The Facts on Biosimilar Drugs

A reference biologic drug is the original patented product.

A biosimilar is a closely related version of a reference biologic drug. Biosimilars are becoming increasingly available and are now used to treat a large number of diseases.

Biologic drugs, including biosimilars, are a class of medicine produced by the metabolism of living organisms. Given their complexity and risks, Health Canada evaluates biosimilars using the same regulatory standards for quality, efficacy and safety as for all other biologic drugs.

Monoclonal antibodies, insulin and vaccines are some examples of biological products. The manufacturing of biologics involves a very complex process that leads to the production of a mixture of molecules. Therefore it is hard to create imitations of the drug. Generic drugs are exact chemical copies of the brand name medicines synthesized following a recipe with standard ingredients. Biosimilars, on the other hand, are products of living cells, which are very sensitive to their environments, and cannot be recreated exactly by a chemical formula. Thus, manufacturers have to create their own, unique process to create a similar, but not identical, product to an existing treatment.

Biosimilars...

- Are imitations of their Health Canada-approved reference biological products.
- Are highly similar to their reference products in terms of their structure and function.
- Have no meaningful differences compared to the reference products in terms of safety and efficacy. This is shown by putting the biosimilar through human clinical trials.

Revised November 2019

LEUKEMIA & LYMPHOMA SOCIETY OF CANADA®

GENERIC vs. BIOSIMILAR

Similarities

Both are versions of Health Canada-approved brand name drugs
Both MAY represent a more affordable treatment option

Differences

GENERIC	BIOSIMILAR
Generics are small and simple chemically synthesized drugs.	**Biosimilars are complex and produced by living organisms.**
The active ingredients are identical to the reference product.	The active ingredients are highly similar to reference product, without any clinically meaningful differences; not an exact copy of the reference product.
Health Canada approval is based on the bioequivalence between the generic and brand name drug; there shouldn't be a significant difference between the rate of absorption and the total exposure of both products.	Health Canada approval is granted after clinical trials prove that the outcome of the biosimilar matches that of the biologic it is imitating, even though they are not structurally identical.
Generic drugs are essentially interchangeable with their respective reference product.	Interchangeability between a biosimilar and its reference product must be individualized according to both the patient and the product involved.

It is important to discuss all concerns about treatment options with your hematologist-oncologist and your pharmacist.

LLSC gratefully acknowledges Alexandre Marineau, B. Sc., M. Sc., Pharm. D. for his important contribution to the content of this publication.

This publication was made possible thanks to the support of

teva | Oncology | Canada

LEUKEMIA & LYMPHOMA SOCIETY OF CANADA®

For more information, don't hesitate to contact us:

1 833 222-4884 • *canadainfo@lls.org* • **llscanada.org**