Collaboration with FDA and Other Stakeholders on Health Priorities

USP will continue its commitment to collaboration with FDA, industry, and other stakeholders by identifying shared priorities based on scientific principles, and leveraging USP’s capabilities to help advance patient safety, public health, innovation, and access to quality medicines.

Year 2 Update

Advancing patient safety and increasing access to quality medicines are as complex as they are critical. To maximize its impact in these efforts, USP continues to prioritize collaboration with diverse stakeholders – including FDA and other global regulators, industry, and healthcare providers – as it works to identify, seek alignment on, and address top priorities. As the global medicines supply chain has grown more complex, and biomedical advancements arrive with greater frequency, USP encounters new challenges and opportunities that benefit from collaboration. Through new and longstanding collaborations, USP has advanced quality and supported a more resilient global medicines supply chain.

Key areas of progress over the past fiscal year include:

FDA’s Drug Competition Action Plan – USP continued its support of FDA’s list of “Off-Patent, Off-Exclusivity Drug Products without an Approved Generic” (the OPOE list) under FDA’s Drug Competition Action Plan to help increase patient access to important generic drug therapies. Over the past year, USP published five monographs associated with five different drug products on the OPOE list that are in the United States Pharmacopeia-National Formulary (USP-NF). Since 2017, USP has developed a total of 17 monographs associated with 16 drug products on the OPOE list and in the USP-NF. USP is continuing to prioritize development of monographs associated with drug products on the OPOE list to support patient access to quality medicines.

Compounding – USP continued to develop monographs to help ensure the quality of products on FDA’s lists of bulk drug substances that can be used in compounding drug products. During the year, USP published five draft compounded preparation monographs (CPMs) in Pharmacopeial Forum for public comment, and six new CPMs in USP-NF. In addition, USP continued to collaborate with stakeholders on revisions to USP General Chapters <795> Pharmaceutical Compounding – Nonsterile.
Preparations, and Pharmaceutical Compounding – Sterile Preparations to help ensure the supply of quality compounded drugs. (See Compounding Resolution update.)

Asia-Pacific Economic Cooperation Forum – In collaboration with the Asia-Pacific Economic Cooperation (APEC) forum and FDA, the USP-APEC Supply Chain Center of Excellence hosted an event on “Confronting Substandard and Falsified COVID-19 Vaccines and Treatments” in partnership with the Pharmaceutical Security Institute, Moderna, and Sanofi. The workshop was attended by 75+ regulators and other key stakeholders across Asia and the Americas. USP also led the APEC Task Force on Post-Market Surveillance and contributed to the APEC Task Force on Internet Pharmacies led by the Alliance for Safe Online Pharmacies to help support access to quality-assured medicines across the region. (See Impact Expansion Resolution update.)

FDA-India Engagement – USP built on pre-pandemic engagements with FDA’s India office in Fiscal Year 2022, initiating further collaborations with them on priorities for the region aimed at strengthening medicines supply chain resilience. These include regulatory strengthening, addressing nitrosamine impurities and anti-microbial resistance, and lowering barriers to adoption of advanced manufacturing technologies.

Global Engagement to Address Impurities – USP engaged stakeholders globally around solutions to help control the risk of impurities in medicines, including through related USP standards and training. (See Impact Expansion Resolution update.)

U.S. Government Supply Chain Engagement – USP continued to work with FDA, the Administration for Strategic Preparedness and Response, the Biomedical Advanced Research and Development Authority, and the Federal Emergency Management Agency on supply chain-related issues. This included sharing data and data-derived insights generated from USP’s Medicine Supply Map to inform policy decisions in support of increasing supply chain resilience. (See Evidence Generation to Inform Policy Resolution update.)

Engagement on Legislation – USP worked to ensure that key recommendations from USP to improve medicines supply chain resilience, including those developed in collaboration with other stakeholders, were shared with legislators for inclusion in legislative proposals developed during the project assisted the country in strengthening post-marketing surveillance to detect nitrosamine impurities in angiotensin receptor antagonists (sartans).

▶ USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority. USP provided the lab with nitrosamine impurities Reference Standards as well as training on nitrosamine testing in line with USP standards.

▶ USP expanded stakeholder engagement with its Nitrosamines Exchange online community in year 2, more than doubling its user base to 1,600 across 60+ countries and 22 language capabilities. The Nitrosamines Exchange is a focused forum for global pharmaceutical stakeholders and experts to share up-to-date information and facilitate real-time conversations on nitrosamine impurities.
year, including the PREVENTS Act and COMPETES Act. As part of a multi-faceted approach to inform and shape the ongoing dialogue on supply chain-related issues, USP remained an active participant with various public-private partnerships and continued to build and strengthen relationships with key committees and offices on Capitol Hill. During the year, USP made over a dozen submissions, including statements for the record, comments to proposed legislation, and letters of support for key supply chain resilience policies.

**Planned for Year 3**

- In collaboration with FDA, USP will release an infographic on biosimilars quality designed to help healthcare practitioners and patients have informed conversations about using biosimilars.
- USP will continue to identify the priorities of FDA and other stakeholders, and look for opportunities for collaboration to help advance patient safety, public health, innovation, and access to quality medicines.
- USP will identify opportunities for collaboration on responding to quality paradigm shifts in biopharmaceuticals, including potentially in the areas of new drug delivery systems, analytical technologies, and novel vaccine platforms and adjuvants.
- USP will bring together regulators from the 21 APEC economies at USP headquarters in Rockville for a seminal dialogue on supply chain resilience during the APEC USA 2023 host year.
- USP will publish a comprehensive supply chain report entitled “A Holistic View of the Global Medicines Supply Chain and Recommendations to Improve Resilience and Ensure Access to Quality Medicines.” Based on dialogue and gathered evidence, the report will be positioned as a foundational resource to inform policy reforms, investments, and the utilization of standards to improve supply chain resilience and maintain global public health.
- USP will continue to expand regulatory engagement internationally – including through formal memorandums of understanding – to advance capability building and medicines supply chain resilience. Specific focus areas will include pharmaceutical impurities and dietary supplement quality.

**Contact**

For additional information on this Resolution, contact Sohail Mosaddegh at sohail.mosaddegh@usp.org.