

***Pan American Network for Drug Regulatory Harmonization (Red PARF) - Medicine
Working Group Registration
Aide Memoire – Elluminate
November 9, 2010 - 10:00 to 11:00 a.m.***

Participants Present

CAN: Marcela Pezzani V. (Chile) - Member, Maria Teresa Ibarz (Venezuela) – Alternate

FIFARMA: Eunice Rojas – Member

MERCOSUR: Silvia Boni (Argentina) - Member, Monica Soares (Brazil) – Alternate

SICA: Rodrigo Perez Massip (Cuba) – Member

ALIFAR: Miguel Maito – Member

PAHO / WHO - Secretariat: Adriana Ivama

Excused Absent

NAFTA: Molzon Justina – Member, apologized for not being able to participate

Summary of discussion

Introduction and presentation: Adriana Ivama welcomed the participants, especially the two new members of the Working Group (WG), Marcela Pezzani and Silvia Boni and weighed and presented the objectives of the session: "Update on the Working Group participants and work plan". Then the participants introduced themselves individually.

Appointment of the Coordinator of GT:

Prior to the session, only Silvia Boni expressed interest in coordinating the group, and this was agreed on during the meeting by consensus.

Work Plan review and approval:

The draft workplan was discussed and updated. It included the frequency of meetings and the priorities of the WG.

Review and comment and proposal for completion of the document to be submitted to the VI Conference:

An agreement was made to review timetable as part of the work plan.

Other:

There was a brief summary of the Steering Committee meeting held in Santiago, Chile during October 5-6, 2010. Attention was called to the low attendance and participation in this WG and was seen as a challenge to overcome. Due to problems with communication/connection, the participation of some members has been somewhat limited. A suggestion was made for the creation of a sharepoint for the group, as a tool to post and share documents and information. All members will receive an invitation to introduce themselves and create a profile and a password shared environment.

Summary of closure and agreements

Ms Silvia Boni from ANMAT was accepted by consensus, as the oncoming coordinator. Upon agreement to hold at least a monthly meeting via Elluminate, a tentative schedule of meetings is proposed (Annex 1) for review. As a result of the discussion, a revised work plan (Annex 2) was obtained and there was agreement

on the review of the registration requirement document. To the date, no comments were received, due to the agreement to re-submit it to public consultation of all members of the PANDRH. At the request of ALIFAR, the document should be renamed Guidelines for Medicines Registration. Nevertheless for the consultation it will be circulate as it is now. Once the comments are systemised, the document will be subject to discussion by the WG for agreement of a new version. This new version will then be submitted to the Steering Committee for approval during the Sixth Session (July/2011). Simultaneously, the draft Guidelines on the Application of harmonized requirement will be reviewed internally by the WG together with the initial requirements document (draft submitted by Dr. Maria Teresa Ibarz, to be circulated by the Secretariat), after obtaining the agreement from the WG, it will be sent for assessment by the SC and to the conference.

The participation of the members was acknowledged and emphasis was placed on the importance of follow-up on agreed activities and the continued active participation of all members.

The meeting was then adjourned.
