J Bioequiv Availab, Volume 12

Challenges With Successful Commercialization Of Biosimilars

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Commercialization rights for novel therapeutic products are protected for a finite period by patents and other measures. After expiration of patents and other exclusivity rights, other manufacturers are allowed to make copies of these products, referred to as generics in the case of small-molecule pharmaceuticals and biosimilars in the case of biopharmaceuticals (1). Biosimilars are biological products that are highly similar to and have no clinically meaningful differences from an existing approved reference product (1). They offer improved affordability and are thus expected to have major impact on accessibility of biotherapeutics, including in developing and emerging economies. The global market value of biosimilars is expected to reach $36 billion by 2020 (2). Biosimilars are defined by the European Medicines Agency (EMA) as biological medicines that are highly similar to another already approved biological medicine (the 'reference medicine') (3). They are approved according to the same standards of pharmaceutical quality, safety, and efficacy that apply to all biological medicines. There are some key differences between the production of biosimilars and that of the traditional small-molecule generics. Capital investments, as well as operating costs associated with manufacturing of biosimilars, are significantly higher than that for small-molecule generics, along with the associated risk of failure. The heterogeneities are a result of the size and complexity of the molecules themselves, as well as activities in the host cell that is used to express the product, the bioreactor conditions under which the cells are grown, and the purification process utilized for generating the final product.

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