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Challenges With Successful Commercialization Of Biosimilars

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Abstract

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.

Biography:

Prof. Dr. Anil Batta is presently professor & Head with senior consultant in Govt. Medical College, Amritsar. He did his M.B.B.S. and M.D. in Medical Biochemistry from Govt. Medical College, Patiala in 1984 and 1991, respectively. His research interest is mainly in clinical application especially cancer and drug de-addiction. He has supervised more than 25 M.D., M.Sc. and Doctorate researches and published more than 130 international research papers. He is the chief editor of America's Journal of Biochemistry. He is also working as advisor to the editorial board of International Journal of Biological and Medical Research. He has been deputed member Editorial Board of numerous International & National Medical Journals of Biochemistry. He has also been attached as technical advisor to various national and international conferences in Biochemistry. He has been attached as hi-tech endocrinal, genetics and automated labs of Baba Farid Univ. of Health Sciences, Faridkot. He has chaired various sessions in

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