

Biogenerics-need for regulatory development in India

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Biogenerics are biological products manufactured after expiry of the patent of innovator biopharmaceuticals and these are also called as Biosimilars or “follow-on biologics”.

Globally, a large number of blockbuster bio therapeutic products are going off patent in the next few years. India has a robust pharmaceutical industry including the biopharmaceutical sector which is actively engaged in the production and marketing of biosimilar products. In the less regulated Indian market, there exist many biosimilars, despite the fact that no specific guidelines exist in India for their approval. Biologic drugs are more expensive and are ideal targets for developing cheaper alternatives. Several steps are still needed for India to be perceived as a country that leads the world in providing quality biological products. In India, the focus is primarily on the availability and affordability of life-saving drugs. In this context every product needs to be evaluated on its own merit irrespective of the innovator brand. The formation of the National Biotechnology Regulatory Authority may provide a step in the right direction for regulation of these complex molecules. However, in order to have efficient machinery for initial approval and ongoing oversight with a country-specific focus, cooperation with international authorities for granting approvals and continuous risk-benefit review is essential.

In this context attempts are made to find out the current and future market potential for biosimilar products in India. This also reveals the loopholes present in the regulations for controlling the biosimilar market. The next generation of more affordable biological medicines is no longer a distant dream in India, but a present-day reality in European healthcare.

Biography

Nagappagari Madhuri is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. She has completed her B. Pharm from JSS College of Pharmacy Mysore during the year 2012. Presently she is pursuing M. Pharm in Industrial Pharmacy in JSS College of Pharmacy Mysore. She has attended various national and international conferences. Her current areas of interest are formulation research and development, Novel drug delivery system.

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The evaluation of BA/BE impact on the Saudi national pharmaceutical industry

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According to our initial data the total drug consumption in Saudi Arabia is growing from around \$2.7 billion in 2008, to \$3.5 billion in 2011. An estimated 85% of these drugs are imported brand names and a small percentage of them are imported generics, while only 15% are expected to be local generics. Despite this overall growth, there is a lack of significant R&D in the local pharmaceutical industry. Very minimal research into bioequivalence and bioavailability has been and will remain a limiting factor to the growth of the local generic market portion. As demand will continue to increase with population growth, this increase will always favor imported brands, and this will increase the economic burden of importing pharmaceuticals.

The Saudi Food and Drug Authority (SFDA) and pharmaceutical companies are the major source of data. Collected data is used to calculate the total annual drug consumption in Saudi Arabia. The analyzed data is focused on comparing brand versus generic use, and on consumption by pharmacological classification.

Our discussion will focus on highlighting the benefits of conducting BA/BE business locally. We aim to extract useful recommendations of how to increase the market's share of local generics, as well as how this can lead to improving the generic drug industry, lowering cost effects, and creating more jobs. Furthermore, there is great opportunity to invest more on exporting drugs into the GCC and Middle East countries.

Biography

Rezk is the founder of the clinical pharmacology and analytical chemistry core laboratory at University of North Carolina at Chapel Hill. Honors include; the UNC Chancellor's award for innovation, and the State of North Carolina Governor's award for innovation in science. He acts as the PI for many HIV-research projects. Rezk published 36 papers in reputed journals and 32 scientific abstracts. Currently, Rezk is in charge of developing BE/BA unit and clinical pharmacology research center in KSA. His research interests include innovation in analytical chemistry and clinical pharmacology.