

Similarities and Differences Between Brand Name and Generic Drugs

Why is this important to my patients?

Some patients have the misperception that generic drugs are inferior to brand name drugs.¹ They may be uncertain about using generic drugs initially, but they are in fact more likely to adhere to treatment when prescribed lower-cost generics.²

For patient information, see the CADTH publication *Generic Drugs: Your Questions Answered*.

Brand Name Drugs

- Also called “innovator drugs”
- Initially marketed as new chemical entities
- First version sold by the innovator manufacturer is known as the Canadian Reference Product

Generic Drugs

- Copies of brand name drugs
- Produced after the original patent expires

How are generic and brand name drugs the same?

Generic and brand name drugs have identical active ingredients, and generic drugs must meet Health Canada’s standards for bioequivalence.

Bioequivalent drug formulations have the same bioavailability; that is, the same rate and extent of absorption. New drug formulations must meet standards set by Health Canada. If the generic drug is bioequivalent, it is assumed that it will produce the same therapeutic effect as the brand name drug. This means that new clinical studies are not needed for generic drugs.

There is a common misperception that generic drug concentrations can be 80% to 125% of the brand name formulation; in other words, that the variance may be up to 45%. This is not true.

- One of the key parameters for bioequivalence is the area under the curve (AUC). The AUC is a mathematical calculation based on a graph of blood concentration versus time, and it correlates well with total drug exposure.

- The AUC of a generic formulation must be no less than 80% or no more than 125% of the brand name formulation. There is international consensus that differences within this range are not clinically significant.
- More importantly, the 90% confidence interval of the AUC must also fall within 80% to 125%. Recall that the confidence interval is a range of measurements within which we can be confident that the true result lies. So, for the entire confidence interval to fall within the 80% to 125% range, the variance is generally less than 5%.³

For detailed information, see the CADTH publication *What are Bioavailability and Bioequivalence?*

Generic drugs are sometimes manufactured by brand name companies. These drugs may be called “ultragenerics” or “pseudogenerics.” In 2004, 27% of generic drugs in Canada were pseudogenerics.¹

How are generic and brand name drugs different?

Although the active ingredients are the same, the excipients (inactive ingredients) may differ. This is only important in rare cases when a patient has an allergy or sensitivity to one of the excipients.

The product may also be slightly different in colour, shape, or markings.

The biggest difference is cost. Generic drugs are generally less expensive than brand name comparators.

Why do generic drugs cost less?

Generic drug companies don’t have the expense of researching and developing a new chemical entity.

There is usually competition among generic drug manufacturers.

How do I know if a generic drug is safe for my patient?

Health Canada must review and approve all drug products before they can be sold in Canada.

Generic drug manufacturers must show that their drug is bioequivalent to the brand name comparator.

All manufacturers must meet the same federal standards for good manufacturing practices. These include quality standards for ingredients, assays, manufacturing processes, and facilities.

What makes generic and brand name drugs interchangeable?

Interchangeability is not the same thing as bioequivalence. Health Canada determines bioequivalence based on comparative bioavailability studies. Each province or territory determines interchangeability based on its own policies or regulations.

When might it be unsafe to switch brands?

Some patients may have allergies or intolerances to excipients such as lactose, gluten, sulfites, or tartrazine. For these patients, check the drug's excipients in the *Compendium of Pharmaceuticals and Specialties (CPS)* or call the manufacturer.

What about critical dose drugs?

A few drugs that are highly toxic or have a narrow therapeutic range are known as critical dose drugs. Examples are cyclosporine, digoxin, flecainide, lithium, phenytoin, sirolimus, tacrolimus, theophylline, and warfarin. Health Canada sets different standards for these drugs. Bioequivalence requirements for critical dose drugs are stricter than for other drugs.

For drugs with a narrow therapeutic range such as antiepileptics and antiarrhythmics, there have been anecdotal reports of differences between brand name and generic drugs. However, controlled trials looking for increased toxicity or exacerbation of disease have consistently failed to show clinically important differences.²

What about biologics?

Biologics are a class of drugs derived through the metabolism of living organisms, rather than being synthesized in a laboratory. Biologics include insulin analogues, interferons, erythropoietin, and monoclonal antibodies such as infliximab or adalimumab.

Subsequent entry biologics (SEBs) are new versions of biologics that come to the Canadian market after the patent for the original product has expired. Unlike generic drugs, SEBs are not equivalent to the innovator drug because their chemical characteristics cannot be precisely duplicated during the manufacturing process.

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Health Canada reviews each SEB as if it were a new drug. It does not consider an SEB to be bioequivalent or interchangeable with the innovator product.

How do I report an adverse event?

If your patient experiences an adverse reaction, you can report the details to Health Canada. This applies to all drugs (prescription and non-prescription), natural health products, biologics such as blood products or vaccines, radiopharmaceuticals, and disinfectants, and is not just for generic products.

You can file a report with MedEffect Canada by phone, fax, mail, or online. Use the form in the back of the CPS, or get more information at www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php.

Bottom Line:

- Generic and brand name drugs are bioequivalent.
- Clinically important differences have not been reported in well-controlled trials.
- Generic drugs create savings that can be redirected elsewhere.

References

1. Canadian Health Services Research Foundation [Internet]. Ottawa: CHSRF. Myth: generic drugs are lower-quality and less safe than brand-name drugs; 2007 Jun [cited 2011 Dec 1]. Available from: <http://www.chsrf.ca/PublicationsAndResources/Mythbusters/ArticleView/07-06-01/0f090ed6-335a-463a-8cf0-55df449fc2c8.aspx>
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