Transition Pathway Brochure for IBD Patients

Helping inflammatory bowel disease (IBD) patients best understand transitioning/switching from a reference biologic to a biosimilar

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This brochure was created by the Canadian Digestive Health Foundation, in collaboration with health care professionals.

CDHF Canadian Digestive Health Foundation

Biosimilars in Canada

What is a biosimilar?

A biosimilar is a drug proven to be highly similar to its reference biologic and has been authorized for sale in Canada.

Biosimilars can only come to market after the 20-year patient protection on a reference biologic drug has ended.

Are biosimilars the same as reference biologics?

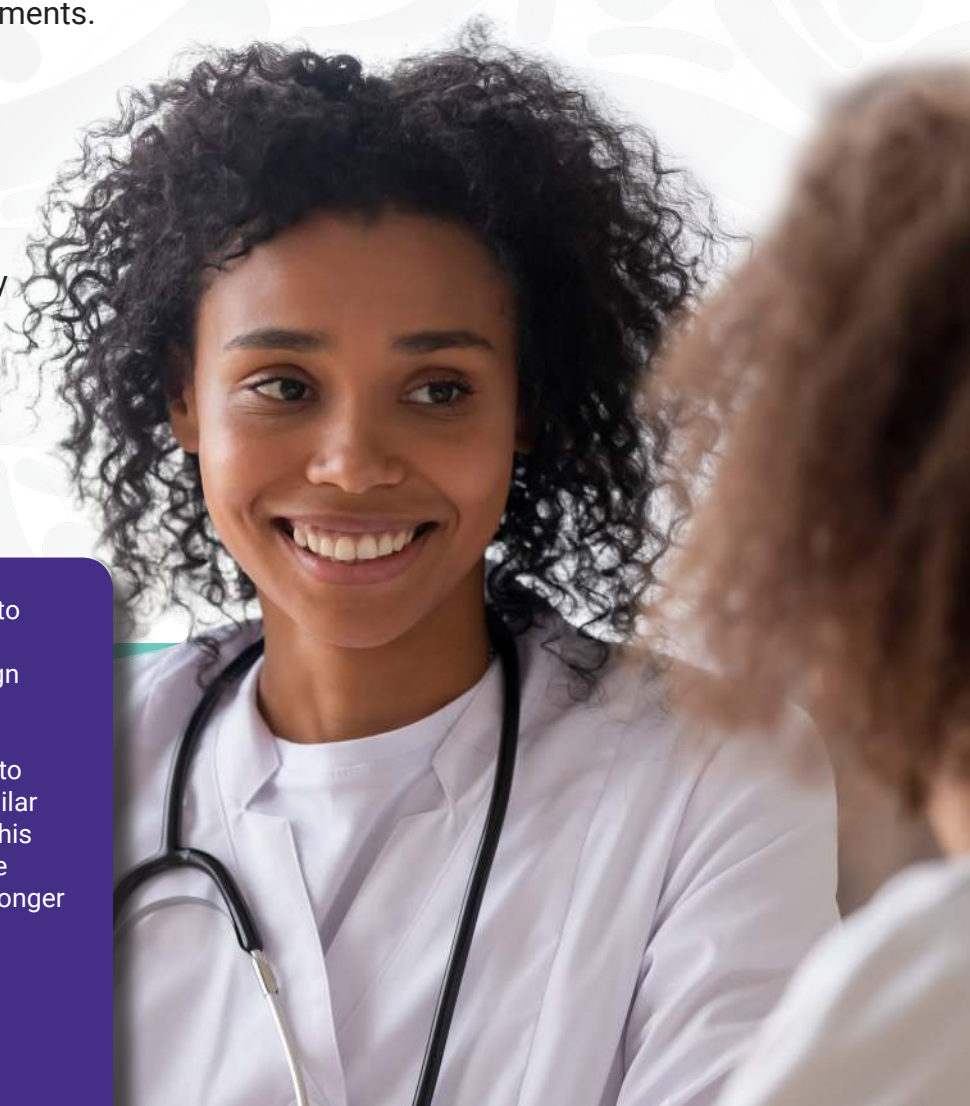
No. Reference biologics and biosimilars are complex molecules made from living cells. Due to this fact, biosimilars are **highly similar**, but not identical versions, of their reference biologic drugs.

Biosimilars are NOT the same as generic drugs

Generic medications are exact copies of a brand-name drug. Generics contain the same chemical substance(s) as branded drugs and provide the same therapeutic effect. Biosimilars are similar to but not exact copies of a reference biologic. The difference lies in the inactive components within the product. Because biologics and biosimilars are made with living cells, and not chemicals, they are more complex and have a natural variability.

