Reference Information

This information is intended to help pharmacopoeias that are considering applying to join the PDG understand the resource requirements for participants and members.

- PDG Meetings -done in 2023:

  1) Held by host pharmacopoeia (PDG rotates host among member pharmacopoeias on a yearly basis):

  - Annual Fall meeting (face-to-face)
    - 3 - 4 October 2023 at Hyderabad, India
    - PDG stakeholder event was held on 5 October 2023
  - Agenda-setting meeting for annual meeting (virtual)
    - September 2023
  - Spring interim videoconference (virtual)
    - March 2023
  - PDG-IPEC meeting (virtual)
    - December 2023
    - PDG internal preparation meeting was also held in December 2023
  - Monthly meetings (virtual)
    - 10 meetings were held in 2023
  - Meetings related to PDG membership expansion (virtual)
    - 3 meetings to evaluate the pilot programme
    - 7 subteam meetings to discuss data confidentiality and Information-sharing
  - Other ad-hoc meetings (virtual)

  2) Held by the co-ordinating pharmacopoeia (“CP”; PDG nominates a CP for each subject when it is added to the PDG work programme):

  - Expert teleconference (virtual)
    - G-07 Elemental Impurities (CP: USP): April 2023
    - E-32 Povidone and E-54 Copovidone (CP: USP): August 2023
    - E-62 Sterile Water for Injection (SWFI) in Containers (CP: USP): September 2023
    - Q-09 Particulate Contamination (CP: USP): November 2023

- Additional meetings where PDG pharmacopoeias have been represented:
  - ICH meetings
    - 10 - 13 June 2023 in Vancouver, Canada

- 28 October - 1 November 2023 in Prague, Czech Republic

✧ IMWP Meeting

- 8 - 9 November 2023 in Mexico City, Mexico

◆ Topics discussed in 2023:

✧ Harmonization of general chapters and excipient monographs

- 31 general chapters (1 under discussion towards first harmonization and 10 under revision)
- 62 excipient monographs (14 under discussion for initial harmonisation and 10 under revision)

  Note: the numbers are as of Dec. 2023.
- PDG comments timeline

Stage No.	Timelines
Pre-PDG	- Agreement for new topics or revision requests: 12 months
Stage 1	- Answer on first draft (from CP): 3-4 months - Technical TCs following decision that one is required: ideally 1-2 months
Stage 2	- Comments sent to CP after end of consultation period: within 2 months
Stage 3A	- Preparation of Stage 3A draft - Review of Stage 3A draft: within 2 months
Stage 3B	- Following agreement on 3A draft, preparation of 3B package: within 2 months - Send sign-off package (Stage 3B): 4 weeks before PDG meeting

✧ Future of PDG: three strategic discussions

- Workstream 1: Engagement with Regulators
- Workstream 2: Engaging Industry
- Workstream 3: Engagement of other Pharmacopeias
  - ➢ PDG membership expansion (operation and evaluation of pilot programme)
  - ➢ Data confidentiality and information-sharing (completed)

✧ Maintenance of ICH Q4B guideline

✧ Improving the pharma environmental footprint

✧ Nitrosamine Impurities

◆ Budgets:

✧ All members bear their own travel expenses

- ✧ The host member pharmacopoeia bears expenses for the face-to-face (or hybrid) annual meeting (once a year) venue and any PDG events/webinars that host member pharmacopoeia holds.
- ✧ Other contributions to the PDG, such as a document sharing platform, webinar platform, etc., are shared among PDG members.

- ◆ Human resources information (dedicated to PDG)
  - ✧ Staff: about 3 full time equivalents (FTEs) (or about 6000 hours/year)
  - ✧ Independent experts: about 1-2 FTE (or about 2000 – 4000 hours/year)
  - ✧ Note: the estimate above is the average for the PDG pharmacopoeias (EP, IPC, JP and USP) in 2023.
  - ✧ Note: as stated in the PDG Statement of Harmonization Policy, pharmacopoeial documents are harmonized in the PDG based on decisions of the expert bodies of each pharmacopoeia. The PDG works transparently in many ways, including, principally, the public notice and commenting procedures of each pharmacopoeia. Input from experts may be needed for PDG topics other than its harmonisation work; expert resources over and above the estimates above may therefore be required.