



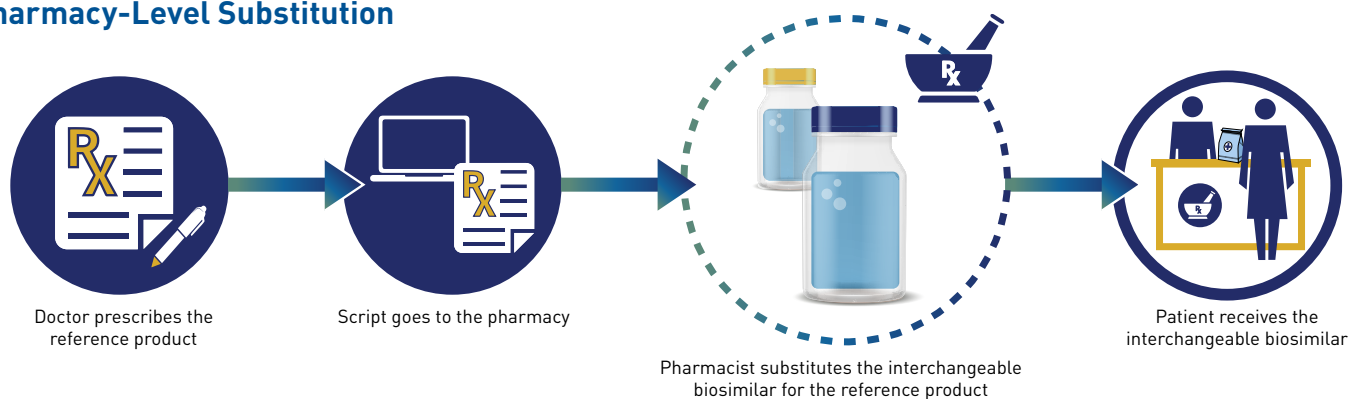
# Interchangeable Biological Products

An interchangeable biological product is a biosimilar that meets additional requirements and may be substituted for the reference product at the pharmacy, depending on state pharmacy laws. Interchangeable biological products (also called interchangeable biosimilars or interchangeable products) may help increase patient access to biologics.

## Interchangeable Biosimilars

- An interchangeable biosimilar may be substituted at the pharmacy for the reference product without the intervention of the prescribing health care provider — much like how generic drugs are routinely substituted for brand-name drugs.
- Not all biosimilars are interchangeable. Companies must submit an application with adequate information to support an interchangeability determination for their product to be approved as an interchangeable biosimilar.

## Pharmacy-Level Substitution



## Interchangeable Biosimilar Approval Process

- Unlike a reference product, which is approved in a standalone application, all biosimilar and interchangeable biosimilars are approved through an abbreviated pathway that compares the product to the reference product to show biosimilarity.
- For approval as an interchangeable biosimilar, manufacturers must provide additional data that reflect how the interchangeable biosimilar may be used in the marketplace with patients. Like generic drugs, patients receiving their medications through their pharmacies may switch between a brand-name biologic and an interchangeable biosimilar.
- To assess the safety of switching, manufacturers generally conduct studies in which patients alternate between the reference product and the interchangeable biosimilar and compare those patients to patients who are just being treated with the reference product. The results must show no decrease in effectiveness or increase in safety risk associated with switching.
- While this additional information helps FDA to determine the safety of pharmacy-level substitution, this does not mean that an interchangeable biosimilar is safer or more effective than other biosimilars.

All biological products are approved only after they meet FDA's rigorous approval standards, so health care professionals and patients can be confident in the safety and effectiveness of a biosimilar product, whether or not it has also been approved as an interchangeable biosimilar, just as they would be for a reference product.

Explore FDA's biosimilar resources for health care professionals at [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars).