J Develop Drugs 2016, 5:4(Suppl)
http://dx.doi.org/10.4172/2329-6631.C1.021

Biosimilar regulation in GCC

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Biosimilars are the new forms of innovator biopharmaceutical products that are marketed after patent's expiration. These are generic versions of medicines obtained from various biological sources that depend on the same mechanism of action, and are used for the same therapeutic indication, as the innovator product. Regulatory agencies evaluate biosimilars based on their level of similarity to, rather than the exact replication of the innovator drug. On the other hand, generics pharmaceuticals are facing various hurdles due to strict regulations at various fronts. Because of tremendous scope in near future, the world is falling behind in the race to make copies of complex biotech drugs, which are expected to meet the huge demand as well generate billions of dollars in sales in the coming years. It has been emerged globally as one of the fastest growing development opportunities in the pharmaceutical sector. Many generic pharmaceuticals companies are switching their mode to biosimilar drugs. There is a tremendous increase in healthcare infrastructure in Gulf Cooperation Council (GCC) country. The increasing rate in neuropsychiatry disorder, cancer and various life-style related diseases in GCC region, it is expected that the total health-care expenditure in GCC country is expected to reach US $60 billion in 2025. However, implication of favorable policies, norms and regulations aimed at reducing industry price, profits and Foreign Direct Investment (FDI). This region also facing challenges like lack of specialized research and development, lack of enough expertise and safety issues. Therefore, GCC seems to be one of the hot destinations for gearing up to take next big jump on biosimilars.

A regulatory update on the US generic drug review and approval process following the implementation of 2012 generic drug user fee law

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It has been three years since the implementation of Generic Drug User Fee Amendment in US. Significant changes associated with a complete Over Half of generic drug review and approval process has since been implemented. Meanwhile, FDA has published many guidance documents to deal with filing and review procedures, organization of ANDA submission, and scientific requirements such as those for stability and impurities. At the same time, the formation of Office of Pharmaceutical Quality (OPQ) combined the quality reviews of new drugs, biotechnology products and generic drugs (Life Cycle Products) under a single organization and incorporated the manufacturing sciences and product surveillance into the review system. These changes under the concept of risk-based CMC reviews and GMP inspections and life cycle management present certain challenges to a generic drug company which plans to enter US generic market. The presentation will detail the changes implemented in the last three years and discuss their implications and common issues regarding how to prepare a good ANDA application.