Biosimilar FAQ's

What is a biosimilar?

A biosimilar is a biologic medication that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biologic (aka reference product).

- Examples of biologics and their biosimilars include:
  - Humira (adalimumab) and Amjevita (adalimumab-atto)
  - Lantus (insulin glargine) and Semglee (insulin glargine-yfgn)

To be approved by the FDA, a biologic reference product goes through a rigorous process to ensure safety, efficacy, and quality. Biosimilars go through a similar, yet abbreviated process. In this approval process, a proposed biosimilar is compared and evaluated against an already approved biologic product. A biosimilar is only verified if it is highly similar and has no clinically meaningful difference in safety, purity, and potency compared to its reference product.

Are biosimilars generics for biologics?

Biosimilars and generic products are similar in the sense that they are generally more affordable than their reference or brand name product. However, generic drugs are typically smaller and simpler, which ultimately makes them easy to replicate. Since biologic products are not perfectly reproducible due to their variations in proteins, a biosimilar will not perfectly match its reference product each batch.

Biosimilars and their reference products:

- Are made with the same type of living sources (e.g., animal cells)
- Are given to the patient in the same way (e.g., autoinjectors or prefilled syringes)
- Are provided in the same doses and strengths
- Provide the same potential for treatment benefits
- Carry the same potential side effects.

What is an interchangeable biosimilar?

Per the FDA, two drug products are considered to be bioequivalent if they are equal in the rate and extent of which the active ingredient is available at its site(s) of action.

Interchangeable biosimilars are biosimilars that are required to meet further requirements by the FDA. Not all biosimilars have an interchangeable biosimilar. The manufacturer of the proposed interchangeable biosimilar must provide data that it is as efficacious and safe.

An interchangeable biosimilar can be substituted by a pharmacist without the intervention of the prescribing health care provider.

When is it appropriate to use a biosimilar?

Biosimilars may be utilized in patients who have never received a reference product (treatment naïve), as well as in patients who have been treated with a reference product (treatment experienced).

Where can I find additional information?

The FDA Purple Book database provides information regarding all FDA-approved biological products, including reference products and their licensed biosimilar and interchangeable products. https://purplebooksearch.fda.gov/

References:

https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals

https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices

https://www.fda.gov/animal-veterinary/abbreviated-new-animal-drug-applications/bioequivalence