MYELOMA CANADA
MAKING MYELOMA MATTER

InfoSheet

GENERIC DRUGS IN CANADA

What are generic drugs, or 'generics'?

Generic drugs are pharmaceutically equivalent (bioequivalent) copies of brand name drugs. Compared to their brand name counterparts, generic drugs:

- are created to have no significant difference in terms of safety, efficacy, mode of administration, quality, and expected behaviour in the body;
- contain identical medicinal ingredients;
- may have different non-medicinal ingredients.

To be available for sale in Canada, a generic drug must be approved for sale by Health Canada and must demonstrate bioequivalence to its brand name counterpart.

- **Bioequivalence means that there is no significant difference between the generic and brand name drug in how:**
  - quickly medicinal ingredients are absorbed;
  - quickly medicinal ingredients reach a certain level in the blood (bioavailability);
  - the generic drug acts in the body and that it's as safe and effective as its brand name counterpart.

Innovative brand name drugs are usually protected by national and international patents, as well as data protection requirements (period of market exclusivity). Generic drugs can 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 have created/developed a generic drug and want to sell it in Canada must complete a generic drug submission for review by Health Canada.

- **Generic companies conduct studies with human volunteers to ensure that the pharmaceutical bioequivalence of a generic drug to its brand name version are met.**
  - The two drugs are taken by different groups of people at the same dose and in the same way (i.e., oral, injection);
  - For each group, level(s) of the medicinal ingredient(s) in the blood are measured at specific timepoints to calculate the drugs' bioavailability.

- 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, i.e.: what the body does to a drug as the drug moves through and out of the body (i.e., absorption, bioavailability, distribution, metabolism, and excretion).

- **The generic drug submission must also contain information on how the drug will be made (i.e., processes, ingredients with amounts and specifications) and tested (i.e., during manufacture, before being distributed or sold).**

How are generic drug submissions reviewed?

Generic drug submissions go through a very similar review process as brand name drug submissions by scientists in the Health Products and Food (HPFB) Branch of Health Canada.

- **The HPFB review process includes a thorough evaluation of the submitted information, and:**
  - may sometimes include external consultants and advisory committees;
  - evaluates the safety, efficacy and quality data to determine potential benefits and risks of the generic drug;
  - reviews information about the drug that will be provided to healthcare professionals and patients (e.g., drug label and product brochure).

What if my body reacts differently to a generic drug?

If you experience any allergies, sensitives, or side effects, let your healthcare provider know that you were switched to a generic drug and that you are reacting to it differently than you did to the brand name version. Together, you can discuss your options and what medication is right for you since brand name drugs are typically still available once generics come to market.

- **Prior to taking any prescribed drug, whether it be a brand name or a generic, speak to your healthcare provider about:**
  - expected side effects and how to manage them;
  - serious side effects, what to look out for, what to do, and when to go to your nearest emergency room.

Learn more here:

Health Canada, Access to Generic Drugs in Canada (2018)
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/access-to-generic-drugs.html (accessed 19/08/2021)

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