



MINUTES

Pan American Network for Drug Regulatory Harmonization (PANDRH) Steering Committee Meeting

Location: *Elluminate* session organized by the Secretariat

Date: April 8th, 2010

Time: 10:00 am – 12:00 pm (Washington DC local time)

Link for participants:

<https://sas.illuminate.com/site/external/launch/meeting.jnlp?sid=1110&password=M.74C3A81930EDADA241C6AD2B5EFFD7>

AGENDA

Topics to be discussed	Discussion leader
Opening	James Fitzgerald
Ratify members of working groups	José Peña
Guidance for working groups	José Peña
General information	José Peña

Opening

- James Fitzgerald opened the meeting by welcoming participants and stating that he would not be able to remain present for the entire *Elluminate* session. José Peña was assigned as the moderator for the session. It was also stated that a Spanish/English translation by María de los Angeles Cortés Castillo would occur simultaneously throughout the session. The list of participants can be found in Annex 1.

Ratification of the working group members

-Representatives from each group were asked to update the status of the responses to the pre-established questions regarding the integration of the active PANDRH working groups. It was stated that responses have only been received from some parts of the NAFTA region, ALIFAR, FIFARMA and from the Andean Region. A summary of the received responses can be found in Annex 2.

-The session was opened for a discussion concerning the challenges related to designating members to each working group.

- MERCOSUR: A meeting will be held in the last week of April 2010 during which members (two representatives) will be designated for each group. These representatives are available to assume coordination of the working groups.

-CARICOM: Representatives have been selected and responses have been sent to the representative in Trinidad. These responses will soon be sent to the Secretariat. CARICOM will follow up with the Secretariat to confirm that the responses have been received.

-NAFTA: Representatives from Health Canada have been identified for the working groups for Vaccines, Pharmacovigilance and Biological Products/Biotechnological Products. Health Canada will proceed by contacting Mexico and the United States to confirm that there will be representatives in each of the working groups for this sub-region.

-ALIFAR: Will designate representatives in 10 days (April 18th, 2010) to those working groups who currently do not have any.

-FIFARMA: Will designate a representative to the working group for medicinal plants. They had not previously designated a representative for this group due to the nature of the products they work with.

- José Peña emphasized the importance of fulfilling commitments, including defining working group members. Defining group members is particularly important because of the upcoming VI Conference for PANDRH programmed for March, 2011. It is

important that the Steering Committee holds a meeting with the physical presence of all members by August, 2010 in order to define the agenda and the expected results of the conference.

-The following proposals were approved upon general consensus by the meeting participants:

- Final date to nominate members to the working groups: May 15th, 2010
 - Final date for PAHO focal points to contact members of each working group to finalize coordinators, objectives and working plans: from May 15th, 2010 to July 1st, 2010.
 - A virtual meeting to allow each working group to update the Steering Committee: July 15th, 2010.
- Those sub-regions that have not submitted their candidates for the working groups will be excluded from the memos, the selection of the coordinator, the objective setting process, and working plans. These initiatives will become the responsibility of other members of the group and of the Secretariat.
 - If groups are formed prior to May 15th, 2010; they may initiate activities, without having to wait for the deadlines mentioned above.
 - It is necessary to consider the revision, prioritization and incorporation of the working plans mentioned at the V PANDRH Conference, held in Buenos Aires, Argentina in 2008.
 - At the request of various participants, the Secretariat will include all members of the Steering Committee in all messages between the Secretariat and working groups. The Secretariat will also include focal points of the PAHO sub regions. Doing this will allow for better follow-ups of the activities assigned to each member.

General Information

- General announcements:
 - o The recently published document of the working group for vaccines, entitled “Harmonized requirements for the licensing of vaccines in the Americas and Guidelines for preparation of application,” was published in PAHO’s webpage. It is currently available in Spanish and English. It will soon be available in French
 - o James Fitzgerald remains in communication with Brazil regarding the location of the VI PANDRH Conference (March, 2011). He will also soon confirm whether or not the Steering Committee meeting to occur in August, 2011 will be held in Brasilia.

ANNEX 1: List of Participants

ALIFAR:

Miguel Maito

ANDEAN REGION:

Victor Dongo

CARICOM:

Maryam Hinds

FIFARMA:

José Manuel Cousiño

CENTRAL AMERICA:

Eric Conte

MERCOSUR:

Patricia Aprea, Marina Rossi

NAFTA

Michael Ward

SECRETARIAT [PAN AMERICAN HEALTH ORGANIZATION (PAHO)]

James Fitzgerald, HSS/MT-WDC

José Peña, HSS/MT- CHI

José Luis Castro, HHS/MT- ARG

María de los Ángeles Cortés, HSS/MT-WDC

José Maria Parisi, HSS/MT-WDC

María Luz Pombo, HSS/MT-WDC

Adriana Ivama (Consultant PAHO Region CARICOM)

IT SUPPORT

Julie Buekens, HSS/MT

ANNEX 2: Responses received during the April 8th, 2010 meeting regarding the integration of PANDRH working groups

REGISTRO DE MEDICAMENTOS (DRUG REGISTRATION)				
Participantes	Titular/Alterno (país)- Main/Alternate (country)	Teléfono-Phone	E-mail	Dirección-Address
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NAFTA				
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FIFARMA	Eunice Rojas (ECU)	593 2299 4745	eunice.l.rojas@gsk.com	Los Rios 442 y Loja, La Colina, Sangolqui
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BUENAS PRACTICAS DE LABORATORIO (GLP)				
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ALIFAR	-----			
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BUENAS PRACTICAS CLÍNICAS (GCP)				
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VACUNAS (VACCINES)				
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FARMACOVIGILANCIA (PHARMACOVIGILANCE)				
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COMBATE A LA FALSIFICACIÓN DE MEDICAMENTOS (COUNTERFEIT)				
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PLANTAS MEDICINALES				
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FIFARMA				

CLASIFICACIÓN DE MEDICAMENTOS (CLASIFICATION OF DRUGS)				
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PROMOCIÓN DE MEDICAMENTOS (PROMOTION AND PUBLICITY)				
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PRODUCTOS BIOLÓGICOS / BIOTECNOLÓGICOS				
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