These slight variations exist within all biologic and biosimilar medications, including batches of reference biologics that have been on the market for years. Biologics and biosimilars must meet Health Canada's safety, immunogenicity*, and efficacy requirements.

As well, it must be developed and manufactured following the same strict quality requirements as any other biologic; therefore delivering the same therapeutic benefits as its reference biologic.



* The body's ability to prompt an immune response to a foreign substance. In this case,the immune response would be to a biologic or biosimilar medication. When this occurs, it means the medication will no longer be effective.

Transitioning to a biosimilar is safe and effective

To be approved in Canada, a biosimilar must be proven to have no clinically meaningful difference to its reference biologic. What does this mean? Well, biosimilars MUST show no differences in outcomes for patients taking a biosimilar, when comparing it to patients taking the reference biologic drug.

Rigorous standards for authorization by Health Canada mean that patients and health care providers can have the same confidence in the quality, safety and efficacy of a biosimilar.

Health Canada supports switching from a biologic to a biosimilar and considers that a one-time switch from a reference biologic drug to a biosimilar to be acceptable. Health Canada also recommends that the decision to switch be made by the physician/prescriber and patient, taking into account clinical evidence and any policies of the relevant jurisdiction.

Reasons for Transitioning/Switching to a Biosimilar:

Medical transition

Occurs when a patient, not doing well on their current reference biologic or biosimilar is transitioned/switched to another reference biologic or biosimilar to regain maximum disease control.

Policy transition

Occurs when a public or private drug plan's reimbursement policy changes, and requires patients to transition/switch from their reference biologic to a biosimilar. In some provinces, health care plans are enforcing a switch to the biosimilar version before the end of the transition period to avoid any disruption to your coverage.

Before switching, both gastroenterologists and their patients must be fully informed about the reimbursement policy changes and have all available information about the biosimilar.

Are there any research studies on biosimilars?

There are more than 100 research studies on patients with inflammatory arthritis, gastrointestinal and skin disease who have successfully transitioned from an anti-TNF reference inhibitor biologic to its TNF inhibitor biologic biosimilar.

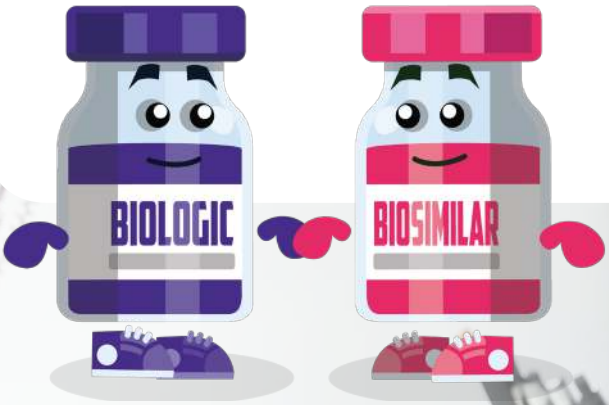
Benefits of Biosimilars

1. There will be cost savings to drug plans and patients who may have to pay out of pocket expenses associated with drug costs., alleviating stress and financial burden.

