Biosimilars Info Sheet

Level 1: Foundational Concepts

Biological Products, Biosimilar Products, and Interchangeable Biosimilar Products

What Are Biological Products?

Biological products (also called biologics) are regulated by the U.S. Food and Drug Administration (FDA) and are used to prevent, treat, and cure diseases and medical conditions. Biologics are a diverse category of products and are generally large, complex molecules. Biologics may be produced through recombinant DNA technology in a living system, such as microorganisms (like yeast or bacteria) or animal cells, and are often more complicated to characterize than small molecule drugs. There are many types of biologics approved for use in the United States, including growth factors (such as filgrastim), hormones (such as insulin), monoclonal antibodies (such as adalimumab), and vaccines (such as those for influenza and tetanus) that treat many conditions. Biologics include reference products, biosimilar products (also called biosimilars), and interchangeable biosimilar products (also called interchangeable biosimilars) **(Figure 1**).

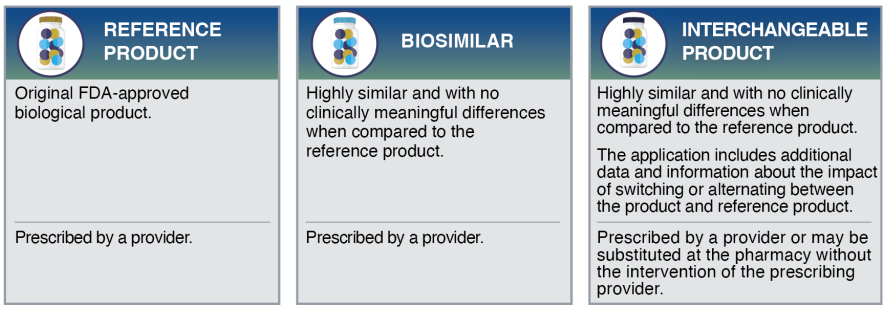

Figure 1: Descriptions of Reference, Biosimilar, and Interchangeable Products

What Is a Reference Product, and How Is It Related to a Biosimilar?

A **reference product** is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable biosimilar is compared. A reference product is approved based on, among other things, a full complement of safety and efficacy data.

A **biosimilar** is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product. A proposed biosimilar is compared to and evaluated against a reference product using techniques that evaluate key characteristics such as purity, molecular structure, and bioactivity. Clinical studies are conducted comparing the proposed biosimilar and the reference product to show that there are no clinically meaningful differences in terms of safety, purity, and potency (i.e., safety and effectiveness).

What Is an Interchangeable Biosimilar?

An **interchangeable biosimilar** is a biosimilar that the FDA has concluded meets the standards for interchangeability. These standards include:

- The interchangeable biosimilar can be expected to produce the same clinical result as the reference product in any given patient, and
- The risk in terms of safety or diminished efficacy of alternating or switching between the interchangeable biosimilar and the reference product is not greater than the risk of using the reference product without such alternation or switch.

A biosimilar manufacturer must specifically seek approval for an interchangeable biosimilar product. A product approved as an interchangeable biosimilar means that it may be substituted for the reference product at the pharmacy without the intervention of the prescribing health care provider, subject to state pharmacy laws. Health care providers do not need to wait for a biosimilar to be approved as an interchangeable biosimilar before prescribing a biosimilar. All biologics are approved only after they meet FDA's rigorous approval standards; thus, health care professionals and patients can be confident in the safety and effectiveness of a biosimilar, whether or not it has also been approved as an interchangeable biosimilar, just as they would be for a reference product.