

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 biosimilar is available for one of my drugs, should I switch?

Biosimilar drugs are effective and safe. So, if you switch, you can expect the same benefits and potential side effects from the biosimilar as from the original biologic drug. Speak to your care team if you have any questions about switching.

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 is an option for most patients.
- Biosimilars offer a choice for patients and save money that can be spent elsewhere.

Questions or comments about CADTH or this tool?



Online:
cadth.ca



Email:
requests@cadth.ca



Twitter:
[@CADTH_ACMTS](https://twitter.com/CADTH_ACMTS)



New at CADTH Newsletter:
cadth.ca/subscribe

DISCLAIMER

This material is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose; this document should not be used as a substitute for professional medical advice or for the application of professional judgment in any decision-making process. Users may use this document at their own risk. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not guarantee the accuracy, completeness, or currency of the contents of this document. CADTH is not responsible for any errors or omissions, or injury, loss, or damage arising from or relating to the use of this document and is not responsible for any third-party materials contained or referred to herein. Subject to the aforementioned limitations, the views expressed herein do not necessarily reflect the views of Health Canada, Canada's provincial or territorial governments, other CADTH funders, or any third-party supplier of information. This document is subject to copyright and other intellectual property rights and may only be used for non-commercial, personal use or private research and study.

ABOUT CADTH

CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs and medical devices in our health care system.

CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

April 2021