Biosimilars: Promising and Rapidly Emerging Biotherapeutics

Sonali Manwatkar and Bimlesh Kumar

Abstract The fastest-growing category of biopharmaceuticals is known as a "biosimilar," which refers to a biological medication that is replicated and sold at a lower price than the original biological product. Treatment with such biologics has additional benefits over conventional medication due to the involvement of a specific target, high efficacy, and fewer adverse effects. In addition to preventive use of biologics being used to avoid the return of the illness condition, diseases like cancer, autoimmune diseases, and inflammatory ailments can be cured. However, their exorbitant price places a heavy load on health care. Biosimilars are created as a result of the biologics' patents expiring, with the intention of giving more patients access to cutting-edge treatment at a reasonable price. Biosimilars are not only identical to the reference standard used by the original creator, but also very identical in terms of efficacy and safety. The WHO sets internationally recognized norms and criteria that are widely accepted for the assessment of biotherapeutics as part of its obligation to confirm the global safety, efficacy and quality of products. The regulatory agencies have put a high priority on safety, and the development process follows a step-by-step methodology that is thoroughly explained in this chapter. Global regulations are contrasted, and suggestions are made for developing at the lowest possible expense. To accelerate the development process, the key components to establishing biosimilarity are outlined, including analytical and bioanalytical characterisation, nonclinical testing, clinical pharmacology testing, and clinical efficacy testing. There is also a summary of FDA-approved products. The goal of the current chapter is to deliver a brief compilation of biosimilars, their process of manufacturing, regulatory requirements, and to discuss both their current and prospective future roles in the field of medical sciences/biotherapeutics.

S. Manwatkar (✉)
School of Pharmacy, Vishwakarma University, Pune 411057, India
e-mail: sonali.manwatkar@vupune.ac.in

S. Manwatkar · B. Kumar
School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab 144411, India
e-mail: bimlesh.12474@lpu.co.in

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