

## USP Statement to the 74th World Health Assembly Agenda Item 16.1: COVID-19 Response

Thank you for the opportunity to share our comments at the 74th World Health Assembly.

The United States Pharmacopeial Convention (USP) is a nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. Ensuring a strong global supply chain is critical to the COVID-19 response and to addressing future global crises. USP is committed to working with global stakeholders on a concerted and coordinated response.

Patients around the world depend on quality-assured essential medicines—and their ingredients—sourced from manufacturers who operate according to international quality standards. Acute disruptions, such as the COVID-19 crisis, expose and exacerbate vulnerabilities in the supply chain that increase the harm to patients. USP therefore supports the global community's efforts to strengthen supply chain resilience, including advancing the use of pharmacopeial standards, to help ensure the supply of quality-assured medicines.

In particular, USP calls on global stakeholders to:

- **Increase transparency**, including expanding requirements for industry and healthcare providers to report on existing or potential drug shortage indicators.
- **Bolster quality assurance** through workforce training of regulatory and national drug quality control laboratories personnel and supporting industry compliance to international standards, including good manufacturing practices.
- **Strengthen regulatory systems** by adopting guidelines for emergency use authorization, reviewing new applications more efficiently, conducting risk-based post-market surveillance, and expanding patient safety surveillance.
- **Expand local production capabilities**, including exploring last-mile manufacturing of COVID-19 vaccines, to foster more resilient and equitable supply chains and promote health security.
- **Enhance global cooperation** through increased information-sharing, recognition and reliance agreements among pharmacopeias and regulators to accelerate access to essential medicines and vaccines and disincentivize substandard and falsified medicines.

USP is committed to supporting the public health response to COVID-19, including efforts to build a more resilient global medicines supply chain and to strengthen the supply of trusted, quality COVID-19 vaccines, treatments, and preventatives.