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

PHARMACOPOEIAL DISCUSSION GROUP (PDG)

Portland, USA, 1st-5th June 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).

Harmonization has been achieved on 9 of the 11 General Chapters identified by the ICH Q6A Guideline. Minor revisions for general chapters, in response to user comments, were signed off on *Tests for Specified Micro-organisms, Microbial Enumeration Tests*. In addition, PDG signed off a minor revision of the chapter *Bulk and Tapped Density*.

New items for sign-off included excipient monographs *Magnesium Stearate, Polysorbate 80, and Stearic Acid*. Valuable input from industry facilitated this outcome. In addition, revisions to *Talc, Benzyl Alcohol, Lactose Anhydrous* and *Lactose Monohydrate* were signed off. At present, 25 of the 35 General Chapters and 39 of the 62 excipient monographs have been harmonized.

PDG considered process improvements and identified the following next steps and action items for immediate implementation:

- Establish 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
- Selected experts to be included in the communication as appropriate when a topic reaches an impasse or in other exceptional cases
- Move toward a common online repository of PDG information and the use of up-to-date technology for the exchange of PDG information
- Continue to include "Process Improvement" as a standing agenda topic

Interaction with ICH Q4B EWG: Interactions between PDG and Q4B EWG continue to evolve in a positive manner. Based on stimuli from PDG, Q4B EWG discussed a possible expansion of the scope of their work programme. In addition, PDG and Q4B EWG continue to actively work on ideas to improve communications and processes between the two groups.

Interaction with Industry: PDG met with industry representatives. Topics for discussion included:

- Partnership for Harmonisation
- Chapters of interest to industry (Chromatography, pH, Heavy Metals)
- Industry views on Harmonisation by Attribute

Discussions on the first topic focused on a bilateral approach to prospective harmonisation of APIs between the EP and USP. A pilot program will begin in summer 2008. JP indicated that it cannot participate and wishes to continue to focus on harmonisation of General Chapters and Excipients. JP will observe the process.

Heparin: Following the recent serious problems with heparin, the three pharmacopoeias have all taken emergency measures to react to the safety issue; the revisions undertaken by each pharmacopoeia are following the same general direction.

At the upcoming Strasbourg Heparin Workshop on June 19-20 2008, organized by EDQM, NIBSC, and USP, experiences by official control laboratories and industries will be discussed, with the aim of improving the analytical test methods. The three pharmacopoeias will work collaboratively to optimise the respective heparin monographs.

Excipients Council: A meeting with TRIPEC (IPEC-Americas, IPEC-Europe and JPEC) was held. Progress on the harmonization of excipient monographs and associated issues was discussed.

The PDG will hold its next face-to-face meeting in November 2008 in Brussels, Belgium.

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