FREQUENTLY ASKED QUESTIONS:

BIOLOGICS & BIOSIMILARS

WHAT ARE BIOLOGIC DRUGS?

Biologic drugs are large-molecule medications that are manufactured using living organisms or cells. Because of their larger size, these molecules tend to be more complex compared to their chemically made counterparts.

Examples of biologics are vaccines, insulin, growth hormones, and monoclonal antibodies. They are used to treat a variety of diseases such as diabetes, anemia, hormone deficiencies, cancer, inflammatory bowel diseases, and rheumatoid arthritis. As more benefits from using biologic drugs are found, these medications are being used to treat more and more diseases.

WHAT IS A REFERENCE OR ORIGINATOR BIOLOGIC?

The first version of a biologic drug to be produced is called the reference or originator.

WHAT ARE BIOSIMILARS?

Biosimilar drugs are the next versions of the biologic drug produced after the reference biologic drug's patent expires.

For a list of reference biologics and their corresponding biosimilar(s), please click here. Note that this list captures commonly prescribed biosimilars under GSC plans and is not an exhaustive list.

IS A BIOSIMILAR DRUG AS EFFECTIVE AS A REFERENCE BIOLOGIC?

Biosimilars work in the same way as the reference biologic drug but are less expensive. Patients can expect the same efficacy from biosimilars as the reference biologic. Biosimilar manufacturers submit studies to Health Canada to prove that their biosimilar works as well and is as safe as the reference biologic.

ARE BIOSIMILAR DRUGS SAFE?

Health Canada monitors and regulates all drugs, including biosimilars. Health Canada ensures biosimilar drugs are as effective and safe as their reference biologic version. Biosimilars are produced with the same regulatory standards as reference, or originator, biologic drugs.

IS A BIOSIMILAR DRUG THE SAME AS A GENERIC?

No. Biosimilars are biologic drugs that are highly similar to the originator biologic. However, they are not exactly the same. Due to the complex manufacturing process required to create biologics, it is impossible to create an exact copy of the original product. This is also true between batches of the originator biologic; small differences may be present.

Health Canada has a separate approval process for biosimilar drugs which requires manufacturers of biosimilars to demonstrate that, despite these small differences, there are no expected clinically meaningful differences between biosimilar and originator biologic drugs in terms of efficacy and safety.

Unlike traditional small-molecule drugs that are chemically created and allow for exact copies to be made, biosimilars cannot be considered generics because they are not the same and cannot be considered bioequivalent. Pharmacists cannot auto substitute a biosimilar for an originator biologic like they do for generics of brand-name medications. A new prescription specifying the biosimilar to use must be obtained from the prescriber in order to switch to a biosimilar.

WHY SWITCH?

Real-world evidence shows that switching patients from originator biologics to biosimilars is a safe and effective practice.

A peer-reviewed study found that there have been more than 178 clinical trials worldwide, involving approximately 21,000 switched patients, which confirm that switching from an originator biologic drug to a biosimilar biologic drug is not associated with any major efficacy, safety, or immunogenicity issues.

Biologic medications are expensive with many costing somewhere between $10,000 and $25,000 per patient, per year – or more. Biosimilars present drug plans with significant cost savings which can be reinvested back into the health care system to fund more medications or to provide more services and support. Many Canadian jurisdictions have already implemented biosimilar switching polices. These policies have also existed in many European countries for more than 10 years.

Canadian jurisdictions that have implemented biosimilar switching polices requiring patients on a reference biologic to transition to a corresponding biosimilar version:

- British Columbia Biosimilar Initiative
- Alberta Biosimilar Initiative
- Quebec Biosimilar Initiative
- New Brunswick Biosimilar Initiative
- Northwest Territories Biosimilar Initiative
- Nova Scotia Biosimilar Initiative
- Saskatchewan Biosimilar Initiative

TIPS FOR SPEAKING TO PATIENTS ABOUT SWITCHING

As a pharmacist, you are a trusted source of patient information. As a trusted expert, you can set the tone for patient expectations and comfort when switching to a biosimilar. Treatment-experienced, stable patients using an originator biologic may need more support to help them through the switching process.

Important information patients need to know about biosimilars:

- They are safe and effective.
- They are well researched. The EU has successfully implemented switching programs for more than 10 years, and many provinces in Canada have done so as well with similar successes.
- They work similarly to the current medication with no increased risk of adverse reactions.
- Biosimilars undergo a rigorous approval process before receiving Health Canada approval.
- Switching to biosimilars does not involve any major changes to the patient routine or dosing.
- They are similarly dosed; however, patients may need training on different self-administration devices, if applicable.
- They are accompanied by patient support programs, if applicable.
- Though the patient support program company will change, it is expected that patients will receive similar levels of support.

Understanding the nocebo effect

The nocebo effect is a phenomenon in which a patient's beliefs, attitudes, and previous experiences create a negative expectation. This often has an adverse impact on treatment success and could lead to treatment failure. It is important that you, as pharmacists, acknowledge the nocebo effect in your patient interactions.

To help guard against a potential nocebo effect, the pharmacist should:

- Acknowledge the nocebo effect,
- Be attentive and empathetic,
- Promote a neutral or positive outlook,
- Give balanced information about desired effects and adverse effects, and
- Suggest a plan for follow up.

MORE INFORMATION

Health Learning Free Accredited Online Course

Supporting Patients with Biosimilars: The role of the Community Pharmacist

Biosimilars Canada

Home - Biosimilars Canada

Health Canada

Health Canada Biosimilar Fact Sheet

CADTH

Biosimilar Drug - Healthcare provider Handout

Biosimilar Drugs: Your Questions Answered Patient Handout

References:

Pharmacy Association of Saskatchewan. Adapted from: https://www.skpharmacists.ca/site/res/Switching%20from%20a%20Biologic%20to%20a%20Biosimilar

Biologic and Biosimilar Drugs: FAQs. Saskatechewan Biosimilar Initiative. Adapted from: https://www.saskatchewan.ca/residents/health/prescription-drug-plans-and-health-coverage/extended-benefits-and-drug-plan/biosimilars/biosimilars-faqs

Biosimilars Initiative for health professionals. British Columbia Biosimilar Initiative. Adapted from https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/biosimilars-initiative-health-professionals

BIOLOGICS AND BIOSIMILARS: SUPPLEMENTAL INFORMATION

This list captures commonly prescribed biosimilars under GSC plans and is not an exhaustive list.

Drug	Biosimilar(s)	Reference biologic
infliximab	Inflectra® Renflexis® Avsola™	Remicade®
insulin glargine	Basaglar™ Semglee®	Lantus®
filgrastim	Grastofil® Nivestym™	Neupogen®
etanercept	Brenzys® Erelzi®	Enbrel®
pegfilgrastim	Lapelga® Fulphila™ Ziextenzo® Nyvepria™	Neulasta®
insulin lispro	Admelog®	Humalog®
glatiramer*	Glatect™	Copaxone®

rituximab	Ruxience™ Truxima™ Riximyo® Riabni™	Rituxan®
adalimumab	Amgevita® Hadlima® Hulio® Hyrimoz® Idacio® Abrilada® Yuflyma™	Humira®
insulin aspart	Trurapi™ Kirsty®	NovoRapid®
enoxaparin	Noromby™ Redesca® Inclunox®	Lovenox®

*Non-biologic complex drug