PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION

FOURTH PAN AMERICAN CONFERENCE ON DRUG REGULATORY HARMONIZATION

Document-IV-8

Pharmacopeial Working Group (PWG)

I. Background

I.1Objective

The PWG is composed of representatives from the four active pharmacopeias in the Americas: Farmacopea Argentina (FA), Farmacopeia Brasileira (FB), Farmacopea de los Estados Unidos Mexicanos (FEUM), and the US Pharmacopoeia (USP/Secretariat). The mission of this working group is to create a forum for discussion and exchange of information which will facilitate the adoption of harmonized procedures. A possible objective of the PWG is to have a Harmonized PHARMACOPEIA of the Americas.

I.2 Internal Meetings

Since its formation, the PWG is coordinated by USP and has met on twelve occasions, as follows:

Meeting 1: April 14, 2000/Washington, DC, USA (coincident with the USP Quinquennial Convention
Meeting 2: May 1, 2000/Sao Paulo, Brazil.
Meeting 3: August 1, 2000/Porto Alegre, Brazil.
Meeting 4: March 4, 2001/Orlando, USA.
Meeting 5: November 20, 2001/Washington, DC, USA.
Meeting 6: June 25, 2001, Buenos Aires, Argentina.
Meeting 7: December 19, 2002/USP Headquarters, Rockville, MD, USA.
Meeting 8: Teleconference July 22, 2003.
Meeting 9: Teleconference October 7, 2003.
Meeting 10: November 4-5 2003, Cancun, Mexico.
Meeting 11: Teleconference April 28, 2004.
Meeting 12: Teleconference December 15, 2004.

All these meetings provided the opportunity to establish relationships, exchange information on the administrative and scientific structure and procedures, and to explore possibilities for collaboration within the context of PANDRH.

I.3 Public Meetings

Several meetings were held in order to promote the participation of the pharmaceutical industry:

a) *Strategic Decision* was a workshop held in Sao Paulo, March 2001, sponsored and organized by Farmacopeia Brasileira;
b) *The Impact of Pharmacopoeias on the Production and Regulation of Medicines and on Global Harmonization.* The Argentine Association for Industrial Pharmacy and

Biochemistry (SAFYBI) hosted this forum on November 2001 in Buenos Aires;

c) *The Impact of Pharmacopoeias in International Trade.* FEUM hosted this international forum which was held in Mexico City, on January 31, 2002.

The United States Pharmacopeia (USP) held formal meetings with pharmaceutical manufacturers through its *Prescription/NonPrescription Stakeholders Forum.*

I.4 General Procedures Harmonization

The group discussed and adopted harmonized procedures for the following general chapters: Bacterial Endotoxins, Residue on Ignition, Extractable Volume, and Particulate Matter in Injections. Mechanisms for public announcement of the agreement for the harmonized texts are under evaluation.

1.5 Harmonization of Monographs

A protocol for new monographs developed by the group was approved (see attachment).

Based on the work plans and priorities of the four pharmacopoeias, the group identified “Amiodarone” as a pharmaceutical substance and ”Cat’s Claw” as a botanical material suitable for a pilot program aiming to develop a new monograph. At the present time, these monographs have been included in the revision process of all the PWG’s participants.

II. Proposal

Taking into account the recommendations proposed at the Pan American Conferences, the Pharmacopeial Working Group, through the Steering Committee of the IV Conference, requests the following:

1. To acknowledge the present report ;

2. To approve the Mission Statement of PWG as follows:

   To create a forum for discussion and interchange of information that facilitate the adoption of harmonized procedures, with a possible objective of a Harmonized Pharmacopoeia of the Americas;

3. To endorse the proposed protocol for the harmonization process (see attachment).

ANNEX I
PROTOCOL FOR NEW MONOGRAPHS DEVELOPED BY THE PHARMACOPEIAL WORKING GROUP (PWG)

Step 1. By consensus, one monograph is selected to be harmonized according to the work plans and priorities of the four pharmacopeias. A Leader Pharmacopoeia (LP)is also selected.

Step 2. LP prepares a draft according to its internal procedures. That draft is sent to the other members of PWG with all the information which may be shared in accordance to the LP's by laws.

Step 3. Each pharmacopoeia sends the draft to the corresponding Expert Committees for revision. Later on, those comments are sent to LP within 45 days from the date of reception.

Step 4. LP reviews the comments and prepares a second draft and a summary report about the discrepancies and agreements about the subject. After approval of the Expert Committee of LP such draft is sent to all the other members within the 30 days of having received the comments (sent by each member).

Step 5. The Expert Committee of each pharmacopoeia reviews the summary report and suggests if the complete harmonization is possible or will continue by attributes or the harmonization should be suspended. Not later than 45 days a response should be sent to LP.

Step 6. PL receives the comments and if any of the pharmacopeias suggest that the complete harmonization or by attributes is not feasible, the process is suspended. If the answer is positive, LP prepares a third draft which is sent then to the other members for public comment indicating the tests and/or specifications where discrepancies may arise.

Step 7. Each pharmacopoeia writes the proposal in its language and style and submits this text for public review stating the intention of harmonization, the degree of agreement reached and all the differences. The public review will be for a period of not less than 60 days and not longer than 90 days. Each pharmacopoeia applies its internal procedures for reviewing the comments received. Later on, each pharmacopoeia sends a report to LF within 30 days when the public review process has ended.

Step 8. PL analyzes the reports and sends the results to all the other PWG's members together with a third draft. If necessary, Steps 5, 6 and 7 may be repeated.

Step 9. In accordance with the results and only after two other cycles of revision, the pharmacopeias agree to have reached the harmonization of the official text, to continue the revision or to cancel the harmonization process. An agreement is signed if the parties agreed to harmonize a specific monograph. Each pharmacopoeia is responsible not to modify any harmonized monograph without previously notified the other three pharmacopeias. When an amendment is proposed, the change will follow the procedures stipulated by this protocol.