# Industry Engagement in USP's Standards-Setting Process

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# Six Ways Industry Can Stay Engaged With USP's Standards


*Disclaimer: The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.*

# What Can Industry Do?

## Six ways industry can stay engaged with USP's standards

- **Standards Development:** Participate in USP's standards-setting process
- **Stakeholder Events:** Join USP-hosted stakeholder events
- **Expert Contribution:** Serve as a USP Expert Volunteer
- **Advocacy & Collaboration:** Engage with compendial trade groups
- **Regulatory Awareness:** Monitor FDA guidances and public comment opportunities
- **Strategic Governance:** Participate in USP's Convention

# Why Are We Doing This?

- Compendial changes are complex…
  - impact multiple functional areas within a company.
  - impact multiple products within a company.
  - must address compliance with global registrations.
  - must address pharmacopoeias around the world.
- Improvements to the surveillance process can help to ensure consistent compliance with compendial requirements.
- Results in:

  **Compendial End-to-End Process**

# Compendial End-to-End Process

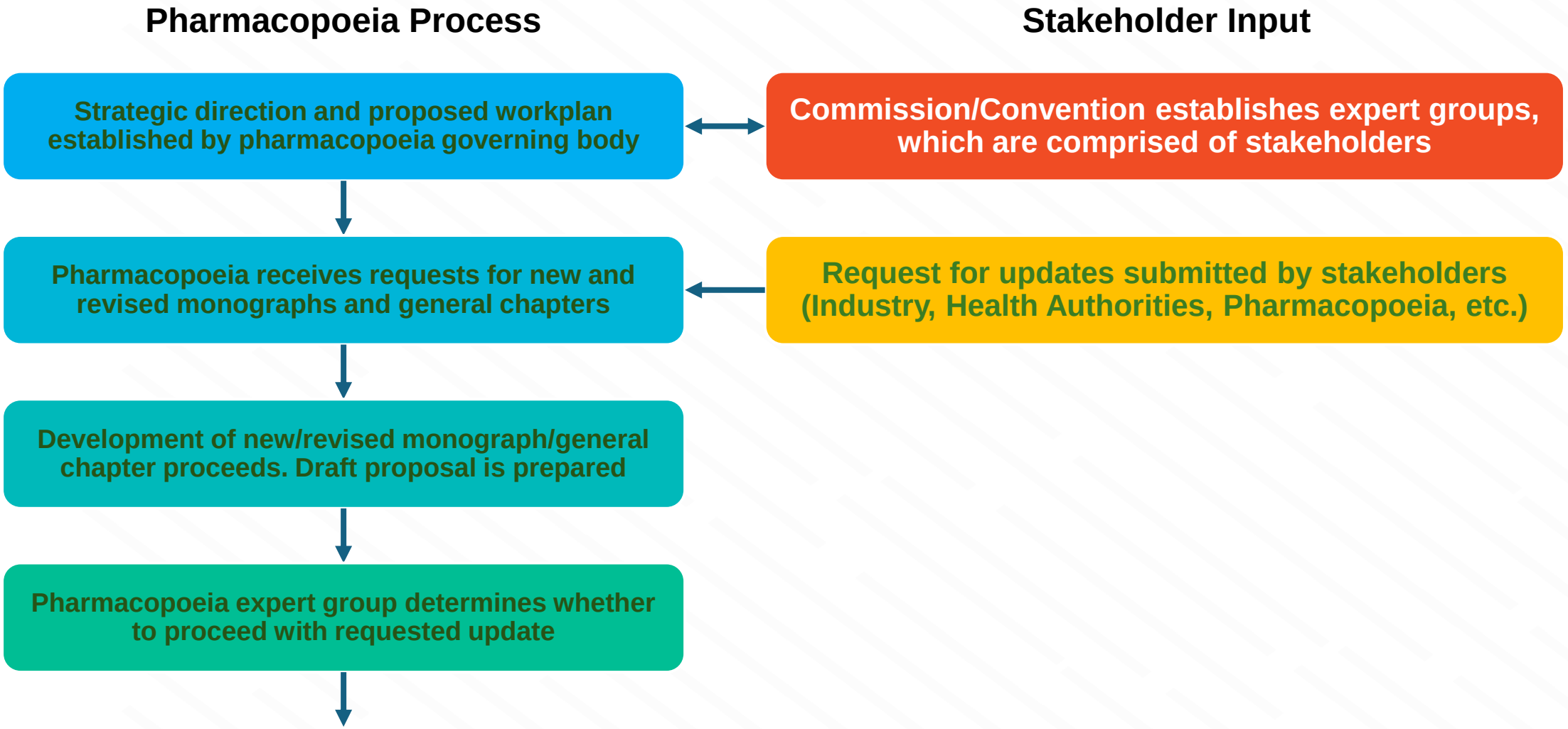
Ensure ongoing compliance with new and revised compendial requirements through a customer-centric end-to-end process.

