

Press Release

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Strasbourg, France, 12-13 November 2014

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia, Japanese Pharmacopoeia, and the United States Pharmacopeia] was hosted by the Ph. Eur./EDQM in Strasbourg, France, 12-13 November 2014.

At present, 29 of the 36 General Chapters and 48 of the 62 excipient monographs on the current work programme have been harmonised. Sign-offs at this meeting included new monographs on "Hydroxypropylcellulose, low substituted" and on "Sodium laurylsulfate", as well as a revised monograph on "Saccharin sodium".

In-depth discussions on 26 additional items currently on the work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off.

In addition, a general discussion on the future of pharmacopoeial harmonisation took place.

In a spirit of increasing transparency, PDG had decided in June 2014 to publish the meeting highlights of their meetings in the future. In the meantime, highlights of the June 2014 meeting have been finalised (http://www.pmda.go.jp/files/000152569.pdf).

The meeting highlights for the November 2014 meeting can be found (http://www.pmda.go.jp/files/000152619.pdf).

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on November 13, 2014. Topics discussed included monographs for Polyethylene Glycol, Copovidone, Hydroxyethylcellulose, Ethylcellulose, Carboxymethylcellulose Sodium, Saccharin Sodium, Pregelatinized Starch, Petrolatum and Petrolatum, White, Silicon Dioxide and Silicon Dioxide, Colloidal.

Next Meeting

The next face-to-face PDG meeting will be hosted by the Japanese Pharmacopoeia on June 30 and July 1, 2015 in Tokyo, Japan.

Contact:

JP Secretariat

Division of Pharmacopoeia and Standards for Drugs, Office of Standards and Guidelines Development, PMDA

TEL: +81-(0)3-3506-9431 FAX: +81-(0)3-3506-9440