CHALLENGES

The biosimilars quality imperative

Author

Mr KV Subramaniam
President & CEO, Reliance Life Sciences, India

Mr KV Subramaniam is a Chemical Engineer from Madras University, India an MBA from the Indian Institute of Management, Ahmedabad and a Chartered Financial Analyst. In a career spanning 28 years with the Reliance Group and Indian Petrochemicals Corporation, he has been responsible for several functions – from corporate business development, corporate planning, project management and economic analysis to marketing; in a range of businesses – from petrochemicals, energy, alternative energy, infrastructure, insurance, education, health care and agriculture to life sciences.

GLOBAL biopharmaceutical industry sales exceeded $90 billion in 2009 with double-digit growth, which is expected to continue into the foreseeable future. This stellar performance needs to be seen in the backdrop of lackluster performance of the global pharmaceutical industry, which continues to struggle under the burden of significant reduction in innovation productivity, unprecedented loss of major blockbuster drugs and overall difficult global economic conditions.

The entry of biosimilars could pave the way for affordable therapies, consequently benefiting a larger patient population on a global basis. The biosimilars market in India is estimated at about $127 million (₹600 crore), while the US and EU markets for biosimilars are estimated to reach $21 billion by the year 2015.

India has the opportunity to be the biosimilars capital of the world. We have the basic endowment, in terms of competencies and capabilities, for attaining this stature. We have also made an impressive beginning, in comparison to other countries, with first generation biosimilars—insulin, interferon alpha, EPO, GCSF and TPA. Indian companies are also actively working on developing several biosimilar monoclonal antibodies and biobetter products. This beginning will gain momentum in terms of a wider range of products, higher scale of operations and greater participation in export markets.

However, to be a truly global leader in this space, India would have to focus on the quality of biosimilars, apart from developing human competencies and working to access regulated markets. Quality is also important from the perspective of India earning respect in the global biopharmaceutical industry and being able to access regulated markets.

One of the ironies in the Indian regulatory system is that Indian biosimilar developers and manufacturers have to go through a demanding evaluation process of the Institutional Biosafety Committee (IBSC) and the Review Committee on Genetic Manipulation (RCGM), while imported products do not pass through intensive scrutiny on quality. Healthcare service providers are also, by and large, not sensitive to quality aspects of biosimilars and their clinical consequences in terms of poor efficacy and immunogenecity.

The biosimilar industry also needs to lay a strong emphasis on quality of biosimilars, by focusing on the right sequence, having single cell clones and conducting extensive product characterization; including such critical aspects as purity, impurity profiles, host cell proteins, isoform analysis, and glycosylation patterns.

India cannot afford to miss the global opportunity in the biogenerics space. To become a global biosimilars leader, industry players, regulators and clinical practitioners must be sensitive to the quality imperative and place biosimilars quality at the top of their development agenda. BS

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