PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

STATEMENT OF HARMONISATION POLICY

Revision October 2021

European Pharmacopoeia

Signature	Name	Date
P. Dörr	Petra Dörr	28/10/2021

Japanese Pharmacopoeia

Signature	Name	Date
Y. Goda for Y. Yoshida	Yukihiro Goda	15 Nov, 2021

United States Pharmacopeia

Signature	Name	Date
T. M	Kevin Moore	9-Nov-2021

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1. General Information

In 1989, the Pharmacopoeial 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). Since then, the PDG has generally met twice a year – either face-to-face or by videoconference – to work on pharmacopoeial harmonisation topics. Since May 2001, the World Health Organization (WHO) has participated in PDG activities as an observer.

2. Purpose

A pharmacopoeial monograph for a medicinal product, an active ingredient, an excipient or any other product used in the manufacture or compounding of a émedicinal product generally provides a name, a definition, a description, and sometimes packaging, labelling, and storage statements. Thereafter, the monograph provides the tests, procedures and acceptance criteria that constitute the specification. For frequently cited procedures, a monograph may refer to a general chapter for editorial convenience. PDG works to harmonise excipient monographs and general chapters. This will reduce manufacturers' burden of performing analytical procedures in different ways, using different acceptance criteria. At all times, PDG works to maintain an optimal level of science consistent with protection of the public health.

3. Definition of Harmonisation

PDG has defined harmonisation of a pharmacopoeial monograph or general chapter as follows:

> *A pharmacopoeial general chapter or other pharmacopoeial document is harmonised when a substance or preparation tested by the harmonised procedure yields the same results and the same accept/reject decision is reached.*

Harmonisation is achieved when the text has become official in all three pharmacopoeias.

4. Indication of Harmonisation

4.1 When using a fully harmonised pharmacopoeial monograph or general chapter, an analyst will reach the same results, irrespective of which PDG pharmacopoeia is referenced. This approach provides a basis for interchangeability (same accept/reject decision) and each pharmacopoeia will flag, in an appropriate manner, its fully harmonised monographs and general chapters.

4.2 When full harmonisation of a pharmacopoeial monograph or general chapter is not possible, PDG works to harmonise using an approach termed "harmonisation by attribute." According to this approach, some elements of a monograph or general chapter may be harmonised but others may not. When a monograph or general chapter is harmonised by attribute, a combination of approaches is needed. For non-harmonised elements, reliance on the individual PDG pharmacopoeia is necessary.[1]

5. Process

Harmonisation of pharmacopoeial documents in PDG occurs based upon decisions of the expert bodies of each pharmacopoeia. PDG works transparently in many ways, including, principally, the public notice and comment procedures of each pharmacopoeia. The details are described in the Working Procedures of the PDG.

6. Implementation

The implementation of a harmonised document varies in the three PDG regions, depending upon their legal requirements, need for translation, and publication schedules. Each pharmacopoeia generally allows a defined period of time after publication to implement official harmonised texts to allow manufacturers and other users to achieve conformity.

7. Revision of Harmonised Monographs and General Chapters

The pharmacopoeias participating in PDG have agreed not to revise unilaterally any harmonised document after publication. Should revisions be necessary for any appropriate reasons, the initiating pharmacopoeia notifies the other pharmacopoeias and revision proceeds according to the Working Procedures of the PDG.

8. Maintenance of ICH Q4B annexes

While not part of the International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the PDG is closely collaborating with ICH and tasked with the maintenance of the 14 annexes of ICH Q4B that give details on regulatory interchangeability of 16 PDG harmonised pharmacopoeial texts. The PDG prepares revised Q4B Annexes and submits them to ICH for possible regulatory consultation, adoption and publication. Other pharmacopoeias are informed by the PDG via the contact list of the International Meeting of World Pharmacopoeias (IMWP). More information can be found in Annex 5 of the ICH Standard Operating Procedure of the ICH Working Groups (available here).

[1] All three PDG pharmacopoeias contain a statement in the General Notices regarding alternative methods. Use of alternative methods is subject to approval by the competent authority.