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Quality of biosimilars produced in developing countries

The first recombinant DNA-derived therapeutic proteins were introduced in 1980s. These were mainly copies of endogenous human proteins such as insulin. Although few molecules are available, annual total sales of biotechnology drugs amounted 71 billion $ in 2008) and knew a 17% progression per year. Biotechnological drugs have become an essential part of modern pharmacotherapy and are expected to exceed a 50% share in the pharmaceutical market in the next few years. Ever since the formation of the first biotechnology company more than three decades ago, almost 180 biopharmaceutical products have been marketed across the globe. The patency of the oldest of these biotechnology-derived products is now expired, as a result of which, the development of biosimilars increased. Some biosimilars have already gained approval in Europe and other countries such as USA. The challenging issues center on the intrinsic complexity of biopharmaceuticals, which are high-molecular weight three-dimensional structures and the heterogeneity of these recombinant proteins in most cases, produced in living cells by different manufacturing processes (i.e. differences in host cell, culturing, purification, formulation, nature of starting materials including stabilizers and other additives, and primary packaging. Biosimilars, unlike generic versions of conventional drugs, are not identical to their innovator product or to each other, and their complex production is sensitive to even slight changes in the manufacturing and storage conditions. Small changes in the manufacturing process can alter the product's efficacy, immunogenicity and safety.

Biosimilars increased access to these medicines at an affordable price in developing countries.

SEDICO is a biopharmaceutical company that got an opportunity to manufacture some of these biosimilars. SEDICO biotech products, such as insulin, erythropoietin, streptokinase, angiokinase, follicle-stimulating hormone (FSH), aprotinin, filgrastim (G-CSF) and somatropin (Growth Hormone), have been available in the market for more than seven years. In this article, some biosimilars which were tested and examined over years in SEDICO was chosen as a representative example of biotech products in south countries. Various analytical assays are used to study consistency of physicochemical and biological properties between production batches of a potentially similar biopharmaceuticals demonstrating the robustness of the manufacturing process and statistical quality-control. It is important to recognize the limits of existing assays so that the results can be accurately interpreted for market authorization. SEDICO ensured that its biopharmaceuticals have similar efficacy and safety profiles to the reference products through more extensive clinical trials than the limited testing done for generic versions of low molecular weight chemical medicines. The results confirmed that the quality of most of SEDICO biosimilars seems to be equal or better than the originals and at lower cost. Biosimilars provide cost savings and greater accessibility to biopharmaceuticals. A thorough knowledge surrounding biosimilars ensure the appropriate use of biopharmaceuticals.

Biography

Wael Ebied has completed his BPharm at the age of 23 years from Tanta University and postgraduate studies in Al Azhar University School of Pharmacy. He is the Senior Technical, QA & EHS Manager at SEDICO Pharmaceuticals and Products Transfer Project & LSS Team Leader for Merck & Co. External Partner. He has published some papers in reputed journals.

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