Generic *vs.* Brand-name Medicine

CGPA
Making Patient Care Affordable

All prescription medication – both generic and brand-name – are reviewed by Health Canada and must meet the same standards for quality, safety, and effectiveness to be authorized for sale. Generic medicines are developed, designed and laboratory tested to demonstrate that generics work **the same** way in the body as the original brand-name drug.

Generic prescription medicines have **the same** active ingredient, the chemical that produces the desired effect on the body, as the brand-name product. The generic medication also must have **the same** amount of active ingredient. Non-medicinal ingredients, such as fillers and preservatives, might be different from the brand-name product, but these ingredients are also regulated by and subject to the Health Canada review process.

Health Canada's standards are informed by the most current scientific studies and are internationally recognized as being among the most rigorous. These standards are required to be met at every stage in the development and production of a generic prescription medication.

Prescription Drug Development ... Health Canada's Role

To develop a prescription drug, manufacturers produce the Active Pharmaceutical Ingredient (API) internally or source the API from a domestic or international supplier that meets Health Canada's regulations. The generic drug formulations are compounded, tested against the original brand-name, submitted for clinical trials and lab tested to evaluate the medicine's bioequivalence.

The product formulations and test results are submitted to Health Canada for assessment and in some cases reviewed by external experts and advisory committees to ensure the quality, safety, and effectiveness of the proposed drug.

The manufacturer also submits the medication literature that will be distributed to healthcare practitioners and consumers. The literature – product descriptions, labels, packaging, and consumer brochures – is reviewed and assessed for accuracy and clarity to ensure they meet Health Canada's health product communication and advertising regulations.

Domestic manufacturing Standards ...
Health Canada's role

Before a prescription drug company (brand-name or generic) can mass-produce and market their products in Canada, **their business and their facilities must be licensed and meet Health Canada regulations.**

All companies must prove that their laboratories, production floor, packaging, distribution facilities all comply with the Good Manufacturing Practices (GMP) developed and monitored by Health Canada. **At every stage of production, there are specific, written requirements to ensure an overall and effective approach to product quality control.**

International regulations and quality control ...
Health Canada's role

The fact is that the pharmaceutical sector is a globalized industry. Both brand-name and generic manufacturers source their active pharmaceutical ingredients internationally. Products that are researched and developed domestically can be manufactured overseas, and domestically manufactured products are exported to offshore markets.

As a Standing Regulatory Member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Health Canada ensures that their Good Manufacturing Practices (GMP) are embedded in the international guidelines and that these requirements continue to improve and keep pace with new scientific and technological advances.

All offshore manufacturing sites, producing active pharmaceutical ingredients or finished prescription products, are inspected to confirm that they meet Health Canada's GMP requirements. And Health Canada requires Canadian manufacturers and importers to identify the foreign sites from which the ingredients, or finished products originate and tracks their quality control standards.

Treatment quality and Safety monitoring ... Health Canada's role

Health Canada plays an active role throughout the entire life cycle of a prescription drug - both brand-name and generics – setting manufacturing standards and monitoring and reviewing the product after it is available as a treatment.

When a brand-name or generic prescription drug is available for treatment, **Health Canada scientists and clinicians monitor the 'real-world' safety and effectiveness of the product.** They investigate and evaluate reports from manufacturers, health professionals, hospitals and consumers.

If issues arise, actions are taken such as revising safety bulletins for healthcare professionals and consumers, creating new product labeling, initiating a safety study, or removing the product from the market.

Health Canada also maintains a publicly accessible database of reports on adverse drug reactions and side effects for healthcare professionals and patients and includes the most current safety information on all products that are in use.

Canada's Generic Pharmaceutical Industry

CGPA member companies are a strategic asset and play a vital role in Canada's economy and healthcare sector.

Through manufacturing facilities here in Canada and the global supply chain, generic pharmaceutical companies produce and deliver more than 77% of the prescription medicines dispensed in community pharmacies and used in hospitals and medical clinics across the country.

Daily average number of prescriptions dispensed using generics and biosimilars in 2024.[1]

1,822,000

Average price per prescription in 2024[2]

Generics

$22.53

Brand-name

$170.30

In 2024, the **average annual savings for each household** from the use of generic prescription medicine.[3]

$4,100.00

1. Data source: IQVIA, 856M prescriptions in 2024, 77.7% dispensed using generics. CGPA calculation.
2. Average retail price is based on total price of prescriptions (price of drug plus any mark-ups and professional dispensing fees) divided by estimated prescriptions dispensed in Canadian retail pharmacies (excludes hospitals; includes retail new and refills).
3. IQVIA and most recent data available from Statistics Canada.