Resolution

Year 1 Resolution Update: Collaboration with FDA and Other Stakeholders on Health Priorities

Resolution

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.

Alignment with USP's Mission

Over the course of USP's history, standards, training, and advocacy have been deployed by USP to help address the health priorities of the U.S. government and other governments around the world. As the medicines supply chain and economy further globalize and biomedical advances create new challenges and health priorities, USP can increase its impact by partnering with governments to support their objectives when they are aligned with USP's mission.

Year 1 Update

Key areas of collaboration on public health priorities over the past fiscal year include:

Methanol Contamination – Consistent with a request from FDA, USP worked quickly to issue Revision Bulletins requiring the "Limit of Methanol" identification test in monographs for alcohol and dehydrated alcohol. The revisions address public health risks associated with methanol contamination of alcohol-based hand sanitizers. Since alcohols are widely used as pharmaceutical ingredients, the revisions also address contamination risks to the supply chain beyond hand sanitizers. USP and FDA held joint stakeholder calls with manufacturers and compounders to address the changes and answer questions.

FDA's Drug Competition Action Plan – USP is committed to continuing to support FDA's list of "Off-Patent, Off-Exclusivity Drug Products without an Approved Generic" (the OPOE list) under the agency's Drug Competition Action Plan to help increase access to important generic drug therapies. Since 2017, USP has developed 12 monographs associated with 11 drug products on the OPOE list that are in the *USP–NF*. USP is prioritizing monographs associated with drug products on the OPOE list.

Compounding – USP is working on the development of monographs for drugs on FDA's lists of bulk drug substances that can be used in compounding drug products.

COVID-19 – USP's COVID-19 Vaccine Handling Toolkit and related international

version, which focus on operational considerations for maximizing doses and minimizing waste while maintaining safety and quality, were developed through collaborations with U.S. and international government agencies as well as USP Expert Committees.

Standards Engagement Model – USP is increasing engagement in support of standards through new engagement tools and expanded use of existing tools. For example, to stimulate early scientific discussion around nitrosamine risk assessment, USP launched its first online community Nitrosamines Exchange. The community now has over 400 members. USP has also launched the first Stakeholder Engagement Planning Committee for this cycle, focusing on the Prescription/Non-prescription Stakeholder Forum. Committee members—40% of whom are new this cycle—include stakeholders from FDA, industry, and academia. Open Forums, another new engagement tool this cycle, have drawn hundreds of stakeholders to events targeted at specific standards-setting areas and challenges.

Planned for Year 2

- USP will continue to identify FDA and other stakeholder priorities and look for opportunities to collaborate to help advance patient safety, public health, innovation, and access to quality medicines.
- USP will seek to identify opportunities for collaboration on responding to quality paradigm shifts in biopharmaceuticals.

Contact

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