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

Press Release

PDG prepares pilot for global expansion of membership

The Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP), with the World Health Organization (WHO) as an observer, is preparing a pilot to integrate additional world pharmacopoeias. This is a critical step in the PDG's commitment to expanding recognition of harmonised pharmacopoeial standards with a view to achieving global convergence.

Since it was founded in 1989, the PDG has successfully harmonised and maintained 29 general chapters, including such important analytical procedures as Dissolution Testing, Sterility and Microbiological Examination. In addition, the PDG has harmonised 46 excipient monographs and has approximately 20 new texts in its pipeline. The aim of the three founding pharmacopoeias is to extend this significant success story to further jurisdictions/regions and to create an inclusive global platform from which to elaborate harmonised pharmacopoeial standards.

To this end, the PDG has been working on 3 areas considered as key to ensuring the future of the Group: (1) membership expansion as a means of enhancing its global outreach, (2) stakeholder engagement and (3) regulatory engagement. The first outcome of these efforts has been a detailed plan for extending PDG membership beyond the original 3 pharmacopoeias, together with entry criteria for new members. This plan will help ensure that the successes of the past 32 years are not compromised and that the current pharmacopoeial harmonisation model can continue to work effectively with new members. The PDG will further adjust its working methods based on the lessons learned after the expansion procedure is rolled out.

The PDG put the finishing touches to its plan for extending PDG membership during its annual meeting in October 2021. The plan is intended to be announced by the end of October 2021, inviting other world pharmacopoeias to join forces in providing strong, science-based harmonised pharmacopoeial standards.

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