

## USP Statement to the 74<sup>th</sup> World Health Assembly Agenda Item 13.6: Substandard and falsified medical products

Thank you for providing us with an 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 preventing and mitigating substandard and falsified (SF) medical products.

SF medical products pose a major threat to global health, causing more than one million deaths per year, reducing the effectiveness of authentic medical treatment, wasting national resources, and contributing to antimicrobial resistance.

Global pandemics like COVID-19 can disrupt the supply of quality-assured medicines and lead to increased proliferation of substandard and falsified medical products, including COVID-19 preventives, therapeutics, and vaccines.

USP supports a comprehensive global approach to addressing SF medicines, including:

- **Ensuring medicines adhere to public quality standards**, which can assist manufacturers in complying with current good manufacturing practices.
- **Building regulatory capability**, including training, skills, and knowledge development to provide more stringent oversight for medical products, thereby securing a more resilient supply chain.
- **Strengthening surveillance systems and technologies**, including improved detection of SF medicines and innovations such as hand-held portable devices, blockchain, or track-and-trace systems.
- **Facilitating global cooperation** through increased information-sharing and recognition and reliance agreements among pharmacopeias and regulators to coordinate access to essential medicines and vaccines and disincentivize substandard and falsified medicines.
- **Raising global awareness** through global advocacy and outreach campaign to inform and empower policymakers, healthcare practitioners, and patients.

USP is committed to working with WHO and stakeholders to prevent and mitigate the threat of substandard and falsified medical products.