

25 April 2023, Strasbourg, France

Pharmacopoeial Discussion Group achievements – Interim videoconference (15 March 2023)

The Pharmacopoeial Discussion Group (PDG)¹ held its interim videoconference on 15 March 2023.

In the context of the [pilot for expansion of its membership](#), the established PDG members and IPC discussed the progress of IPC on the criteria of the PDG pilot program, as well as the challenges faced and suggestions by IPC. This open discussion will allow the PDG to make any necessary adjustments to the pilot program prior to its conclusion at the annual PDG meeting scheduled in October 2023.

The PDG also reviewed questions from the ICH Assembly in November 2022 surrounding the outcome of a proof-of-concept study run by the PDG for the [maintenance of the ICH Q4B annexes](#). It was agreed to continue providing clarity around the recommendation made to the ICH Assembly in November 2022 offering PDG proposals for the revised drafts of the three selected Q4B annexes (Annex 6: Uniformity of Dosage Units, Annex 7: Dissolution and Annex 8: Sterility) and for a working procedure for the regular maintenance of the existing annexes. The PDG will meet and prepare its recommendations for the next steps of this study with questioners at the ICH Assembly in November 2022 prior to the ICH Assembly in June 2023. With the successful completion of this work, further alignment of pharmacopoeias around the globe on the general texts covered by the ICH Q4B annexes will be reached.

As part of the means to enhance its global outreach, the PDG provided an update to the early engagement model for stakeholders using an initiative that is being tested with the excipient Polysorbate 20 as a pilot. A concept paper on the potential for harmonisation of Polysorbate 20 had been shared and is currently under review by the PDG members. This was submitted in parallel with a revision proposal for the existing PDG monograph, "Polysorbate 80" as noted in the [first press release in October 2022](#).

The role and impact of Pharmacopoeial Harmonisation by PDG on the environment was discussed by the PDG members. Advancing to a greener future and improving sustainability through efficiencies with global pharmacopoeial harmonisation while ensuring quality medicines has become increasingly important in a changing global climate. Further discussion on this initiative will take place at the annual PDG meeting where each PDG pharmacopoeia will provide some information on specific areas where our respective pharmacopoeias are currently making an impact in this space and where the impact could be expanded globally.

All the PDG members affirmed the [previously signed PDG Confidentiality Commitment](#), acknowledging that this commitment supports the PDG's harmonisation policy and works to harmonise excipient monographs and general chapters.

The PDG remains fully committed to pursue and enhance its efforts to expand development and recognition of harmonised pharmacopoeial standards.

1. Comprising the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP), with the Indian Pharmacopoeia Commission (IPC) as pilot participant and the World Health Organization (WHO) as observer.

The next annual meeting will be hosted by the USP on 3 and 4 October 2023 in Hyderabad, India – the first face-to-face meeting since 2019. The PDG is planning a Stakeholder Interaction event in Hyderabad on 5 October 2023 and further information on this event will be shared in due course of time.

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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.

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.