Generic and similar products in Latin American countries: Current aspects and perspectives on bioequivalence and biowaivers

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In the XIX and XX centuries, Latin American countries have experienced several changes on politics and economics, facing problems related to progress and growth, technological development, demographic transition, and the environment. In the 2010s this region presents a high level of health demands, which causes financial difficulties, especially in expenditures with medicines. In this scenario have emerged policies to regulate and harmonize the register of generic and similar products based on in vitro and in vivo assays that support therapeutical equivalence and interchangeability, but heterogeneity is still observed, especially in terms of the assessment criteria and time from application until marketing authorization. Data obtained from the pharmaceutical market predict that this segment could reach USD 1,200 billion by 2016, mainly from market expansion in the leading emerging countries and from generi