Press release

28 June 2022, Strasbourg, France

Pharmacopoeial Discussion Group videoconference meeting

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 interim videoconference in two sessions on 15 and 28 March 2022. During this videoconference, the PDG discussed several strategic aspects.

As announced in a press release issued in October 2021, the PDG launched a pilot phase to allow additional pharmacopoeias to join the PDG with a view to expanding recognition of harmonised pharmacopoeial standards. In the weeks after the last annual meeting, which was held in October 2021, the PDG invited other world pharmacopoeias from regions not yet represented to apply to participate in a one-year pilot phase which is scheduled to start after the PDG annual meeting in autumn 2022. The PDG held three webinars with seven other pharmacopoeias to explain the details of this pilot project and the work of the PDG. As of 15 March 2022, five pharmacopoeias have shown an interest in joining forces with the PDG through this project. Interested pharmacopoeias were invited to submit their applications by 15 April 2022. The PDG will review each application to ensure that the candidate pharmacopoeia meets the entry criteria and start the pilot phase with the selected pharmacopoeia(s) that best meet the PDG entry criteria for the pilot. For full transparency towards the PDG stakeholders, these criteria and the detailed plan for the pilot phase can now be found on the websites of the three PDG pharmacopoeias (Pharmacopoeial Harmonisation).

The PDG discussed ways of further improving interactions with stakeholders in its harmonisation work. While full transparency is provided through the individual processes of each pharmacopoeia involved, it was agreed that early interaction with stakeholders could be improved and might help to expedite the harmonisation process. The PDG will therefore discuss in the coming months new ways of getting stakeholders involved at the beginning of the harmonisation process and will reach out to them after a final conclusion has been reached. It has been agreed to test this new approach using *Polysorbate 20* which has therefore been added to the work programme.

The discussion also focused on the ongoing proof-of-concept study for the maintenance of the ICH Q4B annexes. After the last annual meeting, the PDG addressed a number of unresolved questions, completed an initial review of additional submissions from the pharmacopoeias of the non-founding ICH Regulatory Members, and agreed to move on to the next steps with a view to concluding the initial proof-of-concept study on three selected Q4B annexes (Annex 6: Uniformity of Content/Mass, Annex 7: Dissolution Test and Annex 8: Sterility Test). The PDG intends to report the outcome of this study to the ICH Assembly in November 2022.

In addition, the PDG discussed a proposal from one member to revise chapter *Q-06 Bacterial Endotoxins* to include a new method G that uses recombinant Factor C (rFC) as reagent. The proposal had previously been discussed during technical teleconferences attended by experts from each pharmacopoeia. These meetings highlighted differences in approach between the pharmacopoeias. The other PDG pharmacopoeias feel that more data is needed and that other recombinant reagents should also be considered (e.g. recombinant cascade reagents using Factor C, Factor B and Proclotting enzyme). The PDG thus concluded that the revision proposal could not be accepted. Therefore, each pharmacopoeia will deal with test methods using recombinant reagents – including rFC – in its own way, and the PDG will continue to exchange information for potential future alignment among its member pharmacopoeias.

The PDG remains fully committed to continuing and even stepping-up its efforts to expand development and recognition of harmonised pharmacopoeial standards.

The next annual meeting will be hosted by the JP on 18 and 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: *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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