



Strasbourg, 15/06/2010

## PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Tallinn, Estonia, 7-10 June 2010

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 of the current work program have been harmonised. General chapter sign-offs include the Dissolution (revision) and corrections to Capillary Electrophoresis. Excipient sign-offs include revisions to Butyl Paraben, Citric Acid, Anhydrous and Citric Acid, Monohydrate. The two latter revisions are the outcome of PDG's review of previously harmonised excipient monographs. This exercise is aimed at achieving a higher level of harmonisation of previously signed-off monographs.

### *Interaction with ICH Q4B*

Harmonisation has been achieved on 9 of the 10 General Chapters identified by the ICH Q6A Guideline. PDG's submission of Bulk and Tapped Density and Bacterial Endotoxins enabled Q4B to sign-off the two texts at step 2. PDG re-emphasised the importance of consistent regulatory positions on harmonised text. In their joint meeting, PDG and Q4B reflected on additional possibilities to accelerate declaration of regulatory interchangeability of pharmacopoeial texts.

### *Other Topics*

The three pharmacopoeias discussed other topics, including elemental metal impurities, and potential melamine contamination in excipients. Viscosity testing methods and the potential for alternative methods for the characterisation of rheological properties of excipients were considered.

### *Excipients Council*

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation (IPEC-Americas, IPEC-Europe and the Japan Excipients Council) was held on June 10, 2010. Topics, among others, included cellulose, povidones, viscosity tests, and melamine.

The PDG will hold its next meeting in November 2010 in Fukuoka, Japan.

**Contact:** Caroline Larsen Le Tarnec  
Public Relations Division, EDQM  
Tel.: +33 (0) 3 88 41 28 15  
E-mail: [caroline.letarnec@edqm.eu](mailto:caroline.letarnec@edqm.eu)

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