Biosimilar Policies

Non-Medical Switch Myths Debunked

Myth: Scientific evidence supports a non-medical switch (NMS) policy

Reality: No, it does not. A report from INESSS[1] found that there is very little (to no) data that supports the safety of non-medical switching. A paper published in the *Journal of the Canadian Association of Gastroenterology*[2] echoes this finding. Paper co-author, Dr. Grigorios Leontiadis, said, "Based on what we learned, we cannot recommend a non-medical switch policy for patients stable on biologic treatment."[3]

Myth: Non-medical switch policy is the only solution to increase uptake and save money

Reality: There are other options. A **Lowest Cost Alternative** policy already works well for generic drugs across Canada and it can apply easily to biosimilars.[4,5,6] This will avoid patient harm from switching for non-medical reasons and give the government or private payer all the savings desired.

Myth: NMS doesn't incur any additional cost to the healthcare systems

Reality: Switching to biosimilars requires medically necessary consultations, increased monitoring, patient education, follow-up visits, and testing. NMS can lead to more than 60 avoidable surgeries for every 2,000 IBD patients.[7] Gastroenterologists predict that 1 in 11 will experience a disease flare after switching. The process medically required for NMS also increases risk of exposure to COVID-19 infection.[3]

Myth: NMS is needed to increase biosimilars uptake

Reality: No, it is not necessary, and it is harming patients.[8] Health Canada and CADTH have adopted measures to make it easier and faster to review biosimilars. Public drug programs have also implemented coverage policies to promote their use i.e., new starts,[9] tiering,[10] lowest-price method, similar to how generic drugs are treated in the market. Additionally, the market share of biosimilars is expected to grow at a rate of 113.9% by 2024.[11] Biosimilar uptake will increase naturally as more biosimilars arrive in Canada and physicians prescribe newly diagnosed patients on biosimilars.

Myth: Switching to biosimilars will save money

Reality: Not necessarily. Savings depend on the discount prices that public drug plans accept. For example, the manufacturers of originator biologic Remicade® (infliximab) offered to match the price of biosimilars Inflectra® and Renflexis®. The government denied this offer![12] Yet, the biosimilar Grastofil® (filgrastim) had an uptake of more than 90% in 2018-2019 but its price was only a 25% discount from the originator biologic.[13]

Myth: NMS has been successful in European countries and in BC

Reality: Non-medical switching does not exist in Europe. Not one country in Europe, where biosimilars have existed for more than a decade, forces stable patients to switch to a biosimilar or different biologic to maintain drug coverage.[1] Although BC's NMS policy was based on a European model, its forced switching policy is now the most aggressive switching policy in the world. Our survey clearly shows that patients are suffering from the medication switching and that pushes cost to other parts of healthcare.[9]

Myth: the panCanadian Pharmaceutical Alliance requires transparent pricing of biologic products

Reality: the pCPA is an arbitrary negotiating group that forms its own rules as it conducts joint negotiations for brand name and generic drugs in Canada.[14] It has no regulatory power in Canada. It is simply an agreement from participating federal/provincial/territorial drug plans. These rules can change in an instant.

Myth: Biosimilar uptake in Canada is lagging behind OECD countries

Reality: Biosimilars approved in EU after 2013 have market shares between 0% and 43%. Older biosimilars approved in 2006 have a market share of up to 91%.[15] Yet, Canada approved its first biosimilar in 2014 and the market share is rapidly increasing.

We support biosimilar use for new patients, but we oppose switching stable patients to a biosimilar.

1 Dufort I *et al.* At a Glance State of Knowledge Safety of Switching Biologics and their Interchangeability page. Available at: https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Medicaments/CoupDoeil_switching_biologics_EN.pdf.

2 Moayyedi P *et al.* Joint Canadian Association of Gastroenterology and Crohn's Colitis Canada Position Statement on Biosimilars for the Treatment of Inflammatory Bowel Disease. *Journal of the Canadian Association of Gastroenterology.* 2020;3:e1-e9.

3 Cision Canada. Media Release. Joint Statement from the Canadian Association of Gastroenterology and Crohn's and Colitis Canada. 2019-10-24.

4 5.11 Low Cost Alternative Program. Government of British Columbia page. Available at: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/pharmacare-publications/pharmacare-policy-manual-2012/pricing-policies-product-reimbursement/low-cost-alternative-program.

5 Drug benefit list and drug review process. Government of Alberta page. Available at: https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx#:~:text=The%20least%20cost%20alternative%20price,products%20in%20the%20interchangeable%20grouping.

6 Achieving the Best Value for Money. Government of Saskatchewan page. Available at: https://www.saskatchewan.ca/government/health-care-administration-and-provider-resources/saskatchewan-health-initiatives/achieving-the-best-value-for-money.

7 Kaplan GG *et al.* The Argument Against a Biosimilar Switch Policy for Infliximab in Patients with Inflammatory Bowel Disease Living in Alberta. *Journal of the Canadian Association of Gastroenterology.* 2020;3(5):234-242.

8 Forced to Switch: Canadian Biosimilar Experience Survey Report. Gastrointestinal Society page. Available at: https://badgut.org/biosimilars-survey-report-2020/.

9 New starts are applied in British Columbia (for biologics used in oncology), Ontario, Quebec, New Brunswick, Newfoundland and Labrador, and the Territories.

10 Government of Manitoba. Information for Health Care Professionals page. Available at: https://www.gov.mb.ca/health/pharmacare/profdocs/notice_tiered_biologics.pdf.

11 IQVIA. *PharmaFocus 2024 Update.* Canadian Drugstore and Hospital Audit. MAT August 2020.

12 Janssen Inc. Statement on Alberta Biosimilars Initiative page. Available at: https://www.janssen.com/canada/sites/www_janssen_com_canada/files/janssen_statement_on_alberta_governments_biosimilar_initiative.pdf.

13 CompassRx, 6th Edition. Government of Canada page. Available at: https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/compassrx-6th-edition/intro.html.

14 Home. pan-Canadian Pharamceutical Alliance page. Available at: https://www.pcpacanada.ca/node/30

15 ASBM Releases Fact Sheet on British Columbia vs EU Substitution Policies. Alliance for Safe Biologic Medicines page. Available at: https://safebiologics.org/2019/08/asbm-releases-fact-sheet-on-british-columbia-vs-eu-substitution-policies/.

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