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

Press Release

JP and USP Prepare a Pilot Program to Promote Harmonization of Pharmacopoeial Standards of Drug Substances and Drug Products

The Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP) are pleased to announce the development of a pilot project to promote the prospective harmonization of pharmacopoeial standards for drug substances and drug products.

The JP and USP, along with the European Pharmacopoeia, have been working on the retrospective harmonization of general chapters and excipient monographs through the Pharmacopeial Discussion Group (PDG) since its inception in 1989. Furthermore, the USP and Ministry of Health, Labour and Welfare (MHLW)/ Pharmaceuticals and Medical Devices Agency (PMDA) signed the memorandums of cooperation (MOC) and confidentiality arrangement in September 2016 and June 2017, respectively, with the aim of further strengthening relations and promoting cooperation between these organizations.

This prospective harmonization pilot will be conducted as a part of the activities of the MOC between the USP and MHLW/PMDA and will take place outside of the PDG process for harmonization of excipients and general chapters. Pharmacopeial harmonization works to further reduce a manufacturer's burden of performing compendial tests by aligning pharmacopeial standards in different regulatory jurisdictions. This prospective harmonization pilot looks to expand the work of convergence of pharmacopeial standards currently performed by PDG to drug substances and drug products. Dapagliflozin Propylene Glycol Hydrate and Dapagliflozin Propylene Glycol Tablets (named Dapaglifozin Propanediol and Dapagliflozin Tablets in the US) have been selected as the articles for the pilot program.

The JP and USP will bilaterally work on harmonization of Dapagliflozin Propylene Glycol Hydrate and Dapagliflozin Propylene Glycol Tablets monographs, discuss the possibilities and challenges of expanding harmonization of pharmacopoeial standards to drug substances and drug products, and based on lessons learned further contribute to harmonization and international cooperation of pharmacopoeias worldwide.

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