PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION-PANDRH

BIOTECHNOLOGICAL WORKING GROUP (BIO WG)

BACKGROUND, MISSION, OBJECTIVES, MEMBERS AND WORKING PLAN

Date: 27 September 2010

Background

The importance of having a working group on biological products that dealt with aspects of their regulation was recognized during the IV Conference of the Pan American network on drug regulatory harmonization held in March 2005 in Dominican Republic *(1)*.

During the V Pan American Conference on Drug Regulatory Harmonization, held in November 2008, in Argentina, there was a round table discussion on biological-biotechnological products. The interest of some Latin American and Caribbean countries in having harmonized documents on the regulation of this type of product was pointed out *(2)*.

On January 15th 2010, the Steering Committee of the Pan American Network for the Drug Regulatory Harmonization (PANDRH) agreed by consensus to the creation of a working group on biotechnological products *(3)*, whose objectives and working plan would be established by the members of this group.

Subsequently, and consistent with the PANDRH statutes *(4)*, the biotechnological products working group members, which represent the sub regions of North America, Central America, Caribbean countries, Andean Community, and MERCOSUR, as well as the pharmaceutical associations represented in ALIFAR and FIFARMA, were designated by the PANDRH Steering Committee.

In June 2010, in the Dominican Republic, the first meeting of the PANDRH biotechnological products working group took place (5). There the representative of Brazil, Marcelo Moreira, was elected as the coordinator of the group. The mission, objectives, and working plan proposed by the working group members are presented below.

Mission

Promote the development of the regulation of biotechnological products in the countries of the Americas Region, and to generate more effective and harmonized mechanisms for the regulation of this category of medicines.

Objectives

1. Compile a list of all regulations related to biotechnological products in place at country level and make them available at the Regional level.
2. Establish a glossary of terms to help understand the situation in Member States and to facilitate the further development of related documents.
3. Promote the exchange of information among National Regulatory Authorities of the Region.
4. Identify Regional documents and guidelines for development in the short and medium term and elaborate them as appropriate.
5. Identify other issues related to the regulation of biotechnological products that may require special treatment and establish working plans to address them.
6. Develop tools and training programmes to strength capacity building among the National Regulatory Authorities of Members States in relation to the regulatory oversight of biotechnological products and related matters.

TABLE 1: MEMBERS OF THE PANDRH BIOTECHNOLOGICAL PRODUCTS WORKING GROUP (BIO WG)

Participants (Participantes)	Main/Alternate (country) Titular/Alterno (país)
MERCOSUR	Patricia Aprea (Main) ARG
	Marcelo Mario Matos Moreira (Altern) BRA
ANDEAN COMMUNITY	Hans Vásquez (Main) PER
	Patricia Carmona Sepúlveda (Altern) CHI
CENTRAL AMERICA	Pendent
	Ana Beatriz Cordero (Altern) GUT
CARIBBEAN COUNTRIES	Junia Walcott (T&T)
	Maryam Hinds (BAR)
NORTH AMERICA	Elwyn Griffiths (Main), CAN
	Pendent
ALIFAR	Néstor Annibali (Main), ARG
	Valentina Carricarte (Altern), ARG
FIFARMA	Lucas Marletta (Main), ARG
	José Manuel Cousiño (Altern), CHI
MAIN DESIGNATED BY THE SECRETARIAT	Olga L. Jacobo, CUB
SECRETARIAT RESPONSIBLE	María luz Pombo

Consistent with the terms of reference of the PANDRH working groups, the following activities are proposed as part of the follow-up studies necessary to identify technical differences between countries and to formulate harmonized proposals relating to the regulation of biotechnological products in the Region.

TABLE 2: WORKING PLAN OF THE PANDRH BIOTECHNOLOGICAL PRODUCTS WORKING GROUP (BIO WG)

