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Understanding Generic Drugs and Biosimilar Drugs

Advances in the treatment of myeloma have led to the use of many different medications. Generic and biosimilar drugs are an important part of modern health care. They provide effective treatment options while meeting all of Health Canada's standards for quality, safety, and effectiveness. Although generics and biosimilars are not the same thing, both are carefully reviewed before they can be authorized for use in Canada.

This InfoSheet explains what generics and biosimilars are, how they are reviewed, and what they mean for the treatment of myeloma.

Key takeaways

- Generic drugs contain the same medicinal ingredient as their brand-name counterpart and must demonstrate bioequivalence.
- Biosimilars are highly similar to their reference product but are not identical.
- Both generics and biosimilars undergo Health Canada review before they can be authorized for use in Canada.
- If you have any concerns about switching medications, talk to your health care team.

Generic drugs

What are generic drugs, or "generics"?

Generic drugs contain the same medicinal ingredient(s), in the same strength and comparable dosage form as their brand-name counterparts. They are pharmaceutically equivalent because they demonstrated "bioequivalence." This means that the medicinal ingredient(s) is absorbed into the body at a comparable rate and amount and reaches a similar level in the bloodstream over time.

Compared to their brand-name counterparts, generic drugs:

- Are expected to provide the same therapeutic effect and meet the same standards for safety, quality, and effectiveness
- Contain the same medicinal ingredient(s), in the same strength and dosage form
- May contain different non-medicinal ingredients, such as fillers, colours, or preservatives

Brand-name drugs are usually protected by national and international patents, as well as data protection requirements (period of market exclusivity). Generic drugs can typically only be sold after these protections expire.

More than one generic version of the same brand-name drug may be available.

How are generic drugs tested and reviewed?

Companies who want to sell a generic drug in Canada must complete a generic drug submission for Health Canada to review.

- Generic drug companies conduct studies to demonstrate the bioequivalence of a generic drug to its brand-name counterpart.
- The generic and brand-name drugs are given to healthy volunteers at the same dose and route.
- Blood samples are collected at specific times to measure the amount of the active ingredient in the blood. This allows researchers to compare how quickly and how much of an active ingredient enters the bloodstream.
- Results and data from the studies are provided in the generic drug submission. This includes information of the generic drug compared to the brand-name drug, for example: what the body does to a drug as the drug moves through and out of the body (i.e., absorption, distribution, metabolism, and excretion).
- Generic drug submissions to Health Canada must also contain information on how the generic drug is manufactured and tested. This includes the ingredients used, their amounts and specifications, manufacturing processes, and quality control testing.

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How are generic drug submissions reviewed?

Generic drug submissions go through a review process by scientists in the Health Products and Food Branch (HPFB) of Health Canada to ensure the drug meets the required standards for quality, safety, and effectiveness.

The HPFB scientists review the information submitted by the generic manufacturer. The thorough review may include:

1. Evaluation of the drug's bioequivalence
2. Consultation with external experts and advisory committees
3. Evaluation of the drug's safety, efficacy, and quality to determine whether the drug meets Health Canada's requirements
4. Review of the information that will be provided to health care professionals and patients (e.g., drug label and product monograph)

What if my body reacts differently to a generic drug?

Some people may notice a change in their body's response to the medication or side effects after switching from a brand-name drug to a generic. **If you experience a change after switching, let your health care team know right away.** Your health care team can help to determine the cause of the reaction or change and discuss whether any adjustments to your medications are necessary.

Questions to ask your health care team

Prior to starting any new medication, whether it is brand or generic, talk to your health care team about:

- ☐ Common side effects and how to manage them
- ☐ Serious side effects and what to do if they happen
- ☐ When to seek emergency medical care

Generic drugs are carefully reviewed and continuously monitored by Health Canada to ensure that they meet the standards for quality, safety, and effectiveness. If you have any concerns about switching or starting a generic medication, talk to your health care provider, particularly your pharmacist. They can help you understand the medication and determine the best option for you.

Learn more here: Health Canada, Access to Generic Drugs in Canada
(accessed August 21, 2026)

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Biosimilars

What are biologic drugs and "biosimilars"?

Biologic drugs are complex medications made with the help of living cells or organisms. They are used for a variety of conditions, including sometimes in myeloma.

A biosimilar drug, or biosimilar, is a biologic drug that is highly similar to a previously approved biologic drug, known as a reference biologic (for example, the brand-name form of a biologic drug).

Biosimilars are not identical to their reference biologic due to natural variability during manufacturing. However, Health Canada requires biosimilars to demonstrate that there are no clinically meaningful differences in their safety or effectiveness compared with the reference biologic.

Compared to their reference biologic, biosimilars are:

- Highly similar in structure and function
- Not expected to have any clinically meaningful difference in efficacy or safety
- Manufactured to the same regulatory standards as other biologic drugs

To be available for sale in Canada, a biosimilar must be reviewed and authorized by Health Canada.

How are biosimilars different from generic drugs?

Biosimilar drugs and generic drugs are not the same. Generic drugs are chemically made and contain the same medicinal ingredient(s) as their brand-name counterpart. However, biosimilars are made using living cells or organisms and are highly similar but not identical to their reference biological drug. This is because biologic drugs are large, complex, and can have some natural variability during the manufacturing process.

Biosimilars also require more testing than generic drugs. Health Canada reviews information from different types of studies to confirm that a biosimilar is highly similar to its reference biologic.

How are biosimilars tested and reviewed?

Biosimilars are tested using a step-by-step comparison with their reference biologic. The goal is to show that a biosimilar is highly similar to its reference biologic and that there are no clinically meaningful differences in safety, effectiveness, or immune response.

Testing may include:

1. Structural and functional studies that compare the characteristics and biological activity of the two drugs
2. Studies that compare how the drugs work in cells in the laboratory
3. Clinical studies in humans that compare how the drugs behave in the body, their effectiveness, safety, and the body's immune response to the drugs

These studies are done to identify differences between the biosimilar and the reference biologic and to determine whether those differences could have an effect on people who take them.

How are biosimilar submissions reviewed?

Health Canada thoroughly reviews the evidence provided by the manufacturer, including all the information about the drug's structure, function, quality, manufacturing, and clinical studies. All this information is considered when they are making the decision whether or not to authorize a biosimilar. After authorization, biosimilars are continuously monitored to help identify any issues with their safety or effectiveness.

Can I switch between a reference biologic and biosimilar?

A biosimilar may be used in place of its reference biologic for an approved indication. If your health care team recommends switching to a biosimilar, they can explain why the switch is being made and what to expect. If you have questions or concerns, please speak with your health care team.

What if my body reacts differently to a biosimilar drug?

Some people may notice a change in their response to the medication or an unwanted effect after starting or switching to a biosimilar. **If you experience a change after starting or switching, let your health care team know right away.** They can help determine the cause and discuss whether any adjustments to your treatment are necessary.

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Questions to ask your health care team

Prior to starting any new medication, whether it is a biosimilar, a generic, or another medication, talk to your health care team, including your pharmacist, about:

- ☐ Common side effects and how to manage them
- ☐ Serious side effects and what to do if they happen
- ☐ When to seek emergency medical care

Learn more here: Health Canada, Biosimilar biologic drugs in Canada: Fact Sheet.
(accessed September 1, 2026)

Reference:
Apotex Inc. (2025). *Under the lens: A closer look at biosimilars in Canada.*

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