IMPROVING THE SUPPLY OF QUALITY MEDICAL PRODUCTS

Stockouts and shortages of quality-assured essential medical products—including those required to prevent maternal and child deaths, combat the HIV and AIDS epidemic, and control infectious disease threats—are still common in many countries and can lead patients to obtain medicines from informal markets where quality is not assured. Conflicting policies, challenges in adhering to good manufacturing practices, and insufficient market intelligence data can all impede the supply of, and ultimately, access to quality-assured medical products.

The Promoting the Quality of Medicines Plus (PQM+) program, a U.S. Agency for International Development-funded program led by USP, works to increase access to quality-assured medical products and strengthen quality assurance systems by working with manufacturers to improve the supply of quality-assured priority essential medical products.

KEY PQM+ STRATEGIES

Raising the standard of manufacturing capacity

Through PQM+, we support manufacturers of essential medical products to adopt quality-by-design approaches across the pharmaceutical product lifecycle. PQM+ focuses on known and recognized challenges around data integrity, quality management systems, stability, and formulation to ready manufacturers for WHO prequalification or other approvals. PQM+ is helping to:

+ Provide end-to-end technical support to manufacturers to bring production practices in line with current good manufacturing practice (GMP) and file dossiers for product approval and marketing authorization.

+ Facilitate technology transfer from industry innovators to local manufacturers and support a greater understanding of the latest science and emerging technological advancements.

+ Develop, compile, and disseminate quality target product profiles, monographs, and manufacturing know-how to improve technical competency and facilitate investment decisions for local manufacturers.

Improving access to market intelligence and data analytics

While the pharmaceutical market for high-value products is well-studied, market intelligence on essential medicines with lower profit margins receives less attention and analysis. Helping local manufacturers to access information on market size and potential, procurement, and supply gaps can help support data-driven market entry decisions. PQM+ is helping to:

+ Map and share information on regional sources of raw materials and technical expertise with manufacturers of essential, priority medical products.

+ Share data on manufacturing capacity for priority active pharmaceutical ingredients and finished pharmaceutical products, building on existing data sources.

+ Develop information and strategies to spur local manufacturer investment in GMP quality upgrades and expansion of product lines to increase the production of quality-assured medical products to reduce shortages.

Supporting bioequivalence studies

Bioequivalence studies help demonstrate that a generic product functions in the same way as a branded, innovator product and thus will have the same clinical effect. PQM+ supports regulators in low- and middle-income countries to build capacity to inspect clinical research organizations (CROs) and improve dossier review while working with manufacturers and CROs to expand capacity to conduct high-quality bioequivalence studies. PQM+ is helping to:

+ Strengthen capacity of manufacturers, regional bioequivalence centers, and CROs to conduct bioequivalence studies in line with international standards.

+ Support regulatory authorities to develop or revise national bioequivalence requirements in line with international guidelines and strengthen capacity for evaluating bioequivalence as part of dossier evaluation.