# 1. Standards-Development

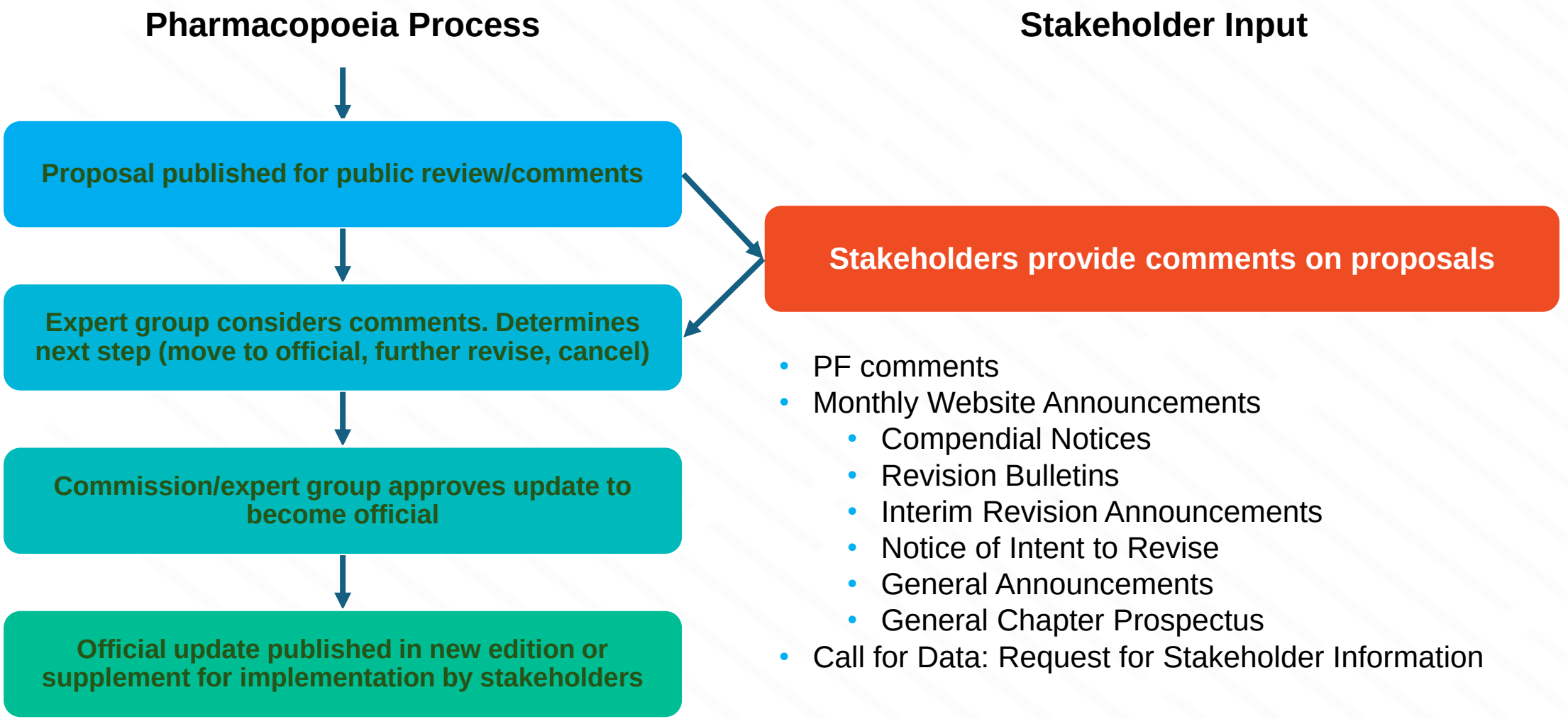
## Participate in USP's standards-setting process

