Overview of the Public Commenting Open Forum Held March 29, 2022

Jessica Simpson, MPH
April 11, 2022
Main theme: stakeholder input

- Discussed where stakeholder feedback has been received, what was heard, and how it’s been implemented thus far
- Reviewed standard setting process and opportunities for engagement throughout
- Mural session to gather more feedback and prioritize ideas we’ve heard
- Reviewed upcoming comment form and asked for further input
- USP hears stakeholder feedback and is continuing to act on it
Stakeholder input

- Compendial Process Improvement Project Team has provided recommendations to USP throughout its history
- Multiple surveys
  - USP customers, PNP attendees, PF users, USP-NF users
- FDA Quarterly meetings
- Customer Advisory Board
- Prescription/Non-Prescription Stakeholder Forum
  - Industry presentations
  - Breakouts
- User interviews
Stakeholder input

- How to have an impact on standards—early in the process and during PF
- Want to know more about commenting
  - How to comment effectively
  - Understand the comment process
  - Dispensation of comments
- Desire for transparency in the standards-setting process
- Implement a standardized comment form
- Incorporate line numbers in PF
- Want more opportunities to communicate with Expert Committees and more feedback on comments
Comprehensive engagement example and timelines

Example standard goes through one PF publication, moves to ballot, and is approved at ballot

*these decisions are made following Robert’s Rules
**changes must adhere to Rules and Procedures of the CoE
Current/Future of Public Comments Process

Our Goal is to identify best solutions to improving public commenting for both USP and Stakeholders

Question #1: Given the current USP commenting cycle with "Hard Stops" between opportunities to comment, WHERE are the best places in the timeline, and WHAT IDEAS can you share for incorporating two-way dialog between the USP/Expert Committee and stakeholders?

Themes:
Commenters want to know there is understanding of their comments, opportunities to ask for clarity are utilized.

Desire for commenters to know a proposal is an Accelerated revision (e.g., IRA, Notice of Intent to Revise.)

Publication of full comments
Mural session outcome

**Question #2:** What could the USP do to get Stakeholders to utilize more fully the current opportunities for engagement/comments-sharing regarding standards development?

**Themes:**

**Engage to understand impact to Industry**

*Engage earlier*

*Frequency of Commentary increased, make information more accessible and timely*

**Make sure to engage on right topics in the right time**

Suggest including a link to "Events and Training" and "Get Involved" on USP-NF home page and/or in help drop down on the official USP-NF
Mural session outcomes

- Asked stakeholders to use 2 votes to prioritize 4 previously submitted ideas

**Voting results**

- 22 votes
  - A tracking system for each response/form to enable stakeholders to check on comment status online without going through the liaison each time
    - Unique voters 21

- 21 votes
  - Viewing other commenter's comments publicly, for commenters who agree that their comments may be published
    - Unique voters 19

- 5 votes
  - Implementing a standardized comment form that characterizes comments as critical/other?
    - Unique voters 4

- 4 votes
  - A tool to highlight the exact text you are commenting on that are consistent between online publications and PDF downloads
    - Unique voters 4
Comment form updates launching June 2022

Launching June 2022

Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of? *
- Myself
- Organization

Organization Type: *
- Select
- Company
- Academic Institution
- Government
- Trade Organization
- Other

Public posting of comments: *

Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of? *
- Myself
- Organization

Organization Type: *
- Trade Organization

Organization Name:
### Saving draft and accessing past comments

**Launching June 2022**

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<tr>
<th>DOCUMENT</th>
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Resources

- Rules and Procedures of the Council of Experts
- Request for Revision information and guidelines
  - Stakeholders are welcome to submit information and recommendations for developing new monographs or revising proposed or existing official monographs. Revisions may be to an entire monograph or specific monograph tests, procedures, and/or acceptance criteria. USP also welcomes proposed revisions to general chapters.

- Commentary location and schedules

- Overview of the USP-NF training webinar (free, 49 minutes)

- Accelerated Revision Process and Guideline
  - The Rules and Procedures of USP's Council of Experts specify processes that can be used to make revisions to the USP–NF official more quickly than through USP's standard revision process. These accelerated processes include Errata, Interim Revision Announcements (IRAs), and Revision Bulletins.
Thank You

Empowering a healthy tomorrow