



BIOSIMILARS vs. GENERICS

As more biosimilars come to clinic, policies must ensure that patients can access these new drugs, the resulting health benefits and potential for financial savings.

At a glance, biosimilars may seem comparable to generic drugs. But policymakers must understand the differences between small-molecule drugs and biologic medicines as they make informed decisions that are in patients' and providers' best interests.

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BIOSIMILARS

Biological medications are complex drugs that are manufactured from living sources, such as microorganisms and tissues.

Biosimilars are biological medications based on innovator biologics.



They're both treatments created based on another medication.

- Are derived from living sources
- Are not identical to the innovator biologic
- Have no clinically meaningful difference from their innovator biologic
- Are often injected or infused
- Look very similar to their reference biologic, other than a different label
- Have a different name than their reference product because they are a different product



The approval pathway for biosimilars was established by the:

**Biologics Price Competition
and Innovation Act
2010**

This legislation established an application pathway for biosimilars, recognizing they are not generics. It also solidified the biological medication regulatory process.



GENERICS



A generic is a chemical medication that is the same as an existing brand-name drug.

It has the same active ingredients, works the same way and provides the same clinical benefit.

- Are chemical
- Are identical to the brand-name drug
- Are an equal substitute for their brand-name counterpart
- Are typically taken orally
- May look completely different than their reference product
- Have the same non-proprietary name as their reference product because, on a molecular level, they are the same product

The approval pathway for generics was established by the:

**Hatch-Waxman Act
1984**

This act created an abbreviated new drug application, given that generics are the same as their brand-name product.

BIOSIMILARS vs. GENERICS

Similar, Not the Same

The nature of biological medications and how they're created means that there's is no such thing as a "biogeneric." A biosimilar can never be an exact replica of its innovator product. But these drugs, once approved, are still proven to be clinically safe and effective when prescribed.

Much like generics, biosimilars can treat a wide variety of conditions. All treatment decisions, however, should be carefully considered by both patient and provider.

Making the Swap

Because the active ingredients are identical, generic medications can be substituted out for a patient's brand-name medication by the pharmacist without approval from the prescribing clinician. However, in most cases, switching from an innovator biologic to a biosimilar requires approval from the prescribing clinician. The exception is interchangeable biosimilars.

But not all biosimilars are considered interchangeable. To become interchangeable, biosimilars must undergo further testing and meet additional requirements set by the FDA. All 50 states have passed legislation that allows interchangeables to be substituted for the innovator biologic at the pharmacy level without the prescribing clinician's involvement. This process is comparable to pharmacists switching out a patient's brand-name prescription for the generic.

Shaping Policy

As policies regarding biosimilars continue to take shape, policymakers must understand what makes biosimilars different from generics. Whether it's making treatment decisions or crafting biosimilar policies, involved parties should carefully weigh their options to identify the best path forward.

