



MINUTES

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

Location: *Elluminate* session organized by the Secretariat

Date: January 15th, 2009

Time: 10:00 am – 1:00 pm (Local time -Washington DC)

Spanish Elluminate Link:

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

English Elluminate Link:

<https://sas.illuminate.com/site/external/installinfo/meeting?sid=1110&password=M.DE1FDE1114CCFC1B6F804D8991037B>

AGENDA

Subject	Responsible
Opening	James Fitzgerald
Updates regarding / renewal of the PANDRH Working Groups	José Peña
Establishment of a new working Group on Biotechnological Products	José Peña
Organization of VI PANDRH Conference	José Peña
Other Issues	James Fitzgerald

Opening

- James Fitzgerald, representing PANDRH's Secretariat, inaugurated the virtual meeting of the network's Steering Committee. The list of participants can be found in Annex 1.
- The Caribbean Regions, MERCOSUR and Central America were not present when the meeting was opened. A request to continue the meeting was submitted and was approved by general consensus.
- It was indicated that the recording of the virtual meeting as well as the corresponding minutes will be sent out to the representatives of the Steering Committee. A deadline to receive comments on the minutes was established (two weeks from the sent out date). If the comments are not sent out by the pre-established deadline, this will be considered as approval of the minutes.
- The proposed agenda was approved by general consensus.
- Dr. José Peña, representing the PANDRH Secretariat, presented the activities completed during the previous Steering Committee meeting, which was held in Washington, DC between July 28th and July 29th, 2009. A summary of these activities can be found below:
 - Revision and approval of the statutes,
 - Elaborating and sending the responses to INVIMA's, FIFARMA's, and AIS' requests.
 - Elaborating and sending the minutes of the Steering Committee meeting held in July 2009, which will shortly be published on the webpage.
 - Completion of a workshop geared towards the coordinators of the working groups. The workshop promoted the use of virtual tools available to PANDRH (share point, elluminate, and a mailing list). Additionally, it indicated that the training involving these tools is currently pending for the members of each of these working groups.

Updates regarding / renewal of the PANDRH Working Groups

- Completion of the description of: the roles of the members of the working groups, the quantity of active members, and of the simultaneous activities completed by the Secretariat. This presentation will be available in the meeting's recording.
- The general objectives of each of the working groups were presented, including: their member participation (ANR, Industry and others), their activities, their results and their coordination. The recommendations from the Secretariat regarding the renewals, ratification or rectification of each group were also presented. This information can be found in meeting's recording.
- Dr. Peña summarized the proposal of the Secretariat, as is indicated below, and proposed that the Steering Counsel presents the decisions regarding these topics in March 2010.
 1. Ratify or renew the participation of members of the working groups of Drug Registration, Good Laboratory Practices, Good Clinical Practices, Vaccines, Drug Surveillance, Forgery, Medicinal Plants, and Drug Promotion. This will be based on compromise, motivation by each working group as well as their ability to work in accordance with the plans originally proposed by these groups.
 2. Cease the activities of the Good Manufacturing Practices and Bioequivalence working groups. It is proposed that virtual forums will be created (mailbox) by the Secretariat in order to provide updated information regarding the topics discussed by these groups.
 3. Determine the continuity of both the Pharmacopeia and of the Drug Classification working groups.
- The session was opened for discussion, indicating that all of members of the Steering Committee were present in the meeting, with the exception of Central America's Eric Conte, who on January 14th, 2010 sent Dr. José Peña a message regarding his absence and his position regarding the discussed topics.

- José Cousiño, from FIFARMA, indicated that he agreed with the Secretariat's proposals, requesting to correct the names of the FIFARMA representatives in the working groups during the meeting. He also suggested the ratification of these members in the next meeting, being held in March 2010. He accepted the secretariat's suggestions 1 and 2. Regarding suggestion 3, he proposed that the Pharmacopeia group remain and the conclusion of the Drug Classification working group.
- Justina Molzon, from NAFTA, agreed with the proposal and in turn suggested that the coordinators and the Secretariat establish an operational suggestion box .
- Miguel Maito, from ALIFAR, agreed with the presentation and almost entirely accepted the suggestions. In regards to the Pharmacopeia technical group, he suggested consulting with countries in the Region that possess their own Pharmacopeias. He also suggested to follow the GMP guideline implementation in the countries.
- Victor Dongo, from the Andean Community, agreed with the presentation and with all of the proposed suggestions. He also indicated that he would have liked to see indicators for each group.
- Maryam Hinds, from CARICOM, expressed her agreement with all of the suggestions. She suggested the participation of experts and ANR within the working groups in order to reinforce each of their activities. She also indicated that the Caribbean Region needs to have a major role in the working groups.
- Daniel Gollan, from MERCOSUR, approved suggestions 1 and 2 and suggested that the implementation of GMP guide be evaluated in PANDRH countries. He suggested the development a technical group that incorporates drug classification (with the participation of 2 or 3 sub regions and of the secretariat). In regards to the Pharmacopeia working group, he suggested that the topic be discussed at a regional level due to the pre-existing bilateral agreements between countries.

