Press release

1 March 2022, Strasbourg, France

PDG 2021 autumn meeting held by videoconference

The Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia, with WHO as observer, held its annual autumn meeting via videoconference from 5 to 8 October 2021. Due to the COVID-19 pandemic, the face-to-face meeting originally scheduled was again organised as a videoconference.

The focal point of this meeting was the landmark decision to launch a pilot phase to allow additional pharmacopoeias to join the PDG with a view to expanding recognition of harmonised pharmacopoeial standards. Further information on the pilot phase can be found in a separate press release issued in October 2021.

Also on the agenda was a progress report on a proof-of-concept study for the maintenance of the ICH Q4B annexes. The pharmacopoeias of the non-founding ICH Regulatory Members were asked to provide an evaluation of their texts against the PDG sign-off texts. The PDG reviewed the first submissions received, identified any unresolved questions, and agreed on the next steps with a view to concluding the initial proof-of-concept study. The PDG intends to report to the ICH Assembly on the outcome of the study in 2022.

A number of individual items on the work programme have now been finalised. Three newly elaborated texts and revisions were signed off by correspondence. A key achievement was the harmonised general chapter *Chromatography*, successfully signed-off after years of hard work and complex negotiations. A separate press release has been published to mark this achievement.

Initial harmonisation work on two important excipient monographs – *Petrolatum (Paraffin, yellow soft)* and *Petrolatum, white (Paraffin, white soft)* – has also now been completed. In addition, revision of the excipient monograph on *Stearic acid*, which now includes an alternative apparatus for the freezing point test, has been finalised. A further 3 texts and 15 sign-off cover sheets have been corrected and will be published on each pharmacopoeia's website (Harmonisation status for Excipient monographs). This means that 29 of the 31 general chapters and 48 of the 60 excipient monographs on the current work programme have now been harmonised among the PDG Pharmacopoeias.

The meeting concluded with a discussion on an important item on the work programme, the test for bacterial endotoxins. The co-ordinating pharmacopoeia reported the outcome of a technical teleconference between the respective experts in each region. The PDG discussed opportunities for harmonisation of the test for bacterial endotoxins using recombinant factor C. Discussions will continue in a subsequent technical teleconference between the experts.

Details of the different topics discussed and decisions taken can be found in the Meeting Highlights published on the websites of the three PDG pharmacopoeias.

Even without the benefits of face-to-face meetings – not least the many opportunities for fruitful exchanges they offer – the PDG remains fully committed to continue and even step-up its efforts to expand development and recognition of harmonised pharmacopoeial standards.

The next annual meeting will be hosted by the JP on 18-19 October 2022, either in Tokyo, Japan, or by videoconference, depending on the pandemic situation.

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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. 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. 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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