Press release

27 October 2023, Strasbourg, France

Pharmacopoeial Discussion Group achievements

The Pharmacopoeial Discussion Group (PDG) held its annual autumn meeting from 3 to 4 October 2023. The group welcomed the Indian Pharmacopoeia Commission (IPC) as a new member during the meeting (link). The addition of the IPC, a first in the over 34-year history of the PDG, facilitates the reach and enhances the impact of pharmacopoeial standards harmonisation. The PDG now includes the IPC, along with the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP). The World Health Organization (WHO) continues as an observer. The USP hosted the meeting in Hyderabad, India which was the first PDG meeting held outside of the United States, Europe, or Japan as well as the first face-to-face format since 2019 due to the COVID-19 pandemic. A PDG stakeholder event also took place on 5 October 2023.

The PDG discussed lessons learned from the one-year pilot for expansion (link), including what went well and challenges to address from the IPC perspective. The operational impact of adding a pharmacopoeia was also reviewed and the future strategy, structure, and organization of the PDG including further membership expansion were discussed. This is necessary to ensure the PDG continues to perform efficiently and effectively in the future.

One of the primary outcomes of the meeting was the follow-up on the maintenance work of the ICH Q4B annexes on pharmacopoeial harmonisation (link). The PDG reviewed and updated the ICH Q4B Guideline and Annex 5 for the ICH SOP at the meeting. These documents will be presented at the ICH meeting in Prague in November, 2023. The PDG will also present a timeline of next steps for the work on the Q4B annexes based upon the results of the proof-of-concept study.

Regarding improving engagement with regulators, the Ph. Eur., IPC, JP and USP reported on the current interactions with their respective regulators and exchanged dialogue on them. The USP as the host of the meeting gave a detailed explanation of interactions with its own regulator, the US FDA. for the other members to deepen their understanding of the unique regulations in the US. The PDG agreed to continue the open dialogue between the involved pharmacopoeias to further understand the challenges to pharmacopoeial harmonisation resulting from working within our respective different regulatory environments.

The PDG discussed approaches and challenges to nitrosamines and agreed to create a subteam to identify the scope of collaboration for the future. The PDG also discussed the approaches to use recombinant reagents for Endotoxin testing with the aim to align on methods used. The group also further discussed various activities undertaken to help address the pharmaceutical industry's environmental footprint and the importance for the work of pharmacopoeias.

Individual work programme sign-offs, which were handled by correspondence prior to or soon after the meeting, included corrections of the general chapters "Microbial Enumeration", "Bulk Density of Powders", "Chromatography" and "Dynamic Light Scattering". The PDG has successfully harmonised 30 of the 31 general chapters and 48 of the 62 excipient monographs on the current work programme.

PDG Stakeholder Event

On 5 October 2023, the PDG Stakeholder Event was held in Hyderabad with attendance by Indian stakeholders including hybrid participation. Representatives from the Ph. Eur., IPC, JP, USP and WHO provided Indian interested stakeholders with an overview and strategic vision of the PDG, its processes and a look at its over 30-year history in harmonising pharmacopoeial excipient and general chapter quality standards. PDG members discussed the perspectives from each pharmacopoeia as well as case studies.

Next Meeting

The next face-to-face PDG meeting will be hosted by the Ph. Eur. and is set for 1–2 October 2024 in Strasbourg, France.

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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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