Frequently Asked Questions – For Prescribers and Health Care Professionals

What is changing with the PEI Biosimilar Initiative?

The Biosimilar Initiative requires patients to use a biosimilar version of a biologic drug, when one is available, to keep their coverage through PEI Pharmacare. Information about which drugs are included in the **PEI Biosimilar Initiative**, along with switching timelines, is available in the PEI Pharmacare Formulary and shared with pharmacists and prescribers through PEI Pharmacare Bulletins.

As new biosimilars become available, the Biosimilar Initiative will also apply to other originator biologics listed on the PEI Pharmacare formulary.

What is the process for switching patients?

Prescribers play a key role in the switching process. As a trusted and experienced information source, a prescriber may set the tone of the discussion, facilitate continuity of care, and empower the patient to understand and realize the best outcomes. The following steps may help patients with their switch to a biosimilar.

- Discuss switching to a biosimilar with the patient.
- Initiate enrolment in the patient support program for the biosimilar (if applicable).
- Write your patient a new prescription, indicating the chosen biosimilar. (Biosimilars are not considered interchangeable)

Do I need to submit a new special authorization (SA) request for the patient to have coverage for the corresponding biosimilar?

- When switching a patient to a biosimilar, a new SA does not need to be submitted, ***unless*** the patient's current SA is expiring.
- No SA renewal requests for an originator biologic will be considered during the transition phase unless the patient has an approved exemption due the timing of their appointment (see below).

What if I can't see my patient to switch them to a biosimilar before their special authorization is due for renewal?

If you can't accommodate your patient for a switching appointment before their special authorization is due for renewal, your patient (or a member of the healthcare team) can complete the online biosimilar switching exemption form or the paper biosimilar switching exemption form. The special authorization coverage for the originator biologic may be extended for 1 month following the patient's appointment date. The patient's appointment *must* be scheduled prior to the end of the switching period.

My patient is pregnant. Can I delay switching to a biosimilar until after delivery?

Yes. Your patient (or a member of the healthcare team) can complete the online biosimilar switching exemption form or the paper biosimilar switching exemption form. Your patient will be required to switch to using a biosimilar within 3 months after delivery.

My patient is using an insulin pump that has not been shown to be compatible with the biosimilar version of their insulin. Can coverage be maintained for the originator insulin?

If the biosimilar version of your patient's insulin has not yet been shown to be compatible with their insulin pump, your patient (or a member of the healthcare team) can complete the online biosimilar switching exemption form or the paper biosimilar switching exemption form. Information about insulin pump compatibility with biosimilar insulins can be obtained by contacting the insulin pump manufacturer. Your patient will need to switch to a biosimilar once there is information available to support the compatibility of the biosimilar insulin and the pump.

Which biosimilar should I prescribe?

The originator biologics included in the initiative and their respective biosimilars that are covered by PEI Pharmacare are identified in the PEI Pharmacare formulary.

How can I determine if a product is a biosimilar?

The product monograph will contain information to identify that a drug is a biosimilar. Health Canada has requirements for the Product Monograph of a biosimilar. It must include:

- A statement that the product is a biosimilar to its originator. This statement can be found immediately above "PART 1: HEALTH PROFESSIONAL INFORMATION" within the drug product monograph.
- A statement that indications have been granted based on similarity between the biosimilar and the originator.
- Comparative clinical data generated by the biosimilar sponsor summarized in tabular format, and
- Safety and efficacy information from the product monograph of the originator for all indications authorized for the biosimilar.

Health Canada's Summary Basis of Decision (SBD) documents are also available and explain the basis for decisions on biosimilar approval.

Are there patient support programs available for biosimilars?

Yes, manufacturers of biosimilars often provide patient support programs comparable to the originator biologics.

Why is the Biosimilar Initiative necessary?

Biologic drugs have become Canada's largest drug expense, with costs increasing at an unsustainable rate. Biologic drugs account for some of PEI Pharmacare's largest expenditures. Biosimilars present a significant opportunity for cost savings and health system sustainability as they are up to 40% less expensive than originator biologics at list price and they are safe and effective. Switching patients to less expensive biosimilars is expected to result in significant health system savings. The Biosimilars Initiative will support patient access to public drug coverage and new drug benefits.

Have other provinces implemented similar biosimilar Initiatives?

Yes. Most Canadian provinces have implemented biosimilar initiatives. Tens of thousands of patients have been safely switched to biosimilars, including those living with inflammatory arthritis, diabetes, psoriasis, and inflammatory bowel disease. In addition, biosimilar switching has been performed extensively in Europe, where countries have had over 15 years of experience with biosimilars.

Does switching to a biosimilar impact patient outcomes?

Health Canada indicates that patients and health care providers can be confident that biosimilars are effective and safe for each of their authorized indications, and that no differences in efficacy and safety are expected following a change in routine use between an originator biologic and its biosimilar in an authorized indication. There are many research studies which show little to no clinical differences between biosimilars and their originators, either when used with new patients, or for patients transitioning to a biosimilar. For more information on biosimilars and studies on switching to them, refer to Biosimilar Resources for Health Care Providers.

Is Immunogenicity a concern with switching to a biosimilar?

No. Health Canada requires an assessment of immunogenicity, prior to biosimilar authorization to rule out clinically meaningful differences with respect to the risk and impact of immunogenicity. Ongoing assessment by the manufacturer post-market is also required. Analyses of switching and interchangeability over the past 10 years in the EU (European Union) have shown that immunogenicity is not affected by switches between products.

Where can I find more information on biosimilars and switching?

See Biosimilar Resources for Health Care Providers .

If you still have questions, you can call (902) 368-4947.