Pharmacopeial Cooperation and Convergence

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.

Year 2 Update

Through collaboration with other global pharmacopeias, USP works to advance convergence around robust, science-based quality standards. Convergence helps build capabilities among emerging pharmacopeias and increase global alignment on the definition of quality to allow governments, manufacturers, and healthcare professionals to expand access to safe, quality medicines, improve patient safety and public health, and create a more resilient global medicines supply chain. One of the ways the convergence of quality standards makes this possible is through increased availability of quality ingredients for medicines in regions of the world where they are needed most. USP supports convergence and capability building among emerging pharmacopeias through scientific exchange, training programs, and other stakeholder engagement activities.

Key areas of progress over the past fiscal year include:

Pharmacopeial Discussion Group Collaboration – USP worked with the Pharmacopeial Discussion Group (PDG), which includes USP, the European Pharmacopoeia, and the Japanese Pharmacopoeia, to increase the reach and impact of PDG harmonization efforts.

- The PDG launched a pilot for expansion of group membership to include other prominent global pharmacopeias, with the Indian Pharmacopoeia Commission serving as the inaugural participant. This milestone marks the culmination of two years of discussions in the effort to initiate the pilot with objective criteria for new member participation and to help ensure its success.
- The PDG reached consensus on harmonization of standards for chromatography across related USP, European, and Japanese pharmacopoeial chapters. Representing
a significant milestone in pharmacopeial convergence, the approved United States Pharmacopeia–National Formulary text for the harmonized chapter was posted on USP’s website in November 2021 and will become official in December 2022.

China Engagement – USP engaged in significant technical collaborations with the Chinese Pharmacopoeia (ChP), launching initiatives on standards for biologics, metal packaging, and the use of quantitative nuclear magnetic resonance (qNMR) spectroscopy for quality assurance. These efforts, which built on a USP-ChP memorandum of understanding signed in Fiscal Year 2021, included formation of a USP-ChP working group on metal packaging that aims to outline a related pharmacopeial chapter by year-end.

Webinar with EDQM on Drug Substance Harmonization – USP and the European Directorate for the Quality of Medicines & Healthcare (EDQM) co-sponsored a joint webinar to advance their long-standing, mutual effort to prospectively harmonize drug substance monographs. The webinar increased project visibility and drew 150+ participants to discuss related opportunities, challenges, and proposed adjustments to the program based on lessons learned. The mutual convergence effort initially resulted in four prospectively harmonized monographs for active drug substances when it began in 2008 and continued with 19 additional prospectively harmonized drug substance and drug product monographs.

ICH Engagement – USP has been an observer to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly since 2016 and participates in a number of ICH Expert Working Groups, including those on pharmaceutical continuous manufacturing and analytical procedures. During the year, USP contributed to development of draft ICH guidelines in both areas and submitted related technical comments to help ensure alignment with USP standards and policies.

Interactive Dashboard for COVID-19 Treatments – Ten international pharmacopeias – including USP – collaborated to publish an interactive dashboard of active pharmaceutical ingredients and monographs for existing generic drugs being investigated as COVID-19 treatments. Over 700 monographs were listed on the dashboard.

Planned for Year 3

- USP will work with its PDG partners to evaluate lessons learned from the group’s expansion pilot and consider potential next steps including continuation, conclusion, or further formalization of the pilot.
- USP will continue to work with its PDG partners on standards where convergence will have the most impact on global access to quality medicines, including a focus on potential harmonization of standards for elemental impurities.
- At a September 2022 event of the International Meetings of World Pharmacopoeias (IMWP), USP will lead a discussion with PDG on lessons learned from COVID-19 response efforts by the World Health Organization (WHO).
- USP will conduct hybrid bilateral meetings with WHO, the European Pharmacopoeia, British Pharmacopoeia, and Japanese Pharmacopoeia in fall 2022 to identify key technical areas for future work.
USP will strengthen bilateral collaborative partnerships with global pharmacopeias in key technical and strategic areas, such as analytical quality by design, and qNMR technology.

Contact
For additional information on this Resolution, contact Kevin Moore at ktm@usp.org.