

USP Statement on the World Health Organization's (WHO) Publication: Delivering Quality-Assured Medical Products for All 2019-2023 – WHO's Five-Year Plan to Help Build Effective and Efficient Regulatory Systems

The United States Pharmacopeia (USP) congratulates the WHO for its publication of the [WHO 2019–2023 plan](#) to build effective and efficient regulatory systems to deliver quality-assured medical products for all.

We commend the plan's focus on helping national regulators protect the public while enabling timely access to quality products and encouraging innovation. Closely aligned with WHO's 13th General Program of Work, we note this plan's regulatory initiatives will focus on Member States' goals to increase access to universal health coverage, support health emergency responses, and promote healthier populations, with specific deliverables and key performance indicators.

The plan is timely. The upcoming transitions toward greater government-led procurement of medicines make it critical that Member States have the right frameworks, tools, and resources to be able to ensure availability of quality-assured medical products for today and tomorrow.

In lower- and middle-income countries (LMICs), quality-assured essential medicines remain out of reach for nearly two billion people worldwide. Challenges span the medicines' life cycle, from manufacturing to distribution, to variable procurement policies and regulatory capacity. Beyond political will, solutions to quality challenges will depend on:

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

A key component of having quality-assured products is adherence to science-based, public quality standards as part of robust regulatory frameworks. USP prioritizes building capacity for quality-assurance in our work around the world. Through the Promoting the Quality of Medicines (PQM) program, funded by USAID and implemented by USP, we have supported countries to strengthen their regulatory systems and helped manufacturers achieve international quality standards and WHO Prequalification.

As we look to support the goals above through our standards, capacity building, and advocacy, we appreciate the WHO's leadership in this space and look forward to engaging at multiple levels to help Member States realize medicines' benefits for patients everywhere.

The United States Pharmacopeia (USP) is a nonprofit organization in official relations with the WHO under the WHO Framework of Engagement with Non-State Actors (FENSA). USP sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements worldwide, and is committed to facilitating access to quality-assured medicines, vaccines, and other health products.