to test medicines. EMI now calibrates EFDA's lab equipment, which has reduced the cost of calibration by almost 90%. At the celebration, PQM+ highlighted the importance of equipment calibration in the quality assurance of medical products. Equipment used in labs – such as scales, weights, thermometers, hydrometers and pipettes – must be precise, reliable and correctly calibrated to ensure the accuracy of results.

Bangladesh opens new national laboratory

The Directorate General of Drug

Nepal progresses toward accreditation

PQM+ collaborates with Nepal's

Administration (DGDA) in Bangladesh inaugurated a new medical device laboratory this spring. Dr. Md. Anwar Hossain Howlader, Secretary, Health Services Division, Ministry of Health and Family Welfare attended the ceremony, as did Major General Mohammad Yousuf, Director General at DGDA, and Liza Talukder, Project Management Specialist, USAID Bangladesh. The new facility will help improve quality assurance of medical products.

Department of Drug Administration (DDA) to strengthen its medical product quality assurance and quality control systems, including enhancing the testing capacity of its National Medicines Laboratory (NML). In preparation for meeting ISO 17025:2017 requirements for accreditation, PQM+ recently trained NML staff on analytical method validation and measurement of uncertainty, both of which are critical components for ensuring the consistent validity of test results.

Expanding access to medicines for children

Each year, more than 700,000 children under the age of 5 die from pneumonia and other treatable respiratory infections. Nearly all of these infections could be effectively treated with oral amoxicillin in pediatric formulations or injectable gentamicin. Amoxicillin and gentamicin are inexpensive and effective in treating pneumonia and other respiratory infections, but they must be made more accessible. USAID, UNICEF, the Global Child Health Task Force, PQM+, and other USAID-funded projects have issued a **Call to Action** outlining four bottlenecks for countries to address to improve access and use of these important medicines. **Read more**.

New dashboard for NTD medicines data

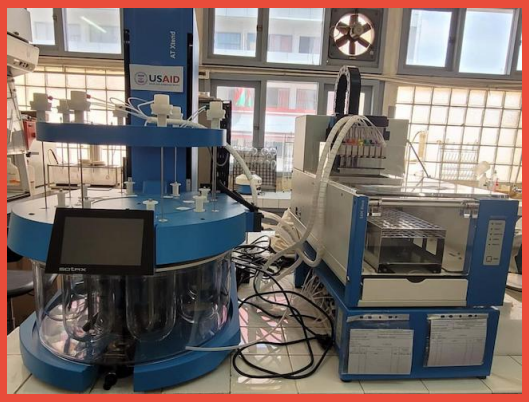
The new **NTD Dashboard** offers a centralized location on the source, dosage forms and strengths, and registration status of quality-assured medicines to prevent or treat neglected tropical diseases (NTDs). The dashboard includes data on both active pharmaceutical ingredients and finished pharmaceutical products. It focuses on seven preventive chemotherapy and transmission control NTD medicines of

interest: albendazole, azithromycin, diethylcarbamazine, ivermectin, mebendazole, praziquantel, and tetracycline eye ointment. This tool is designed to assist procurement agencies, manufacturers, donors and others plan for the procurement and supply of preventive chemotherapy and transmission control medicines for NTDs. **Explore the dashboard**.

News

Madagascar lab donation

On July 10 at a ceremony at Madagascar's Ministry of Public Health, USAID's Mission Director Anne N. Williams handed over essential pharmaceutical laboratory equipment and supplies to the General Secretary of the Ministry of Public Health, Dr. Lethicia Lydia Yasmine. With support from PQM+, Madagascar's Medicine Regulation Agency (AMM) will use the equipment to test the efficacy of maternal and child health, family planning, and antimalarial medicines already on the market.



The equipment includes a medicines dissolution tester, which analyzes how well medicines dissolve and release active ingredients in the body. **Read more**

PQM+ extended to 2025

USAID recently extended PQM+'s period of performance to September 2025. This no-cost extension signals the importance of the program's work to sustainably strengthen medical product quality assurance systems in low-and middle-income countries. PQM+ is collaborating with **25 countries** to expand access to quality-assured medical products used to prevent and respond to tuberculosis, malaria, neglected tropical diseases, COVID-19, and other infectious diseases as well as improve maternal, newborn and child health.

In June, PQM+ hosted a global retreat at USP's headquarters in Rockville, Maryland. We welcomed 29 staff from 13 countries. Colleagues around the world also joined online for the week-long work planning event.