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# Production of biosimilars in developing countries: Challenges and opportunities: SEDICO case Study

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Control of chronic diseases is a major challenge for public health systems in developed and developing countries. However, high cost limited their use in developing countries. The expiration of the patents on many Biopharmaceuticals such as insulin, human growth hormone and erythropoietin opened the door for licensing these products as biosimilars. This might contribute to increased access to these medicines at an affordable price.

Unlike traditional generic pharmaceuticals, biosimilars (also called 'follow-on biopharmaceuticals' in the USA) aim to copy a complex recombinant, three dimensional protein structures with high molecular weight. According to the guidelines of the EMEA, extensive comparability testing will be required to demonstrate that the biosimilars has a comparable profile in terms of quality, safety and efficacy as the reference product. The pharmacologic properties of biological medicines depend on the production and purification processes. Therefore, Biosimilars differ from generic drugs. Only if their quality, efficacy, and safety are clearly documented biosimilars may be chosen because of their lower costs.

In a few years ago, SEDICO, "South Egypt Drug Industries Company", an Egyptian pharmaceutical company, biotech products were available in the Egyptian market such as "Insulin, erythropoietin, streptokinase, angiokinase, follicle-stimulating hormone (FSH), aprotinin, filgrastim (G-CSF) and somatropin (Growth Hormone)".

The results confirmed that SEDICO biosimilars can compete with the originator products in the Egyptian and some export markets with high quality challenge and lower cost opportunity.

The biosimilars of SEDICO qualify with respect to their authenticity, purity, quality, safety, efficacy, and immunogenicity. The primary reason for prescribing a biosimilar in developing countries is its lower price. SEDICO' recombinant proteins have been established in clinical use. SEDICO succeeded to supply biosimilars with accepted quality and with affordable prices.

SEDICO biosimilars were examined for its quality by analytical methods. The analytical tests to demonstrate comparability and similarity of EPO as a biosimilar product to a reference drug with respect to protein content, activity, physiochemical integrity and stability, as well as immunogenicity are discussed. Clinical studies and post-authorization pharmacovigilance will provide essential evidence for product quality. SEDICO Biotech products are clinically tested and trusted in multicenter studies performed in many universities and medical research units.

## 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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