Pharmacopoeial Discussion Group Meeting
Meeting Highlights
1–2 October 2024, Strasbourg, France
Hosted by the Ph. Eur.

1. Expansion of the PDG

Since October 2023, when the Indian Pharmacopoeia Commission (IPC) became the fourth PDG member (link), the PDG has been continuously working to organise the next steps for further expansion. In summer 2024, the PDG announced publicly the launch of the next phase in its global expansion initiative aimed at increasing convergence of harmonised pharmacopoeial standards (link). Pharmacopoeias interested in becoming members were encouraged to review the entry criteria, framework and reference information and are invited to submit their formal applications by 31 December 2024. The PDG will examine the applications by the summer of 2025, with the aim of formally welcoming candidate participants in October 2025.

In the meantime, the PDG will review the strategy, structure and organisation of the PDG as well as revision of the PDG operational procedures to ensure continued effectiveness in the future with more members.

2. ICH Q4B maintenance

The PDG has been working on the follow-up on the maintenance work of the ICH Q4B annexes on pharmacopoeial harmonisation, defining the next steps following the significant achievement of the ICH Assembly's approval of the revised Q4B(R1) guideline and the related ICH SOP Annex 5 at the June 2024 meeting in Fukuoka.

The PDG will finalise the work on the revision of annexes 6, 7 and 8 for Uniformity of Dosage Units, Dissolution and Sterility, respectively. The pharmacopoeias of the ICH regulatory members that have joined the ICH over the last 2 years will be invited to participate in this work. In addition, the PDG discussed the timeline for the maintenance of all other annexes, based on the responses received from ICH regulatory members and/or their pharmacopoeias. The harmonisation efforts through ICH Q4B maintenance target all ICH regulatory members and their pharmacopoeias, which include 10 world pharmacopoeias and 17 regulatory members, representing harmonised pharmacopoeial standards worldwide.

3. Regulatory engagement

The PDG discussed their current interactions with their respective regulators. As the host of the meeting, the Ph. Eur. provided a comprehensive overview of its interactions at regulatory level and shared updates on legislative and regulatory changes. The PDG agreed to maintain open dialogue among the pharmacopoeias involved to better understand the challenges of pharmacopoeial harmonisation within different regulatory environments.

4. Hot topics for consideration by the PDG

4.1. Discussion on how the PDG can collaborate on topics of high interest

4.1.1. Nitrosamines

The PDG initiated a productive discussion on the objectives of the Nitrosamines subteam. Since January 2024, the subteam has met regularly to share knowledge and experience on nitrosamine impurities. Each PDG member addressed their particular challenges associated with these impurities and broached potential approaches to identifying collaborative opportunities for the future.

4.1.2. Testing for bacterial endotoxins using recombinant reagents

The meeting provided an excellent opportunity for each PDG pharmacopoeia to share updates on their individual developments, exchange insights, and discuss areas of common interest.

4.1.3. Revision of ICH Q6 guidelines

The PDG is interested in the current revision of the ICH Q6 guidelines and used this meeting to discuss potential opportunities for exchanging opinions and to reflect on the potential impact of the ongoing revision on pharmacopoeias based on the published information.

5. PDG work programme and harmonisation topics signed off – all 31 General Chapter harmonised

The PDG considered individual work programme sign-offs, which were handled by correspondence prior to or soon after the meeting. As ever committed to transparency, the current work programme, including all ongoing items, is available on the websites of the PDG pharmacopoeias (General Chapters (link), Excipients (link)).

An important milestone, the sign-off of the general chapter G-07 Elemental Impurities also represents a more global achievement as the PDG has now – after 35 years of consistent effort and fruitful collaboration – successfully harmonised all the general chapters on its work programme (31) in addition to 48 of the 62 excipient monographs listed.

5.1. General Chapters

5.1.1. G-07 Elemental Impurities (USP) – new chapter

The PDG signed-off on the successfully harmonised general chapter Elemental Impurities (G-07). The implementation of this harmonised chapter along with the application of ICH Q3D concepts promote the development of individual monographs with aligned requirements for elemental impurities among the regions of the PDG pharmacopoeias.

5.1.2. G-02 Bulk density of Powders (Ph. Eur.) – corrected chapter

The PDG signed-off on the correction of this text to correct the titles of Methods 1 and 2, to update Figure 3 and change a significant figure of a value of the drop in Method 2.

5.1.3. G-06 Tablet Friability (USP) – updated sign-off cover sheet

The PDG signed-off on a revised version of the sign-off cover sheet of this text represents the first implementation by the IPC, which is therefore the first text harmonised amongst the four pharmacopoeias.

5.2. Excipients

5.2.1. E-40 Corn Starch (USP) – revised monograph

The PDG signed-off on the revision of this text that has been modified to clarify the specific size and shape requirements of the Identification Test A method.

6. Next Meeting

The next annual meeting will be hosted by the JP, on 30 September – 1 October 2025, in Tokyo.