theBiosimilars Generation

Biosimilar Biologics Basics

As patents for original-brand biologics expire, other companies are allowed to make biosimilar versions of these medicines. Biosimilars are highly similar and have no clinically meaningful differences in efficacy and safety compared to their original-brand biologic. Since 2009, Health Canada has approved 24 biosimilars of original-brand biologics present on the Canadian market and healthcare providers have been prescribing biosimilars to their patients living with complex chronic diseases[1].

Provincial drug plans have begun implementing "switch" policies that change coverage for specific biologic medicines used to treat inflammatory arthritis, diabetes and inflammatory bowel disease. Under a switch policy, patients and their prescribers have a certain period to discuss switching from an original-brand biologic to its new biosimilar version.

The first therapeutic oncology biosimilar received Health Canada approval in 2018, followed by public funding in 2019[2]. At the same time, the pan-Canadian Pharmaceutical Alliance (pCPA) and Cancer Care Ontario have partnered to lead a pan-Canadian biosimilars strategy with the goal of ensuring the appropriate implementation and cost-effective use of therapeutic oncology biosimilars in hospitals and cancer centres[3].

As the use of biosimilars increases across Canada, Sandoz Canada Inc. has prepared this information tool to present the facts on biosimilars.

Question?

What challenges do biologic medicines pose to public drug plan budgets?

Biologics Costs

Biologics have revolutionized the treatment of many disabling and life-threatening diseases over the past 20 years but are also a significant contributor to increasing prescription drug costs. For example, biologic medicines account for less than 2% of prescribed drugs in Canada, yet the costs associated with them represent nearly 30% of Canada's total prescription drug costs[4].

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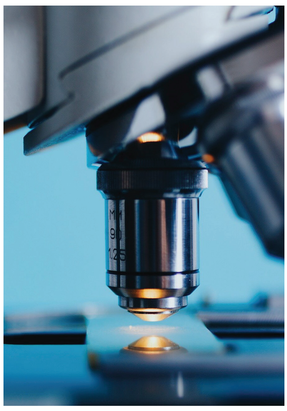

Question?

Is the safety and effectiveness of switching to biosimilar medicines from original-brand biologic medicines backed by evidence?

Safe to Switch

Yes. Under Health Canada's rigorous approval process, beginning with structural and functional studies and continuing with human clinical studies, a biosimilar must demonstrate that it is highly similar to a biologic medicine that is already authorized for sale and has no clinically meaningful differences in efficacy and safety compared to the original-brand biologic.

In the context of biosimilar switching, Health Canada states: "No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication[5]."

Over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine.

Question?

Will switching patients to biosimilar medicines improve patient access and care?

Quality with Savings

Yes. The broader use of biosimilar medicines can also help public and private drug plans cover new and innovative drugs. The Patented Medicines Pricing Review Board has estimated that private and public drug plans across Canada could save from $332 million CDN to $1.81 billion CDN in the third year following biosimilar entry across a portfolio of product[6].

Through the launch of its biosimilars switching policy, British Columbia is improving the sustainability of its PharmaCare program by adding new medicine listings and boosting existing medication coverage for patients[7].

$1.81 billion

Drug plans across Canada could save up to $1.81 billion in the third year (after listing on formularies)[6]

Question?

Biosimilars cost less, does that make them inferior?

Innovation Off-Patent

No. When the patent of an original-brand biologic expires, other manufacturers are allowed to make a biosimilar version of the medicine. Manufacturers that make biosimilars of other original-brand biologic medicines typically do not have the same costs to bring the product to market and can therefore offer it at a lower price[8].

Question?

What should patients consider when starting on a biosimilar?

Informed Decision-Making

The decision to start on a biologic – original-brand or biosimilar – can be life-changing and should be made by a well-informed patient and their healthcare professional based on the available clinical evidence and in consideration of treatment goals, tolerance of side-effects, accessibility of treatment and affordability.

Question?

If you have been prescribed a biosimilar, where can you get more information about the medicine?

Finding Facts

Your physician or pharmacist has valuable information about biosimilars. You should also look for additional evidence-based information from your provincial drug plan, patient groups or patient support program. This may include one-point-of contact / nursing support, securing coverage / reimbursement and providing financial assistance to patients, as well as education for patients.

1. **Canadian Biologic Drug Market, Biosimilars Canada** (12 months ending March 2020)
2. **Health Canada: MVASI Product Monograph** https://pdf.hres.ca/dpd_pm/00045004.PDF
3. **Pan-Canadian Oncology Biosimilars Initiative** https://www.cancercareontario.ca/en/programs/provincial-drug-reimbursement/oncology-biosimilars-initiative
4. **IQVIA. PharmaFocus 2023 Update.** Canadian Drugstore and Hospital Audit. Canadian CompuScript. MAT December 2019
5. **Health Canada Fact Sheet on Biosimilars: Switching** https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html
6. **Patented Medicines Prices Review Board. Potential Savings from Biosimilars in Canada** https://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/2017_Conference_Posters/post_6_biosim.pdf
7. **British Columbia Ministry of Health: Biosimilars Initiative** https://news.gov.bc.ca/releases/2019HLTH0080-001072
8. **Canadian Agency for Drugs and Technologies in Health (CADTH): Biosimilar Drugs: Your Questions Answered** https://www.cadth.ca/sites/default/files/pdf/biosimilar_drugs_patient_en.pdf

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