Marlene Llópiz-Avilés, J Bioanal Biomed 2016, 8:5(Suppl)
http://dx.doi.org/10.4172/1948-593X.C1.022

Marlene Llópiz-Avilés
Association of Medical Specialists in the Pharmaceutical Industry – Mexico

Biosimilars: Latin America´s coming on board: Regulatory approval and market access

Biotechnological medicines are medicinal products of biotechnological origin that contain proteins derived from DNA technology. Biotechnology is the use of living organisms such as plant and animal cells, bacteria, viruses and yeasts for the production of medicines that include such biological factors as cytokines, hormones, clotting factors, monoclonal antibodies, vaccines, etc. Biosimilars are attempted copies of existing biological medicinal products or protein drugs. They are made with a different cell line and a different manufacturing and purification process. Biosimilars come about from the expiry of patent protection for many original medicines. They are considered as possible products at lower costs in comparison to modern therapies for patients and governments and are often more acceptable by patients. Less time and money is spent on clinical research for them to reach the market, as well as less pharmacovigilance. The experience with biosimilars to date is limited and long term safety and efficacy are unavailable. Immunogenicity is often unknown. Because of the above, there is need for appropriate regulations, the clear identification of potential problems and close pharmacovigilance. Latin America has become a new marketplace for the commercialization of biosimilars. However, the lack of regulations, requiring strict clinical trials and close pharmacovigilance has created Latin America an easy target for local and foreign companies to market biosimilars. As in all countries, significant clinical and non-clinical testing should be required for biosimilars to be marketed in Latin America. Substantial NDA-type dossiers should be submitted and post-market safety surveillance must be carried out. For that to occur, substantial manufacturing investments, and sales promotion and marketing are required to be set in place. Latin America can certainly become a safe marketplace for biosimilars only and now that regulatory strategies are set in place, and clinical and non-clinical trials are conducted with detailed pharmacovigilance before and after their marketing. The objectives are: 1. To make companies in Europe and worldwide aware that Latin America is setting down clear regulations on biosimilars; 2. For LatAm to follow the EMA guidelines on biosimilars; 3. For the worldwide standardization of guidelines on biosimilars.

Biography

Marlene Llópiz-Avilés is a renowed Pharmaceutical Medicine Specialist with over 25 years of experience in regulatory affairs, pharmacovigilance, medical affairs, clinical research and market access for diverse drugs. She holds a Bachelor of Arts degree from Austin College, Texas; an MD degree from Universidad Anáhuac, Mexico and an MPH degree from Harvard University. She is currently President of the Association of Medical Specialists in the Pharmaceutical Industry (AMEIFAC) (2015–2017). She is a Secretary General and board member of the International Federation of Associations of Pharmaceutical Physicians (IFAPP) from 2009 to date; Latin American member of the CPhI Worldwide Advisory Board (2014 to date); President and Chairperson for the Mexican Chapter of the Association of Clinical Research Physicians September 2012 to date. She received Harvard School of Public Health Alumni Award of Merit in 2005; and Austin College Leadership Award 2014. She is listed in 100 Most Inspiring People in the Life-Sciences Industry by the readers of PharmaVoice and the first Latin American honoree in 2010 and again in 2011 – the only Latin American woman to be recognized for two consecutive years. She also received 1999 Distinguished Alumni Award from Austin College in Texas, and 2011 Medal and Leadership Award of Merit from the Universidad Anahuac Medical School (Only woman to receive this award). She is Honorary Editorial Board Member of the journal *Pharmaceutical Medicine* (2014).

mllopiz@hotmail.com