

PDG entry criteria

Purpose of the PDG:

The PDG harmonises excipient monographs and general chapters. This reduces the burden on manufacturers to perform analytical procedures in different ways, using different acceptance criteria. At all times, the PDG endeavours to maintain an optimal level of science consistent with protection of public health.

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

Criteria/prerequisites to joining PDG discussions:

All pharmacopoeias of the PDG meet the following conditions:

- Have approaches and policies equivalent to those of the existing PDG members, achieved by implementing the principles laid down in the Good Pharmacopoeial Practices (GPhP), with the following enhanced principles and/or requirements in certain sections of the original GPhP text, i.e.:

Section 6.1. General considerations

- 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 Products (FPPs) authorised. 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 the 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 and a transparent commenting 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 programmes;
 - 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 in the 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 *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 the basis for harmonisation of all items on the PDG work programme.

● Implementation of the PDG work programme

Each PDG pharmacopoeia is expected to implement all PDG harmonised general chapters, and PDG harmonised excipient monographs, unless otherwise justified to the PDG. A stepwise approach may be applied to implementing PDG signed-off texts.

Before joining the PDG:

The applicant submits to the PDG a commitment to implement all PDG harmonised texts together with a timetable for their implementation.

- Evaluation of own text versus the PDG sign-off text and provision of:
 - for texts already considered harmonised, a detailed review of potential residual differences between own pharmacopoeial text and the signed-off PDG text, as well as an English version of their text. A justification for any residual differences must be provided;
 - for other signed-off PDG texts, a commitment to harmonise the texts with a

concrete implementation timeline and strategy. The implementation timetable will be made publicly available;

- a justification for each individual PDG harmonised excipient monograph that would not be implemented.
- Commitment to provide an annual status update of the implementation of all signed-off PDG texts to the PDG. The status update will be made publicly available;
- Commitment to active engagement in all ongoing items on the work plan, especially with regard to responding in a timely manner with the official position and possible comments and participating in all meetings on general and technical topics.

Candidate participants have a one year observing period (as Candidate in the Observing phase) and are encouraged to attend technical meetings, although they are not expected to submit comments on ongoing items on the work plan. Candidate participants are expected to attend regular meetings and the annual PDG meeting (in-person).

After joining the PDG

- complete implementation of all PDG harmonised general chapters;
 - complete implementation of all PDG harmonised excipient monographs (unless otherwise justified to the PDG);
 - new members 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 a new member submits a revision request or a new proposal for excipients, they must complete implementation of any general chapters, such as G-20 Chromatography, that are referred to in the monograph.
 - annual report including regular completion timetable to track implementation of existing harmonised texts in each pharmacopoeia, which would be made publicly available;
 - for ongoing work on items on the work programme, new members are also expected to actively participate and encouraged to make technically valuable comments, but items on the work programme will not revert to an earlier stage solely as a result of commentary from new members.
- Availability of final published documents (at least local harmonised text and related text – general notice, general method, etc.) in English.
 - Appropriate revision cycle (at least once per 5 years).
 - Confidentiality policy in place to secure data shared within the PDG, and policy transparently

available to the PDG. Signing of the PDG “candidate participation and commitment to confidentiality” before participating in the first meeting.

- Commitment to securing the resources required to engage in all PDG activities (see the reference information for the required resources).