- Follow USP's key compendial announcements: PF, compendial notices, and new official text
- Submit PF comments
- Request a revision
- New monograph development
- What do after text if official
- Know USP's publican schedule
- Read the Commentary!

# Compendial Standard Setting Process: Overview (1/2)

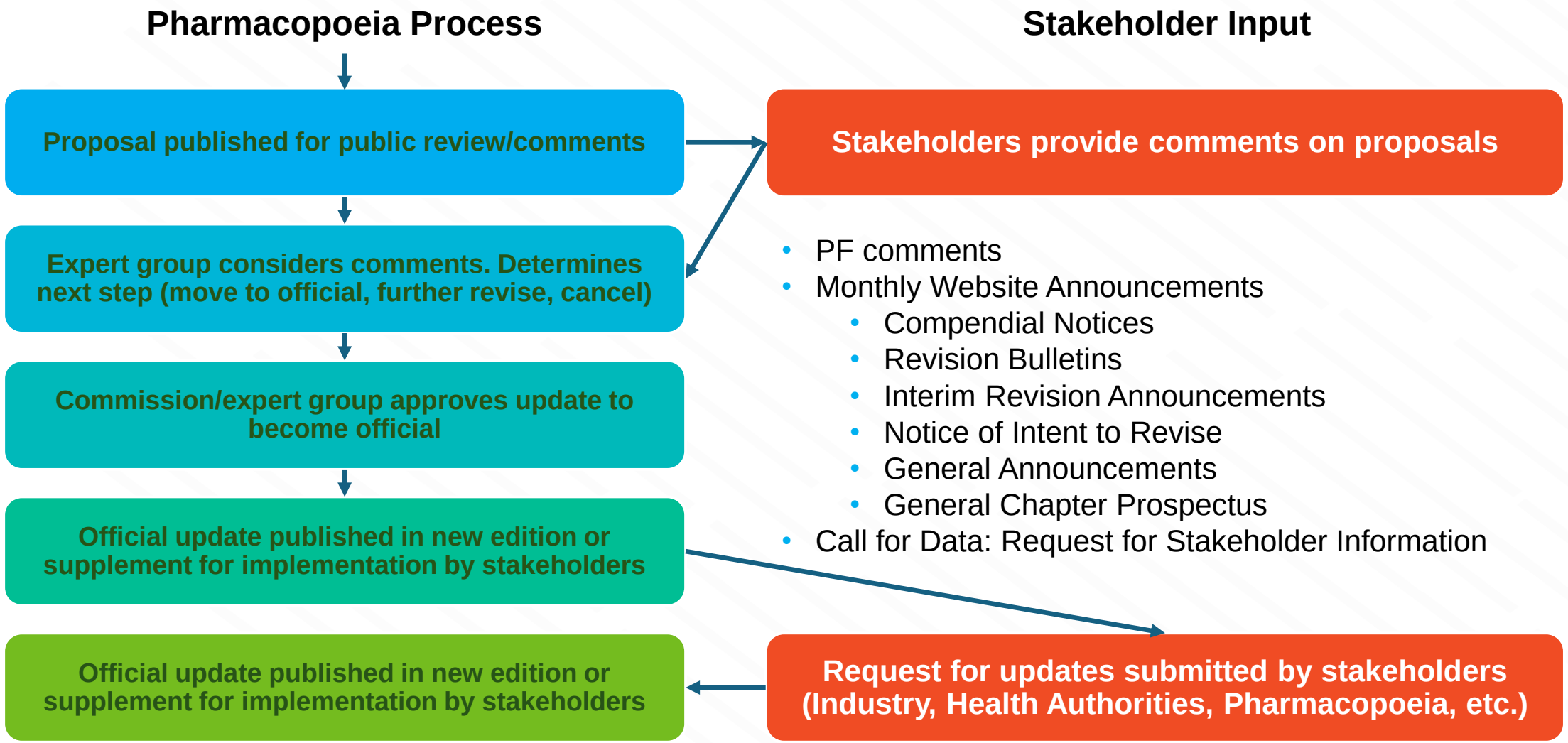


# Compendial Standard Setting Process: Overview (2/2)

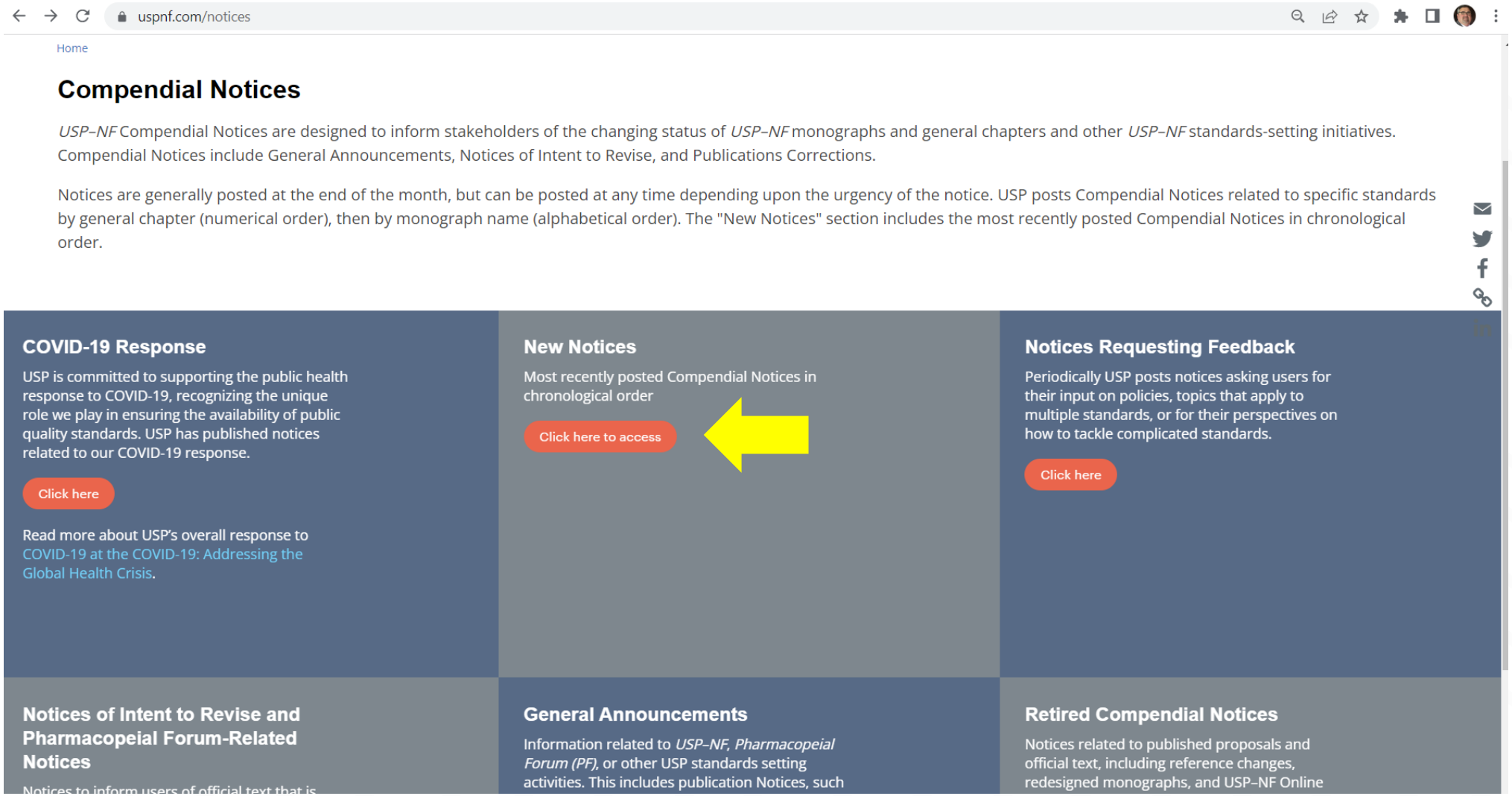


# Recent Examples of Key Items for Stakeholder Comment/Input

# Compendial Standard Setting Process: Overview (2/2.1)



# USP Compendial Notices



# USP Notice of Intent to Revise

## Publication Announcements

- Changes to USP's Description and Solubility Reference Table (posted 30-Sep-2022)
- Chemical Information Updates (posted 16-Dec-2022)
- Correction to Official Date of Posted IRA for Enoxaparin Sodium Monograph (posted 23-Nov-2022)
- Documentary Standard Updated for Equation Uniformity (posted 16-Dec-2022)
- Monographs Affected by Revision to <126> Somatropin Bioidentity Tests (posted 30-Sep-2022)
