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Pharmacopeial Discussion Group (PDG)

> Please see recent Pharmacopeial Discussion Group Working Procedures Changes here (http://www.uspnf.com/notices/pdg-procedure-changes) effective April 1, 2018.

In 1989, the Pharmacopeial Discussion Group (PDG) was formed by the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe, the United States Pharmacopeial Convention, Incorporated, and the Japanese Pharmacopoeia of the Ministry of Health, Labour and Welfare (MHLW). The Indian Pharmacopoeia Commission (IPC) officially joined as a member in the PDG on October 2023 and the World Health Organization (WHO) has participated in the PDG as an observer since May 2001. The PDG has generally met twice a year – either face-to-face or by videoconference – to work on pharmacopeial harmonization topics.

1. PDG Purpose

The purpose of PDG is to harmonize pharmacopeial standards (excipient monographs and selected general chapters) in three major regions of the world. Harmonization reduces manufacturers' burden of having to perform analytical procedures in different ways, using different acceptance criteria, in order to satisfy pharmacopeial requirements that vary across regions. At all times, PDG strives to maintain a consistent level of science across the three pharmacopoeias, with the shared goal of protecting the public health. A pharmacopeial monograph for an active ingredient or excipient, preparation, or other substance used in the manufacture or compounding of a medicinal product generally provides a specification by way of a name, definition,

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description, tests, procedures, and acceptance criteria and sometimes packaging, labeling, and storage statements. For frequently cited procedures, or for broad-based guidance, a monograph may reference a general chapter.

Definition of Harmonization: PDG has defined harmonization of a pharmacopeial monograph or general chapter as follows:

> "A pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the document's harmonized procedure yields the same results and the same accept/reject decision is reached."

When using a fully harmonized pharmacopeial monograph or general chapter, an analyst will perform the same procedures and reach the same accept/reject decisions irrespective of which PDG pharmacopeia is referenced. This is called interchangeability, and each pharmacopeia will identify, in an appropriate manner, each fully harmonized monograph and general chapter.

When full harmonization of a pharmacopeial monograph or general chapter is not possible, the PDG uses an approach termed harmonization by attribute. In this approach, some elements of a monograph or general chapter are harmonized, but others are not. When a monograph is harmonized by attribute, interchangeability is achieved only with respect to the harmonized elements. For nonharmonized attributes, compliance with the individual pharmacopeial requirements in each region is necessary.

2. PDG Process

Harmonization of pharmacopeial documents in PDG is based upon decisions of the expert bodies of each pharmacopeia, which are reached in accordance with the procedures followed by each pharmacopeia. PDG works transparently in many ways, principally through the public notice and comment process of each pharmacopeia. The details are described below under PDG Working Procedures.

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Implementation

The implementation of a harmonized document varies in the three PDG regions, depending upon their legal requirements, need for translation, and publication schedules. Each pharmacopeia generally allows some period of time after publication to implement official harmonized texts to allow manufacturers and other users to achieve conformity. Harmonization is not achieved until the text becomes official in all three pharmacopeias.

Revision of Harmonized Monographs

The PDG pharmacopeias have agreed not to revise unilaterally any harmonized document after publication. Should revisions be necessary for any appropriate reason, the initiating pharmacopeia notifies the PDG, and revision proceeds according to the PDG Working Procedures.

3. Statement of Harmonization Policy

4. PDG Working Procedure

5. Interaction with ICH-Q4B

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