



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

AUTHORIZED GENERICS

THE ISSUE WHAT IS AN AUTHORIZED GENERIC?

Authorized generics are the actual brand-name drug product manufactured by the brand-name company, but sold as a generic by a licensee or subsidiary of the brand company, competing with independent generics.

WHY ARE AUTHORIZED GENERICS A PROBLEM?

Because they are identical to the branded drugs and approved by the patent holder, authorized generics do not encounter the product development, federal regulatory approval and legal costs and barriers to market entry that apply to independent generics.

Authorized generics are commonly licensed by brand-name drug companies to ensure that generic manufacturers cannot profit from their investments in product development, R&D and years of litigation to bring an independent generic to market.

This problem is exacerbated by the fact a brand-name drug company is able to control the timing of the release of its authorized generic as other generics are entering the market, thus ensuring that it obtains a large portion of available market share. This weakens the

incentive for generic firms to try to get cost-saving generic drugs to market since no matter how much earlier they enter the market than other generic firms, the authorized generic can always get to market early.

Brand-name drugs in Canada have 20-year patent protection. In Canada, brand-name firms also have the benefit of an automatic 24-month injunction against Health Canada approval of generic competitor. This means that the first genericized version of a drug typically faces considerable legal expenses when entering the market.

In Canada, it typically takes between three and six years to develop and obtain regulatory approval for generic drugs. For an independently developed generic drug product, a submission must be filed with Health Canada containing sufficient information for Health Canada to assess the bio-equivalence of the drug to the brand-name product, as well as evidence of tests conducted regarding potency, purity and stability of the new generic drug. The required studies are costly and often require several years.

After the submission is filed and these costs have been incurred, a generic company is required under the

PM(NOC) Regulations to notify the brand-name company that it intends to bring its product to market. It is at this point that the brand company can trigger the automatic 24-month injunction against the generic firms competing product.

In contrast, in order for an authorized generic to obtain Health Canada approval, all that is required is a letter from the brand company to Health Canada stating that the authorized generic is identical to the brand-name product. This process may take only days to complete at minimal cost to the brand company of licensee.

CGPA POSITION

If a brand-name drug company uses the automatic injunction under the *Patented Medicines (Notice of Compliance) Regulations* to claim patent infringement and block an independent generic, an authorized generic should not be allowed to be approved by Health Canada until after expiry of that patent.