- Monographs Affected by Revision to <211> Arsenic (posted 29-Apr-2022)

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## Monographs Affected by Revision to <211> Arsenic

**Type of Posting:** Notice of Intent to Revise
**Posting Date:** 29–April–2022
**Targeted Official Date:** 01–June–2023
**Expert Committee:** Various

In accordance with the 2020–2025 Rules and Procedures of the Council of Experts, this is to provide notice that USP and its Expert Committees, as applicable, intend to revise multiple monographs in response to a revision of General Chapter <211> *Arsenic*.

General Chapter <211> was proposed for comment in *PF* 47(1) and will be official on June 1, 2023. USP has identified other documentary standards referencing General Chapter <211> impacted by the revisions in *PF* 47(1). These references will be updated beginning on June 1, 2022 and continue through November 1, 2022 and will become official June 1, 2023. A list of the monographs that will be modified can be found here. Specific target publications are subject to change.

Interested stakeholders are encouraged to alert USP staff to any impact they may recognize related to the update of those monographs.

Should you have any questions or comments, please contact Kahkashan Zaidi, Principal Scientific Liaison (kxz@usp.org), or the affected monograph's liaisons.

# USP Revision Bulletins

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## Revision Bulletins

Revision Bulletins are published in USP–NF Online by the first of each month. Each Revision Bulletin includes a notice that provides the reason for the change and the official date.

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### Esomeprazole Magnesium

| | |
|---|---|
| **Type of Posting** | Revision Bulletin |
| **Posting Date** | 19-Dec-2022 |
| **Official Date** | 20-Dec-2022 |
| **Expert Committee** | Small Molecules 3 |

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Esomeprazole Magnesium monograph. The purpose of this revision is to widen the *Acceptance criteria* for the *Content of Magnesium* test from 3.30%–3.55% on the anhydrous basis to 3.30%–3.70% on the anhydrous basis.