Establishment of a new working Group on Biotechnological Products

- José Peña introduced the PANDRH statutes related to article III.3.8, which is related to the formation of the working groups.
- It was indicated that, as part of the established compromises in the previous Steering Committee meeting, FIFARMA's and the Secretariat's suggestions regarding the creation of a biotechnological products were received. These suggestions were previously sent to the Steering Committee.
- The Steering Committee opened up a discussion regarding the approval of creating a biotechnological products working group.
- The discussion was extended to more than one hour and each participant's commentaries can be found in full in the meeting's recording. A summary of these commentaries can be found below:
 - a. There is a great interest in creating a working group that conforms to PANDRH statutes with its future ratification in the VI Conference of the Network.
 - b. The working group needs to be the one who suggests and discusses their objectives, their plans, as well as other related activities.
 - c. It was suggested that a US and a Canadian representative be included in this (and in all) working groups in addition to other experts who have been working on this topic.
 - d. It was mentioned that the overview carried out by the secretariat regarding the regulation of biological products/biotechnology in the Latin American Region and in the Caribbean has been published. The publication includes information gathered from 17 countries and demonstrated the needs presented by Regional realities. A copy of this publication will soon be mailed to the members of the Steering Committee.
 - e. All of the participants, with the exception of the ALIFAR representative, agreed with the suggestion of creating a biotechnology working group. ALIFAR requested that his disagreement (in regards to this particular case) with paragraph

- III.3.8 of the Regulations, which discusses the creation of a working group in exceptional cases, be officially stated.
- James Fitzgerald indicated that: this was a discussion that initially started in the previous PANDRH Conference, and that independently of the creation of a working group, PAHO will continue creating activities in this area with the technical support of Member countries. This activity has been performed since more than two years, with the NRAs support.
 - Following meeting discussions, the ALIFAR representative expressed his approval towards the creation of a biotechnological products working group, allowing for a general consensus to be reached.
 - It is hoped that for the March 2010 meeting: the Steering Committee will propose representatives of each sub region and of the industry for this working group.

Organization of VI PANDRH Conference

- José Peña announced the existence of a proposal by Panama to be the host country for the next PANDRH Conference. Panama confirmed that they do not have the available financing for this conference (January 14th, 2010).
- There also exists an offer made by Brazil to host the conference in March 2011 in Brasilia. Brazil offered to finance important event costs. This proposal was submitted by a vote and was then approved following general consensus.
- The minutes from this meeting will be sent to the members of the Steering Committee prior to January 22nd, 2010.

Other Issues

- The meeting was closed by indicating the advantages that a virtual system brought to the meeting, independently of the connection loss that occurred at the beginning of the meeting due to technical difficulties.
- Thanks were given for the exchange of opinions regarding the topic of biotechnological and for ALIFAR's reflection pertaining to the proposal for the

creation of a biotechnological working group. It was also emphasized that the Secretariat recognizes all of the existing initiatives regarding the particular topic, yet this does not limit the participation of these individuals in the PANDRH activities.

- The virtual meeting was closed by thanking the assistants responsible for its organization.

ANEX 1: List of Participants

ALIFAR:

Miguel Maito

ANDEAN REGION:

Victor Dongo

CARICOM:

Maryam Hinds

FIFARMA:

José Manuel Cousiño

CENTRAL AMERICA:

Without representation, sent commentaries to suggestions made by the Secretariat on January 14th, 2010

MERCOSUR:

Daniel Gollan

NAFTA

Justina Molzon

Michael Ward

SECRETARIADO [PAN AMERICAN HEALTH ORGANIZATION (PAHO)]

James Fitzgerald, HSS/MT-WDC

José Peña, HSS/MT- CHI

José Luis Castro, HHS/MT- ARG

María de los Angeles Cortés, HSS/MT-WDC

José Maria Parisi, HSS/MT-WDC

María Luz Pombo, HSS/MT-WDC

Victoria de Urioste (Consultor OPS Región Andina)

Adriana Ivama (Consultor OPS Región CARICOM)

Juana M. de Rodríguez (Consultor OPS América Central)

COMPUTER SYSTEM SUPPORT

America Valdes, HSS/MT

Tania Pereyra, HSS/MT