Chemical Medicines Monographs 5 Expert Committee
July 18–19, 2016
USP–U.S.
Rockville, MD

Executive Summary

A quorum was present and Ms. Amy Karren, Chair, presided over the Chemical Medicines Monographs 5 Expert Committee (CHM5 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the CHM5 EC, grouped by topic.

1. **CHM5 Portfolio and Work Plan Overview:** Expert Committee (EC) members discussed the EC Work Plan.

2. **Joint Standards-Setting Subcommittees (JS3s):** EC members received an update on the work of JS3s since their implementation and an overview of the revised workflow for JS3 approval of Reference Standard (RS) Replacement and Continuation lots.

3. **Impurities Identification During Method Development:** EC members received a presentation on the USP Compendial Development Laboratory's use of mass spectrometry to identify impurities.

4. **Identification of Desonide Glyoxal in the USP Desonide Impurities Mixture RS:** USP staff reviewed how Reference Standard Scientists identified Desonide Glyoxal in the USP Desonide Impurities Mixture RS.

5. **Harmonizing With International Conference on Harmonisation (ICH) Impurity Limits:** USP staff reviewed the challenges of harmonizing with ICH impurity limits.

6. **Potential Removal of Packaging & Storage Statement from Monographs:** EC members received an update on the removal of Packaging and Storage statements from drug substance and drug product monographs, and the replacement of container specifications for excipient, dietary supplement, and compounded preparation monographs.

7. **Updates and Overviews:** EC members received updates and overviews on the following:
    - Chemical Medicines Collaborative Group (CHMCG) recommendations
    - *USP–NF Style Guide*
    - Development and revision of USP monographs for Over-the counter drug products
    - USP nomenclature process
    - Up-to-Date and monograph modernization
    - RS Continued Suitability for Use program
    - General Chapters Expert Committee activities
    - General Chapters <476> *Organic Impurities in Drug Substances and Drug Products* and <1086> *Impurities in Drug Substances and Drug Product*