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.” There are currently 26 FDA approved biosimilar drugs with more anticipated in the future. 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. 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). 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. 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.

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.