

Canada takes major steps toward enhanced biosimilar access

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The past decade has seen increased use of expensive specialty biologic medicines to treat life-threatening and debilitating illnesses, such as cancer, rheumatoid arthritis and Crohn's disease. During this time, drug payers in Canada have awaited major cost savings from anticipated biosimilar competition, but the savings have been slow to come due to regulatory, patent and market access barriers. Over the last month, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Government of British Columbia have taken significant steps to enhance the use of biosimilar drug products across Canada.

Biologic medicines are used to treat a wide range of medical conditions and represent the largest expense for public drug plans in Canada. Biosimilars are highly similar versions of biologics, bioengineered using living organisms. To obtain approval, biosimilars must have no clinically meaningful difference in safety or efficacy when compared to a reference biologic. Once approved, these products are priced significantly lower than the reference product.

Biosimilar products first entered the Canadian market in 2009 with the approval of Omnitrope (somatropin). To date, Health Canada has approved at least nine biosimilars.^[1] Despite the potential cost savings to Canadians, uptake of biosimilars has been quite slow. For example, biosimilars for infliximab (i.e., Inflectra and Remsima) are used at a rate of 5 to 10% in Canada after four years on the market, while European countries like Norway and the United Kingdom have respective use rates of 98% and 90%.^[2] However, recent actions taken by CADTH and the Government of British Columbia suggest that biosimilar products will be funded by provincial governments more quickly in the future, leading to expanded access to more affordable drug products across Canada.

CADTH announced on May 23, 2019, that as of June 1, the CADTH Common Drug Review and the pan-Canadian Oncology Drug Review (pCODR) will generally no longer review biosimilar drug submissions. This recent change in process applies to drug products that were previously submitted, with ongoing reviews scheduled to be completed after June 1, 2019. Following regulatory approval by Health Canada, manufacturers will now work directly with the pan-Canadian Pharmaceutical Alliance (pCPA) and provincial governments to negotiate formulary listing and funding terms for biosimilar products. CADTH has acknowledged that circumstances could arise where a particular biosimilar should be subject to its common drug review process, but such situations will be considered on a case-by-case basis.^[3]

Prior to this change, following regulatory approval by Health Canada, a biosimilar drug product would be evaluated by CADTH, which would then issue a recommendation to the pCPA and provincial governments on the reimbursement of the biosimilar. CADTH's decision to cease conducting reviews of biosimilars has removed a step from the funding process, which should accelerate access to these drug products through listing on provincial drug plans. The recent position taken by CADTH on the review of biosimilars echoes the agency's

stance on “traditional” small molecule generic drug products, which are also not typically subject to review by the organization.^[4]

Four days later, on May 27, the Government of British Columbia announced that it would be expanding the use of biosimilars to offer coverage of more treatments through its publicly funded PharmaCare program. In British Columbia, patients using biologic drug products to treat ankylosing spondylitis, diabetes, plaque psoriasis, psoriatic arthritis or rheumatoid arthritis will transition to biosimilar products over the next six months, by November 25, 2019. The Government of British Columbia will cover the biologic and biosimilar versions of products during this six-month transition period and then cease to fund the biologic, except in exceptional circumstances. There are plans to expand this new PharmaCare biosimilar funding program to gastroenterological drug products used by patients with Crohn’s disease and ulcerative colitis.^[5]

Access to biosimilar drug products should expand significantly in the coming years if other provinces follow the approach to biosimilar funding recently set by CADTH and the Government of British Columbia. Over time, biosimilar market penetration could begin to approach the levels seen with small-molecule generic products, where substitution for the reference product is near-automatic and public and private cost savings are significant.

For more information on Canadian regulatory approval and funding of biosimilar drug products, contact J. Bradley White, Nathaniel Lipkus or Jaymie Maddox.

[1] <https://staging.osler.com/osler/media/Osler/Content/PDFs/Biosimilars-in-Canada.pdf>; <https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04418.html>.

[2] <https://news.gov.bc.ca/releases/2019HLTH0080-001072>

[3] <https://www.cadth.ca/cadth-pharmaceutical-reviews-update-issue-8>

[4] <https://www.cadth.ca/cadth-pharmaceutical-reviews-update-issue-3>

[5] <https://news.gov.bc.ca/releases/2019HLTH0080-001072>