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Biosimilars, interchangeable biological products provide safe, effective treatment options

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Biosimilars are safe and effective biological medications that have met the Food and Drug Administration's (FDA's) rigorous approval standards. These medications can provide more treatment options for patients, increase access to lifesaving medications and potentially lower health care costs through competition.

Biosimilars have been approved to treat pediatric conditions, including juvenile idiopathic arthritis, type 1 diabetes mellitus, Crohn's disease and ulcerative colitis.

Biological products, or biologics, generally are large, complex molecules made from living sources such as bacteria, yeast and animal cells. They are different from drugs, also called small molecules, that are made through chemical synthesis, like aspirin.

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved biologic, called a reference product. Biosimilars are made using the same types of sources, are administered the same way and have the same strength, dosage form, treatment benefits and potential side effects as the reference product.

A biosimilar may be used in patients who previously were treated with the reference product (treatment experienced) and in patients who have not received the reference product (treatment naïve).

A biosimilar that meets additional FDA requirements may be approved as an interchangeable biosimilar. Similar to generics, interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, depending on state pharmacy laws. The additional information helps FDA determine that patients can be switched back and forth between the reference product and the interchangeable product without an increase in safety risks or diminished effectiveness. However, this does not mean interchangeable biosimilars are safer or more effective than other biosimilars.

As of November 2021, the FDA had approved biosimilars for 11 reference products: Avastin (bevacizumab), Enbrel (etanercept), Epogen (epoetin-alfa), Herceptin (trastuzumab), Humira (adalimumab), Lantus (insulin glargine), Lucentis (ranibizumab), Neulasta (pegfilgrastim), Neupogen (filgrastim), Remicade (infliximab) and Rituxan (rituximab). In addition, two biosimilars have been approved as interchangeable: Semglee (insulin glargine-yfgn) as interchangeable with Lantus (insulin glargine) and Cyltezo (adalimumab-adbm) as interchangeable with Humira (adalimumab).

The FDA's Office of Pediatric Therapeutics (OPT), Division of Pediatric and Maternal Health (DPMH) and Office of Therapeutic Biologics and Biosimilars (OTBB) contributed to this article. OPT resides in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH resides in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM). Both ORPURM and OTBB reside within the Office of New Drugs in the Center for Drug Evaluation and Research.

Resources

- FDA's biosimilar resources for health care professionals
- FDA's *Purple Book: Database of Licensed Biological Products*