NORTH Dakota | Health & Human Services
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What are biosimilars?

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

Human pharmacokinetic and pharmacodynamic studies comparing a proposed product to the reference product are generally fundamental components to demonstrate similar exposure, efficacy, and safety.

Should I be concerned about using a biosimilar?

Biosimilars can be considered the equivalent of another lot of their reference product since even reference products vary from lot-to-lot. Switching between reference products and biosimilars and among biosimilars is no different than is switching from lot-to-lot of a reference product over time. Switching or substitution should not cause concern to patients or health care providers.

As part of the approval process, the FDA assesses the manufacturers' strategies to control for the pattern and degree of variations between different lots of the biological product to keep a consistent mix of variants between the lots to help ensure consistency in safety and effectiveness.

Biosimilar products can be used in patients who have previously been treated with the reference product or used in patients that have not previously been treated with a biologic. Biosimilars are expected to generally have the same type and amount of immunogenic response as the reference product, so if the patient does not respond to the biologic or develops anti-drug antibodies, then the same can be expected with the corresponding biosimilar or reference product.

What is the difference between a biosimilar and a generic?

In contrast to a chemical, which is synthesized and can be exactly copied, a biologic medication is made from living sources creating a natural variability that occurs in both biosimilars and the reference product and cannot be exactly copied. Because of this, the information needed to demonstrate that a biologic is biosimilar to another biologic can be much more extensive than what is needed for a generic.

How can I help my patients with the transition to a biosimilar?

Physicians, nurses, and pharmacists play essential roles in consistent education regarding biosimilars to patients, which is crucial in reducing the nocebo effect and improving acceptance of biosimilars.

Prevent the nocebo effect – provide reassurance that they can expect the same safety and effectiveness from the biosimilar over the course of treatment as they would with the reference product and discuss why the change is happening (i.e., reduced cost to the health system).

What references are available to help my staff and my patients understand biosimilars?

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

https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

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