

# IPC Updates

## PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The Pharmacopoeial Discussion Group (PDG) held its annual meeting from September 30 to October 1, 2025 in Tokyo, Japan. The group welcomed the Korean Pharmacopoeia (KP) as a candidate participant in this meeting [\[link\]](#). In this capacity, KP joined the discussions alongside the PDG members—the European Pharmacopoeia (Ph. Eur.), the Indian Pharmacopoeia Commission (IPC), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP). The World Health Organization (WHO) continues to serve as observer of the group.

The KP introduced its contents, principles for revision, implementation plan for the PDG harmonized texts and future plans. As outlined in the framework for including new members in the PDG [\[link\]](#), the KP will participate in PDG activities under the Observing Phase for the next year. Following the Observing Phase, the KP will enter an **active participation phase** lasting at least one year, during which it will contribute more directly to PDG activities.

In this meeting, the PDG discussed the maintenance work on the ICH Q4B annexes on pharmacopoeial harmonization. The group is engaged in a 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 [\[link\]](#). The group will continue its review and discussions with the ICH and the pharmacopoeias involved to ensure that the work progresses efficiently and remains focused on achieving the most beneficial outcome.

the PDG also decided on a new way of organizing its work in different internal teams and agreed on the concept and next steps to guide its future direction. This new approach is designed to enhance PDG's efficiency and optimize resource utilization.

In addition, the PDG discussed and agreed on a further revision of its working procedure [\[link\]](#). This revision will merge non-harmonised attributes and local requirements in PDG texts into

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“non-harmonised parts”, reflecting the recent expansion of the group’s membership and to make sure that PDG texts are clear to users. The black diamonds will continue to indicate non-harmonised parts, while the white diamonds, used in the Ph. Eur. and JP, and which were helpful when there were only three members but are complex to maintain with four and more members, have now been removed. These changes, which simplify the content for users and improve clarity, will be implemented in each pharmacopoeia whenever feasible. With more than three PDG members, it is even more important for users to verify the content of the sign-off cover sheets which clearly explain, if applicable, which residual parts have not been harmonized.

Lastly, the PDG initiated a topic on information sharing between the PDG partners on the key areas of focus for pharmacopoeias such as environmental sustainability and complex generics.

Individual work programme sign-offs (handled by correspondence prior to the meeting) included two major revisions:

- revision of the general chapter Q-09 Particulate Contamination (see PDG press release [\[link\]](#));
- revision of the general chapter Q-02 Disintegration to include Test B intended for dosage forms larger than 18 mm.

The current work programme, including all ongoing items, is available on the website (General chapters [\[link\]](#), Excipients [\[link\]](#)). The PDG also decided to begin discussions on aligning the webpages of each pharmacopoeia regarding the PDG, ensuring that similar, relevant information is provided to stakeholders.

## **Excipients Council**

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on October 1, 2025. Topics discussed included the PDG work programme on Polysorbate 20.

## **Next meeting**

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