

PHARMACOPEIAL DISCUSSION GROUP ACHIEVEMENTS

Japan, Tokyo, 1-3 October 2019

The latest face-to-face meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP)] was hosted by JP in Tokyo, Japan on 1-2 October 2019. WHO participated as observer. The PDG 30th Anniversary Symposium was also held on 3 October 2019.

Individual work programme sign-offs at this meeting included revisions to monographs on E-55 Gelatin and E-60 Sodium Lauryl Sulfate. The PDG monograph on Gelatin now covers all grades, while the monograph on Sodium Lauryl Sulfate has been revised to include a new Identification by infrared spectrophotometry and a revised Assay method. It was also reported that the revision to Q-07 Colour was signed off by correspondence in June 2019. Thus 28 of the 31 General Chapters and 46 of the 60 excipient monographs on the current work programme have now been harmonized among the PDG Pharmacopoeias. In-depth discussions on other items on the current PDG work programme also took place with a view to resolving outstanding issues and advancing the items towards sign-off. In addition, the Coordinating Pharmacopoeia reported back on the success of the technical teleconference in July 2019 on the revision of Q-09 Particulate Contamination.

The PDG discussed and agreed a way forward for the future maintenance of ICH Q4B annexes. The timeline will be presented to the ICH Assembly during the November 2019 ICH meeting. Work has already started to update the ICH Q4B annexes in accordance with the new maintenance process ([Standard Operating Procedure of the ICH Working Groups Annex 5](#)), which was approved by the ICH Assembly at the 2018 ICH Meeting in Charlotte. The PDG has performed an initial review of all the ICH Q4B annexes, as well as the related sign-off texts and each pharmacopoeia's local texts. A mechanism for sharing the outcome of PDG evaluations of Q4B annexes, as well as the drafts and final texts of pharmacopoeial activities, with other pharmacopoeias outside of PDG was also discussed at the meeting. PDG will share the scheme with the other pharmacopoeias at the next International Meeting of World Pharmacopoeias (IMWP).

The meeting highlights can be found at:

<http://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0008.html>

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on 2 October 2019.

PDG 30th Anniversary Symposium

On 3 October 2019, the PDG 30th Anniversary Symposium was held in Tokyo and was attended by a number of stakeholders. Representatives from the Ph. Eur., JP, USP and WHO gave presentations on the 30-year history and future perspectives of the PDG. Stakeholder representatives also shared their expectations with the PDG.

The presentations are available at:

<https://www.pmda.go.jp/english/symposia/0162.html>

Next Meeting

The next face-to-face PDG meeting will be hosted by the USP and is tentatively set for 22-23 September, 2020 in Rockville, Maryland, USA.

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