

Strasbourg, 03/11/2006

Note for the Editors

The European Pharmacopoeia is one of the co-founders of the Pharmacopoeial Discussion Group (PDG) set up in 1990 with the pharmacopoeias of Japan and the United States. This group meets regularly (twice a year), with the location of the meetings rotating among Europe, Japan and the United States. Monographs and general methods of analysis proposed by national associations of manufacturers of pharmaceutical products are selected for convergence and harmonisation among the three pharmacopoeias.

PHARMACOPOEIAL DISCUSSION GROUP (PDG)

Chicago, USA, 23-25 October 2006

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

Povidone and Rice Starch: These harmonised monographs were signed off.

Harmonisation has been achieved on ten of the eleven General Chapters related to the ICH Q6A Guideline.

Color: A Stage 4 draft of a General Chapter on Color measurement is in preparation and is expected by Spring of 2007.

Bacterial Endotoxins: A Stage 4 revision of the harmonised Bacterial Endotoxins chapter has been distributed and will be published in each pharmacopoeial forum by Spring 2007 for public review and comment.

General chapters for Bulk and Tapped Density, Density of Solids, Powder Fineness, and Porosimetry by Mercury Intrusion, as well as a revision to the Sterility Test chapter and the monograph for Stearic Acid are expected to be signed-off at the next meeting.

At present, 20 of the 33 General Chapters and 35 of the 62 excipient monographs have been harmonised.

Revision of PDG Working Procedures: PDG has approved a revision to the PDG Working Procedures which has been agreed in principle, in June 2006 to describe the interaction with Q4B. This proposal changes the interpretation of Stages 6 and 7 and adds a Stage 6C (Indication of harmonisation). The former Stage 7 (Inter-regional implementation) was redefined to be "Inter-regional acceptance". The date of Stage 7 will be common to all three Pharmacopoeias and will be assigned after receiving formal notification of regulatory acceptance from Q4B. These efforts will be beneficial for users of the pharmacopoeias and facilitate the work of the Q4B EWG.

Interaction with ICH Q4B: PDG and Q4B met on October 26, 2006. Items for discussion included ongoing evaluations of the Q4B procedure for the establishment of regulatory acceptance (interaction with PDG after Stage 6). The PDG provided Q4B with considerations regarding the test chapter on Extractable Volumes of Parenterals. In addition, the PDG discussed ongoing evaluations of submitted documents for Dissolution, Particulate Matter in Injections, Residue on Ignition/ Sulphated Ash. The PDG and Q4B pursued efforts to improve their respective working procedures.

PDG intends to provide documents for evaluation by the Q4B on the topics of Disintegration, Content Uniformity/ Uniformity of Mass, Microbial Contamination prior to the next ICH EWG meeting.

Excipients Councils: A meeting with TRIPEC (IPEC-Americas, IPEC-Europe and JPEC) was held on October 26, 2006 where progress on the harmonisation of excipients monographs and associated issues will be considered.

The PDG will hold its next meeting in May 2007 in Brussels, Belgium

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 46 member states.

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