

***Pan American Network for Drug Regulatory Harmonization (Red PARF) - Medicine
Working Group Registration***

Aide Memoire - Elluminate - December 17, 2010 - 10:00 to 11:40 a.m.

Participants:

MERCOSUR: Silvia Boni (Argentina) - Member

SICA: Josip Lora - Alternate

ALIFAR: Miguel Maito - Member

PAHO / WHO: Secretariat: Adriana Ivam

The following representatives apologized for not being able to participate:

CAN: Marcela Pezzani V. (Chile) - Member,

SICA: Rodrigo Perez Massip - Member

Summary of discussion

Meeting Dates: confirmed the meeting dates for next year. Although there are some dates that not all participants are available, it was decided to discuss the dates and go a few months before any adjustments if necessary.

Aide memoire: Mr. Maito reiterate the request for review to the memory of the previous meeting. Adriana reported having done. The reviewed file is attached to this minute.

Discussion and review of the document on Harmonized Requirements for Registration of Medicines: The group began discussing the Glossary and concluded that a more careful review is necessary. Eg. It noted the need to separate the Technical Responsible for the Product, the technical responsible for the laboratory, the Legal Representative and Registration Holder. It was suggested not mentioning the casuistic of the countries. It was suggested adding an annex, the possible equivalence of terms in different countries. Each Representative has circulated the document to the countries of sub-regional block and they will send their considerations to the secretariat, if possible one week before the next meeting.

Discussion of the Implementation Guide: the review was postponed, due to the need to to prioritize a more extensive revision of the Proposal for Harmonized requirement. Once agreed requirements and changes, these are incorporated into the implementation document to then be circulated for discussion in the month of January .

SharePoint: The Secretariat reported on the delay in the invitation and the implementation of SharePoint the GT due to technical problems with PAHO Portal migration. As soon as the problem is solved, it will be sent an invitation to the registration in SharePoint. A briefing session on how to use elluminate will be delivered once the system is available.

Summary and closing agreements:

It was agreed that each representative will strengthen consultation with representatives of the countries of sub-regional block to send comments to the document.
