

Strategies and innovation in biosimilar drug development, achievement and challenges – An Indian perspective

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Biosimilars or follow-on biologics are protein-based therapeutic products that are near identical (similar) and comparable to the branded therapeutic product. They have the same qualitative and quantitative composition as the reference biological drug but are not equivalent due to differences in the host cell strain, raw materials used, and the manufacturing process. While the entry of biosimilars into the regulated market like EU and US faces lot of regulatory challenges, they have thrived in developing markets with more relaxed regulatory regimes. Biosimilar versions of insulin, human growth hormone, interferons, erythropoietin, interleukin, G-CSF, GM-CSF, hepatitis B vaccine and other biotech products are generating sales in many developing markets, including China and India. The challenge for manufacturers which have developed products for these markets will be whether their standards comply with the more rigorous regulatory requirements of the EU and the US.

The business of Avesthagen Biologicals is focused on the development of a comprehensive range of internally developed cost-effective biosimilars and antibody therapeutics. We are focusing on the development of biosimilar versions of molecules in a wide range of therapeutic areas including oncology, cardiovascular, anemia, autoimmune disorders and arthritis for which the patent protection of the originator is either not valid for India and certain developing markets or is expected to expire during the course of development between 2012 and 2018. Our near-term focus is to launch these molecules in the Indian Market followed by the BRIC countries. Our long-term focus is to launch the products in the United States and Europe, once the relevant patents begin to expire.

Biography

Villoo Morawala-Patell is the Founder, Chairperson & Managing Director of Avesthagen Limited. She has obtained a bachelor in science from Osmania University, Hyderabad, a master in science from Bombay University, Mumbai and a doctor of philosophy in plant molecular biology from the University of Louis Pasteur, Strasbourg, France. She is a key member of the Task Force and Vision Group for Biotechnology, instituted by the Government of Karnataka and a founding member of the Association for Biotechnology Led Enterprises. Dr. Villoo has also received the Karamveer Puraskar from the Indian Confederation of Non-Governmental Organisations for her contribution in the field of agriculture and healthcare and the Adolfo Ibanez University Award for her achievements in innovation.

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