



Chemical Medicines Monographs 2 Expert Committee
April 25–26, 2016
USP–U.S.
Rockville, MD

Executive Summary

A quorum was present and Dr. Ernest Parente, Chair, presided over the Chemical Medicines Monographs 2 Expert Committee (CHM2 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the CHM2 EC, grouped by topic.

1. **USP 40–NF 35 Ballot Discussion:** Attendees met in Closed Session and reviewed the ballot items for the May–June 2016 ballot.
2. **CHM2 Portfolio and Work Plan Overview:** Expert Committee (EC) members discussed the EC Work Plan.
3. **Soft Gel Capsules:** EC members received an update on plans to develop and revise documentary standards for soft gel capsules.
4. **Polidocanol and Polidocanol Injectable Foam Monographs:** EC members received an update on the development of the Polidocanol and Polidocanol injectable foam monographs. The Polidocanol drug submission history, quality attributes, and the challenges in establishing performance and quality tests were presented and discussed.
5. **Impurities in Inorganic Drug Substances and Drug Products:** EC members received an update on USP's review of impurity tests in inorganic drug substance and drug product monographs. The purpose of this presentation was to review the impurity tests in different inorganic drug substance and drug product monographs, and identify and evaluate the critical tests for measuring the quality of these types of drug substances and drug products.
6. **Harmonizing with International Conference on Harmonisation (ICH) Impurity Limits:** EC members received a presentation on the challenges of harmonizing with ICH impurity limits.
7. **Other Updates:** EC members received updates on the following topics:
 - Chemical Medicines Collaborative Group
 - Over-the-Counter Monograph System
 - Impurities Identification in Compendial Development Laboratory
 - General Chapters <476> *Organic Impurities in Drug Substances and Drug Products* and <1086> *Impurities in Drug Substances and Drug Products* Update