



XI

Resolution

Year 1 Resolution Update: Pharmacopeial Cooperation and Convergence

Resolution

USP will lead efforts to advance convergence around robust science-based standards across pharmacopeias. USP will focus efforts on those standards where convergence will have the most impact on global access to quality medicines.

Alignment with USP's Mission

Through scientific exchange, training programs, and engagement in critical collaborative venues, USP remains committed to pursuing convergence with other national and regional pharmacopeias to build capabilities among emerging pharmacopeias while advocating for robust, science-based standards to improve patient safety and public health. For this work to be successful, it will be important for industry and regulators to continue their support by working with USP to identify and advance more efficient mechanisms and approaches for convergence.

Year 1 Update

Key progress areas over the past fiscal year include:

COVID-19 Response – USP led efforts to trigger the pharmacopeial alert system through the World Health Organization International Meetings of World Pharmacopoeias (IMWP) to help provide a platform for global pharmacopeias to convene and collaborate around COVID-19 response efforts. The alert system facilitated creation of a COVID-19 alert team and related activities, including monthly meetings and global cooperation on the role of global pharmacopeias in the development of COVID-19 vaccines and therapeutics. Outcomes included an interactive dashboard listing standards from IMWP for COVID-19 treatments, and development of a first-of-its-kind IMWP monograph for favipiravir antiviral treatment that could serve as a model for other potential treatments.

Workshops – USP co-hosted the following workshops dedicated to pharmacopeial convergence:

- ▶ A virtual workshop with the Parenteral Drug Association in September 2020 on the role of pharmacopeias in responding to public health crises, which included over 200 participants from industry, global regulatory bodies, and pharmacopeias.
- ▶ A virtual workshop with Japan's Pharmaceuticals & Medical Devices Agency in June 2021 on the "Role of Quality in Pharmaceuticals," which included over 800 participants,

primarily scientists and regulators from Japan and Southeast Asia, and showcased the role of pharmacopeias alongside industry and regulators in responding to public health crises.

Pharmacopeial Discussion Group – PDG partners, which include USP, the *European Pharmacopoeia*, and *Japanese Pharmacopoeia*, initiated strategic workstreams to reform how PDG engages regulators, industry, and other pharmacopeias. The most significant of these reforms—which collectively represent the first major changes to PDG since its inception in 1989—is creation of a pilot for global expansion of the PDG with specific criteria that would need to be met for other pharmacopeias to participate.

China Engagement – USP signed a memorandum of understanding with the *Chinese Pharmacopoeia* for technical collaboration in areas including packaging components, biologics, and botanicals/dietary supplements/herbal medicines.

Planned for Year 2

- ▶ The IMWP will evaluate lessons learned at the end of 2021, after publication of the favipiravir pilot monograph, to determine if it would be valuable to continue this activity for other collaboratively developed standards.
- ▶ The PDG will finalize criteria for other pharmacopeias to join the group and evaluate applications seeking inclusion, with the goal of beginning the expansion pilot by fall 2022.
- ▶ USP will begin development of glass packaging standards through a newly formed working group with experts from the *Chinese Pharmacopoeia*. Additional working groups are in development for collaboration in the areas of biologics and botanical/dietary supplements/herbal medicines.

Contact

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