The Esomeprazole Magnesium Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Claire Chisolm, Senior Scientist II (301-230-3215 or cnc@usp.org).

https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/esomeprazole-mag-rb-notice-20221219.pdf

# USP Interim Revision Announcement (IRA)

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## Interim Revision Announcements (IRAs)

IRAs are published in Pharmacopeial Forum (PF) as proposed IRAs. After a 90-day notice and comment period and approval by the relevant USP Expert Committee, IRAs are published as official text in the USP–NF Online. The PF posting dates, comment deadlines and IRA posting, and official dates can be found here.

Monograph names listed prior to April 1, 2021 link to the combined IRA posting in which the announcement appeared. Titles posted after April 1, 2021 link to the published standard in *USP–NF Online*.

Archived Interim Revision Announcements can be found here.

### New IRAs

- Acetaminophen (posted 18-Nov-2022; official 01-Jan-2023)
- Ammonium Sulfate (posted 18-Nov-2022; official 01-Jan-2023)
- Enoxaparin Sodium (posted 18-Nov-2022; official 01-Dec-2023)
- <209> Low Molecular Weight Heparin Molecular Weight Determinations (posted 30-Sep-2022; official 01-Nov-2022)
- <411> Folic Acid Assay (posted 30-Sep-2022; official 01-Nov-2022)
- Folic Acid Tablets (posted 30-Sep-2022; official 01-Nov-2022)
- Levalbuterol Hydrochloride (posted 30-Sep-2022; official 01-Nov-2022)
- Levalbuterol Inhalation Solution (posted 30-Sep-2022; official 01-Nov-2022)

https://www.uspnf.com/official-text/iras

# USP Accelerated Revisions by Official Date

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## Accelerated Revisions by Official Date

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### Albuterol Inhalation Solution

| | |
|---|---|
| **Type of Posting** | Revision Bulletin |
| **Posting Date** | 30-Apr-2021 |
| **Official Date** | 1-Nov-2023 |
| **Expert Committee** | Small Molecules 5 |

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Albuterol Inhalation Solution monograph. The purpose for the revision is to provide an additional 30-month implementation period for the Albuterol Inhalation Solution monograph, and to change its official date from May 1, 2021 to November 1, 2023.

Comments were received that the marketed Albuterol Inhalation Solution products are using the name "Albuterol Sulfate Inhalation Solution," and an extended implementation time may be required for the marketed product nomenclature to be revised. The approved title "Albuterol Inhalation Solution" is consistent with <1121> Nomenclature and with the Monograph Naming Policy for Salt Drug Substances in Drug Products. The additional 30-month implementation period, as described in <1121> Nomenclature, is provided to facilitate adoption of the monograph and changing the name of the marketed products to "Albuterol Inhalation Solution."

The Albuterol Inhalation Solution Revision Bulletin will supersede the monograph becoming official on May 1, 2021.

Should you have any questions, please contact Shankari Shivaprasad, Principal Scientist (301-230-7426 or sns@usp.org).

https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/albuterol-inhalation-solution-rb-notice-20210430.pdf

# USP Errata

## Errata

Access USP–NF Errata

**View Errata Postings for *USP–NF* Spanish Edition (in Spanish).**

Errata are considered to be text erroneously published in the *USP–NF* that does not accurately reflect the intended requirements as approved by the Council of Experts. Errata are posted at the end of each month.

For more information on errata official dates, please view the Compendial Notice that posted on February 12, 2021.

Errata are corrected in the *USP-NF Online* publication on the same date as the errata table is published. Revision symbols will designate changes: ▲new text▲ (ERR 1–Jul–2018).

