What you need to know about biosimilar drugs

For patients starting or switching to biosimilars

What are biologics and biosimilar drugs?

- Biologics are medications that are made from living cells, like animal cells, bacteria or yeast.
- Since biologic drugs are made by living cells, every batch that is made is almost the same.
- Biosimilars are highly similar to the reference biologic drug (the original brand name biologic drug).
- Europe has been using biosimilars for more than 10 years and has approved almost 60 different biosimilars.
- Health Canada has approved biosimilar treatments for arthritis, ankylosing spondylitis, psoriasis, ulcerative colitis, Crohn's disease, diabetes and cancer.

Are biosimilars the same as generic drugs?

- No. A generic drug has the exact same active ingredients (the chemicals that make the drug work) as a brand name drug.
- For example, you can buy ibuprofen as Advil (brand name) or a store brand (generic).
- Biosimilar drugs are not exact copies but are highly similar to the reference biologic drug.

Do biosimilars work as well as reference biologic drugs?

- Yes, reference biologic drugs and biosimilars work the same way.
- If you were taking a reference biologic drug and are now taking a biosimilar drug, you should expect to have the same results and the same side effects.

Why are biosimilars now being sold in Canada?

- Until recently reference biologic drugs were protected by a patent.
- While reference biologic drugs are patent protected only one company can sell that biologic, which makes them very expensive.
- As the patents for reference biologic drugs expire, other companies can start selling biosimilars.

What is the benefit of using biosimilars to our healthcare system?

- Biologic drugs are very expensive to the healthcare system. In 2016, Canada spent more than $3.6 billion on these drugs.
- Biosimilars are sold at a lower price, so the healthcare system saves money.
- The money saved by using biosimilars can be put back into the cancer system to help pay for, and improve access to, new treatments.

How does Health Canada monitor how biosimilar drugs are made?

- Biosimilars are approved and monitored by Health Canada to the same standards as the reference biologic drug.
- Health Canada and manufacturers are both responsible for monitoring biologics and biosimilars.
- Manufacturers must report any serious side effects to Health Canada, inform them of any studies with new safety information, and request their approval for any changes made to the drug.
- Companies that make biosimilars must give information to Health Canada comparing the biosimilar with the reference biologic drug.
- For a drug to be called a biosimilar, the company that makes the biosimilar must prove to Health Canada that it is safe and works just as well as the reference biologic drug.

Will my care be different if I am taking a biosimilar?

- Your care will be the same whether you take a reference biologic drug or a biosimilar drug.

- As with taking any medications, if you have any problems while taking biosimilars, speak to your healthcare team right away.

Where can I find more information?

- Health Canada's Biosimilars Fact Sheet has detailed information about biosimilars.

This fact sheet was developed in consultation with

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