Understanding the Safety and Efficacy of Biosimilars

The Food and Drug Administration (FDA) defines a biosimilar agent as a "biological product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components." FDA's statement continues, that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."[1] There are currently 26 FDA approved biosimilar drugs[2] with more anticipated in the future. The Biologics Price Competition and Innovation Act (BPCI Act)[3], created an abbreviated approval process for a biological product that is demonstrated to be biosimilar to a reference product. The FDA approves a product as biosimilar by utilizing data derived from analytical, animal, and clinical studies.

According to the FDA, biosimilars can be used in patients who have previously been treated with the reference product (treatment-experienced), as well as in patients who have not previously received the reference product (treatment-naïve)[4]. Leading academic medical associations advocate for the use of biosimilar agents. In 2018 the American College of Rheumatology recommended biosimilar use, encouraging providers to incorporate these drugs into the treatment plans of patients with rheumatologic diseases where appropriate.[5] The American Society of Clinical Oncology (ASCO) published a statement, also in 2018 on biosimilar agents, supporting their use where clinical trials demonstrated sufficient evidence.[6]

Biosimilar agents are safe. The European Medicines Agency (EMA) first approved biosimilar drugs in 2006. After more than 10 years of post-marketing surveillance, there have been no reported differences in the safety profile of biosimilar agents compared with their originators. As healthcare expenditures rise, biosimilars represent a clear strategy to help control cost while maintaining quality. Medical professionals and patients need familiarity with biosimilars to assure confidence in their therapeutic equivalence.

The European Union pioneered the regulation of biosimilars since the approval of somatropin in 2006. Globally, there is extensive pharmacovigilance and experience proving safety and efficacy of these agents. Since 2006, there are more than 55 biosimilar agents approved in Europe and 26 biosimilar agents approved in the US.

What is a biosimilar?

Described by the US Food and Drug Administration (FDA), a biosimilar is "biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components." "There are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."[1]

Are biosimilars considered generic medications?

A biosimilar is not considered as a generic of a biological medicine. This is due to natural variability and complex manufacturing of biological medicines, which do not allow an exact replication.

How are biosimilar approved in the US?

The Biologics Price Competition and Innovation Act (BPCI Act), created an abbreviated approval process for a biological product that is demonstrated to be biosimilar to a reference product. Through this application process, the biosimilar product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure.[1]

How can we get more information?

Please go to www.centene.

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[1] US Food and Drug Administration. Scientific Considerations in Demonstrating Biosimilarity. URL: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product

[2] US Food and Drug Administration. Biosimilar URL: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

[3] US Food and Drug Administration. Prescribing Biosimilar and Interchangeable Products URL: https://www.fda.gov/drugs/biosimilars/prescribing-biosimilar-and-interchangeable-products#patients

[4] US Food and Drug Administration. Prescribing Biosimilar and Interchangeable Products URL: https://www.fda.gov/drugs/biosimilars/prescribing-biosimilar-and-interchangeable-products#patients

[5] Bridges SL Jr1, White DW2, Worthing AB3, Gravallese EM4, O'Dell JR5, Nola K. The Science Behind Biosimilars: Entering a New Era of Biologic Therapy. Arthritis Rheumatol. 2018 Mar;70:334-344. doi: 10.1002/art.40388.

[6] Lyman GH1, Balaban E1, Diaz M1, Ferris A1, Tsao A1, Voest E1, Zon R. American Society of Clinical Oncology Statement: Biosimilars in Oncology. J Clin Oncol. 2018 Apr 20;36:1260-1265. doi: 10.1200/JCO.2017.77.4893.

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