Press release

6 January 2023, Strasbourg, France

Pharmacopoeial Discussion Group achievements

The Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP), with the World Health Organization (WHO) as observer, held its annual autumn meeting from 18 to 21 October 2022. Due to the COVID-19 pandemic, the meeting was again organised through videoconference. For the first time, the Indian Pharmacopoeia Commission (IPC) joined the meeting as a pilot participant in the PDG pilot for global expansion.

The PDG members were delighted to welcome the IPC. The IPC introduced its organisational structure, its pharmacopoeia and its plan for harmonising with the PDG. This was a landmark meeting in the PDG's 33-year history since the PDG welcomed an additional pharmacopoeia, marking the launch of a one-year pilot for expansion of its membership, as announced in an earlier press release. The lessons learned from this pilot will be used to further adjust and refine the group's working methods and will identify any changes necessary to ensure that the PDG continues to perform efficiently at the end of the pilot.

One of the primary outcomes of the meeting was the consensus reached on a proof-of-concept study for the maintenance of the ICH Q4B annexes. Following exchanges with the four other pharmacopoeias involving the discussion at the PDG interim videoconferences on 15 and 28 March 2022, revised drafts of three selected Q4B annexes (Annex 6: Uniformity of Dosage Units, Annex 7: Dissolution and Annex 8: Sterility) had been prepared. Based on these drafts, the PDG finalised the report with recommendations for some key questions, which had been raised in this proof-of-concept study. The PDG reported the conclusions of this study and recommendations for next steps to the ICH Assembly in November 2022.

In addition to membership expansion as a means of enhancing its global outreach, the PDG has been working on the two other areas considered to be critical to ensuring its future: (1) stakeholder engagement and (2) regulatory engagement, as announced in the press release in October 2021. A draft concept paper for the early engagement model for stakeholders was proposed using the excipient "Polysorbate 20" as a pilot; this was submitted in parallel with a revision proposal for the existing PDG monograph, "Polysorbate 80", which has a similar technical content.

With regard to improving engagement with regulators, the Ph. Eur., JP and USP reported on the interactions with their respective regulators and exchanged opinions on some of them. The JP as the host of the meeting gave a detailed explanation of interactions with its own regulators (i.e. the Ministry of Health, Labour and Welfare: MHLW, and the Pharmaceuticals and Medical Devices Agencies: PMDA) on adoption of the ICH Q3D guideline as an example for the other members to deepen their understanding of regulations in Japan. The PDG agreed to continue the open dialogue between the involved pharmacopoeias to further our understanding of the challenges to pharmacopoeial harmonisation resulting from working within our respective different regulatory environments.

Following the interim videoconference in March 2022, the PDG decided to add two items, "Purified Water" and "Water for Injection", to its work programme in response to stakeholders'

request. Adding those two key excipients, essential for any aqueous liquid preparation, to the harmonisation work programme shows the commitment of the PDG to its goal of preparing impactful harmonised texts.

A number of individual items on the work programme have now been finalised. The achievements will be reported in a separate press release.

Even without the benefits of face-to-face meetings – not least the many opportunities for fruitful exchanges they offer – the PDG continues to deliver and remains fully committed to pursue and enhance its efforts to expand development and recognition of harmonised pharmacopoeial standards.

Next meeting

The next annual meeting will be hosted by the USP on 3 and 4 October 2023, at a place to be determined.

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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.

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.

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