Activities	Date	Responsible(s)
Objective 1: Compile all regulations related to biotechnological products in place at country level and make them available at Regional level		
1.1. Compile the regulations for biotechnological products from each NRA participant of the BIO WG and from WHO recommendations, including those for similar biological products where available.	2010	BIO WG / Secretariat
1.2. Compile the regulations for biotechnological products from other NRAs, including those for similar biological products where available.	2010	BIO WG / Secretariat
1.3. Disseminate at Regional level the information compiled through the mechanism established for this purpose (PAHO Web or another one)	2011	Secretariat
Objective 2: Establish a glossary of terms to facilitate the further development of related documents		
2.1. Identify terminology related to biotechnology products (from the regulations compiled in the Objective 1) that will be placed in a glossary of terms	2010	Coordinator BIO WG
2.2. Produce a document that contains the terms related to the biotechnological product regulation based on: 2.2.1. Definitions established in regulations compiled in Objective 1 2.2.2. Glossary of Drugs: Development, Evaluation, and Use (PAHO/WHO) http://paho.publisher.ingentaconnect.com/content/paho/paho999/1999/00000001/00000001;jsessionid=3dv5qfulfl6lu.alice	2011	BIO WG
2.3.Disseminate and consult on the draft of the glossary of terms produced by the BIO WG	2011	Secretariat
2.4. Generate final proposed Regional glossary of terms for biotechnological products for presentation to the PANDRH Steering Committee	2011	BIO WG

Objective 3: Promote the exchange of information among National Regulatory Authorities of the Region		
3.1. Generate a proposal to promote the exchange of information related to the regulation of biotechnological products among NRAs of the Region	To be defined	BIO WG
3.2. Create a system for exchanging information on the biotechnological product regulation	2010-2011	Secretariat
Objective 4: Identify documents and guidelines to be developed in the short and medium term and elaborate them as appropriate		
4.1. Linked with the other objectives	Continue	BIO WG / Secretariat
4.2. Translate into Spanish and Portuguese the document entitled "WHO Guidelines on evaluation of similar biotherapeutic products (SBPs)" *(6)* and acquire copyright permission for its later publication	2010	Coordinator / Secretariat
4.3. Technical review of the Spanish and Portuguese translations of the document "WHO Guidelines on evaluation of similar biotherapeutic products (SBPs)"	2011	BIO WG (Spanish and Portuguese speaking countries)
4.4. Publication of the Spanish and Portuguese document "WHO Guidelines on evaluation of similar biotherapeutic products (SBPs)" to support further work of PANDRH	2011	Secretariat
Objective 5: Identify other issues related to the regulation of biotechnological products that may require special attention and establish working plans to address them		
5.1. Linked with the other objectives	Continue	BIO WG / Secretariat

5.2. Propose information that should be included at the PAHO Web space for the PANDRH BIO WG	2010	BIO WG / Secretariat
Objective 6: Develop tools and trainings programmes to strength capacity building among National Regulatory Authorities of Member States in relation to the regulatory oversight of biotechnological products and related matters.		
6.1. Linked with the other objectives	Continue	BIO WG / Secretariat
6.2. Disseminate reference material related	Continue	BIO WG / Secretariat

In accordance with the statutes of the PANDRH *(4)*, in its session V.4.4., the proposed working plan will be previously presented to the PANDRH Steering Committee for its approval before it will be posted at the PAHO Web space for the PANDRH BIO WG.

References:

1. Pan American Health Organization [Internet]. Washington DC: Pan American Network on Drug Regulatory Harmonization. IV Pan American Conference on Drug Regulatory Harmonization, conclusions and recommendations, March 2005, Dominican Republic. Available from:

   http://www.paho.org/english/ad/ths/ev/pandrh_conclusions_recommendations-ivconference.pdf

2. Pan American Health Organization [Internet]. Washington DC: Pan American Network on Drug Regulatory Harmonization. V Pan American Conference on Drug Regulatory Harmonization, conclusions and recommendations conclusions and recommendations, November 2008, Argentina. Available from:

   http://new.paho.org/hq/index.php?option=com_content&task=view&id=1060&Itemid=513

3. Pan American Health Organization [Internet]. Washington DC: Pan American Network on Drug Regulatory Harmonization. Virtual meeting, January 2010. Available from:

   http://new.paho.org/hq/index.php?option=com_content&task=view&id=1060&Itemid=513

4. Pan American Health Organization [Internet]. Washington DC: Pan American Network on Drug Regulatory Harmonization. PANDRH Statutes. Available from:

   http://new.paho.org/hq/index.php?option=com_content&task=view&id=1060&Itemid=513

5. Pan American Health Organization [Internet]. Washington DC: Quality and Regulation, Regulation of biotechnological products Regional meeting. PANDRH Biotechnological working group report, 17 June 2010, Dominican Republic. Available from:

   http://new.paho.org/hq/index.php?option=com_content&task=view&id=201&Itemid=1179&lang=en

6. World Health Organization [Internet]. Geneva: WHO Guidelines on evaluation of similar biotherapeutic products (SBPs). Available from:

   http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf