

PHARMACOPOEIAL DISCUSSION GROUP
HARMONIZED DOCUMENT

Statement of Harmonization Policy
(Revision November 2003)

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1. General Information

In 1989, the Pharmacopoeial Discussion Group (PDG) was formed with representatives from the European Directorate for the Quality of Medicines in the Council of Europe, the United States Pharmacopoeial Convention, Incorporated, and the Japanese Pharmacopoeia in the Ministry of Health and Welfare (now the Ministry of Health, Labour and Welfare). Since that time, PDG generally meets twice a year to work on pharmacopoeial harmonization topics. In May 2001, PDG welcomed the World Health Organization as an observer. While not part of the International Conference on Harmonization (ICH), PDG usually meets in conjunction with ICH and provides the ICH Steering Committee with reports of its progress. To facilitate harmonization of some ICH Quality guidelines and the Quality section of the Common Technical Document, PDG representatives attend certain ICH expert working group discussions as observers.

2. Purpose

A pharmacopoeial monograph for an active ingredient, an excipient, a preparation or other substance used in the manufacture or compounding of a medicinal product generally provides a name, a definition, a description, and sometimes packaging, labeling, 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 harmonize 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 Harmonization

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

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

3.1 When using a fully harmonized pharmacopoeial monograph or general chapter, an analyst will reach the same accept/reject decisions, irrespective of which PDG pharmacopoeia is referenced. This approach provides a basis for interchangeability and each pharmacopoeia will identify, in an appropriate manner, such a monograph or general chapter.

3.2 When full harmonization of a pharmacopoeial monograph or general chapter is not possible, PDG works to harmonize using an approach termed "harmonization by attribute." According to this approach, some elements of a monograph or general chapter may be harmonized but others may not. When

a monograph is harmonized by attribute, a combination of approaches is needed. For non-harmonized elements, reliance on the individual PDG pharmacopoeia is needed.¹

4. Process

Harmonization 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 Pharmacopoeial Discussion Group.

5. 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 pharmacopoeia 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 pharmacopoeias.

6. Revision of Harmonized Monographs and General Chapters

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

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.