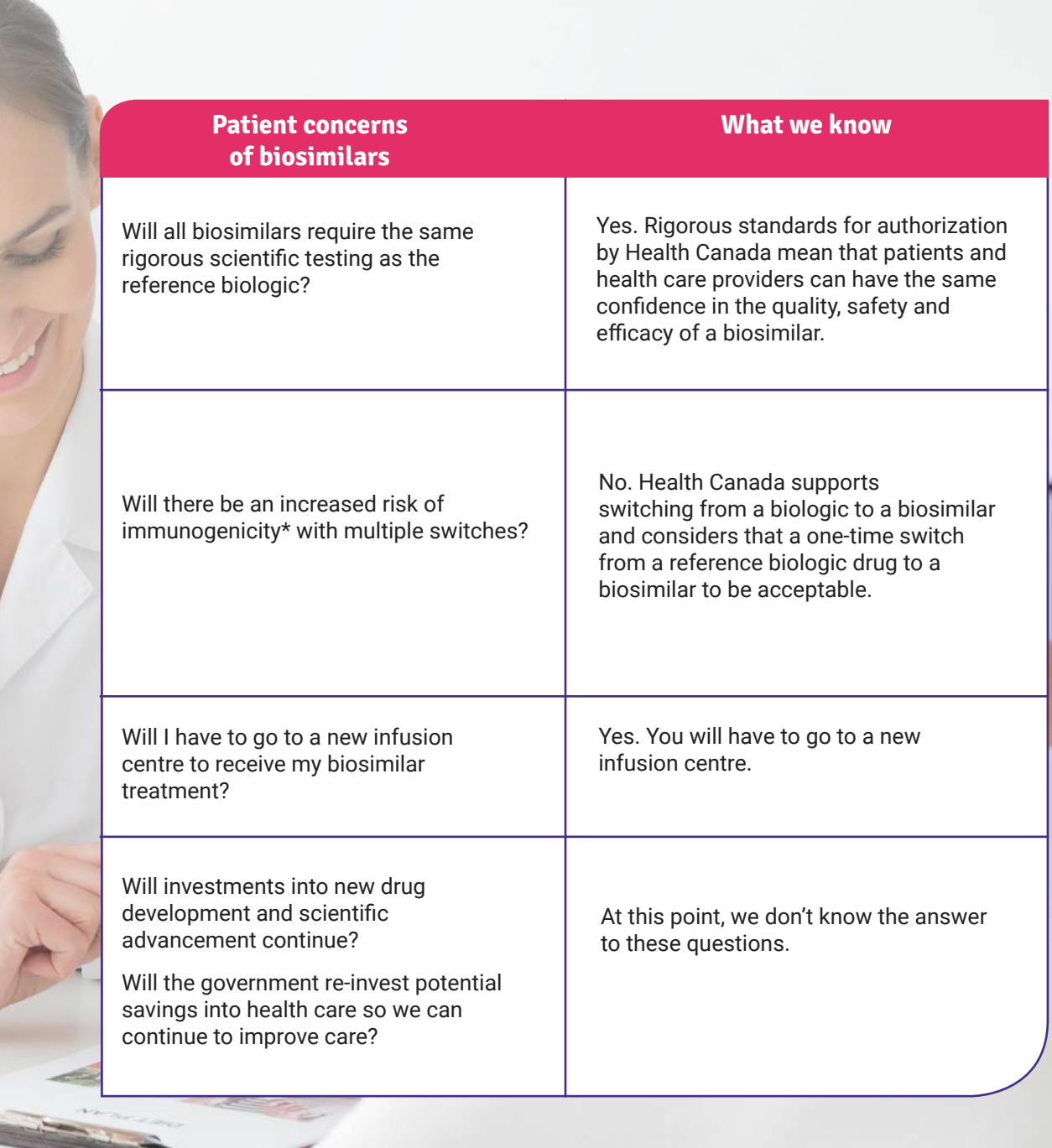
2. There's a considerable strain on our health care system, and it's likely not sustainable. We need to come up with inventive strategies to save costs but still provide excellent care for our patients. Biosimilars may be a way that we can achieve this.

3. pCPA has made it mandatory that biosimilars provide the same level of support in their patient support programs as those offered by a reference biologic.

4. Treated with the originator, you are unlikely to experience any new side effects after transitioning. As always, your gastroenterologist will monitor your treatment carefully, just like they did with your previous biologic, whether it was an originator or a biosimilar.



Recent report from the Federal Government (PMPRB, Patent Medicines Pricing Review Board) estimated that biosimilars have the potential to save Canadian Drug Plans up to $1.8 Billion PER YEAR



Patient concerns of biosimilars	What we know
Will all biosimilars require the same rigorous scientific testing as the reference biologic?	Yes. Rigorous standards for authorization by Health Canada mean that patients and health care providers can have the same confidence in the quality, safety and efficacy of a biosimilar.
Will there be an increased risk of immunogenicity* with multiple switches?	No. Health Canada supports switching from a biologic to a biosimilar and considers that a one-time switch from a reference biologic drug to a biosimilar to be acceptable.
Will I have to go to a new infusion centre to receive my biosimilar treatment?	Yes. You will have to go to a new infusion centre.
Will investments into new drug development and scientific advancement continue? Will the government re-invest potential savings into health care so we can continue to improve care?	At this point, we don't know the answer to these questions.

Empower yourself, learn all you can.

We encourage you to ask questions.
Speak to your gastroenterologist to learn more and be informed!

Some questions to consider:

- Has this biosimilar been studied in a rigorous way in patients with IBD?
- What am I concerned about?
- Is my disease stable enough to make a transition/switch to a biosimilar?
- Are there any challenges I should be aware of in the transitioning process?

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Have you already transitioned/switched?

If you have already transitioned/switched, CDHF wants to hear from you. Please fill out our online survey to help us understand the recent experiences of people living in Canada who have switched/transitioned from Remicade® (infliximab) to the biosimilar versions of infliximab: Inflectra® and Renflexis™. Type the following URL into your browser to get started: **https://conta.cc/2oMIUMv**

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For more information, visit CDHF.ca.

CDHF is the official Foundation of the Canadian Association of Gastroenterology (CAG). We are directly connected to Canada's leading digestive health experts, physicians, scientists and other health care professionals. You can trust us to provide you with credible, science-based information that is up to date and unbiased.