



STRASBOURG, 19/11/08

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

PHARMACOPOEIAL DISCUSSION GROUP (PDG)

Brussels, Belgium, 10-13 November 2008

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 Harmonization (ICH).

Harmonisation has been achieved on 10 of the 11 General Chapters identified by the ICH Q6A Guideline. During the meeting, the general chapter *Laser diffraction measurement of particle size* was signed-off. In response to evaluation of the text by ICH Q4B, the corresponding ICH Expert Working Group discussing the regulatory interchangeability of harmonised texts, a minor revision for the general chapter on *Dissolution Testing* was signed off. A revision of the general chapter *Bacterial Endotoxins* was signed off which will allow the submission of the corresponding package to ICH Q4B for evaluation in the summer of 2009.

New items for sign-off included the excipient monograph *Carmellose*. In addition, a minor revision of the monograph *Magnesium Stearate* was signed off. PDG agreed to add *Lactose for inhalation* to their work program.

At present, 26 of the 35 General Chapters and 40 of the 62 excipient monographs have been harmonised. In the course of indicating the harmonisation statement in the three pharmacopoeias, PDG has agreed to evaluate their respective texts in order to better identify residual differences with a view of achieving harmonisation at a higher level.

PDG revisited the process improvement measures implemented following the June 2008 Portland meeting and acknowledged the positive effect on the overall harmonisation process, namely by the establishment of a small working group to monitor and communicate PDG topics on a regular basis, to follow up on the PDG work programme, and to keep activities on track. In addition, a pilot model of a common online repository of PDG documents and the use of up-to-date technology for the exchange of PDG information will be tested in the coming two weeks.

Interaction with ICH Q4B

Interactions between PDG and Q4B continue to evolve in a positive manner. Following a discussion between PDG and Q4B to widen the scope of Q4B activities, the ICH Steering Committee approved the addition of presently 5 general chapters to the Q4B work program, namely:

- tablet friability
- analytical sieving
- bulk and tapped density
- capillary electrophoresis
- polyacrylamide gel electrophoresis

PDG has agreed to provide the respective documentation for Q4B evaluation during the first quarter of 2009.

Interaction with Industry

PDG met with industry representatives on Tuesday evening, November 11, 2008. Topics for discussion included

- State of work in the PDG, recent process improvements
- Current state of interaction with ICH Q4B
- Industry feed-back on pharmacopoeial harmonisation
- EP/USP update on pilot project of prospective API harmonisation

Industry associations welcomed the changes to PDG procedures and the progress made. Since the adoption of the ICH Q4B guideline in November 2007 defining the procedures of the expert working group, interaction with PDG had greatly improved, leading to an increase in the overall achievements in pharmacopoeial harmonisation and the subsequent statement of regulatory interchangeability issued by ICH Q4B. Industry emphasised the importance of these activities. Industry also welcomed the information on the pilot project on prospective harmonisation of active pharmaceutical ingredients (API) between the EP and USP, which was initiated during the Portland meeting. At this point in time, it is anticipated that the first draft monograph will be published for comments in the second half of 2009.

Heparin

The three pharmacopoeias exchanged information on the further process of revising the heparin monographs. It was decided to closely follow future activities with a view of ensuring harmonised approaches.



Excipients Council

A meeting with TRIPEC (IPEC-Americas, IPEC-Europe and JPEC) was held on November 13, 2008 where progress on the harmonization of excipient monographs and potential additions to the work program was discussed.

The PDG will hold its next face-to-face meeting in June 2009 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.

Contact: Caroline Larsen Le-Tarnec

Public Relations Division, EDQM;

Tel: + 33 3 88 41 30 30 (Dial 4);

E-mail: Via the Helpdesk on the EDQM website