07 July 2014, Strasbourg, France

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and the United States Pharmacopeia (USP)] was hosted by the USP in Rockville, Maryland, on 25-26 June 2014.

At present, 29 of the 35 General Chapters and 46 of the 62 excipient monographs on the current work programme have been harmonised. Sign-offs at this meeting included a new general chapter "Thermal Analysis" and a revised general chapter "Polyacrylamide Gel Electrophoresis." The latter reflects recent developments and current practices and allows for greater flexibility in the use of ready-made gels. In addition, a new monograph for "Glucose Monohydrate/Anhydrous" was signed off.

In-depth discussions on 27 additional items currently on the work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off.

Other Topics

In light of the anticipated sign-off of the ICH Q3D guideline for elemental impurities, PDG members agreed to harmonize their general chapters on methods related to elemental impurities, with USP serving as the coordinating pharmacopoeia.

PDG members also agreed to add a general chapter on dynamic light scattering to its work program, with JP as the coordinating pharmacopoeia.

Participating pharmacopoeias also discussed harmonising viscosity measurement methods, and agreed to conduct a feasibility study with the "Carmellose Sodium," "Hydroxyethylcellulose," and "Hydroxypropylcellulose Low Substituted" monographs.

Following on the discussion at its previous meeting, PDG members agreed on concrete actions to improve its working procedures and improve transparency to stakeholders. As of this June 2014 meeting, a summary document of the outcome of the meeting will be made available on the websites of the three pharmacopoeias.

Next Meeting

The next face-to-face PDG meeting will be hosted by the European Pharmacopoeia on November 12-13, 2014 in Strasbourg, France.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**

The Convention on the Elaboration of a European Pharmacopoeia[1], which is celebrating its 50th anniversary in 2014, is a continent-wide initiative for setting common quality standards for medicines. It has the objective of progressively elaborating a common European Pharmacopoeia, which defines a single set of specifications for active substances and excipients used in medicines that will become the official standards applicable within these countries. The European Pharmacopoeia also describes test methods to ensure the quality of these medicines.

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are now thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.* There are twenty-seven observers: *Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*

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.