Pharmacopoeial Discussion Group Meeting

Meeting Highlights

September 30–October 1, 2025
Tokyo, Japan
Hosted by the JP

1. **Expansion of the PDG membership**
   The PDG announced the launch of the second phase of its global expansion initiative aimed at increasing convergence of harmonised pharmacopoeial standards in August 2024 (link). After a review of applications, the PDG agreed to welcome the Korean Pharmacopoeia (KP) as a candidate participant, as reported in the July 2025 press release (link). The KP joined the PDG activities for the first time at PDG Annual meeting 2025 held in Tokyo, Japan, introducing its contents, principles for revision, implementation plan for the PDG harmonized texts, and future plans. The KP will participate in all upcoming PDG meetings during the one-year observing phase to gain an understanding of the PDG's processes.

2. **Establishment of new work-sharing teams**
   The PDG agreed to establish work-sharing teams, designed as a concept to discuss specific topics more efficiently. The teams cover topics such as the PDG work programme, strategy and policy, stakeholder engagement, discussions related to ICH, communications, and nitrosamines, and is expected to facilitate more streamlined discussions and continuous progress across the topics.

3. **Revision of PDG working procedure**
   The PDG agreed to revise its working procedure (link). This revision merges non-harmonised attributes and local requirements into "non-harmonised parts", reflecting the increasing number of participating pharmacopoeias and aiming to reduce potential confusion for users. The black diamonds remain as the symbols to indicate non-harmonised parts, while the white diamonds, used in the Ph. Eur. and JP, will be removed. These changes will be incorporated into each pharmacopoeia according to their own timelines.

4. **Regulatory engagement**
   The PDG members continued discussions on their current interactions with their respective regulators. As the host of the meeting, the JP provided an in-depth overview of its interactions with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agencies (PMDA), as well as the recent revision of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD. Act). The PDG will continue an open dialogue among the pharmacopoeias to enhance mutual understanding of the challenges to pharmacopoeial

harmonisation within different regulatory environments.

5. ICH Q4B maintenance

The PDG has been working on the proof-of-concept study for maintenance on three annexes (Annex 6 Uniformity of Dosage Units, Annex 7 Dissolution and Annex 8 Sterility) with the involvement of the pharmacopoeias from the ICH regulatory members that are not part of the PDG (link). In this meeting, the group discussed the progress and challenges of the work, and the future steps. The discussion will continue going forward, including exchanges with the ICH members on the next steps.

6. The PDG related websites of each pharmacopoeia

The PDG discussed aligning the format of each pharmacopoeia's website related to the PDG activities, aiming to make the information provided more consistent and easily accessible.

7. Emerging trends: key areas of focus for pharmacopoeias

The PDG had an open discussion on environmental sustainability and complex generics, sharing updates and insights from each pharmacopoeia on their current activities and developments. The discussion provided a good opportunity to exchange views and gain a better understanding of each pharmacopoeia's approach on these impactful topics. The PDG agreed to include environmental sustainability in standards setting as a standing item at future PDG meetings.

8. PDG work programme and harmonization topics signed off

The PDG confirmed 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)).

8.1. General Chapters

8.1.1. Q-02 Disintegration (EP) – revised chapter

The PDG signed off on a key revision introducing Method B, an apparatus and an analytical procedure for tablets and capsules larger than 18 mm.

8.1.2. Q-09 Particulate Contamination (USP) – revised chapter

The PDG signed off on a major revision which represents a significant step forward in standardized testing procedures applied in the PDG regions for sub-visible particulate matter in all injectable products. This update makes the process more robust and adaptable to different product types, including biologicals. (see PDG press release (link))

8.2. Excipients

8.2.1. E-56 Glucose Monohydrate/Anhydrous (EP) – updated sign-off cover sheet

The PDG signed-off on a revised version of the sign-off cover sheet, changing EP

local attributes from pyrogens to pyrogenicity.

9. Next Meeting

The next annual meeting will be hosted by the IPC, and is tentatively set for 29 September – 1 October 2026 in Ghaziabad, India