Trustworthy

Committed to a future in biosimilars[1,2]

"Biosimilars are a new chapter in the therapeutic oncology setting in Canada and represent a growing focus for Teva since they will allow us to increase access to important therapeutic options. Moreover, Teva's biosimilars will have the potential to reduce costs by providing lower-cost treatment options for patients."

Christine Poulin, Senior Vice President and General Manager of Teva Canada.

At Teva, we understand you have questions about the efficacy and quality of biosimilars. That is why we are investing considerable resources into building your confidence with the highest quality biosimilars, real world experience, support to patient organizations for the development and distribution of comprehensive patient educational tools, and state-of-the-art manufacturing facilities.

We are committed to growing our already expansive portfolio of over 1,800 medicines by investing in the future of biosimilars in Canada, with expertise, experience and dedication you can trust.

Biologics and biosimilars[3-5]

Biologics, sometimes referred to as large-molecule drugs, are protein-based therapeutics. Biologics are produced using unique cell lines and are manufactured from natural sources such as human and/or animal cells, yeast, and bacteria.

Some key defining features of biologics include:[3]

- Being produced in living cell cultures
- Having high molecular weight
- Having complex, heterogeneous structure, and manufacturing process
- Being strongly process-dependent
- Being impossible to fully characterize molecular composition and heterogeneity
- Being unstable and sensitive to external conditions

Biosimilars are biologic medicines that are highly similar to their reference biologic drug, which has already been approved for sale. When producing biosimilars the main difference from the reference biologic is in the clinically inactive ingredients being used in the manufacturing process. There are no clinically meaningful differences in the safety, purity, and potency of biosimilars when compared to the reference biologic.

Biosimilars are approved by Health Canada based on a thorough comparison to a reference drug and may only enter the market after the expiry of the reference biologic drug patents and data protection.[4,5]

It is important to remember that biosimilars are **NOT** generics.

Generic drugs are chemical based, small molecule drugs that are generally easy to copy.[6]

Varying approval processes for biologics, biosimilars and generics[5,7]

Health Canada has developed a robust, science-based regulatory framework for biosimilars that reflects many approaches adopted by other major drug regulatory agencies. Health Canada's rigorous standards for authorization mean that patients and healthcare providers can have the same confidence in the quality, safety and efficacy of a biosimilar as any other biologic drug.

Biosimilar manufacturers must provide information to Health Canada comparing the biosimilar with the reference biologic drug. Similarity is then demonstrated using a step-wise approach beginning with structural and functional studies and continuing to human clinical studies.

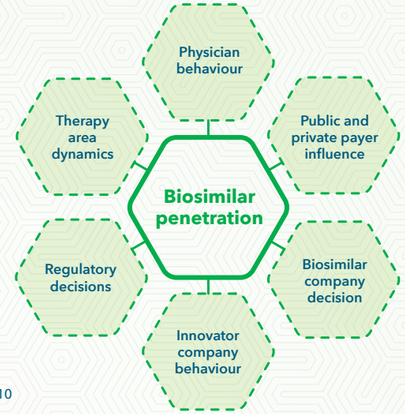
- Unlike generic drugs, biosimilars are not equivalent to the reference product because their chemical characteristics cannot be precisely duplicated during the manufacturing process.
- Health Canada reviews each biosimilar as if it were a new drug. It does not consider a biosimilar to be bioequivalent or interchangeable with the reference product.
- On the contrary, generic drugs must meet Health Canada's standards for bioequivalence.

Team worthy

The future of biosimilars in Canada[8]

The availability of biosimilars in Canada is expected to increase over coming years as more biosimilars become available. This will have a profound and dynamic impact on the Canadian healthcare system. There are a number of varying organizational level factors that will have an influence on the future of biosimilars in the Canadian market.

Teva Canada understands that the Canadian healthcare market is changing. We want to be an active partner of this change. That's why we are focusing our research and development efforts on innovative biologics and biosimilars while remaining dedicated to providing products that both consumers and providers can **trust**.[9]



The benefits of biosimilars in the Canadian market[4,8,10]

While biosimilars are still new in the Canadian landscape, they are quickly gaining notoriety. Pre-2017, only six biosimilars were approved in Canada; however, post-2017, an additional five biosimilars have been approved, showing a growing rate in approval and acceptance for biosimilars in Canada. Biosimilars are predicted to contribute to the sustainability of the Canadian healthcare system via:

Reduced cost

Biosimilars typically cost less than their reference biologics

Increased competition

Biosimilars introduce competition, which in turn may also help reduce costs

Improved drug accessibility

Savings from biosimilars could be put towards funding for other much-needed therapeutic areas

Teva Canada's commitment[9]

At Teva Canada, our promise is to help people "live better days". As an innovator in Canadian medicine, this means we are committed to the future of manufacturing and delivering high-quality biosimilars to all Canadians.

Teva Canada is now focusing on research and development and early stage opportunities to secure its commitment to biosimilars in the upcoming years.

We are looking forward to expanding our medicine cabinet to include a variety of state-of-the-art biosimilars and continuing to help Canadians live better days.

When it comes to biosimilars, you can trust in Teva Canada as a key partner.

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Brands. Generics. **Biosimilars.**