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The Safety and Effectiveness of Generic Drugs

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IT'S YOUR HEALTH



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.



GENERIC DRUGS

A generic drug is a copy of a brand name product, known as the 'reference product'. **Generic drugs** contain the same medicinal ingredients as the brand name drug, and are considered bioequivalent to the reference product. There may be many generic versions of the same reference product.

Nearly 45% of all prescriptions filled by pharmacies use generic drugs, and some hospitals use generic drugs almost exclusively. Chances are that you have received a generic drug at some time, whether you realize it or not.

ENSURING THE QUALITY OF GENERIC DRUGS

The quality standards for brand name drugs and generic drugs are the same.

The ingredients, manufacturing processes and facilities for all drugs 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 generic drug must contain the same amount of medicinal ingredient as the brand name reference product. However, non-medicinal ingredients, like fillers and ingredients that colour the drug, may be different from those of the brand name product. The generic manufacturer must provide studies showing that the different non-medicinal ingredients have not changed the quality, safety or effectiveness of the generic drug.

To prove that their products are safe and effective, generic drug manufacturers must demonstrate that the generic drug performs similarly to the brand name drug.

The studies that compare the generic drug with the brand name drug are called

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“comparative bioavailability” studies. In these studies, the level of a medicinal ingredient in the blood of healthy human volunteers is measured. During the studies, each volunteer gets the brand name drug and the new generic drug. The generic drug must show that it delivers the same amount of medicinal ingredient at the same rate as the brand name drug.



Generally speaking, some drugs, like those injected directly into the blood stream, do not need comparative bioavailability testing. Other drugs, like ointments and creams applied on skin, may not be suitable for comparative bioavailability testing. In these cases, other methods may be used, like comparing the clinical effect of the generic drug with the brand name drug.

THE GOVERNMENT OF CANADA'S ROLE

Health Canada is responsible for evaluating generic drugs for their safety, effectiveness and quality. The process for evaluating drug products is constantly being improved and updated to keep up with international standards of regulatory approval.

FOR MORE INFORMATION

To report a side effect (adverse reaction) or drug interaction for any health product, contact Health Canada at 1-866-234-2345 (toll free in Canada), or visit the *MedEffect Canada* web section at: www.health.gc.ca/medeffect

- Learn more about **Drug Products** at: www.health.gc.ca/drugproducts
- **Drug Identification Numbers (DINs)** at: www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/dinfs_fd-eng.php
- **Natural Product Numbers (NPNs)** at: www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php
- Process for Health Canada's **drug approvals** in Canada at: www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd_e.html

- **Canadian Generic Pharmaceutical Association:** www.canadiangenerics.ca

FOR INDUSTRY AND PROFESSIONALS

- Drugs and health products **applications and submissions** at: www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demanded/index-eng.php
- Drugs and health products **compliance and enforcement** at: www.hc-sc.gc.ca/dhp-mps/compli-conform/index-eng.php

RELATED RESOURCES

- For safety information about food, health and consumer products, visit the **Healthy Canadians** website at: www.healthycanadians.gc.ca
- For more articles on health and safety issues go to the *It's Your Health* web section at: www.health.gc.ca/iyh

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245*

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