



4 Facts About Biosimilars

Biosimilars are FDA-approved medications that are safe and effective for the treatment of many conditions.



1. Biologic medications are generally made from natural and living sources, such as humans, animals, plants, bacteria, or yeast.

Because biologics come from natural sources, they are usually more complex and are more complicated to produce than drugs made from chemicals. Common drugs, such as aspirin, are made from chemicals. The Food and Drug Administration (FDA) has approved several types of biologics to treat many illnesses, such as chronic skin and bowel diseases, arthritis, kidney conditions, and cancer.



2. A biosimilar is a type of biologic medication that is compared to an original biologic already approved by FDA (also known as a reference product).

A biosimilar is generally made from the same type of natural sources as the original biologic, provides the same benefits when treating disease, is given at the same strength and dosage, and causes no new or worsening side effects as the original biologic. The terms “reference product” or “original biologic” refer to the FDA-approved biologic that the biosimilar is compared to. Studies have shown that biosimilars have no major differences in their safety and effectiveness compared to the original biologics. Because all biologics, including biosimilars, are made from living sources, it is normal for natural differences between each batch of medication to occur during the production process. This means that no biologic can be an exact copy. Biosimilars are very similar, but not identical, to the original biologics. FDA carefully reviews the differences before approving biosimilars.



3. An interchangeable medication is a type of biosimilar that can be substituted at the pharmacy. Like other biosimilars,

interchangeables could potentially lead to increased access and lower costs for patients. Unlike typical biosimilars, these medications may be used for the treatment of chronic conditions at home instead of a hospital, infusion center, or doctor’s office. As with the substitution of brand name drugs for generics, the ability to substitute without a prescription can help lead to lower costs for patients. An interchangeable is not safer or more effective than a biosimilar that is not interchangeable. Rather, it simply means that a company has taken additional efforts to meet the standard for its proposed biosimilar to be made interchangeable and has received approval from FDA.



4. Biosimilars, including interchangeables, are safe and effective. FDA carefully

reviews data, studies, and tests to decide whether a biosimilar meets the high standards for approval. As it does with all medications, FDA checks the quality of biosimilars during the production process and reviews reports from patients and health care providers on safety and effectiveness after approval. But before biosimilars are approved, manufacturers must show that the side effects are the same and are no more frequent or severe than those of the original biologic. Patients and health care providers can rely on a biosimilar to be as safe and effective as the original biologic.

For more information on biosimilars, visit

www.FDA.gov/biosimilars

and talk to your doctor to learn more.

