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Biosimilars and non-innovator biotherapeutics in MENA region: Opportunities and challenges

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Abstract

Biotherapeutics are becoming popular for treating a wide range of life threatening diseases and representing a growing segment of pharmaceutical industry. These products are among the most expensive healthcare products. The use of biosimilars has the potential to reduce healthcare cost. The aim of the current work is to examine the regulatory framework for approving biosimilar products in the Middle East and North Africa (MENA) region and discuss the opportunity and challenging of biosimilars in this region.

MENA region can be considered as the most influential and attractive pharmaceutical markets among other emerging markets. The current study review, examine and compare regulatory guidelines for biosimilar products approval from Jordan and Saudi Arabia as an example from regulatory authorities in MENA. We examine the published guidelines from Saudi Food and Drug Authority (SFDA) and Jordan Food and Drug Administration (JFDA).

Health care expenditure in MENA region is increasing over the recent years and the pharmaceutical market is expected to grow to become one the leading region among emerging markets. All of MENA countries spent less that 10% of its GDP on health care expenditure. This percentage is expected to rise within the next few years to make the area more attractive for biosimilar investment. But the regulatory framework for biosimilar in most of these countries is still underdeveloped. Another challenge that will face biosimilar manufacturers is that the pricing strategy for biosimilars is not yet developed.

Biography

Ibrahim Aljuffali is an assistant Professor at the Department of Pharmaceutics, College of Pharmacy, King Saud University. Dr. Aljuffali earned his PhD degree from the University of Georgia (UGA). Dr. Aljuffali also earned a graduate diploma in Pharmaceutical & Biomedical Regulatory Affairs, graduate diploma in Clinical Trials Design & Management and currently is a candidate for a Master of Science Degree in Pharmacy with an *emphasis* in Regulatory Affairs from UGA. Dr. Aljuffali is currently the Director of Regulatory Science Research Unit, Vice Dean for Development and Quality and a Consultant to the President of Saudi Food and Drug Authority.