

USP Statement to the 72nd World Health Assembly Agenda Item 11.7: Access to medicines and vaccines

Thank you for providing us with an opportunity to share our comments at the 72nd World Health Assembly.

The United States Pharmacopeial Convention (USP), a nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements worldwide, is committed to facilitating access to quality-assured medicines, vaccines, and other health products.

While there has been success in expanding access to medicines in lower- and middle-income countries, quality-assured essential medicines remain out of reach for nearly two billion people worldwide. In low- and middle-income countries (LMICs), challenges to quality span the medicine's life cycle, from manufacturing to distribution, to variable procurement policies and regulatory capacity.

We commend the WHO Access Road Map's attention to several areas vital to quality-assurance of medicines. Specifically:

1. Strengthening regulatory systems towards WHO listed authority status
2. Supporting local manufacturing within LMICs
3. Maintaining and expanding the scope of the Pre-Qualification (PQ) Service and quality assurance efforts
4. Improving the prevention, detection, and response to substandard and falsified health products

USP prioritizes these areas in our work around the world. Through the Promoting the Quality of Medicines (PQM) program supported by USAID, we strengthen regulatory systems and help local and international manufacturers achieve WHO Prequalification and internationally recognized good manufacturing practices.

In the United States, USP's public quality standards have facilitated responsible, quality assured generics competition, a cornerstone of access to medicines. As we look to support strategies above, we appreciate ongoing WHO leadership to further welcome partners who bring expertise, resources and experience. We remain committed to the goal of access to quality-assured medicines everywhere.