Press release

7 June 2024, Strasbourg, France

Pharmacopoeial Discussion Group achievements

The Pharmacopoeial Discussion Group (PDG)[1] held its interim videoconference on 15 April 2024.

The primary topic of the meeting was the lessons learned from the PDG expansion pilot programme that was launched in 2022 and ended in October 2023 with the inclusion of the Indian Pharmacopoeia Commission as the fourth member of the group. This discussion led to an exchange on how best to prepare for the inclusion of additional world pharmacopoeias that meet the entry criteria. An agreement on a framework for this next phase was one of the key outcomes of the meeting. The group will work on the details of the next phase, including updated entry criteria, in the coming months before launching a new expansion phase.

The PDG also discussed the maintenance work on the ICH Q4B annexes on pharmacopoeial harmonisation, which covers the revision of the ICH Q4B Guideline and Annex 5 of the ICH Standard Operating Procedure, taking into consideration the comments received from ICH members both at and after the ICH meeting in Prague (Czech Republic) in November 2023. The aim is to present updated drafts and an appropriate response at the next ICH meeting in Fukuoka (Japan) to finalise the proof-of-concept study.

Additionally, the agenda included an update from the nitrosamines subteam – a new initiative launched following a decision at the last annual PDG meeting in October 2023 as part of plans to enhance the future scope of collaboration on this topic – on the possible approaches and challenges related to these impurities.

The significant progress made on the revision of the harmonised general method Q-09 on Particulate Contamination was presented, the aim being to finalise the revision in the course of 2024. This progress demonstrates the PDG's determination to drive forward all texts on its work programme. The current workplan including all ongoing items is available on the website (General Chapters, Excipients).

At the meeting, the PDG members renewed their commitment to strengthening co-operation with the International Meeting of the World Pharmacopoeias (IMWP) and exploring ways to improve how its workplan on new and revised texts is shared. The group will continue its ongoing efforts to broaden the development and recognition of harmonised pharmacopoeial standards.

The next face-to-face meeting will be hosted by the Ph. Eur. on 1 and 2 October 2024 in Strasbourg (France) followed by a stakeholder event on 3 October 2024.

Contact: Evangelos Tasopoulos, Communications and Events Division, EDQM, Council of Europe
Tel.: +33 (0)3 90 21 53 90 – E-mail: evangelos.tasopoulos@edqm.eu

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

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

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.[2] 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.

2. 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.