

Biosimilar Drugs: Your Questions Answered

If you are taking a biologic drug, you may have heard about “biosimilars,” or copies of biologic drugs. Biosimilars that have been approved by Health Canada are safe and effective, but they are different from ordinary copies of brand drugs known as generic drugs. Here’s what you need to know.

What are biologic drugs?

Biologic drugs, also called biologics, are made using human or animal tissue or micro-organisms as a starting material.

What is a biosimilar drug?

A biosimilar is a copy of a biologic drug. In Canada, biosimilars were previously known as subsequent entry biologics (SEBs).

Is a biosimilar comparable to the original biologic drug?

Yes. It is not an exact copy, but it is highly similar. Before a biosimilar can be sold in Canada, its manufacturer must prove to Health Canada that it is highly similar to the original drug, including its effectiveness and safety profile.

Are biosimilars safe and effective?

Yes. Health Canada reviews and approves all drugs before they can be sold in Canada.

Health Canada also has rules about how all drugs are manufactured. All companies selling drugs in Canada must follow the same rules for the manufacturing process and for ensuring the quality of their ingredients.

What are the benefits of biosimilars?

Biosimilars can increase access and choice for patients. As manufacturers compete with each other to make similar products at lower costs, biosimilars create savings that can be used elsewhere.

Why do biosimilars cost less than biologics?

A company must spend many years studying a new drug before it can be approved for sale in Canada. The company then holds a patent on the drug that prevents other companies from selling that product. This allows the first company to earn back the

money it spent on bringing the product to market. When the patent expires, other companies are allowed to make copies of the drug. Companies that make copies of other drugs typically do not have the same costs to bring the product to market and can therefore offer it at a lower price.

If a biologic is available for one of my drugs, should I switch?

It depends. Your pharmacist cannot automatically substitute a biosimilar in the same way that they can substitute a generic drug. However, you and your care team may decide together that switching is an option in your specific case. Maybe you are starting on the drug for the first time, or maybe you are doing well and are closely monitored, or there could be any number of reasons why switching might or might not make sense for you.

Where can I find more information?

Health Canada provides detailed information on its website. A guidance document explains how biosimilars are approved and details the information that manufacturers must submit. A **fact sheet** provides further information on key issues.

Bottom Line:

- Biosimilars are highly similar to the original biologic drug in safety and efficacy, but are not exactly the same.
- Switching to a biosimilar may be an option for many patients. You and your care team should consider your specific situation when deciding to switch.
- Biosimilars offer a choice for patients and save money that can be spent elsewhere.

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