

# Biosimilar Biologics Basics

**i** As patents for original-brand biologics expire, other companies are allowed to make biosimilar versions of these medicines. Biosimilars are highly similar and there are no expected clinically meaningful differences in efficacy and safety compared to their original-brand biologic. Since 2009, Health Canada has approved 52 biosimilars of original-brand biologics present in the Canadian market and healthcare providers have been prescribing biosimilars to their patients living with complex chronic diseases.<sup>1</sup>

**i** Some provincial drug plans have begun implementing “switch” policies that change coverage for specific biologic medicines used to treat inflammatory arthritis, diabetes, inflammatory bowel disease and psoriasis.<sup>2</sup> 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.

**i** The first cancer biosimilar received Health Canada’s authorization for sale in 2018, followed by public funding in some provinces in 2019.<sup>3</sup> 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 biosimilars in hospitals and cancer centres.<sup>4</sup>

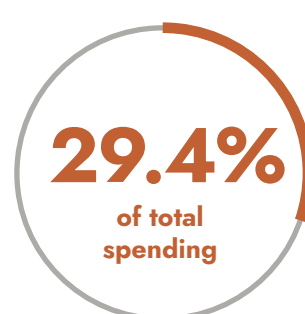
**i** As the use of biosimilars increases across Canada, Sandoz Canada Inc. has prepared this information tool to present the facts on biosimilars.

## Question?

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

### Biologics Costs

Biologics have been **beneficial in the treatment of many disabling and life-threatening diseases** over the past 21 years but are also a **significant contributor to increasing prescription drug costs**. For example, in 2018, biologic medicines accounted for less than 2% of prescribed drugs in Canada, yet the costs associated with them represented nearly 30% of Canada’s total prescription drug costs.<sup>5</sup>



**Public Drug Plan Spending**  
Biologics accounted for \$4.4 billion of public drug program spending (29.4% of total spending).



## Question?

Have biosimilars been tested for safety and efficacy?

### Authorized by Health Canada

According to Health Canada: “Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. 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.”<sup>6</sup>

## Question?

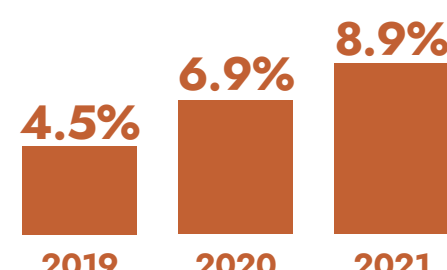
Will switching patients to biosimilar medicines improve patient access and care?

### Quality with Savings

Yes. 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<sup>7</sup>. **These savings through the broader use of biosimilar medicines can be invested into other healthcare services, such as helping public drug plans to cover new drugs.**

Through the launch of biosimilar switching policies, Ontario, Quebec, British Columbia, Alberta, New Brunswick, Nova Scotia, Northwest Territories, Saskatchewan, Newfoundland and Labrador and the Yukon are using biosimilars savings to improve the sustainability of their drug plans by adding new medicine listings and boosting existing medication coverage for patients<sup>8</sup>.

**Uptake of biosimilars is rising steadily**



## Question?

Biosimilars cost less, does that make them inferior?



### Second Generation

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<sup>10</sup>.

## 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. Information on file, Sandoz Canada
2. British Columbia Ministry of Health: B.C. expands biosimilars program <https://news.gov.bc.ca/releases/2020HLTH0257-001569>
3. BC Cancer: Systemic Therapy Update, October 2019 [http://www.bccancer.bc.ca/systemic-therapy-site/Documents/2019%20ST%20Updates/ST%20Update\\_Oct%202019.pdf](http://www.bccancer.bc.ca/systemic-therapy-site/Documents/2019%20ST%20Updates/ST%20Update_Oct%202019.pdf)
4. Pan-Canadian Oncology Biosimilars Initiative <https://www.cancercareontario.ca/en/programs/provincial-drug-reimbursement/oncology-biosimilars-initiative>
5. Canadian Institute for Health Information. Prescribed Drug Spending in Canada, 2021. Ottawa, ON: CIHI; 2022. <https://www.cihi.ca/en/prescribed-drug-spending-in-canada>
6. Ibid
7. Health Canada Fact Sheet on Biosimilars: Switching <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp/health/alt-forms/alt-forms/pdf/brgtherap/applic-demande/guides/Fact-Sheet-EN-2019-08-23.pdf>
8. 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](https://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/2017_Conference_Posters/post_6_biosim.pdf)
9. Ontario Ministry of Health. Executive Officer Notice: Biosimilar Policy [https://www.health.gov.on.ca/en/pro/programs/drugs/opdp\\_eo/notices/exec\\_office\\_eligibility\\_20230310.pdf](https://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/exec_office_eligibility_20230310.pdf)  
Yukon government website <https://yukon.ca/en/supporting-your-patients-switching-biosimilar>  
NLPDP Biosimilar Initiative <https://www.gov.nl.ca/hcs/prescription/biosimilars/>  
Saskatchewan Biosimilars Initiative <https://www.saskatchewan.ca/residents/health/prescription-drug-plans-and-health-coverage/extended-benefits-and-drug-plan/biosimilars>  
Nova Scotia biosimilars initiative <https://novascotia.ca/news/release/?id=20220204002>  
Northwest Territories Biosimilars Initiative <https://www.hss.gov.nt.ca/en/services/biosimilar-initiative>  
Minister of Health and Social Services – Prescription Drug Insurance <https://www.ramq.gouv.qc.ca/en/citizens/prescription-drug-insurance/know-conditions-coverage>  
New Brunswick Biosimilars Initiative <https://www2.gnb.ca/content/gnb/en/departments/health/MedicarePrescriptionDrugPlan/NBDrugPlan/biosimilars.html>  
Alberta Health: Biosimilar Drugs <https://www.alberta.ca/biosimilar-drugs.aspx>  
British Columbia Biosimilars Initiative <https://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/biosimilars-initiative-patients>
10. 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](https://www.cadth.ca/sites/default/files/pdf/biosimilar_drugs_patient_en.pdf)