



USP Stakeholder Engagement on Beyond-Use Date (BUD) Provisions in General Chapters <795> & <797>

May 26, 2020

Background

On March 12, 2020, the USP Appeals Panel issued final decisions on appeals to revisions of standards for sterile and nonsterile compounding, General Chapters <795> and <797>, respectively. The Appeals Panel granted the appeals to General Chapters <795> and <797> and remanded the chapters to the Compounding Expert Committee (CMP EC) **with recommendation for further engagement on the issues raised by stakeholders concerning beyond-use date (BUD) provisions.**

In response to this request, USP is conducting additional stakeholder engagement activities to foster stakeholder input. The initiatives will focus on the issues pertaining to the BUD provisions in General Chapters <795> and <797> with particular attention to:

- ▶ The framework for establishing the BUDs for sterile and nonsterile compounded preparations
- ▶ BUD extensions beyond the defaults provided in the remanded chapters

The goals of the Stakeholder Engagement are to:

- ▶ Engage stakeholders representing a diverse range of perspectives on these topics, and
- ▶ Gather additional information in a constructive series of facilitated sessions.

Stakeholder Engagement Plan

USP has engaged an independent party to help design and lead stakeholder outreach. USP plans to build on the public comments previously submitted to USP in the draft chapters that were published in the *Pharmacopeial Forum* (PF), as well as the information raised in the appeals. Stakeholder engagement sessions will include smaller roundtable discussions with invited participants, as well as broader Open Forums to collect stakeholder feedback. USP will announce the dates of these sessions once they are available. The sessions will allow for virtual participation.

Outcomes and Next Steps

The CMP EC will transition into a new cycle and the new CMP EC will begin its work in the Summer of 2020. USP will leverage the expertise of both the current and new CMP EC to support the Stakeholder Engagement Plan. The input gathered during the course of the Stakeholder Engagement Plan will be considered and evaluated by the 2020 – 2025 CMP EC. Any proposed changes to the compounding chapters will undergo USP's open and transparent standards revision process, wherein they will be published in the *Pharmacopeial Forum* (PF) for public comment for at least 90 days. Following a review of public comments by the 2020 – 2025 CMP EC, any revised text will be published in the *USP-NF* with an official date of at least 6 months from the date of publication.

USP and the CMP EC are committed to moving forward in an open, transparent, and balanced manner as soon as practicable to enable the chapters to be finalized and implemented in a timely manner. For any questions, please contact the USP Healthcare Quality and Safety staff at CompoundingSL@usp.org.