
Dear ECONMED participants:
On this occasion we are pleased to finally share the report on the first session of the Working Group on Biotechnological products of the Pan American Network for the Harmonization of the Pharmaceutical Regulation (PARF), which was held in Punta Cana, Dominican Republic between June 14th-17th with the participation of representatives of national regulatory agencies and/or ministries of health (Argentina, Brazil, Canada, Chile, Colombia, Guatemala, the Dominican Republic), delegates from sub regional organizations (CARICOM, Andean Community, MERCOSUR, NAFTA, SICA) and valuable contributions from s European Regulatory Agencies (Spain, Germany) officials with the presence of relevant pharmaceutical manufacturers associations (FIFAR, ALIFAR).

The meeting opened with a presentation by Dr. J. Peña (PAHO-CHI) on the characteristics, background, and current situation of the network PARF. The coordinator of the new group, Dr. M. Pombo (PAHO-WDC) summarized the objectives of this first meeting: select the coordinating country and to the alternate one, establish the objectives of work of the short- and medium-term group, and agree on communication and coordination mechanisms. Next, Dr. Ivana Knezevic of WHO shared with participants the most recent developments at the global level related to the regulation of biological and biotechnological products, including the provisional recommendations of the13ª International Meeting of Regulatory Agencies (ICDRA) held in September 2008 and the guide *WHO Guidelines on Evaluation of similar biotherapeutic products (SBP)*approved in October 2009 by the WHO Expert Committee on Biological Standardization following several workshops and consultations in Europe and Asia. Dr. Sol Ruiz from the Spanish Medicines and Health Products Agency (AEMPS) explained the process of standardization in the regulatory area developed in the framework of the European Union in recent years. Dr. Olga Jacobo contributed, on behalf of Cuba`s State Centre for Medicines Control (CECMED) the Cuban perspective on the regulation in the country of biotechnological and biosimilar products, placing special emphasis on post-marketing surveillance measures . Dr. Patricia Aprea, in representation of MERCOSUR delivered a presentation both on the situation in the countries of the subregion (BRA,ARG,URU,PAR and VEN a.e) and the challenges and advances reported in the process of regulatory harmonization.

The second day of the meeting counted with the participation of of Mr. Rafael Alonso from Washington University (US) and the Random Foundation (COL) who offered an overview of the situation of the regulation of products biosimilares within the region characterized by the diversity between national situations. Additionally, Dr. Elwyn Griffith from Health Canada (prominent participant in the preparation of the WHO guide) explained process for the approval of a guide on products of reference and extrapolation of indications for *Subsequent-entry biologics* (biosimilars) in Canada stressing the prolonged period of consultations and the variety of stakeholders involved at the federal and provincial levels . Dr. Michael Pfleiderer from the Paul Ehrlich Institute (RFA) in representation of the European Medicines Agency (EMA), described the European experience in the preparation both of clinical and non-clinical guides of biosimilars. Closing the morning session Dr. Ivana Knezevic listed the different examples of biological and biotechnological regulations (Australia, Japan, Korea …). The afternoon session, only for regulatory agencies, was used to briefly listen to the national perspectives from delegates from Argentina, Brasil, Colombia, Chile and Peru.

Brazil and Argentina (both MERCOSUR) were chosen as coordinator and alternate representative of the group. The main objective of the group was identified as continuing to

meet through eliminate, with the deadline of December of the current year to unveil work plan. There was repeated emphasis about the need for having PAHO publications and materials derived from surveys promoted by the organization while there was also insistence on the need for adapting the guide of WHO both to the Spanish language and to the specificities of the Latin American region.

We take this opportunity to reiterate the pertinence to share examples of new regulations or modification of existing regulatory frameworks on biotechnological products.

We welcome to ECONMED the members of the Dominican Republic's Presidential Commission on Pharmaceutical policy, Dr. Marcelo Lalama, Pharmacology professor of the Universidad Central, Quito, Ecuador and Dr. Flavia Poppe from Brazil's PAHO office.