Biosimilars improve patient access to quality medicines

What are biosimilars?

A biosimilar is a biologic* that is very similar to another biologic that's already FDA-approved, called a **reference product**. A biosimilar must also not have any clinically meaningful differences from the reference product.

The use of biosimilars is quickly expanding, **giving more patients access** to quality treatment options for chronic and serious conditions, including **cancer, diabetes, arthritis, and chronic skin, and bowel diseases**.

Although biosimilars may be priced lower than biologics, the **lower cost does not indicate a lower quality product**.

A biosimilar and its reference product have the same:

Dosage form, route and frequency of administration

Strength

Treatment risks and benefits

Quality requirements

Key Stats[1]:

2015
First biosimilar was FDA approved

60+
Biosimilars approved for patient use in the U.S.**

$36 billion
Saved for healthcare systems since the first biosimilar approval

2.7 billion
Days patients have taken biosimilar therapies

Similar to generic drugs, biosimilars may offer patients more affordable treatment options with the same quality when compared to brand name biologics.

Biosimilars are approved for many biologic reference products,[2] including:

- Actemra
- Avastin
- Epogen/Procrit
- Enbrel
- Eylea
- Humira
- Herceptin
- Lantus
- Lucentis
- Neulasta
- Neupogen
- Prolia and Xgeva
- Remicade
- Rituxan
- Soliris
- Stelara
- Tysabri

*Biological products, or biologics, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available. Biologics include a wide range of products such as vaccines, monoclonal antibodies, blood components, allergenics, gene therapy, tissues, and proteins.

**Number of approved biosimilars as of August 2024.

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Quality supports the safety and effectiveness of biosimilars

Biosimilars meet the same quality standards as their reference products and are tested in accordance with the Current Good Manufacturing Practice regulations enforced by FDA.

What does it mean if a biosimilar is interchangeable?

Both biosimilars and interchangeable biosimilars must meet the FDA's requirements for biosimilarity – that they are highly similar and have no clinically meaningful differences from a biologic already approved by the FDA.

The main difference is that an interchangeable biosimilar can be substituted for a reference biologic by the pharmacist without consulting the prescribing doctor, depending on the state law. A biosimilar typically has to be prescribed by name.

Clinical evidence regarding biosimilars indicates that biosimilars and interchangeable biosimilars both meet the same high standards for quality and have the same safety and effectiveness as the reference product. Research shows patients respond more positively when their health care providers notify them about changes to their medication combined with patient-centered education about biosimilars.

What steps help ensure quality biosimilars?

Extensive research and comparative studies by the manufacturer to demonstrate high similarity to the reference product.

FDA review of data and information required for approval of a biosimilar.

Studies directly comparing the biosimilar to the reference product to demonstrate no clinically meaningful differences in safety, purity, and potency (safety and effectiveness).

FDA inspections of the biosimilar manufacturing facilities.

Post-market safety surveillance by FDA and biosimilar manufacturers.

Speak with your pharmacist or healthcare provider today about available biosimilars.

Learn more:

https://www.usp.org/biologics/biosimilars

www.fda.gov/drugs/biosimilars/patient-materials

Reference:

[1] https://accessiblemeds.org/resources/blog/2024-savings-report

[2] https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024

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