Press release

28 April 2020, Strasbourg, France

Pharmacopoeial Discussion Group (PDG) videoconference meeting

The Pharmacopoeial Discussion Group (PDG) held its interim videoconference on Thursday 12 March 2020. The PDG – which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP), with WHO (International Pharmacopoeia) as Observer, to discuss international harmonisation of quality standards – has now completed work on 28 of the 31 general chapters and 46 of the 60 excipient monographs on its current work programme.

The primary focus of the videoconference was to finalise a proposal to send to ICH regarding maintenance of the ICH Q4B Annexes. These discussions were the follow-up to the decision the ICH Assembly took in November 2018 to task PDG with the maintenance of the Q4B Annexes. The PDG proposal takes into account the challenging task of including non-PDG Pharmacopoeias of ICH regulatory members who wish to declare interchangeability with the Q4B Annexes. To evaluate feasibility, the PDG will propose a proof-of-concept study to ICH on three of the Annexes (Annex 6: Uniformity of Dosage Units, Annex 7: Dissolution, and Annex 8: Sterility) as a pilot phase. The initial proposed scheme can be found in a presentation given on behalf of the PDG at the Meet the World Pharmacopoeias Symposium earlier this year. The aim of this scheme is to make it possible for ICH regulatory members other than the three PDG pharmacopoeias to declare interchangeability of the corresponding pharmacopoeial texts. PDG is fully committed to expanding recognition of harmonised pharmacopoeial standards with a view to achieving global convergence of quality standards.

As part of the general streamlining of PDG procedures, the three pharmacopoeias have discussed and worked on revising the PDG harmonisation policy which had last been revised in 2003. The PDG will review the draft of the revised policy by correspondence.

The next annual face-to-face PDG meeting will be hosted by USP on 22 and 23 September 2020 at USP in Rockville, Maryland, U.S.

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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 the 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.[1] Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

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.*