Press release

28 February 2023, Strasbourg, France

Pharmacopoeial Discussion Group achievements: sign-off on harmonisation texts

As announced in the press release on 6 January 2023, the Pharmacopoeial Discussion Group (PDG) held its annual autumn meeting on 18-21 October 2022. In attendance were the three established members of the PDG – the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP) – together with the Indian Pharmacopoeia Commission (IPC) as pilot participant in the PDG pilot for global expansion and the World Health Organization (WHO) as an observer.

This press release covers the successful harmonisation of general chapters and excipient monographs on the PDG work programme. To find out more about the other topics discussed at the meeting, please see our previous press release and the meeting highlights.

Individual work programme sign-offs, which were handled by correspondence following the meeting, included revisions of the general chapters "Bulk density of powders", "Powder Flow", and "Peptide Mapping", and corrections to the excipient monographs "Carmellose Calcium", "Hydroxypropylcellulose, Low Substituted", "Hypromellose", "Lactose, Anhydrous", "Lactose, Monohydrate", and "Methylcellulose". The correction of these sign-off coversheets on 30 excipients was also signed-off following the revision of the respective monographs in JP18-1 so that the coversheets now reflect the implementation of the ICH Q3D guideline by JP. Finally, the initial harmonisation work on the general chapter on "Dynamic Light Scattering" has been completed and is due to be signed-off separately in the near future.

Following the PDG sign-off of these texts, the PDG will have successfully harmonised 30 of the 31 general chapters and 48 of the 63 excipient monographs on the current work programme.

The schedules for publication and implementation in the corresponding regional texts can be found on the respective website of each pharmacopoeia.

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Note for the Editor: Further information is available on the internet site **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. The European Pharmacopoeia Commission comprises 40 members: 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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