Ontario Health
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Biologic drugs: How they are approved in Canada

What are biologic and biosimilar drugs?

Biologics are drugs made from living cells. They are a different type of drug than traditional medications that are made using chemicals. Because biologics are made from unique living cells, there are always very small differences between batches.

Biologics are used to treat many health conditions, such as cancer, arthritis, diabetes, inflammatory bowel disease, psoriasis, and vasculitis.

Biosimilar biologics (or biosimilars) are highly similar copies of reference biologic drugs (the original brand name biologic drug) that have already been sold in Canada. They work just as well as reference biologics but are much less expensive.

The approval process for a new biologic medication

As with all drugs, there are many steps to getting a new biologic approved in Canada. The approval process can take many years and is very expensive. The steps for getting a new biologic approved in Canada are:

1. A drug company discovers a new biologic drug and decides they want to research how it may be used to treat a health condition.
2. They study the new biologic drug and test it in animals to see if it may work and if it is safe to use.
3. If the animal study goes well, it will be tested in large studies to treat people with a certain medical condition. The studies make sure the biologic is safe and works to treat the condition. New studies must be done in order to use biologics to treat different conditions.
4. Once the studies are done, the company submits the study information to Health Canada for approval.
5. If Health Canada feels the drug is safe and works well, they will approve the biologic.
6. Health Canada then makes sure that the biologic is consistently manufactured and is always good quality.

Since new biologics must be tested in large studies, the cost for developing one is very high. To help to pay for this cost and to promote research, the government gives a biologic drug company a patent for 20 years. For the length of the patent, other companies cannot make copies of the biologic.

The approval process for a biosimilar is slightly different

Approving a biosimilar in Canada is different from a reference biologic but just as in depth. When the patent expires on the reference biologic, other companies can start to make biosimilars. To get a biosimilar approved in Canada:

1. The drug company does studies to show that the biosimilar is comparable to the reference biologic and works in the same way.
2. The company tests the medication in people with a condition the biosimilar is intended to treat. The study must show the biosimilar works as well and is as safe as the reference biologic.
3. Health Canada makes sure that the biosimilar is manufactured with good quality control.

The biosimilar approval process is much shorter because a biosimilar is very similar to the reference biologic that has been available in Canada for years. The studies focus on showing the biosimilar works as well and is as safe as the reference biologic.

Health Canada will not approve a biosimilar if it does not work as well or is not as safe as the reference biologic.

How similar are reference biologics and biosimilars?

Reference biologics and biosimilars must be virtually the same.

In order to get Health Canada's approval, companies must show that the reference biologic and its biosimilar have the same:

- Effect in the people who use them
- Safety profile
- Quality manufacturing processes

Why should we use biosimilars instead of reference biologic drugs?

Using biosimilars instead of reference biologic drugs can save the health care system hundreds of millions of dollars. One study found that just 3 biologics cost the provincial drug plans close to $1 billion in 2019.[3] Using biosimilars for just these three biologics could save the Canadian healthcare system between $179 and $425 million dollars per year.[3]

The money that is saved by using biosimilars can be reinvested into new treatments for Canadians.