

## USP Statement to the 74<sup>th</sup> World Health Assembly Agenda Item 13.5: Antimicrobial resistance

Thank you for the opportunity to share our comments at the 74<sup>th</sup> 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 addressing antimicrobial resistance (AMR).

Poor-quality, or substandard medicines, i.e., those that fail to meet quality standards or specifications, or both, are an often underrecognized driver of AMR. AMR emerges not only when a pathogen is exposed to substandard antimicrobials but can also spread within a product class; in other words, new antibiotics may not always treat infections effectively.

COVID-19 has intensified the AMR crisis in the following ways:

- (1) The COVID-19 pandemic has diverted finite resources and political will. Overstretched regulatory systems are less able to detect poor-quality antimicrobials. Supply chain disruptions and resulting drug shortages can also fuel the market for substandard and falsified medicines.
- (2) Antibiotic misuse to treat COVID-19 remains high; in many circumstances, broad-spectrum antibiotics are being used presumptively. A meta-analysis found that 71.9 percent of hospitalized COVID-19 patients received antibiotics, even though only 6.9 percent had bacterial infections.

USP supports a comprehensive global approach to addressing AMR, including:

- **Preserving the global supply of antimicrobials:** Identifying risks upstream in the antimicrobials supply chain can help avoid disruptions and impacts downstream on patients. Incentivizing adoption of innovations such as advanced pharmaceutical manufacturing can foster additional capacity for essential medicines such as antimicrobials.
- **Building regulatory capabilities of global stakeholders:** Deploying innovative technologies for risk-based post-marketing surveillance can help mitigate substandard and falsified antimicrobials. Public quality standards, which include test specifications, are key tools surveillance programs.

Addressing the threat of AMR will require global cooperation to strengthen regulatory systems and secure the medicines supply chain. USP is committed to working with WHO and stakeholders to prevent the next global public health crisis.