

What's Health Canada Saying About Biosimilars?



What is a Biosimilar?

A biosimilar is a drug proven to be highly similar to a reference biologic drug that has been already authorized for sale.



Biosimilars can only come to market after the 20-year patent protection on the reference biologic drug has ended.



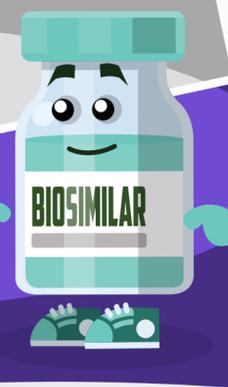
Are Biosimilars the same as Reference Biologics?



Reference biologics and Biosimilars are complex molecules made from living cells.

Due to this fact, Biosimilars are highly similar to, but not identical versions of, their reference biologic drugs.

However Biosimilars must meet Health Canada's rigorous approval process before being approved for use



How does Health Canada approve a Biosimilar?

Data from structural, functional and human clinical studies are carefully analyzed to ensure that the quality, safety and efficacy of the biosimilar are highly similar to the reference biologic drug.



This means that when Health Canada approves a Biosimilar:



- 1) There are no clinically meaningful differences between the biosimilar and the reference biologic drug
- 2) Healthcare professionals and patients can have the same confidence in the quality, efficacy and safety of a biosimilar as any other biologic drug

Can a patient already treated with a reference biologic drug be switched to a biosimilar?

YES!

under well-controlled conditions



Switching is usually a one-time change from the biologic to the biosimilar. Health Canada says switching from a biologic to a biosimilar is acceptable and recommends that the decision to switch be made by the physician or prescriber and patient based on clinical evidence and any policies of the province in which you live.

Biosimilar products first entered the Canadian market in 2009.

Health Canada has already approved 30 biosimilars. And there are over 15 other biosimilars currently under review.

They offer additional treatment options as well as cost savings for patients suffering from a wide variety of diseases.

CDHF.ca/biosimilars

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