

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 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

- No clinical meaningful differences in **safety, purity and potency** compared to the reference product
- That it's designed to **work in the body in the same** way as 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



Myth

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

