



26 October 2017, Strasbourg, France

PHARMAPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph.Eur.), Japanese Pharmacopoeia (JP), and the United States Pharmacopoeia (USP)] was hosted by USP in Rockville, Maryland, U.S.A., September 12 – 13 2017.

PDG has agreed to the implementation of significant changes to the work structure, including:

- Eliminating two stages of PDG harmonization process to streamline and reduce the level of complexity.
- Restructuring meeting format to engage more effectively at the technical level with regards to resolving issues on specific topics.
- Maintaining a twice-yearly meeting frequency with a focus on strategic direction setting.

Under the new structure, harmonization of several PDG topics will be continued in other collaborative venues, such as bilateral discussion or adopt/adapt mechanisms as mentioned in the Good Pharmacopoeial Practices (GPhP). These topics will not be part of the trilateral work program until further notice. Ph.Eur., JP, and USP will continue to closely share information and progress on these topics external to PDG.

Sign-offs at this meeting included a new General Chapter "Conductivity" and revisions to four monographs, including Microcrystalline Cellulose, Hypromellose, Methylcellulose and Calcium Phosphate Dibasic Anhydrous. In-depth discussions on a number of additional items currently on the revised work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off.

The meeting highlights for this meeting can be found here (only available in English): https://www.edqm.eu/sites/default/files/meeting-highlights-pdg_rockville-september2017.pdf

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on September 13, 2017. Topics discussed included elemental impurities as well as monographs for ethylcellulose, hydroxyethylcellulose, polyethylene glycol, povidone, pregelatinised starch, colloidal silicon dioxide and silicon dioxide.

The next PDG meeting will take place via videoconference in April 2018 and the next face-to-face PDG meeting will be hosted by Ph.Eur. and is tentatively set for October 2-3, 2018 in Strasbourg, France.

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



Pharmacopeia is legally-binding in Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There are thirty-nine members of the [European Pharmacopoeia](#) Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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