BIOTECHNOLOGICAL PRODUCTS WORKING GROUP REPORT
PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRH)

Meeting date: 17 June 2010
Place: Punta Cana, Dominican Republic

Members of the working group:

NAFTA	Elwyn Griffiths (CAN)	
CARICOM	Junia Walcott (T&T)	Maryam Hinds (BAR)
CENTRAL AMERICA	Ana B.Cordero (GUT)	
ANDEAN COMMUNITY	Hans Vásquez (PER)	Patricia Carmona (CHI)
MERCOSUR	Patricia Aprea (ARG)	Marcelo Matos (BRA)
FIFARMA	Lucas Marletta (ARG)	
ALIFAR	Néstor Annibali (ARG)	
Main designated by the Secretariat	Olga L. Jacobo (CUB)	

Secretariat: María L. Pombo

Observers:

PAHO: María de los A. Cortés, José Peña Ruz, Jaume Vidal, Dalia Castillo, Tania Pereyra

National Regulatory Authority of Dominican Republic members: Mercedes Soriano, Escarlet Heredia, María Rodríguez

Renato Murillo (Universidad de Costa Rica)

External Consultants on Intellectual Property: Fabiana Jorge, Dolores M. Cullen

Objectives

1. To select the main and alternate country coordinators for the working group (WG).
2. To establish short- and middle-term objectives for the WG, as well as to define the chronogram of activities.
3. To establish communication mechanisms.

1. Selection of the main country coordinator

The selection of the country coordinator was based on the procedure established at the PANDRH Statutes [(1)]. Therefore, each participant received a hard copy of this document.

Prior to the selection process, the WG Secretariat stated that Costa Rica's representative may not vote due to a conflict of interest, and because he does not represent an NRA. It was also stated that numeral V.1.4 related to main members, declares that the Secretariat may designate up to two main members for the WG. In addition, based on the existence of local regulations and

the experience in development of biotechnological products at the national level, the Cuban representative was also included as a WG main member.

Argentina and Brazil volunteered to coordinate the WG mainly because: 1) it permits them to accomplish the objectives and commitments previously acquired as a country, 2) their local regulations pertaining to the subject are advanced, and 3) their long-standing commitments to the NRA evaluation process, for which they are qualified by PAHO as reference NRA.

After voting by the 11 WG members, Brazil was selected as the main coordinator and Argentina as the alternate coordinator.

2. Establishment of short-term and middle-term objectives for the WG, as well as definition of the chronogram of activities

The WG Secretariat suggested that the objectives may be established in light of the possibility of presenting obtained results at the next PANDRH Conference. It was remarked that the revisions presented during the first two days of the meeting should be taken into account. A session for exchange of opinions was also undertaken to indicate different approaches that WG will consider for the plan of actions. Comments from participants were collected and summarized below:

ALIFAR

Remarked that all presentations were of very good level, and recommended to:

- Diagnose the status of these products in the Region.
- Define what is meant by biological and biotechnological products.
- Incorporate the experience of the regulatory authorities in Cuba, EMEA, Canada and Argentina, which might be the starting point to get acquainted with and standardize the terminology used. Take into account the experience accumulated in Argentina, after several years of producing and marketing biotechnological products for therapeutic use.
- Identify and discuss biotechnological products, analyze them and compare the different approval procedures applied in other countries.
- Design guidelines on biotechnological products and, subsequently, on biosimilar products, according to the regulatory requirements and needs of the regional countries, taking into account the guidelines developed by the WHO [(2)].

GUATEMALA

- According to Guatemala, the categories of products involved in the aim of the WG should be defined and the NRA capacities should be strengthened.
- In addition, Guatemala suggests identifying products approved by countries with efficient regulation and learning about the procedures and conditions of approval and taking them into consideration as a reference for other countries.
- Translate reference documents like the WHO guideline for similar biotherapeutic products [(2)] to be used by the countries during product evaluation.

FIFARMA

- Regional Health Authorities should be warned on the need to review the regulatory situation and the safety and efficacy support of biotechnology products, approved in the past as “similars”, but disregarding current WHO regulatory standards. Market characterization: how many biotechnological products have been licensed in the above mentioned approval conditions.

- The WHO document [2] should be translated and taken as a reference, since it is considered a high quality document to be used as a standard and guidance to elaborate local biosimilars regulations in each country.
- In the mid term, the FIFARMA representative proposed generating more accurate recommendations on how to implement the WHO document in local specific regulations of each country, and outline detailed guidance about technically complex subjects in order to be assessed by countries.

CARICOM

- CARICOM suggests develop tools with technical information which supports the evaluation of biotechnological product.
- Situational analysis should be performed to identify strengths and shortcomings at the country level.

CANADA

- Canada suggests establish the aim of the WG, and which products will be included under its responsibility.
- Review the situation at the country level, including strengths, shortcomings and experiences, and, based on these make a proposal for closing the gap.
- Build a baseline for biotechnological and biosimilar products. Record the situation of these products for each country, more specifically, which products are licensed, definitions and regulatory pathways currently used for its license, knowledge of the evaluation procedure. Promote the exchange of information among countries with different grades of development.
- Establish an effective communication system.
- Identify capacity needs at the country level. Organize workshops related with capacity building. Involve countries that could support training activities.
- Select a small group for decision making.

