Biologics, Biosimilars and Switching FAQ

What are biologics?

Biologics are medications used to treat a variety of autoimmune diseases, including some inflammatory forms of arthritis such as rheumatoid arthritis and psoriatic arthritis. They are complex biological compounds that are made with living cells—bacterial or yeast cells or cells obtained from plants or animals—rather than being manufactured chemically like most other drugs. Biologics work by calming the immune system to reduce pain, stiffness and other symptoms.

- **Innovator biologics** are the first medication of their kind to be approved by Health Canada. They are also known as originator biologics or reference biologics. These medications must undergo multiple clinical studies to assess the efficacy and safety of the medication. It can take 8 to 15 years or longer for a biologic to be developed and authorized for use in Canada. The innovator biologic is covered under patent protection, meaning that that only the pharmaceutical company that holds the patent is allowed to make and sell the drug. Patent protection on pharmaceuticals in Canada lasts 20 years.
- **Biosimilars** are highly similar versions of the innovator biologic. When a drug manufacturer's patent for a biologic expires, this means another manufacturer (or the same manufacturer) can produce a very similar version of that biologic, called a biosimilar. It's not an exact copy, but it's very close and there are no expected clinically meaningful differences in efficacy and safety. For a biosimilar to be approved for sale in Canada, the manufacturer must provide information to Health Canada that demonstrates the similarity of their biosimilar to the innovator biologic. The biosimilar must undergo structural and functional studies as well as human clinical studies to demonstrate comparable quality, safety, and efficacy of the biosimilar to the reference biologic.

Are biosimilars the same as generic drugs?

The short answer is no, biosimilars are not the same as generic drugs. Generic drugs are identical copies of the reference drug and are chemically the same.

While innovator biologics and biosimilars are very similar to one another, we cannot say they are exactly the same. This is because of the inherent variability of complex biological compounds. You can think of biologics like apples growing on a tree. There is inherent variability in each apple, even those that grow on the same tree. This is because apples are complex with many factors affecting their growth. Similarly, batches of biologics made will vary slightly from batch to batch with the same manufacturer. However, you can think of regular chemical drugs such as aspirin (acetylsalicylic acid or ASA) to be like coins. When coins are produced, each one is identical to the rest because the manufacturing is reproducible and there is no inherent variability in the product. They remain identical even when produced in a different year.

A generic drug is chemically manufactured to be an exact copy of the original drug, because the active ingredients are relatively easy to duplicate. For example, acetaminophen, a common pain reliever, is the same active chemical ingredient whether you buy the brand name or a generic version. The medicinal ingredients will be identical, but some non-medicinal ingredients such as those used to make the color of the tablet and its coating, may be different.

Biosimilars are highly similar to the originator and produced with different recipes. Due to the complexity and specialized processes involved to make them, biosimilars are only highly similar – not identical to the originator. The same would be true from one batch of originator biologics to the other – that batch would have a slight variability compared to the starting batch. These differences do not impact the safety or efficacy of the drugs. Any significant changes to the recipe or manufacturing process requires approval by Health Canada and batch to batch variations do not require approval if variations are within the limits set.

Biosimilars are also different from generics when it comes to the studies required for Health Canada approval.

Since generic drugs are small molecules with active ingredients that are easy to replicate, generic drugs only need to show bioequivalence to the brand name product to demonstrate safety and efficacy. To be considered bioequivalent, the generic drug must achieve a certain level in the blood and act the same way in the body as the brand name drug. Typically, these studies are done in less than 50 healthy volunteers to demonstrate bioequivalence for Health Canada approval. Clinical trials in people with the condition are not required for a generic version.

Since biosimilars are larger and more complex therapies that are created with living cells, biosimilars must undergo structural and functional studies as well as human clinical trials to demonstrate comparable quality, safety, and efficacy to the reference biologic.

Whatever drug you are getting, whether it is a generic drug or a biosimilar, you can be confident knowing that Health Canada regulations ensure the drugs you receive are safe, effective, and of high quality.

How do biologics/biosimilars work?

In some people with arthritis, high levels of certain proteins are present in the blood and joints leading to inflammation, which can cause pain, swelling and stiffness. Originator biologics and biosimilars work to calm the body's overactive immune system by blocking these proteins and their ability to cause inflammation.

Are biosimilars as effective as the originator biologic?

Yes. Health Canada considers approved biosimilars to be the same as originator biologics. According to Health Canada, "Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications."

Will switching from my originator biologic to a biosimilar cause a health problem?

You should not experience any negative effects from a switch. According to Health Canada: "No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

What is the "nocebo effect"?

It is important to make sure that you have a clear understanding of any treatment proposed. Your doctor or pharmacist can provide you with additional information about a particular treatment. Studies have shown that sometimes people who anticipate negative side effects from a new medication may be more likely to experience them. This is called the 'nocebo effect' and demonstrates the impact negative thinking can have on our bodies. Make sure you get the facts before starting a new treatment so that misconceptions don't interfere with how you perceive its efficacy. Information you find on the internet may not be accurate and you must ensure the information you access is from a reliable and reputable source. Licensed healthcare professionals are your best source of information and they can individualize the information to you.

How long have biosimilars been in Canada?

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For more information about transitioning from an originator biologic to a biosimilar, visit our article on Biologics and Biosimilars.