



STRASBOURG, 30/10/09

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

PHARMACOPOEIAL DISCUSSION GROUP (PDG)

St. Louis, Missouri, 26-29 October 2009

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

At present, 27 of the 34 General Chapters and 40 of the 63 excipient monographs have been harmonised. General chapter sign-offs include the Water Solid Interaction (new) and corrections to Bacterial Endotoxins and Capillary Electrophoresis. Excipient sign-offs include revisions/corrections to Polysorbate 80 and Ethylcellulose.

PDG is reviewing previously harmonised excipient monographs. This exercise is aimed at achieving a higher level of harmonization of previously signed-off monographs and to improve the indication of harmonisation status in the three pharmacopoeias. Ethylcellulose (signed-off at this meeting) is the first result of this exercise. At this meeting, PDG reviewed five additional monographs (*Sodium Chloride; Starch, Potato; Starch, Wheat; Saccharin; and Sodium Saccharin*). The pharmacopoeias will identify additional harmonized excipient monographs to review.

Interaction with ICH Q4B

Harmonization has been achieved on 9 of the 10 General Chapters identified by the ICH Q6A Guideline. PDG will submit Bulk and Tapped Density and Bacterial Endotoxins prior to the next ICH meeting in June, 2010 for Q4B to consider regulatory interchangeability. PDG emphasized the importance of consistent regulatory positions on harmonized text. In response to a Q4B proposal, PDG agreed to jointly develop a Q&A document and other training and educational materials regarding Q4B-PDG activities.

Other Topics

Based on industry input, PDG has agreed to add a general chapter on Chromatography to its Work Programme.

The three pharmacopoeias discussed other topics, including viscosity tests in excipient monographs, metal impurities, and diethylene glycol (DEG) and ethylene glycol (EG) contamination in excipients.

With regard to metal impurities, PDG welcomes the decision to create an ICH Expert Working Group and believes this will advance harmonisation on this topic among pharmacopoeias.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation (IPEC-Americas, IPEC-Europe and the Japan Excipients Council) was held on October 29, 2009. Topics, among others, included cellulose, povidones, viscosity tests, DEG/EG, melamine, metal impurities, and residual solvents.

The PDG will hold its next face-to-face meeting in June 2010 in Europe.

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.

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