

USP to Pilot Process for Early Input on General Chapters

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Based on feedback from stakeholders, USP is implementing a process intended to provide interested stakeholders with the opportunity to submit input on general chapters during the early stages of their development.

General chapters are often identified as high-impact standards. They may be applied to numerous articles or affect major activities in the pharmaceutical supply chain, the practice of pharmacy, or other disciplines. In addition, the broad scope of some general chapters can be related to other guidance for industry and practitioners, such as Good Manufacturing Practices, sanctioned industry standards, and practice standards. Robust input at the early stages of general chapter development has the potential to benefit USP staff and volunteers by suggesting modifications to scope and content that can streamline the development process, save time and effort, and minimize delays in reaching an official publication.

To accomplish this, USP Expert Committee members will develop a brief prospectus for new general chapters or major general chapter revisions prior to their publication in Pharmacopeial Forum (PF). Each prospectus will include information available at the time of its drafting, and thus the contents of each prospectus may differ. The prospectus will be posted to the work plan web page of the associated Expert Committee (<http://www.usp.org/expert-committees>) and to the *USP-NF* Compendial Notices web page (<http://www.uspnf.com/notices>). USP will announce the prospectus posting through its Compendial Updates email service and accept input for one month following the announcement. The Compendial Notice posting will be retired after completion of the input period. This process will be monitored on an ongoing basis to ensure that its goals are being met.

The input received from the prospectus process will be considered as advisory only. The Expert Committees will not publish or respond to all input received on prospectus notices. The Expert Committees may, at their discretion, choose to contact submitters or address certain aspects of provided input in the briefing of a general chapter's PF proposal. Formal comments on subsequent PF proposals must be submitted separately at the time of publication in PF.

Should you have any questions, please contact Horacio Pappa, Ph.D., Director, General Chapters (301-816-8319, hp@usp.org).