PDG Entry Criteria

Purpose of PDG:

PDG currently works to harmonize excipient monographs and general chapters. This will reduce manufactures' burden of performing analytical procedures in different ways, using different acceptance criteria. At all times, PDG works to maintain an optimal level of science consistent with protection of public health.

Each pharmacopoeia of PDG commits to this purpose and to respecting the PDG statement of harmonization policy and PDG working procedures as well as the associated deadlines as an essential part of the harmonization process.

Criteria / Prerequisite to Join Discussion in PDG:

All pharmacopoeias of PDG must meet the following conditions to work for pharmacopoeial harmonization

- Having approaches and policies equivalent to the existing PDG members by implementing the principles laid down in the Good Pharmacopoeial Practices (GPhP) with the following enhanced principles and/or requirements to the original language in GPhP for the following sections :

  Section 6.1. General Consideration

  - Specifications that limit market access by, for example, favouring one manufacturer to the exclusion of others **must** be avoided.

  Section 6.1.2. Open and transparent process

  Pharmacopoeial standards are based on current scientific knowledge and reflect the quality of pharmaceutical substances and Finished Pharmaceutical Product (FPP) authorized. Pharmacopoeias ensure openness and transparency throughout the development and revision of monographs and other texts, which includes:

  - engaging stakeholders in the routine development and revision of pharmacopoeial standards through adequate and timely public consultation (Frequency of public consultation in order not to slow down PDG process: at least three public consultation periods per year for PDG texts (or on an ad hoc basis) with an adequate window for public comment, with a transparent comment process)
  - official publication of signed-off PDG texts at least once every three years, preferably having more frequent revision cycles in order not to delay implementation of sign-off texts.
  - procedure for rapid revision outside of normal process (e.g. mechanism to engage stakeholders in the timely development and revision of standards to address major public health concerns for PDG standards when expeditious revision is required)

- general transparency of the pharmacopoeial approaches
  - publicly available work programs
  - appropriate communication with stakeholders through outreach such as forums, workshops and other interactions
  - timely response to user enquiries
- rapid correction of errors published in compendial texts, including English version, when necessary
- timely and appropriate revision and/or withdrawal of compendial standards, when necessary (The legal status of monographs that have been withdrawn will depend on the national regulatory framework.)

Section 7 Analytical test procedures and methods:

- The monograph must employ validated analytical procedures for tests and assays according to validation guidelines established at the time of the elaboration or revision of the compendial text (including microbiological tests and assays). The validation of analytical procedures described in monographs should comply with the requirements as laid down in the relevant ICH validation guideline such as ICH Q2 guideline (Validation of analytical procedures: text and methodology)

- Application of regulatory guidelines in the pharmacopoeia

  Each pharmacopoeia should apply selected ICH quality guidelines such as Q2, Q3C and Q3D as principles for standard development and as basis for harmonization of all items on the PDG work program.

- Implementation of PDG work program

  Each pharmacopoeia of PDG are expected to implement all PDG harmonized general chapters, and PDG harmonized excipient monographs unless otherwise justified to PDG. To achieve implementation of PDG signed-off texts, a stepwise approach may be applied.

  Before Joining PDG

  Possible new member submits to PDG an implementation plan for all PDG harmonized texts.

  - Evaluation of own text versus the PDG sign-off text and provision of:
    - For texts already considered harmonized, a detailed review of potential residual differences between own texts and the signed-off PDG text as well as an English version of their pharmacopoeial text. For residual differences, a justification for any deviations from the harmonized text must be provided.
    - For other signed-off PDG texts a commitment to harmonize the texts with concrete implementation timeline and strategy. PDG would make the implementation

timetable publicly available.

- a justification for each individual PDG harmonized excipient monograph that would not be implemented.

- Commitment to provide an annual status update of the implementation of all signed off PDG texts to PDG. The status update will be made publicly available.
- Commitment to active engagement in all on-going items on the work plan, especially responding timely with official position and possible comments and participating in all meetings on general and technical topics.

<u>After Joining PDG</u>

- Complete implementation of all PDG harmonized general chapters
- Complete implementation of all PDG harmonized excipient monographs (unless otherwise justified to PDG)
- New member must implement PDG pharmacopoeial general chapters or monographs in question and related PDG texts before making a revision request or new proposal.

  e.g. When new member submit a revision request or a new proposal for excipients, they must complete implementing general chapters such as G-20 Chromatography which are specified in the monograph.
- Annual report including regular completion timetable to track implementation of existing harmonized texts in each pharmacopoeia, which would be publicly made available.
- For on-going work on items on the work program new members are also expected to actively participate and encouraged to make technically valuable comments but items on the work program will not revert to an earlier stage solely as a result of commentary from new members.

- Availability of final published documents in English

- Appropriate revision cycle (at least once per 5 years)

- Confidentiality policy in place needed to secure data shared within PDG and policy transparently available to PDG.