Questions and Answers

Accordion:

What are generics?

Generic medications are equivalent to the original or brand name products both pharmaceutically and therapeutically. In other words, they feature the same amount of active ingredient(s) and the same dosage forms, and meet the same applicable (and other) standards of strength, quality, purity and identification. They are also administered in the same way as the original medications. However, these products may differ in certain ways: format, appearance, branding, packaging, labelling, expiration date and excipients (colouring and flavouring agents, preservatives, etc.).

Why are generics less expensive?

If it is proven that a generic medication is equivalent to the original product both pharmaceutically and therapeutically, it can also represent excellent savings. Generics are less expensive than brand name drugs because their manufacturers do not have to pay for the research and development costs involved in marketing them. Because the efficacy and safety of the original formulation have already been proven, all generics manufacturers need to do is demonstrate that their product is equivalent. Furthermore, because they can benefit from an existing market, marketing costs are much lower.

Are generics as effective as brand name products?

Yes. To get marketing permission from Health Canada for a generic medication, Sandoz has to perform rigorous tests to prove the safety and bioequivalence of its medication compared to the brand name drug. These comparative clinical studies, which are thoroughly reviewed by Health Canada, guarantee:

- the same active ingredient;
- the same dosage;
- the same efficacy;
- the same safety profile.

However, generics may have a different format (shape, packaging, labelling and expiration date) and different excipients (substances that are combined with the active ingredient in a

medication and may affect colour, preservation, flavour and so on).

Why are generics important to global healthcare?

An aging population, changing lifestyles and technological progress are some of the factors contributing to increased medication consumption worldwide. At the same time, healthcare costs keep rising. This makes generics important because they can be used to care for patients who would otherwise not have access to medications and allow public healthcare systems to control their budgets.

Can I substitute a generic medicine for a brand name product?

Patients can usually switch from an original medication to a generic. Our generics go through rigorous testing and they are of the same quality and have the same efficacy as the original medications. They are administered at the same doses and in the same galenic form (tablet, suppository, ointment, injection, etc.). You need to consult with your doctor and/or pharmacist, however, to determine whether a generic product is interchangeable with the original product that you are currently taking.

How are generics approved?

Since the brand name medication has generally been approved for several years when the marketing application is filed by a generics manufacturer, considerable information on the safety and efficacy of the brand name product is already available, which means that the clinical studies for a generic medication need not be repeated in full. Generics manufacturers are required by law to prove the safety and efficacy of their products through a bioequivalence test. The actual production of generics is subject to the same rigorous standards as for any other medications, and manufacturing sites are inspected on a regular basis by regulatory authorities.

Who gives permission for generics to be marketed?

Like any medication, generics must be authorized by a regulatory authority after rigorous scientific evaluation of the efficacy, safety and quality of the product. In Canada, that authority is Health Canada. Brand name medications are patent protected for 20 years from the date on which the patent application is filed. When this period ends, generics manufacturers like Sandoz can market generic versions of the original medications.

What is a bioequivalence test?

A bioequivalence test is a clinical study to determine whether the administration of the same dosage of two medications containing the same active ingredient (the brand name product and the generic product) produces the same blood levels of the active form of the medication over time. Such tests make it possible to guarantee the therapeutic equivalence of generic products without having to repeat all of the studies carried out for the brand name

medications, thereby avoiding unnecessary testing of the same substances on humans and animals.