Errata are posted in the interactive table linked above. Entries are searchable by title, and each column heading can be sorted. In addition, table entries can be downloaded in CSV and PDF format and printed.

| Monograph Title | Section | Source Publication | Page Number | Errata Post Date ▼ | Errata Official Date | Target Errata Print Publication | Target Online Fix Publication | Description |
|---|---|---|---|---|---|---|---|---|
| PALONOSETRON HYDROCHLORIDE | IMPURITIES | *USPNF Online* | Online | 16-Dec-2022 | 1-Jan-2023 | *NA* | *NA* | In *Limit of Unspecified Impurities*: Change **Mobile phase** and **Chromatographic system**: Proceed as directed in the *Assay*. to: **Mobile phase**, **Standard stock solution**, and **Chromatographic system**:... Read More |
| LYSINE ACETATE | IMPURITIES/*Related Compounds* | *USPNF Online* | Online | 16-Dec-2022 | 1-Jun-2023 | *NA* | *NA* | In *Chromatographic system/Spray reagent*: Change 0.2 g of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5) to: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5) |
| METOLAZONE TABLETS | ASSAY/*Procedure* | *USPNF Online* | Online | 16-Dec-2022 | 1-Jan-2023 | *NA* | *NA* | In *Buffer*: Change 1.38 g of monobasic potassium phosphate monohydrate in 900 mL of water. to: 1.38 g of monobasic sodium phosphate in 900 mL of water. |
| MAFENIDE ACETATE FOR TOPICAL SOLUTION | IMPURITIES/*Organic Impurities* | *USPNF Online* | Online | 16-Dec-2022 | 1-Jan-2023 | *NA* | *NA* | In *System suitability*: Change **Samples**: *System suitability solution*, *Standard solution A*, and *Standard solution B* to: **Samples**: *System suitability solution* and *Standard solution A* ... Read More |

https://www.uspnf.com/official-text/errata-table

# Compendial Revision Schedule: USP-NF (1/2)

USP–NF Publication Schedule

| PF Issue | Commentary Period | Anticipated USP-NF Issue | USP-NF Publication Date | Official Date (unless otherwise specified) |
|---|---|---|---|---|
| 51(3) | May 1- July 25, 2025 | USP-NF 2026, Issue 4 | January 30, 2026* | August 1, 2026* |
| 51(4) | July 1-September 30, 2025 | USP-NF 2026, Issue 5 | March 27, 2026* | October 1, 2026* |
| 51(5) | September 2-November 30, 2025 | USP-NF 2026, Issue 6 | May 29, 2026* | December 1, 2026* |
| 51(6) | November 3, 2025-January 31, 2026 | USP-NF 2027, Issue 1 | July 31, 2026* | February 1, 2027* |
| 52(1) | January 1-March 31, 2026 | USP-NF 2027, Issue 2 | September 25, 2026* | April 1, 2027* |
| 52(2) | March 1-May 31, 2026 | USP-NF 2027, Issue 3 | November 20, 2026* | June 1, 2027* |
| 52(3) | May 1- July 31, 2026 | USP-NF 2027, Issue 4 | January 29, 2027* | August 1, 2027* |

Source: uspnf.com

PROPOSAL

# Compendial Revision Schedule: USP-NF (2/2)

## Revision Bulletin Publication Schedule

| Online Posting Date | Official Dates for Revision Bulletins (unless otherwise indicated) |
|---|---|
| July 25, 2025 | August 1, 2025 |
| August 29, 2025 | September 1, 2025 |
| September 26, 2025 | October 1, 2025 |
| October 31, 2025 | November 1, 2025 |
| November 21, 2025 | December 1, 2025 |
| December 19, 2025 | January 1, 2026 |
| January 30, 2026 | February 1, 2026 |
| February 27, 2026 | March 1, 2026 |
| March 27, 2026 | April 1, 2026 |

# Compendial Revision: Commentary

*Commentary*
*USPNF 2026 ISSUE 2*

**September 25, 2025**

In accordance with USP's *Rules and Procedures of the 2025-2030 Council of Experts* (*CoE Rules*), and except as provided in Section 10.02 *Accelerated Revision Processes*, USP publishes proposed revisions to the *United States Pharmacopeia and the National Formulary* (*USP–NF*) for public review and comment in the *Pharmacopeial Forum (PF)*, USP's free bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee (EC) deems appropriate, the proposal may advance to official status or be re-published in *PF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status, a summary of comments received and the appropriate Expert Committee's responses, as well as Expert Committee-initiated changes, are published in the Proposal Status/Commentary section of USPNF.com at the time the official revision is published.

