

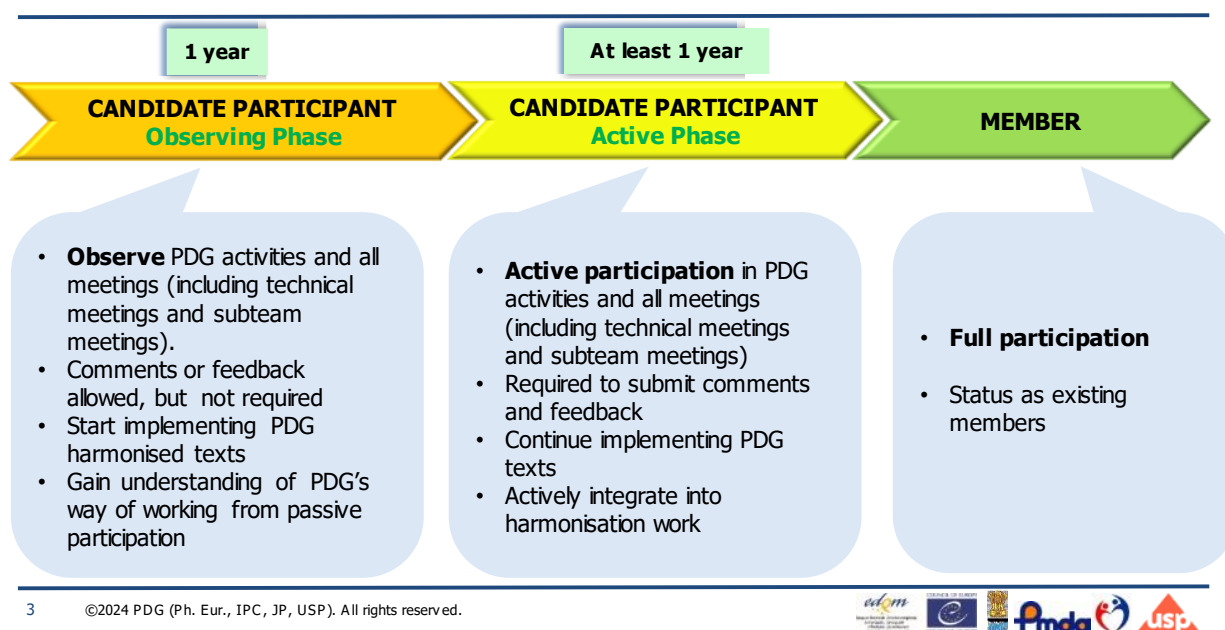
Framework for the PDG to introduce new members

Background and purpose

The PDG expansion pilot programme that took place in 2022 - 2023 successfully ended with the inclusion of the IPC as a fourth member in October 2023. Based on the lessons learned from this pilot, the PDG amended the process for expanding its membership and is now open to further applications for membership. This document explains the framework and the process that will be followed for this new programme. An overview of the timeline can be found at the end of the document.

The framework foresees 2 phases for candidate participants before becoming a new member. Details are listed in the table below.

Framework



Open call for candidate participants

In July 2024, the PDG issues an open call for candidate participants to the other world pharmacopoeias. The PDG shares the “PDG entry criteria” together with this document about the list of PDG meetings and related activities to enable applicants to estimate the resources required to participate in PDG activities (see the “Reference Information”). Applicants will be asked to demonstrate compliance with all of the criteria and to provide an implementation timetable as part of their written application. Applicants have until 15 September 2024 to provide a “statement of intent to apply”, in order to give existing PDG members an idea of how many pharmacopoeias are going to apply to be participants in this programme.

Submission of applications, including their implementation plan for individual PDG harmonised texts to PDG.

The deadline for pharmacopoeias to submit applications, including their implementation plan for individual PDG harmonised texts to PDG is 31 December 2024. The PDG will remain open to new applicants and foresees accepting applications on a regular basis in the future. Pharmacopoeias submitting their application after the deadline will be considered at a later date, after this round of accessions has been closed.

