How are biosimilars authorized for use?

Biosimilar medicines are versions of original-brand biologics that have lost patent protection.

To receive Health Canada's authorization, a biosimilar must demonstrate that it is highly similar and has no clinically meaningful differences in efficacy and safety compared to an original-brand biologic.[1]

Because biosimilar manufacturers must perform comparative studies to demonstrate similarity, the type of data required to support biosimilar authorization differs from that required for an original-brand biologic medicine.[2]

Biosimilar medicines are not the same as the more common generic medicines, which contain identical medicinal ingredients to their original-brand products.

A biosimilar and its original-brand biologic medicine can be shown to be highly similar, but not identical. This is because biologic medicines:

- are often large and complex
- are made from living cells rather than with chemicals and so are naturally variable

Compared to generics, more studies are needed for the regulatory approval of a biosimilar in order to demonstrate that it is highly similar to its original-brand biologic medicine.

After a medicine is authorized for sale, post-market analyses and studies can further demonstrate no meaningful differences in clinical efficacy and safety between a biosimilar and the original-brand biologic.[3]

Since 2009, Health Canada has authorized 33 biosimilars of 15 original-brand medicines.

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[1] **Health Canada Biosimilars Fact Sheet: Biosimilar biologic drugs**
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-drugs.html

[2] **Health Canada Biosimilars Fact Sheet:**
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

[3] **Health Canada Biosimilars Fact Sheet:**
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

The key principles Health Canada uses to evaluate biosimilars align with those of other regulators and international organizations[4] such as the:

- European Medicines Agency (EMA)
- United States Food and Drug Administration (FDA)
- World Health Organization (WHO)

Health Canada's position on the use of biosimilars is consistent with the **International Coalition of Medicines Regulatory Authorities** (ICMRA), a coalition of regulators from 29 regulatory authorities across the world,[5] including:

- Australia
- The United States
- the United Kingdom and
- the European Union

In July 2019, the ICMRA issued a statement on biosimilars, providing assurance on the regulatory processes for the approval and monitoring of biosimilars medicines and highlighting the benefits they can provide for patients and healthcare systems in terms of increased treatment alternatives, access and cost competitiveness.[6]

For more information about biosimilars, please read **Health Canada's Biosimilars Fact Sheet.**

Biosimilar medicines in Canada

It can take approximately ten years to develop and receive authorization for a biologic. Each one requires state-of-the-art research, followed by long authorization processes and very complex manufacturing processes using living micro-organisms. This is why development costs are much more than for chemically synthesized, small molecule generic medicines.

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[4] **Health Canada Biosimilar Fact Sheet: Comparing Canada's biosimilar regulatory framework with those of other countries**
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

[5] **Health Canada Biosimilar Fact Sheet: Comparing Canada's biosimilar regulatory framework with those of other countries**
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

[6] **ICMRA statement about confidence in biosimilar products (for healthcare professionals):**
http://www.icmra.info/drupal/sites/default/files/2019-07/ICMRA_statement_about_confidence_in_biosimilar_product_HCP.PDF

Biologic medicines have been prescribed for 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.

What does this mean for provincial drug plans? According to data from the Canadian Institute for Health Information, public drug programs spent $14.5 billion in 2018, which accounted for 43.4% of prescribed drug spending in Canada.[7] In 2018, biologics used to treat diseases like rheumatoid arthritis and Crohn's disease accounted for the highest proportion of public drug spending for the seventh consecutive year.[8]

Biologic medicines continue to be a growing budget pressure for public drug plans, which, at the same time, want to provide patients with access to new medicines.

The use of biosimilar medicines has the potential to benefit all Canadians. Highly similar and with no clinically meaningful differences compared to an original-brand biologic, but not requiring as much research and development, biosimilars can be offered at a lower cost with significant potential savings for healthcare systems. For example, the Canadian Government's 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 products.[9]

Since 2009, Health Canada has authorized 33 biosimilars of 15 original-brand medicines. Healthcare professionals have been treating Canadians living with complex chronic diseases with biosimilars since 2016.

[7] **Canadian Institute for Health Information - Prescribed Drug Spending in Canada, 2019, page 7**
https://www.cihi.ca/sites/default/files/document/pdex-report-2019-en-web.pdf
[8] **Canadian Institute for Health Information - Prescribed Drug Spending in Canada, 2019, page 9**
https://www.dropbox.com/s/8axt6loywl9t65r/Screenshot%202020-02-21%2014.51.24.png?dl=0
[9] **The Patented Medicines Prices Review Board, Government of Canada. Potential Savings from Biosimilar in Canada poster.**
http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/2017_Conference_Posters/post_6_biosim.pdf