

**Strasbourg, 12/06/2006**

### **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)**

*Yokohama, Japan, 5-8 June 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). Hypromellose Phthalate: This harmonised monograph was signed off.

Methyl Paraben, Ethyl Paraben, Propyl Paraben and Butyl Paraben: It was agreed to initiate the revision of these monographs and EP was nominated as the Co-ordinating Pharmacopoeia.

Uniformity of delivered dose of inhalations: This general chapter was added as a new topic and EP was nominated as the Co-ordinating Pharmacopoeia.

Revision of PDG Working Procedures: PDG has elaborated a revision proposal of the PDG Working Procedures, last revised in July 2003, in order to reflect the interaction with the ICH Q4B EWG. 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. The PDG Working Procedures will be officially revised at the next PDG meeting. These efforts will be beneficial for users of the pharmacopoeias and facilitate the work of the Q4B EWG.

Interaction with ICH Q4B: in order to achieve common regulatory acceptance of harmonised monographs and general chapters in the ICH regions, five documentation packages for harmonised general chapters have been submitted by the PDG to the Q4B EWG for their evaluation. These packages detail the harmonised methods for dissolution, extractable volume, particulate matter in parenterals, residue on ignition/sulphated ash and the sterility test. The methods for residue on ignition/sulphated ash and extractable volume have been recognised to be interchangeable by the Q4B group; PDG is awaiting feedback on dissolution and particulate matter in parenterals. A number of issues remain to be resolved for the sterility test in order to achieve regulatory acceptance. Additionally, packages for the PDG harmonised texts on disintegration, uniformity of dosage units and microbiological quality are in preparation for submission to Q4B. On June 7, 2006, the PDG held a joint meeting with Q4B EWG.

Industry Associations: a meeting with industry associations from the three ICH regions was held on June 6, 2006, to exchange information on PDG updates, progress with the current work program and future harmonization needs. Industry associations were encouraged to play an active role in the harmonisation process as important stakeholders.

Excipients Councils: a meeting was held on June 8, 2006, with Tri-PEC (IPEC Americas, IPEC Europe, Japanese Pharmaceutical Excipients Council) to discuss the work program on harmonisation of excipient monographs. Current issues include the policy for functionality-related characteristics, use of additives and processing aids in excipients, co-processed excipients, and impurities in excipients, and the future of harmonisation.

The PDG will hold its next meeting on October 23-26, 2006 in Chicago, USA.

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