独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Press Release

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The Pharmacopoeial Discussion Group (PDG) held its interim videoconference on Thursday 12 March 2020. The PDG, - which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP) with WHO (International Pharmacopoeia) as Observer, to discuss international harmonization of quality standards, has now completed work on 28 of the 31 general chapters and 46 of the 60 excipient monographs on its current work programme.

The primary focus of the videoconference was to finalize a proposal to send to ICH regarding maintenance of the ICH Q4B Annexes. These discussions were the follow-up to the decision the ICH Assembly took in November 2018 to task PDG with the maintenance of ICH Q4B Annexes. The PDG proposal takes into account the challenging task of including non-PDG Pharmacopoeias of ICH regulatory members who wish to declare interchangeability with the Q4B Annexes. To evaluate feasibility, the PDG will propose a proof-of-concept study to ICH on three of the Annexes (Annex 6: Uniformity of Dosage Units, Annex 7: Dissolution, and Annex 8: Sterility) as a pilot phase. The initial proposed scheme can be found in a presentation (link) given on behalf of the PDG at the Meet the World Pharmacopoeias Symposium earlier this year. The aim of this scheme is to make it possible for ICH regulatory members other than the three PDG pharmacopoeias to declare interchangeability of the corresponding pharmacopoeial texts. PDG is fully committed to expanding recognition of harmonized pharmacopoeial standards with a view to achieving global convergence of quality standards.

As part of the general streamlining of PDG procedures, the three pharmacopoeias have discussed and worked on revising the PDG harmonization policy (link) which had last been revised in 2003. The PDG will review the draft of the revised policy by correspondence.

Next Meeting
The next annual face-to-face PDG meeting will be hosted by USP on September 22-23, 2020 at USP in Rockville, Maryland, U.S.

Contact:
Division of Pharmacopoeia and Standards for Drugs,
Office of Review Management, PMDA
TEL: +81-(0)3-3506-9431 FAX: +81-(0)3-3506-9445