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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)

Brussels, Belgium, 7-10 May 2007

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).

Harmonisation has been achieved on 10 of the 11 General Chapters identified by the ICH Q6A Guideline.

General chapters for Bulk and Tapped Density, Gas Pycnometric Density of Solids, Powder Fineness, Porosimetry by Mercury Intrusion, as well as a revision to the Analytical Sieving chapter were signed-off. This is a major achievement in the field of characterisation of powders, which will be followed at the next PDG meeting by the sign-off of 2 further chapters on the subject : X-Ray powder diffraction and laser diffraction measurement of particle size.

At present, 24 of the 34 General Chapters and 35 of the 62 excipient monographs have been harmonised.

Revision of PDG Working Procedure: PDG has agreed to revise its working procedure in order to adapt more rapidly to necessary revisions.

Interaction with ICH Q4B: PDG has recently submitted packages on uniformity of dosage units and disintegration to Q4B and is in the process of submitting an additional package of 3 general chapters on microbiological quality of non-sterile products. This will bring to a total of 9 packages submitted to Q4B EWG for its evaluation. The Q4B EWG has so far reviewed 5 of the packages and is conducting review of a further 2. The goal is to achieve common regulatory acceptance of harmonised monographs and general chapters in the ICH regions.

Reference standards: PDG members and WHO agreed to collaborate in the establishment of the next batch of endotoxin reference standard. The batch will serve as a future common batch for an International Standard, a USP standard and an EP standard.

Prospective harmonisation: the PDG discussed the possibility of adding to its work programme a number of general chapters related to glycan mapping for glycoproteins. The techniques are in the forefront of techniques currently used for a better characterisation of recombinant DNA proteins.

Excipients Councils: A meeting with TRIPEC (IPEC-Americas, IPEC-Europe and JPEC) was held on May, 10 2007 where progress on the harmonisation of excipients monographs and associated issues has been considered.

The PDG will hold its next meeting in October-November 2007 in Yokohama, Japan.

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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