Press release

21 January 2025, Strasbourg, France

Pharmacopoeial Discussion Group achievements

The Pharmacopoeial Discussion Group (PDG) held its annual meeting on 1 and 2 October 2024 in Strasbourg, France. The meeting marked the one-year anniversary of the PDG working with an expanded team of four members (see "PDG welcomes IPC as a member"). The PDG includes the European Pharmacopoeia (Ph. Eur.), the Indian Pharmacopoeia Commission (IPC), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP). The World Health Organization (WHO) continues as an observer.

One of the primary outcomes of the meeting was the next steps for further expansion. On 30 August 2024, the PDG announced the launch of the next phase of its global expansion initiative, aimed at increasing convergence towards harmonised pharmacopoeial standards (see "PDG announces global membership initiative"). Pharmacopoeias interested in becoming members were encouraged to review the entry criteria, framework and reference information and were invited to submit their formal applications by 31 December 2024. The PDG will review the applications by summer 2025.

In addition to membership expansion, the PDG has been working on the follow-up on the maintenance work of the ICH Q4B annexes on pharmacopoeial harmonisation. The PDG defined the next steps following the significant achievement of the ICH Assembly's approval of the revised Q4B 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 the three annexes for Uniformity of Dosage Units, Dissolution and Sterility. Furthermore, the pharmacopoeias from the ICH regulatory members that have joined the ICH over the last two years and that are not currently part of PDG, will be invited to participate in this work. In addition, the PDG discussed the timeline for the maintenance of all the other annexes, based on the responses received from ICH regulatory members and/or their pharmacopoeias.

In addition, the PDG also held productive discussions and reviewed the objectives and status of the Nitrosamines subteam, the next step being to explore common approaches to identify potential areas of collaboration for the future. Other topics discussed included approaches to testing for bacterial endotoxins using recombinant reagents with a view to identifying commonalities. Lastly, a dialogue was initiated on the potential future impacts of the revision of the ICH Q6 guidelines Specifications, based on the published concept paper.

Individual work programme sign-offs (handled by correspondence prior to or soon after the meeting) included:

- the successful harmonisation of the general chapter Elemental Impurities (G-07) that marks a significant milestone (see "General chapter Elemental Impurities (G-07) harmonised by the PDG"). This sign-off represents a more global achievement as the PDG has now successfully harmonised all the general chapters on its work programme (31) in addition to 48 of the 62 excipient monographs listed. The current work programme, including all ongoing items, is available on the website (General chapters, Excipients);

- the first implementation by the IPC, indicated by a revised version of the sign-off cover sheet of the general chapter Tablet Friability (G-06); this is the first text harmonised among the four pharmacopoeias;
- a revision of the monograph Corn Starch (E-40);
- a correction of the general chapter Bulk Density of Powders (G-02).

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on 3 October 2024. Topics discussed included monographs on Polysorbate 20, Hypromellose and Methylcellulose as well as the control of diethylene glycol/ethylene glycol in some excipient monographs.

PDG Stakeholder Event

The PDG Stakeholder Event was held in Strasbourg on 3 October 2024, with stakeholders from various industry associations worldwide attending both in-person and virtually. Representatives from the Ph. Eur., IPC, JP, USP and WHO presented the recent achievements and challenges from each pharmacopoeia. They also provided a comprehensive overview of the PDG, its history and interactions with other international organisations. One key topic addressed was the expansion of the PDG and its future direction, with the IPC also sharing its perspective as a new PDG member.

Next meeting

The next face-to-face PDG meeting will be hosted by the JP and is set for 30 September and 1 October 2025 in Tokyo, Japan.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Its standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.[1] The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 46 member states.

1. The European Pharmacopoeia Commission comprises 40 members: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom and the European Union.