

**19 April 2021, Strasbourg, France**

## **Pharmacopoeial 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 to 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 to correction of 7 excipient 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 ([Harmonisation status for General Texts](#), and [Harmonisation status for Excipient 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 for the 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.

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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 (for further information, [see the meeting highlights](#)).

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 reflections on opportunities in 2021. 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.

[Meeting Highlights – Pharmacopoeial Discussion Group Meeting, 6 November 2020](#)

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**Note for the Editor:** Further information is available on the internet site <https://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. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.<sup>1</sup> The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 40 members of the [European Pharmacopoeia Commission](#): *Austria, Albania, 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, Turkey, Ukraine, United Kingdom and the European Union.*

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