<u>**Framework for the PDG Pilot to Introduce New Members**</u>

Background and purpose:

The established PDG members (USP, EP, and JP) have agreed to pilot a process for admitting new members to the PDG. This document provides a working framework and the process that will be followed for this pilot. At the end of the pilot, the established PDG members will identify any changes necessary to keep the satisfactory efficiency of PDG performance before finalising the process, prior to a broader rollout.

October 2021: Open call for pilot participants.
The PDG issues an open call for pilot participants to the other world pharmacopoeias. The call includes the "Entry Criteria for New Members" together with this document about the pilot process. Applicants will be asked to demonstrate compliance with all of the criteria including an implementation plan as part of their written application. Applicants have until 31 December 2021 to provide a statement of intent to apply, in order to give established PDG members a sense of how many pharmacopeias are going to apply to be participants in this pilot.

Deadline for pharmacopoeias to submit applications including an implementation plan of individual PDG harmonised texts to PDG: 31 March 2022.

The PDG pilot will remain open to new applicants and foresees accepting applications on a regular basis in the future. However, pharmacopoeias submitting their application after the deadline will be considered at a later date, after the first round of accessions has been closed. The PDG is committed to preserving all the work achieved over the last 32 years and will therefore review the applications with great care. If a significant number of applications is received, the PDG may need to focus on a reduced number of applicants in the first pilot phase in order to ensure that the many ongoing items on the PDG work program continue to progress smoothly and that the applicants can be integrated efficiently into the PDG within the foreseen timelines.

PDG evaluates the applications; PDG discusses applications

Established PDG members will evaluate new applicants based on their best adherence to the criteria. It should be stressed that the decision is not based on the dates applications are submitted.

The PDG will share the work on the detailed evaluation (e.g. sharing the in-depth review of the degree of harmonisation already achieved by applicants on individual items on the workplan). Established PDG members will review the overall applications, and also perform a specific detailed review on the level of adherence to selected harmonized texts. PDG operates by consensus, and a consensus decision will be made on which applicant(s) are selected for participation to the pilot.

Acceptance to Pilot

PDG will submit a formal letter welcoming successful applicant (s) into the PDG Pilot. All applicants will be informed at the same time (acceptance or rejection). Successful applicants are then pilot participants, and as such become regular participants in all PDG activities for a period of one year from the date of

acceptance. Pilot Participants will be invited to and are expected to attend the Fall 2022 PDG meeting, as well as PDG teleconferences, expert teleconferences (exceptions possible), or other ad hoc PDG activities. Pilot participants must comply with the Draft Entry criteria and respect the implementation timelines submitted in their application.

Evaluation of Pilot by established PDG members:

In 2023, the established PDG members will meet to evaluate the Pilot participants' membership and participation in the PDG. Two areas to be evaluated are each individual pilot participant's impact and efforts, and secondly the overall impact on the resources/performance of the PDG.

- Evaluation of Pilot participants

  Each Pilot participant will be evaluated on the following:

  - Attendance at meetings (monthly teleconferences, regular videoconferences, and annual F2F meeting)
  - Participation in technical discussions (if the topic is on their implementation workplan), this includes the ability to find common solutions of the other PDG experts in order to make technical decisions
  - Implementation of Entry criteria, especially follow-up of the implementation timetable
  - Ability to meet promised deadlines
    - Constructive support of PDG progress (i.e. not hindering progress on items)

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

- Evaluation of Resources/performance of PDG.
  PDG will discuss and evaluate the lessons learned from the first pilot process and will decide on any changes needed to the process before rolling out PDG expansion permanently. The following points will be considered:
  - Ability to meet increased or new demands for PDG established members.
  - Presence or absence of challenges in the PDG process for pharmacopoeial harmonisation such as delayed movement of harmonised standards and blocking items.
  - Stakeholder feedback/perception of "expanded" PDG

Annual meeting in Autumn 2023

The established PDG members will make a decision on the following points.

- Final evaluation of the outcome in two areas.
  - PDG performance/resource implications
  - evaluation of pilot phase participants
- Specific questions to be evaluated are as follows.
  - Follow-up with lessons learned to amend the PDG procedure for pharmacopoeial harmonisation.
- Evaluation of both areas (pilot phase and resources/performance of PDG) with possible different outcomes.

- ➢ Whether or not to move pilot participants to full established members.
- ➢ Continue pilot for another year while PDG evaluates possible other models for conducting work.
- ➢ Need to discuss next steps to terminate pilot or to change criteria/model for new members, or to change to a different model for PDG.