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

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Fukuoka, Japan 8-11 November 2010

The Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP) and United States Pharmacopoeia (USP)] met in association with the Expert Working Groups of the International Conference on Harmonization (ICH).

At present, 27 of the 35 General Chapters and 41 of the 62 excipient monographs of the current work programme have been harmonised. General chapter sign-offs include *Uniformity of Dosage Units* (revision) and corrections to sign-off cover sheets for *Extractable Volume* and *Particulate Matter*. Excipient sign-offs include the newly-harmonized *Crospovidone* monograph and revisions to *Lactose Anhydrous* and *Cellulose Acetate Phthalate*. The latter revision is the outcome of PDG's review of previously harmonised excipient monographs.

Following a meeting of experts from the three regions which took place on the Saturday preceding the PDG meetings, the general chapter on *Chromatography* was formally added to the PDG work programme.

Interaction with ICH Q4B

Harmonisation has been achieved on 9 of the 10 General Chapters identified by the ICH Q6A Guideline. PDG re-emphasised the importance of consistent regulatory positions on harmonised text. The sign-off of the revision to *Uniformity of Dosage Units* represented a resolution of the long-standing concern related to the 2% Relative Standard Deviation exemption in the harmonised *Uniformity of Dosage Unit* text that is not accepted by the US.

In their joint meeting, PDG provided Q4B with progress reports on a number of harmonised texts undergoing evaluation of interchangeability in response to their comments.

Other Topics

The three pharmacopoeias discussed other topics, including metal impurities and antioxidant additives in cellulosic excipients.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation (IPEC-Americas, IPEC-Europe, IPEC-China and the Japan Excipients Council) was held on November 11, 2010. Topics, among others, included the cellulosics, propylene glycol, povidone, and silicon dioxide monographs.

PDG will hold its next meeting in June 2011 in Cincinnati, Ohio, USA.

Note for the editor: 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 Pharmacopoeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues.

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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.