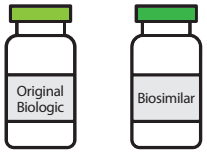
Understanding the Safety and Efficacy of Biosimilars

The Food and Drug Administration (FDA) takes the same precautions to ensure the safety and effectiveness of biosimilars as it does for all medications. For biologics, as with all medication approvals, data provided by pharmaceutical companies is carefully reviewed and steps are taken to make certain that all biosimilars meet standards for patient use. Health care providers and patients can rely on biosimilars to be as safe and effective as their original biologics.[1]

The Biologics Price Competition and Innovation Act (BPCI Act) created an abbreviated pathway through which biosimilars can be evaluated and approved by the FDA. Through this application process, the biosimilar product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product against which the biosimilarity of the proposed biosimilar is being demonstrated. This process helps reduce the time and cost of development without compromising safety and effectiveness, providing patients with greater access to medication options, often at a reduced cost.[1,2]

Before approving a biosimilar, FDA: [1]

Carefully reviews data, studies, and tests to decide whether a biosimilar meets FDA's high standards for approval



Ensures that manufacturers show that there are no differences in side effects, including that the side effects of the biosimilar are not more frequent or more severe than those of the original biologic

After approval, FDA:

Continues to check on the quality of the biosimilar production

Reviews reports from patients and health care providers on the biosimilar's safety and effectiveness

1 US Food and Drug Administration. Biosimilars: What Patients Need to Know. URL: https://www.fda.gov/media/166334/download#:~:text=Biosimilars%20are%20safe%20and%20effective.&text=Patients%20and%20health%20care%20providers,it%20does%20for%20all%20medications.
2 US Food and Drug Administration. Review and Approval. URL: https://www.fda.gov/drugs/biosimilars/review-and-approval
3 US Food and Drug Administration. Overview Health Care Professionals. URL: https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals

What is a biosimilar?

Described by the US Food and Drug Administration (FDA), a biosimilar is a "biologic medication that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biologic, called a reference product."[3]

Both a biosimilar and its original biologic:

- Are made from the same types of sources (e.g., living sources)
- Provide the same benefits when treating diseases or medical conditions
- Are given at the same strength and dosage
- Are not expected to cause new or worsening side effects[1]

Are biosimilars considered generic medications?

No. Biologics generally cannot be copied exactly because the products usually contain a mix of many slight variations of a protein, and this mix is never exactly the same in each dose or batch of the product.[3]

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