ANDEAN COMMUNITI (PERU, CHILE)

- Short-term: build information on biotechnological products licensed and conditions of approval. A glossary of terms is needed.
- Middle-term: improve NRA capacities regarding the evaluation during the licensing process, quality control, Good Manufacturing Practices (GMP), as well as efficacy.
- Reduce the asymmetries on the basis of cooperation among agencies sharing experience with in-person visits in order to gain knowledge on techniques and adopt them in countries, more specifically within: laboratories of production, analytical techniques (quality control), registry, and inspection.
- Work on mutual recognition aspects.

ARGENTINA

- Argentina proposes to harmonize the terminology used.
- Define the aim of the WG (biological products or biotechnological products).

- Specify if the WG aim will cover only what is related to licensing or whether it covers all regulatory aspects involved (requirements for qualification of manufacturing sites, post-marketing surveillance, development of the biotechnological industry in the Region, etc).
- Identify and propose mechanisms for people to gain access to these products.
- Develop guidance (based on existing information), taking into consideration whether the established requirements can be enforced in practice.

CUBA

- Cuba suggests, conduct a survey on legislation and regulation of biological, biotechnological, and biosimilar products. In addition she suggested make local regulations available to everyone; Links could be posted at the PAHO Web.
- Glossary of terms is needed.
- Interchange regulations adopted by well developed NRA, which could provide support to less developed NRA.
- At middle-term, define regulations with regard to these products.

BRAZIL

Brazil representative was pleased for being selected as the coordinator for the BIO WG, and expressed his commitment with all the parties involved, so that the WG achieves the objectives that they define. He agrees with all the proposals and considers that some are achievable in the short- and medium-term. He declares that the ones that are of greater complexity should be placed on the work schedule in order to establish times for their completion.

Brazil's proposal also mentioned the following aspects:

- Identify the potential of each NRA on the regulation of biologicals and biotechnological products.
- Share information with regard to local legislations. Compare them and confirm the asymmetries that exist.
- Establish and harmonize definitions.
- Encourage knowledge development with regard to these products in order to improve legislations of each integral country.

SECRETARIAT

The Secretariat encourages participants to visit the PAHO Web [(1)] to review the minutes of the Steering Committee virtual meeting organized in January 2010. It will offer complementary information to the BIO WG members regarding which products (biological or biotechnological products) should be considered.

Subsequently, the needs of other NRAs [(3)] were presented to the BIO WG for them to decide if these could be considered as WG objectives. In addition the Secretariat urges the following:

- Production of a glossary of terms with up-to-date definitions of biological and biotechnological.
- Production of a regional document that shows modern conceptions on the technical evaluation of biotechnological products that exist in the Region as well as in other parts of the world. Conduct a survey to update current regulations for biotechnological products [(4)], and announce the mechanisms in place at the country level to authorize them.

- Development of a publicly available database coordinated at the regional level and, that contains the list of biotechnological products marketed in the region, including those that are considered non-innovative (approved through a biosimilar approach or by other means).

The analyses of all the above proposals were suggested for the establishment of the WG plan of actions. The plan will include aims, objectives, and chronograms. The deadline for this document is August 2nd 2010. After that, an update should be presented to the PANDRH Steering Committee.

Several recommendations were mentioned, that stipulate the necessity of creating and enhancing common workspaces for the collaboration, dialogue, consolidation, and sharing of experiences among countries. Finally, generating exchange mechanisms to facilitate communication among all sub-regional countries was considered imperative to achieve results that have impacts at regional levels.

3. Establishment of communication mechanisms

All contact information was included in the PANDRH List Server.

There are two communication mechanisms available for the WG members: Elluminate and Share Point. Training for these communication tools will be scheduled by PAHO, and notifications will be sent to all WG members. Provisional training dates will be provided as soon as possible.

CLOSING REMARKS: SECRETARIAT

The objectives achieved during this session were the selection of the coordinators (main and alternate), proposals of objectives for the WG, and the establishment of a deadline to prepare the plan of actions, objectives as well as aims of the group.

The participation of all parties involved was greatly appreciated and collaboration is urged towards the achievement of the WG objectives.

References:

1. Pan American Health Organization [Homepage]. Washington DC: Essential medicines; Quality and Regulation, Pan American Network on Drug Regulatory Harmonization. Available from: http://new.paho.org/hq/index.php?option=com_content&task=view&id=1054&Itemid=513&lang=en
2. World Health Organization [Homepage].Geneva, Switzerland. WHO Guidelines on evaluation of similar biotherapeutic products (SBPs). Available from: http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf
3. Pan American Health Organization [Homepage]. Washington DC: Essential medicines; Quality and Regulation. Available from: http://new.paho.org/hq/index.php?option=com_content&task=view&id=201&Itemid=1179
4. Review of regulation of biological and biotechnological products in Latin American and Caribbean countries. María L. Pombo, José L. Di Fabio, María de los A. Cortés. Biologicals 37 (2009) 271 – 276.