Evaluation of applications by PDG

The PDG members will evaluate new applicants based on their adherence to the criteria with great care. Please note that all applications received in time will be considered equally.

The PDG will share the work on the detailed evaluation among its members (e.g. the in-depth review of the degree of harmonisation already achieved by applicants on individual items on the workplan). Current PDG members will review in the first half of 2025 the applications, and also perform a specific detailed review of the level of adherence to selected harmonised texts. The PDG operates by consensus, and a consensus decision will be made on which applicant(s) is (are) selected for participation in the programme.

The PDG is committed to preserving all the work achieved over the last 35 years. If a significant number of applicants were to be considered eligible, the PDG may need to focus on a reduced number of candidate participants in order to ensure that the many ongoing items on the PDG work programme continue to progress smoothly and that the applicants can be integrated efficiently into the PDG within the foreseen timelines.

Notification of decision

In June/July 2025, the PDG will inform all applicants of the outcome of the evaluation process at the same time, by formal letter. The successful applicants will be invited to take part as candidate participants.

Formal introduction of candidate participant to PDG

Successful applicants become candidate participants in the Observing phase starting in October 2025 and, as such, will be regular participants in all PDG activities for a period of one year from the date of acceptance. Candidate participants in the Observing phase will be invited to attend the Fall PDG meeting in-person, as well as PDG teleconferences, expert teleconferences and subteam/working group meetings (exceptions possible), or other ad hoc PDG activities to learn how the PDG works. Candidate participants in the Observing phase are expected to continue to comply with the Entry criteria and respect the implementation timetables submitted in their application.

The current PDG members will meet quarterly or on an ad hoc basis (e.g. before / after a monthly PDG teleconference) during the Observing phase to discuss candidate participants' evaluation and address any potential issues.

Progression of candidate participant to Active phase

At the end of the Observing phase, the candidate participants will be asked to renew the commitment stated in the application and to submit a progress report, together with updated implementation timetables, and a self-evaluation of attendance at meetings and the sufficiency of resources based on the lessons learned from the Observing phase. The progress report will be submitted by the end of August 2026 and reviewed by existing PDG members by the end of September 2026. Candidate participants will progress to the Active phase and will actively participate in all PDG discussions from the PDG meeting in October 2026 onwards.

Evaluation of the Active phase candidate participants by existing PDG members

In 2027, the current PDG members will meet to evaluate the candidates included in the Active phase with regard to participation in the PDG.

- Evaluation of candidate participants

Each candidate participant in the Active phase will be required to submit an updated progress report (following the entry criteria) and will be evaluated on the following:

- attendance and active participation at meetings (especially monthly teleconferences, regular videoconferences, and annual face-to-face meeting);
- participation in technical discussions (if the topic is on their implementation workplan); this includes the ability to find common solutions with the other PDG experts in order to make technical decisions;
- implementation of Entry criteria, especially follow-up of the implementation timetable;
- ability to meet deadlines:
 - constructive support of PDG progress (especially not hindering progress on items), for example by timely replies (via email, letter, Sharepoint, etc.)
- sufficiency of resources;

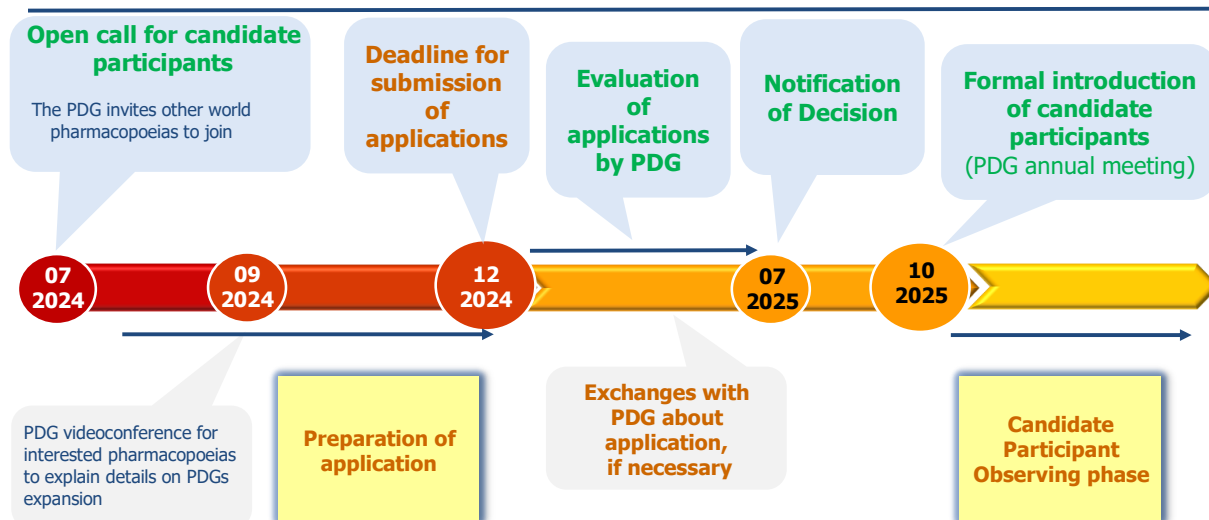
The current PDG members will then prepare a consensus decision on each candidate participant's ability to be admitted as a PDG member. The current PDG members will inform the candidate participant of this conclusion and discuss possible outstanding questions in a written exchange or a teleconference.

Becoming PDG member

- Based on the evaluation above, eligible Active phase candidate participants will progress to full membership with equal status from the PDG meeting in autumn 2027.
- Non-eligible Active phase candidate participants will remain in the phase for an additional year and will be re-evaluated after that period.

Timeline

Timeline: Application and introduction of candidate participants

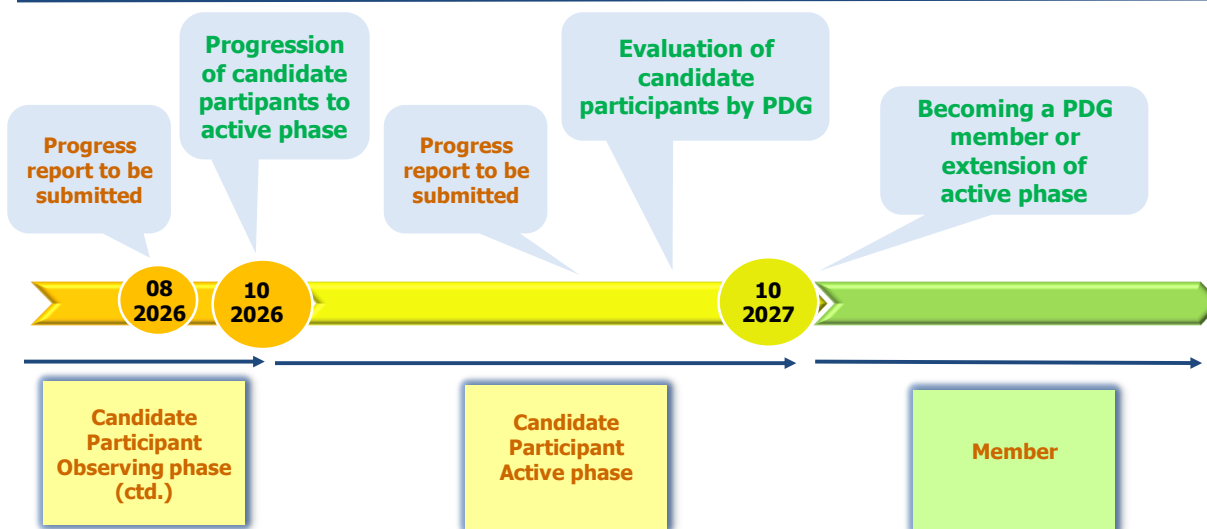


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Timeline: Candidate participants towards membership



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