

CROHN'S AND COLITIS CANADA

BIOSIMILARS IN CANADA



WHAT ARE BIOLOGICS?

Biologic drugs are made using human or animal tissue or micro-organisms as a starting material. Examples of biologics include: vaccines, insulin, and hormones. Biologics used to treat IBD are classified into three categories depending on how they work in the body: anti-TNF (Humira®, Remicade®, Simponi®), $\alpha_4 \beta_7$ (pronounced “alpha 4 beta 7”) integrin blockers (Entyvio®), and antibodies to a section of the IL-12 and IL23 proteins (Stelara®). Biologics are injected under the skin or by intravenous infusion.



WHAT ARE BIOSIMILARS?

A biosimilar is a drug that is demonstrated to be highly similar (but not an exact copy) to the original biologic drug in terms of effectiveness and safety. For example, Remicade® has two biosimilar drugs: Inflectra® and Renflexis®.



ARE BIOSIMILARS THE SAME AS A GENERIC DRUG?

No. Biosimilars are not generic drugs, because they cannot be considered identical to the original biologic drug. Health Canada regulates biosimilars as new drugs.



WHY WOULD PAYERS (GOVERNMENT/PRIVATE) WANT TO DO THAT?

Reasons behind non-medical switch from biologic to biosimilar are related to cost savings and to helping the biosimilars industry in Canada.



IS IT SAFE TO USE BIOSIMILARS? DO THEY WORK?

Yes. Health Canada reviews and approves all drugs before they can be sold in Canada. All companies selling drugs in Canada must follow the same rules for the manufacturing process and for ensuring the quality of their ingredients. **Biosimilars offer safe and effective treatment for people with Crohn's disease and ulcerative colitis** (the two main forms of inflammatory bowel disease). But, we are not supportive of a non-medical switch.



WHAT IS A NON-MEDICAL SWITCH?

A non-medical switch is a decision on drug treatment for patients that comes from someone other than you or your doctor for reasons beyond health and well-being.



WHY IS NON-MEDICAL SWITCH A CONCERN?

Non-medical switch takes away decision-making from patients and their doctors. It is **not in the best interest of patients and is not supported by gastroenterology experts in Canada.**

For more information visit,

crohnsandcolitis.ca/options



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WHICH PROVINCES HAVE IMPLEMENTED A NON-MEDICAL SWITCH POLICY?

To date, **British Columbia and Alberta have implemented this non-medical switch policy affecting patients with Crohn's and colitis. In BC, patients have until March 2020 to switch from a certain biologic to its biosimilar.** Your physician will explain the switch process, answer any questions, and register you with a new patient support program. Other government and private payers are presently considering a non-medical switch policy. This is why Crohn's and Colitis Canada is working so hard to get our messages out to decision makers.



WHAT DOES CROHN'S AND COLITIS CANADA THINK?

Based on extensive review of the perspectives of patients/caregivers, gastroenterologists and nurses, the legal and ethical ramifications of non-medical switch, together with scientific evidence review and expert feedback, Crohn's and Colitis Canada asserts that **non-medical switch from biologic to biosimilar is not in the best interest of patients.** Decisions on treatment should be between you and your doctor. Our Position Statement can be found on the webpage crohnsandcolitis.ca/options.



WHAT DO MEDICAL EXPERTS THINK?

Gastroenterologists, through the Canadian Association of Gastroenterology, do not support non-medical switch of patients well-managed on a biologic to a biosimilar. Their decision is based on a thorough review of available scientific studies. You are supported by your doctor.



IF I AM SWITCHED TO A BIOSIMILAR, WHERE CAN I GET SUPPORT?

If you are forced to switch to a biosimilar, the infusion centre/clinic that administers your medication will also change. Biosimilar manufacturers provide patient support programs (PSP). Your PSP will provide instructions on how to access the new infusion centres that are similar to that of the reference biologic drug. Your physician will initiate the enrolment process into a PSP for you, if required.



IF I SWITCH TO A BIOSIMILAR, CAN I GO BACK TO THE BIOLOGIC?

This is not yet well-understood and there are risks related to immune responses by patients switching back and forth. For this reason, **we do not support switching back to the reference biologic** once the patient has switched to its biosimilar.



WHAT CAN I DO?

We would like to encourage you to write to your local government representative and Minister of Health. We've developed an easy-to-use online platform where you can participate in this **letter-writing campaign**. It is important that your voice is heard by local government! Visit action.crohnsandcolitis.ca/choice.

For more information visit,

crohnsandcolitis.ca/options



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