



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

NATIONAL INTERCHANGEABILITY FOR GENERIC PHARMACEUTICAL PRODUCTS

THE ISSUE

Health Canada's standards of review for generic pharmaceutical products are internationally recognized, but some provinces continue to operate redundant review systems. This needless duplication of the federal approval process delays the market entry of lower-priced generic drugs and costs Canada's health-care system millions of dollars each year.

BACKGROUND

Generic drugs are low-cost versions of brand-name drugs that are produced by several manufacturers once the 20-year patents expire. Generic drugs are identical or bio-equivalent to the brand-name versions in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

All generic pharmaceutical products must undergo an exhaustive evaluation process through Health Canada's Therapeutic Products Directorate (TPD) before they can be licensed for sale in Canada. This process includes a rigorous and exhaustive review of volumes containing detailed chemistry and manufacturing data, and evidence that the generic product is bio-equivalent to the standard reference (brand-name) product. The acceptance standards applied to this evaluation process are amongst the highest in the world, and the expertise of TPD is internationally recognized and respected.

Every province in Canada maintains a drug formulary, which is the list of brand-name and generic drugs for which each province will pay. Provincial governments weigh the therapeutic value of a brand-name drug against its cost and decide

whether to include the product on their formulary. Once TPD approves and licenses a generic product for sale in Canada, the manufacturer submits the product for inclusion on each of the provincial formularies so the lower-priced generic can be used in the place of the more expensive brand-name product.

Since 1995, Health Canada has made a Declaration of Equivalence for the generic drugs it approves with the specific intention that the provinces will rely on that approval as the basis for interchangeability on their drug formularies.

While the listing of generic pharmaceuticals at the provincial level should be a quick and easy process based on Health Canada approval, this is not the current practice. Some provinces remain reluctant to accept TPD's Declaration of Equivalence and choose to operate their own complex regulatory systems with expert committees.

Most provincial assessment processes result in significant delays. Depending on the province, this can range from several days to several months to a year. The submission requirements also differ in each province, increasing the complexity and cost of the regulatory process. All bio-studies and information submitted at the provincial level have already been reviewed by Health Canada.

The current situation results in uneven decision making across Canada in terms of interchangeability of generic products. There is no logical reason why a generic product should be interchangeable in one province and not another. There should be only one set of criteria for interchangeability – and this already exists within Health Canada.

The current provincial processes are also vulnerable to manipulation by third parties that have an interest in delaying the interchangeability of a brand-name product for a less expensive generic drug.

Every province should be able to make a determination of a generic listing to their respective formulary on the basis of the following information:

- **A Notice of Compliance from TPD with Declaration of Equivalence to a Canadian Reference Product (brand-name drug).**
- **A price schedule based on a per unit dosage or on package sizes, or both.**
- **A product monograph.**
- **A company's proof of ability to supply the product.**

Optimal savings can be achieved if the provinces accept Health Canada's Declaration of Equivalency as the basis of interchangeability instead of repeating this work at the provincial level. Ending unnecessary duplication is crucial in this fiscal environment of rapidly escalating drug costs. Streamlining the process would not compromise patient care as Health Canada's standards of evaluation are amongst the highest in the world. It is also important to note that provinces could not be held liable for relying on the federal government's approval because the federal government has jurisdiction under the constitution to evaluate the health and safety of food and drugs.

Private sector drug plans often base their benefits on what drugs are covered by government plans, so a faster process

would also provide Canadian employers and consumers with better access to generic drugs, resulting in significant savings.

TPD currently rules on the equivalence and not interchangeability of a generic drug product because of federal and provincial jurisdictional issues. The scientific criteria for equivalence and interchangeability are one and the same. CGPA believes the provinces would be more willing to adopt a "Declaration of Interchangeability" from Health Canada as the basis of substitution than the current Declaration of Equivalence, and has made this recommendation to officials at Health Canada.

CGPA POSITION

Health Canada approval of a generic pharmaceutical product should serve as the basis for generic interchangeability in all provinces. Ending provincial duplication of the work done by Health Canada regarding the bio-equivalence of generic drugs is an important way to save Canada's health-care system millions of dollars each year without compromising patient care.