

2018 Status on the USP Resolutions

Resolution I: Collaboration with the U.S. Food and Drug Administration – Transcript

Presenter

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Resolution one. USP will increase communication and collaboration with the U.S. Food and Drug Administration (FDA) to promote alignment with FDA's regulatory and scientific policies from the inception of the standards planning and development process. USP will work with FDA, industry, and other stakeholders throughout the process to increase understanding of the regulatory impact of such proposals.

USP continues to identify and embrace effective and impactful approaches to working together with FDA and align with the agency's strategic vision and on our shared goals of supporting innovation, science, and access to quality medicines and foods. We continue to have ongoing discussions with FDA and other partners on ways we can advance FDA's public health mission and contribute to a modern system that protects consumers and patients.

In FY 2018, USP expanded key collaborations with FDA and stakeholders in areas including increasing access to generic drugs, creating quality standards for over-the-counter drug products, and approaches to mitigate misuse and abuse of opioids.

To achieve this, we have convened meetings with FDA's senior leadership to examine ways that USP compendial standards, information, resources, and tools can be developed and revised to facilitate development of important generic medicines and support industry to develop generics for FDA's list of off-patent, off exclusivity drugs currently without competition. We have been working closely with our FDA colleagues in the over-the-counter, veterinary, and dietary supplement space, identifying new opportunities to leverage our resources to address emerging and evolving regulatory and quality paradigms.

Looking to FY 2019 and beyond, USP will continue to seek new opportunities to actively engage with FDA and stakeholders to facilitate development and access to quality medicines, sharing and promoting FDA priorities and advancing positive health outcomes for consumers and patients. We are committed to continue engaging with FDA and to explore other mechanisms to enhance our collaboration on important quality issues and ways that USP can leverage its public standards-setting process to have the most meaningful public health impact.