THE SAFETY AND EFFECTIVENESS OF GENERIC DRUGS

The Issue

More and more, generic drugs are being used to fill prescriptions. Canadians want to be sure that generic drugs are as safe and effective as brand name drugs.

Background

Generic drug is the term used for products that contain the same medicinal ingredients as the original brand name drug, but which are generally cheaper in price. Nearly 30 percent of all prescriptions filled by pharmacies use a generic brand, and hospitals use generic drugs a lot. Chances are that you have received a generic drug at some time, whether you realize it or not.

Ensuring the Quality of Generic Drugs

Whether a manufacturer makes brand name drugs or generic ones, the standards are the same. The ingredients, manufacturing processes and facilities must meet the federal guidelines for Good Manufacturing Practices. As well, all drug manufacturers must perform a series of tests, both during and after production, to show that every drug batch made meets the requirements for that product.

The ingredients are the most important element in the testing of a drug. The ingredient in the drug that helps cure you or make you feel better, is called the "medicinal" or active ingredient. When medicinal ingredients are being manufactured, small amounts of impure materials may be produced as well. Manufacturers have to set limits for any impurities that may remain after the drug is produced. They must also show that the low levels of impurities that remain will not affect the safety and effectiveness of the medicinal ingredient. In addition, manufacturers are required to conduct chemistry studies to prove to Health Canada that the medicinal ingredients being used meet federal standards.

While both generic and brand name drugs must have the same amounts of good quality medicinal ingredients, other ingredients are also found in drugs. Called non-medicinal ingredients, they give the drug its shape and colour. Non-medicinal ingredients in generic products can be different from those of the original brand. Normally, when manufacturers change the non-medicinal ingredients or the manufacturing conditions, they have to provide studies to prove that the effectiveness of the drug has not changed.

Canada

How Health Canada Monitors Generic Drugs

Health Canada is responsible for evaluating generic drugs. To fulfill this responsibility, Health Canada looks at the drug's safety, effectiveness and quality. The current process for evaluating drug products has been in place for almost 30 years and it applies equally to brand name and generic drugs. Health Canada's commitment to high standards has stayed the same over the years. Although some requirements for generic drugs are different from those for brand name drugs, most are the same.

In proving that their products are safe and effective, generic drug manufacturers have two options. One is to repeat most of the chemistry, animal and human studies done by the manufacturer of the original brand name drug. The other is to show how the generic drug performs compared with the original brand name drug. Most manufacturers choose the second option because the original brand name drug has already been proven safe and effective.

The studies that compare the generic drug with the original brand name drug are called "comparative bioavailability" studies. In comparative bioavailability studies, the level of a medicinal ingredient in the blood of healthy human volunteers is measured. During the studies each volunteer receives the original brand name drug and the new generic drug on two separate occasions. The generic drug must show that it can deliver the same amount of medicinal ingredient at the same rate as the original brand name drug.

Some drugs are not suitable for comparative bioavailability testing. Generic drugs that are solutions and are injected directly into the blood stream fall into this category, as do products that are applied directly on the skin. In such cases, other methods, such as comparing the effect of the generic drug with the original brand name drug, may be used.

- To assess drug products, Health Canada's scientists draw on their extensive experience, as well as their work with an expert panel of scientists, physicians and pharmacists from across Canada. This ensures that standards for Canadian drug products remain high.

Need More Info?

Canadian Generic Pharmaceutical Association

http://www.cdma-acfpp.org/index.html