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**Biosimilars: Marketing, development, regulations and molecules approved in Australia, Brazil, Malaysia, Japan, Singapore and South Korea****Tomas Gabriel BAS**

Universidad Catolica del Norte, Chile

The expiration of patents for biological drugs will lead us to the golden age of biosimilars and provide a competitive edge to medium-sized pharmaceutical manufacturers and contract research organizations. Biosimilars are three-dimensional versions of biological products that share an identical protein sequence and common amino acid sequence with the originals (biological drugs) and have demonstrated a high degree of similarity in physicochemical characteristics, efficacy, safety (including immunogenicity) and quality, but with differences in their manufacturing process in the structure of the active protein. However, these biological medicines offer lower-cost alternatives to the original drugs. The paper reviews the literature on biosimilar drugs and covers their therapeutic status, approved biosimilars, and regulatory guidelines in Australia, Brazil, Malaysia, Japan, Singapore and South Korea. The literature suggests that biosimilars are comparable but not identical to the reference product. They are not a generic version of an innovative product and do not ensure therapeutic equivalence. Each country has its own regulatory guideline for biosimilar drugs.

**Biography**

Tomas Gabriel BAS is Director of Center of Innovation and Entrepreneurship and executive director of MBA at Universidad Catolica del Norte (Coquimbo) Chile. He was the director of Institute of Innovation based on Science, University of Talca (Chile). Director of Masters in Technology Management and Director of Masters in Technology Management with emphasis in Biotechnology from the same university in Talca. Manager founder and editor of scientific journal (SciELO) "Journal of Technology Management & Innovation" ([www.jotmi.org](http://www.jotmi.org)). Editor invited of the journal "BioMed Research International" (ISI). Director and co-director of national and international projects in Biotechnology and innovation and knowledge-based industries Natural Resources. Advisor to United Nations Economic Commission for Latin America (ECLA) in Biotechnology (Clusters, Public Policy, Technological Innovation Policy). Advisor to the World Bank in innovation and clusters in natural resources. Expert Advisory Committee on Assessment of Economics and Management of National Scientific and Technological Commission (CONICYT) Sciences. Expert Advisory Committee National Assessments and Scientific Technological Development Fund of Chile (FONDECYT).

[tomas.bas@ucn.cl](mailto:tomas.bas@ucn.cl)**Notes:**