International Society for Cellular Therapy ISCT TELEGRAFT

Latin America Legal and Regulatory Affairs

Watchdog Update

REGULATORY WATCH DOG

Argentina

Argentina does not have clear regulations about Cellular Therapies. However, a new initiative by the local Health Authority brought together a number of countries with the objective of starting Biological Products Regulation in Argentina and the Americas.

This press release was recently published at the ANMAT (Health Authority) web site. Here is the link (in Spanish): http://www.anmat.gov.ar/comunicados/taller-biologicos.pdf

And here is an English translation of the document for your information:

START OF THE BIOLOGICAL PRODUCTS REGULATION WORKSHOP IN THE AMERICAS

With the participation of representatives from 18 countries of the continent, the Biological Product Regulation Workshop in the Americas began October 27, 2016 in the Autonomous City of Buenos Aires. This administration, Health Canada (the Canadian regulatory agency), and the Pan American Health Organization (PAHO/WHO) coordinated to bring this workshop to light.

The meeting has among its objectives giving support to efforts seeking to strengthen the regulatory system for biological drugs, the development and requirements for its evaluation, and generation of initiatives on regulatory convergence.

Dr. Analía Porras, Head of the Medicines Unit and PAHO / WHO Sanitary Technologies, thanked the participants for their presence and highlighted the leadership of ANMAT in the field of regulation of biologics and vaccines.

Subsequently, the National Administrator of ANMAT, Dr. Carlos Chiale, called the conformation of the Regulatory Convergence Network of Biological Products for the Americas, in order to promote information exchange that will help contribute towards any decision.

During the workshop, sessions were held on various issues such as the implementation of the pharmaceutical regulation on items of biological origin, as well as requirements for authorization, production of blood products, marketing of biotherapeutics, and new regulatory challenges. The discussions sought to identify weaknesses and strengths for the establishment of any regulation and opportunities for collaborative work in the short, medium, and long term.

The countries that participated in the meeting were Bolivia, Brazil, Canada, Chile, Colombia, Cuba, Costa Rica, Ecuador, El Salvador, the United States, Guatemala, Honduras, Mexico, Panama, Paraguay, Peru, Uruguay and Venezuela. Associations serving the pharmaceutical industry of the region were also represented.