Myths vs. Facts About Biosimilars

For Medical Professionals

WHAT ARE BIOSIMILARS?

A biosimilar is a medicine that is highly similar to a brand biologic medicine. There are 20+ FDA-approved biosimilars[1] helping patients with common but difficult-to-treat diseases including cancer, arthritis and other inflammatory diseases. 60+ more biosimilars are in development.[2,3]

Biosimilars are safe, effective alternative versions of existing brand biologic medicines (known as "reference products") with scientifically comparable quality, safety and effectiveness. Biologic medicines are expensive for patients, taxpayers and insurers. Biosimilars provide important competition, which can help lower costs and increase patient access to lifesaving medications.

MYTHS	FACTS
"Biosimilars are less safe for patients than brand biologics."	Biosimilars undergo **rigorous FDA testing, review and safety monitoring**. The biosimilars development process is complex and companies that manufac-ture biosimilars are committed to providing safe, effective products to patients. To obtain FDA approval, the route of administration, dosage form and strength of the biosimilar and biologic medication must be the same.
"Biosimilars aren't as effective as brand biologics."	**A biosimilar drug will work as safely and as effectively as a biologic drug.** Patients in Europe have used biosimilars for 10+ years, resulting in more than 700 million days of safe, effective use.[4]
"Biosimilars won't save patients that much money."	Experts estimate that biosimilars will be priced 10 to 35 percent less than their brand-name drug competitors.[5] This means patients could save as much as **$54 billion** in the next decade.[6]
"Biosimilars that are interchangeable are better than normal biosimilars."	An interchangeable biosimilar has simply met additional FDA standards requirements. These additional standards do not mean that the interchangeable product is better or of a higher quality product than an FDA approved biosimilar.[7]

References

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