



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

U.S. IMPORT RULES FOR PRESCRIPTION NARCOTICS

THE ISSUE

The legal and regulatory framework for the supply of prescription narcotic products in the United States poses significant barriers for Canadian generic drug manufacturers seeking to enter U.S. markets. The U.S. framework may also be in contravention of NAFTA.

BACKGROUND

Under the U.N. Single Convention on Narcotics (1961), member states are obliged to control the import and export of controlled substances through the issuance of permits. Countries must also ensure that the total quantity of each drug manufactured and imported in one year does not exceed the total of the quantity consumed for medical and other designated purposes.

There are two major barriers for a Canadian generic company seeking to export prescription narcotics to the United States. First, a Canadian company is unlikely to succeed in register-

ing as a manufacturer or distributor of a controlled substance with the U.S. Drug Enforcement Agency (DEA) because the company would not hold a pharmaceutical manufacturing or distribution license in a U.S. state.

If this barrier was overcome, a Canadian company would still be unlikely to obtain an import permit because section 952 of the **Controlled Substances Act** (CSA) gives clear preference toward allocating quotas to domestic manufacturers.

While Canada is governed by the same international conventions as the United States, Canadian legislation and regulations do not refer to quotas or the management of the controlled substances produced – nor is there any preference for the domestic sourcing of prescription narcotics.

Given the CSA's preference for the domestic supply of narcotics and the

DEA's ability to set production quotas results in a ban on exports from Canada. The U.S. framework for prescription narcotic products may be in contravention of NAFTA.

CGPA POSITION

The CGPA has met with senior officials from a number of Canadian government departments to discuss this important issue. CGPA will meet with U.S. government officials in the near future to discuss, and better understand, how Canadian manufacturers could have increased access to the U.S. market for narcotics.