

PHARMACOPEIAL DISCUSSION GROUP VIDEOCONFERENCE MEETINGS

The Pharmacopoeial Discussion Group (PDG) which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP), held videoconferences on 6 November 2020 and on 12 March 2021. WHO (International Pharmacopoeia) participated as Observer.

By necessity, the first videoconference, a follow-up the strategic videoconference on 22-23 September 2020 replaced the originally planned annual face-to face meeting and was dedicated to discussing individual technical items on the PDG work programme.

Individual work programme sign-offs, which were handled by correspondence following this meeting, included major technical revisions to the chapter on X-Ray Powder Diffraction and the monograph for Croscarmellose Sodium. The PDG had also agreed correction of 7 excipients monographs and correction of sign-off coversheets for 2 excipient monographs. Thus, 28 of the 31 general chapters and 46 of the 60 excipient monographs on its current work programme have now been harmonised among the PDG pharmacopoeias. As ever committed to transparency, the PDG has published the full signed-off texts on each pharmacopoeia's website (link: [general chapters](#), [monographs](#)).

In-depth discussions on several items on the current PDG work programme also took place with a view to resolving outstanding issues and advancing the items towards sign-off. In addition, the PDG discussed the way forward with regards to two important chapters on Chromatography and Elemental Impurities with the aim of agreeing on drafts for sign-off. One of the member pharmacopoeias also shared the extensive comments received for E-45 Sucrose with the other pharmacopoeias.

A particular focus of the videoconference was preparation for the upcoming ICH Assembly meeting, where an update on the PDG's pilot phase proposal for the maintenance of the ICH Q4B annexes would be given with the aim of getting the ICH's approval to start the process.

On 12 March 2021, the PDG held its regular interim videoconference focussing again on strategy and policy topics. The PDG discussed several concrete ideas about how to use opportunities to enhance the global reach and impact of international harmonisation of quality standards. Continuing thought is being given to interactions with regulators, industry and other pharmacopoeias.

The PDG remains fully committed to expanding recognition of harmonised pharmacopoeial standards with a view to achieving global convergence and will continue its reflection on opportunities in 2021.

Next Meeting

The next annual meeting will be hosted by the Ph. Eur. on 5 and 6 October 2021, either in Strasbourg, France or by videoconference depending on the pandemic situation.

Contact:

Division of Pharmacopoeia and Standards for Drugs,
Office of Review Management, PMDA
TEL: +81-(0)3-3506-9431 FAX: +81-(0)3-3506-9445