



# VIII Resolution

## Regulatory Systems Strengthening

USP will collaborate with global regulators and other partners to strengthen regulatory systems.

### Year 3 Update

Scientific and technological innovations continue to push the boundaries of what's possible for preventing, treating, and curing medical conditions, and for saving and improving patients' lives. These innovations, combined with an increasingly complex global supply chain, present challenges for national and regional regulators tasked with ensuring the safety, efficacy, and quality of medical products. At the same time, many regulatory authorities, particularly those in low- and middle-income countries (LMICs), still lack the basic regulatory functions to ensure the quality of essential medical products. This year, USP worked with regulatory authorities and other stakeholders in 25 countries, and at the regional and global levels with groups such as the World Health Organization (WHO), to strengthen regulatory systems. Much of this work is supported by government agencies, including the U.S. Agency for International Development (USAID), the Australian Department of Foreign Affairs and Trade, and others.

Key areas of progress over the past fiscal year include:

**Asia-Pacific Economic Cooperation Forum** – USP engages in the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee and currently hosts two APEC Regulatory Centers of Excellence – one for the Medical Product Supply Chain and the other for Advanced Therapies. This work resulted in key developments during the year.

- ▶ As part of the U.S.'s 2023 host year activities for the APEC forum, USP and FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened over 500 stakeholders from 45 countries representing international regulatory agencies, industry, academia, nonprofits, and multilateral organizations. The two-day meeting featured knowledge sharing and dialogue aimed at advancing global supply chain resilience. This included discussion of the impact of the COVID-19 pandemic, impurities, resources available to help ensure supply chain security, and other public health priorities. (See *Collaboration with FDA and Other*

*Stakeholders on Health Priorities Resolution update.)*

- ▶ In May 2023, the USP-APEC Center of Excellence for Advanced Therapies held a two-day virtual training with more than 150 regulators from APEC and beyond on chemistry, manufacturing, and control challenges in chimeric antigen receptor (CAR) T-cell therapy to address knowledge gaps in real-world applications. (See *Collaboration with FDA and Other Stakeholders on Health Priorities Resolution update.*)
- ▶ USP serves on the Steering Committee of the Global Medical Product Quality and Supply Chain Integrity Priority Work Area, chaired by FDA. In this capacity, in April 2023 USP was announced as the new host of the APEC Supply Chain Security Toolkit, which now permanently resides on the USP website.

**Promoting the Quality of Medicines Plus Program** – This year, USAID’s funding of the Promoting the Quality of Medicines Plus (PQM+) program supported advancement of 25 national regulatory authorities in their maturity levels, as defined by the WHO Global Benchmarking Tool (GBT).

- ▶ PQM+ continued to support operationalization of the African Medicines Agency – an agency of the African Union and continent-wide regulatory body that is designed to complement existing regional initiatives and national regulatory authorities, and which will build on the efforts of the African Medicines Regulatory Harmonization (AMRH) initiative. This included PQM+ support for development of a continental vaccine lot release laboratory framework, an active pharmaceutical ingredient database,

and a concept note for the Bioequivalence Subcommittee of the Evaluation of Medical Products Committee.

- ▶ Nearly all national regulators supported by PQM+ are engaged in the implementation of the WHO’s GBT and working to improve their capacity to regulate medical products. The GBT enables objective evaluation of a country’s regulatory capacity and facilitates formation of institutional development plans to advance regulatory maturity.
- ▶ Collaboration with another USAID-funded program – the Medicines, Technologies, and Pharmaceutical Systems Program (MTaPS) – resulted in a joint MTAps/PQM+ guidance document that guides LMICs in digitizing regulatory information and defines minimum common data standards to support LMICs in modernizing their regulatory information systems to improve oversight, efficiency, and data sharing.
- ▶ PQM+ provided expert feedback on multiple WHO guidelines and normative frameworks including the Global Model Regulatory Framework for Medical Devices, antimalarial drug resistance guidelines, and the Global Competency Framework for Regulators of Medical Products.
- ▶ As part of USAID’s Global VAX initiative, and recognizing the common interest and need for biomanufacturing competency development in LMICs, PQM+ conducted a workshop in South Africa in collaboration with AMRH, the South African Health Products Regulatory Authority, Afrigen Biologics and Vaccines, and the WHO mRNA Technology Transfer Hub. The December 2022 hybrid

workshop aimed to increase the vaccine manufacturing competency of industry, regulators, and academia, and provide a forum for advocacy. Also, as part of Global VAX, PQM+ supported six African regulatory authorities in visiting three vaccine manufacturing sites in India to help build a bridge between regulators and industry by fostering mutual support, harmonization, and collaboration.

- ▶ PQM+ teamed up with the U.S. FDA to develop and host a three-day online conference titled “Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines” in August 2022. The virtual conference provided an important opportunity for regulators, industry, and USAID staff to learn directly from FDA about drug approval pathways and application reviews; the role of the FDA in international regulatory harmonization; and collaboration among FDA, WHO, and national medicines regulatory authorities.

#### **Diethylene Glycol and Ethylene Glycol –**

The WHO urged a call to action after substandard medicines identified in The Gambia, Indonesia and Uzbekistan, and several other countries, were found to contain unsafe amounts of diethylene glycol (DEG) and ethylene glycol (EG) as contaminants. In response, USP developed a toolkit for manufacturers, regulators, and other pharmacopeias to address DEG and EG contamination associated with allergy, cold, and cough medicines.

#### **Planned for Remainder of the Cycle**

- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit, and will work with partners such as the Alliance for Safe Online Pharmacies to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ Through donor-funded programs, USP will continue to support national-level regulators in building capacity for essential regulatory functions, strengthening oversight of expanding local manufacturing sectors, and achieving advanced levels of regulatory maturity. PQM+ will also support efforts to strengthen regional harmonization through ongoing support to regional bodies.
- ▶ USP’s work through the PQM+ program will support AMRH with the issuance of a reliance framework for laboratory lot release in Fiscal Year 2024.
- ▶ Through technical expertise, guidance documents and toolkits, and technical assistance, USP will work to advance regulation of complex generics, impurities, and contaminants to protect patients and ensure access to quality-assured medical products.

#### **Contact**

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