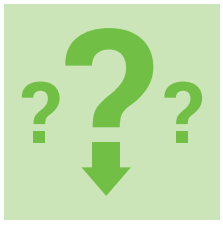
Myths vs. Facts About Biosimilars
For Policymakers

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 manufacture biosimilars are committed to providing safe, effective products to patients. Biosimilars are a natural evolution of the biopharmaceutical lifecycle, benefiting significant evidence out of Europe.	
"Biosimilars aren't as effective as brand biologics."		**10+ years** Patients in Europe have used biosimilars for 10+ years, resulting in more than 700 million days of safe, effective use.[4]	
"Since the first biosimilar was introduced, biosimilars have done little to drive down the cost of reference biologics."		While the biosimilars market continues to develop, markets in which biosimilars have entered indicate that biosimilar products are launching at a significant discount to their branded reference product.[5]	
"Biosimilars are like generic drugs. They are not innovative and cost little to develop."		Biosimilars development programs cost between $100 and $300 million dollars, and often require the biosimilar developer to reverse engineer the proprietary manufacturing processes used to develop the reference product. Biosimilar manufacturers create their own innovative processes for producing their biosimilar.[6]	

References

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