

Biosimilars: Myths vs. Facts

Myth

Biosimilars are the same as generics.

Fact

Generics & biosimilars are both alternatives to brand-name reference products. However, the active ingredients of generics are identical to those of to their reference products, while **biosimilars are highly similar** to theirs.¹ Because biosimilars are not identical to their reference products, they go through a different process for approval.²

Biosimilars are alternatives to their reference biologic products and they are produced from living organisms and are generally large and complex molecules.¹



Myth

Biosimilars aren't as safe or effective as reference products.

Fact

Biosimilars **undergo testing** to demonstrate:³

- compared to the reference product
- the originator biologic product

Biosimilars are monitored as part of post-market surveillance to evaluate safety.³



Myth

Biosimilars cannot impact health care system costs.

Fact

Biosimilars create competitive pricing for biologics, helping to potentially:⁴

- **Reduce** health care system costs
- Increase access to biologic medicines



Biosimilars add to the high costs already burdening the health care system.

Fact

Since the FDA passed the Biologics Price Competition and Innovation Act, biosimilars saved the US health care system over \$37 billion and have the potential to save an estimated \$104 billion from 2020-2024.5



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References: 1. US Food and Drug Administration. Biological product definitions. Accessed May 10, 2021. https://www.fda.gov/files/drugs/published/Biolog uct-Definitions.pdf 2. Scientific considerations in demonstrating biosimilarity to a reference product. FDA Web site. Accessed May 10, 2021. www.fda.gov/downoads/drugs/guidances/ucm291128.pdf 3. US Food and Drug Administration. What is a Biosimilar? Accessed May 10, 2021. https://www.fda.gov/media/108905 4. US Food and Drug Administration. Biosimilars action plan: balancing innovation and competition. July 2018. Accessed April 28, 2021. https://www.fda.gov/media/114574/download 5. Aitken M, Kleinrock M, Muñoz E. Biosimilars in the United States 2020–2024: competition, savings, and sustainability. IQVIA Institute for Human Data Science report. September 29, 2020. Accessed April 28, 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-inthe-united-states-2020-2024

• No clinical meaningful differences in **safety**, **purity and potency**

• That it's designed to **work in the body in the same** way as