



# XIII

# Resolution

## Year 1 Resolution Update: Evidence Generation to Inform Policy

### Resolution

USP will generate and disseminate evidence upon which informed choices can be made for investment in regulatory and quality systems, and reforms to regulatory paradigms that advance quality, patient safety, and public health.

### Alignment with USP's Mission

USP supports the expansion of medicine quality-related research to build strong evidence and materials to advance policy advocacy, capability building, and public awareness.

### Year 1 Update

Key progress areas over the past fiscal year include creation of a range of papers and articles in the following areas to inform policy advocacy, capability building, and public awareness:

**Supply Chain Resilience** – To support the work of the USP Pharmaceutical Supply Chain Center and the Medicines Supply Map, USP published policy papers outlining proposals for strengthening the medicines supply chain. The papers noted critical elements of a resilient supply chain and

included recommendations to help harness the potential of pharmaceutical continuous manufacturing as part of the solution. The papers also addressed challenges posed by information gaps across the supply chain and ways to expand information availability, such as through data sharing.

**COVID-19 Vaccines** – In addition to other tools and resources USP created in response to COVID-19, we developed a white paper with practical strategies and tools to address substandard and falsified COVID-19 vaccines. USP also prepared a brief highlighting the importance of USP quality standards and resources in ensuring access to quality-assured COVID-19 vaccines in the U.S. A USP blog article highlighted policy recommendations to foster broader access to quality-assured COVID-19 vaccines, as informed by a roundtable co-hosted by USP, the World Health Organization, and the Sabin Vaccine Institute.

**Antimicrobial Resistance** – USP Quality Institute fellows wrote two peer-reviewed journal articles demonstrating how substandard medicines accelerate drug resistance in *Escherichia coli* bacteria and malaria disease treatment. Additionally, USP developed a paper with policy recommendations more broadly examining how substandard medicines can lead to antimicrobial resistance, particularly in the context of the COVID-19 pandemic.

**Pharmacopeial Principles –** USP developed a paper describing seven principles as a framework to govern a core function of pharmacopeias, which is to establish public quality standards that foster trust in medicines.

### **Planned for Year 2**

- ▶ USP will continue to advance policies to build a more resilient global supply chain.

- ▶ USP will further develop a policy agenda that actively supports biomedical innovation.
- ▶ USP will continue to engage stakeholders to highlight the negative impact of substandard and falsified medicines around the world and make recommendations to mitigate issues raised by such products.

### **Contact**

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