PROMOTING THE QUALITY OF MEDICINES

What is Poor Medicine Quality?

Poor quality medicines do not meet official standards for strength, quality, purity, packaging, and/or labeling. They may be legally registered, innovator or generic products; or they could be counterfeits – deliberately mislabeled for identity, strength or source. Whether counterfeit or unintentionally substandard, poor quality medicines have serious health implications including treatment failure, adverse effects, increased morbidity, mortality, development of drug resistance, and wasted resources. Recent reports indicate the availability of substandard and counterfeit medicines has reached a disturbing proportion in many resource-limited countries.

The Promoting the Quality of Medicines (PQM) Program, supported by the United States Agency for International Development and implemented by the United States Pharmacopeia, is addressing the problem through the following activities.

- **Disseminating information –** To monitor trends in poor medicine quality, PQM publishes a *Media Reports on Medicines Quality*. Summarized reports of substandard and counterfeit medicines are organized by region and updated monthly. The *Media Report* serves as a tool to increase awareness about the gravity of this problem among health care professionals, policymakers, and the general public. It is available on the PQM website: www.pqmusp.org.
- **Assessment and training –** PQM evaluates national quality assurance and quality control systems in developing countries to determine what technical assistance might offer improvement. PQM staff provides training in basic test methods using the GPHF Minilab® and in the laboratory, good laboratory practices, data and records management, and compendial methods to strengthen the capacity of medicine quality control labs.
- **Surveillance** – Working with national disease control programs, local universities and other organizations, PQM builds local capacity to collect and test medicine samples from private- and public-sector dispensing points, e.g., hospitals, clinics, pharmacies, and retailers, to monitor the quality of accessible products in a country or region. Data is provided to the government, alerting them to violations and allowing them to take enforcement action.
- **Good manufacturing practices** – PQM assesses medicine manufacturing plants for compliance with international standards of good manufacturing practices. It helps companies with dossier review, then provides the needed technical assistance to improve their processes and the facilities to meet World Health Organization (WHO) prequalification status or ISO 17025 accreditation.
- **Regional and international collaborations** – PQM develops conferences and regional meetings on approaches to improving medicine quality in collaboration with other regional and international health organizations including Roll Back Malaria, Malaria Action Coalition, WHO Office of Essential Drugs and Medicines/Quality, Safety and Efficacy, and WHO Regional Offices**,** among others.

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