

22 November 2012, Strasbourg, France PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP) and United States Pharmacopeia (USP)] met on November 6 and 7, 2012 in Rockville, Maryland, USA. At present, 28 of the 35 General Chapters and 43 of the 62 excipient monographs of the current work programme have been harmonised. Excipient signoffs at this meeting include revisions to the *Cellulose Acetate, Ethanol*, and *Ethanol*, *Anhydrous* monographs.

Other Topics

The three Pharmacopoeias discussed potential approaches to sharing information with users regarding the degree of harmonisation of monographs that have completed the PDG process and been implemented by the Pharmacopoeias. An important discussion surrounded the PDG approach to handling additives in excipients, providing an important path forward for a number of current topics on the PDG work programme. In particular, this was discussed with regard to the *Hydroxypropylcellulose* and *Hydroxyethylcellulose* monographs. Additional topics discussed included progress on the harmonisation of general chapters such as Chromatography and Color.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on November 6, 2012. Topics, among others, included cellulosics, glucose monographs, propylene and polyethylene glycol, copovidone, and the silicon dioxide monographs. The groups also discussed new approaches to improving interactions to strengthen and accelerate harmonisation of excipient monographs, which will be further elaborated in the coming months.

Next Meeting

The next face-to-face PDG meeting will be hosted by the European Pharmacopoeia in June 2013 in Strasbourg, France.

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

Note for the Editor: Further information is available on the internet site: www.edgm.eu

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia1 is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

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.

¹There are currently thirty-seven members of the European Pharmacopoeia Commission: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Iteland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, United Kingdom and the European Union and twenty-five observers The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 18 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, Syria, Tunisia, United States of America.