The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference or conflict between the contents of the *Commentary* and the official text, the official text prevails.

***No comments were received for the following proposals:***

**Monograph/Section(s):** CLOBETASOL PROPIONATE TOPICAL SPRAY/Multiple Sections
**Expert Committee:** Small Molecules 5
**No. of Commenters:** 4

**Comment Summary #1:** The commenter indicated in the test for Organic Impurities, that the acceptance criteria for "Clobetasol" and "Clobetasol propionate related compound A" are different from what has been approved and recommended revising to be consistent with what has been approved.

**Response:** Comment incorporated. The acceptance criteria for Clobetasol was widened from NMT 0.5% to NMT 1.0% and Clobetasol propionate related compound A was widened from NMT 0.5% to NMT 1.0%.

PHENDIMETRAZINE TARTRATE TABLETS
PIROXICAM CAPSULES
QUINIDINE GLUCONATE INJECTION

**Monograph/Section(s):** DAPAGLIFLOZIN TABLETS /Multiple sections
**Expert Committee:** Small Molecules 3
**No. of Commenters:** 4

**Comment Summary #1:** Commenters recommended adding a dissolution test to the monograph because the molecule is BCS class III (high solubility–low permeability). In addition, Dissolution is a required test in EDA regulations in Egypt.

**Response:** Comment not incorporated.
An additional dissolution test can be considered for inclusion as a future revision upon receipt of approved specifications and supporting data.

Source: uspnf.com/official-text/proposal-statuscommentary

# 2. Stakeholder Events

## Join USP-hosted stakeholder events

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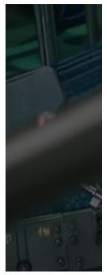

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## USP Workshop: Hot Topics in Orally Inhaled and Nasal Drug Product Performance Testing

March 19, 2025 | March 20, 2025

# 3. Expert Contribution

## Serve as a USP Expert Volunteer

- Follow USP's Call for Candidates (before and during cycle)
  - Expert Committees – Chair and member positions every five years
  - Expert Panels – Formed throughout the cycle as needed and report to Expert Committees
  - More information at: callforcandidates.usp.org
- See who from your organization is represented in USP volunteer system

# 4. Advocacy & Collaboration

## Engage with compendial trade groups

**Industry/Trade Associations (US, EU, International)**

- AAM: Association for Accessible Medicines
    - AAM-USP Working Group
- CHPA: Consumer Healthcare Products Association
- CJIG: Compendial Joint Industry Group
- EFPIA: European Federation of Pharmaceutical Industries & Assoc.
- IFPMA: International Federation of Pharmaceutical Mfr. & Assoc.
- IPEC: International Pharmaceutical Excipients Council
- JAICG: Joint Association Ingredient Collaboration Group
- JPMA (Japan), RDPAC (China), Sindusfarma (Brazil)
- MWCDG: Mid-West Compendial Discussion Group
- NJPQCA: New Jersey Pharmaceutical Quality Control Association
- PDA: Parenteral Drug Association

# 5. Regulatory Awareness

## Monitor FDA guidances and public comment opportunities

*Examples of FDA guidances with compendial implications*

- Reformulating Drug Products That Contain Carbomers Manufactured With Benzene (December 2023)
- Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol (October 2023)
- Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and Other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol (May 2023)
- Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs) (August 2023)
- Control of Nitrosamine Impurities in Human Drugs (September 2024, Rev.2)

# 6. Strategic Governance

## Participate in USP's Convention

- Find out who your representative is
- Respond to USP's Call for Resolutions
- Attend USP Convention Sector (e.g., Generics and Biologics/Biosimilars) and Regional Chapter meetings

Association for Accessible Medicines

Your Generics & Biosimilars Industry

# Thank You!

accessiblemeds.org

biosimilarscouncil.org