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Economic and regulatory scenario for biosimilars in Latin America

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The purpose of this presentation is to analyse the current biosimilars market opportunity in some South American countries and Mexico. Colombia, Mexico, Brazil, Argentina, Chile, Uruguay, Bolivia and Venezuela have their potential opportunities and challenges explored by the author.

Latin America is a very interesting region characterized by its cultural, socio economic and political diversity. It is reasonable to understand that its range of perspectives regarding the appropriate scenario for biosimilar regulation is precisely due to this diversity. Moreover, the Latin American regulatory scenario for biologics and biosimilars is changing too fast. Policies for reviewing and approving biosimilar drugs, including the desire to support local production capabilities for biosimilars make part of this analysis. These factors, coupled with the interaction of local thought leaders with the international community, contribute to the overall level of "Biosimilar Emphasis" that exists within each country.

Brazil, for example, has led the development and implementation of evolved biosimilar regulation within the region with its 2010 resolution RDC 55/2010 that created new regulatory pathways for new biologic products and similar biologic products. This Brazilian legislation is particularly unique within the region.The two pathway system coupled with governmental prioritization of local manufacturing capabilities in Brazil may promote increased biosimilar utilization within the country.

Many complex molecules will lose patent in the next few years, and the corresponding level of evidence required to sufficiently convince regulators to their approval is different in each country. The author will present and discuss some examples of intention copies currently marketed as biosimilars in this market and the amount of comparable safety and efficacy to evidence the biosimilarity to their reference molecules .The level of implementation of WHO guidelines, the size of market and the ideological bias that exists within the region regarding the appropriate threshold for regulatory requirements for biologics copies approval may impact to potential manufacturers interested on Latin America.

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