



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

CANADA'S ACCESS TO MEDICINES REGIME (CAMR)

THE ISSUE

Canada's Access to Medicines Regime (CAMR) imposes onerous requirements on a generic company seeking to obtain and use a license to export drugs for humanitarian purposes – far beyond what is required by a landmark World Trade Organization (WTO) Decision. The regime has proven unworkable in practice, and significant changes are needed.

BACKGROUND

On August 30, 2003 the WTO released its Decision on the Implementation of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health. The goal of the WTO Decision is to make generic drugs available for export to developing and least-developed countries to assist in their fight against HIV/AIDS, malaria and other diseases. Canada was the first country to introduce legislation under this Decision, and the Jean Chrétien Pledge to Africa Act (now known as CAMR) came into force in June 2005.

As predicted by the Canadian Generic Pharmaceutical Association (CGPA) during consultations on the legislation, the regime is falling short of the goal of providing Canadian-made generic pharmaceuticals to people in the developing world who desperately need them. CAMR has been drafted

in a way that ensures it is controlled by the multinational pharmaceutical companies who hold patents for drugs. Major changes are required. The minor amendments implied by the questions in the Government of Canada's November 24, 2006 consultation paper on CAMR are insufficient.

The WTO Decision calls for a system that will work quickly in view of **"the importance of a rapid response"** if an importing country gives notice that it is in need of a drug. But many of the drawn-out steps in CAMR are unnecessary and counterproductive. They also go far beyond the requirements of the WTO Decision.

For example, a triple-combination HIV/AIDS product produced by generic drug maker Apotex was approved by Health Canada for export for humanitarian purposes in August 2006, yet the application for a compulsory license to supply the product to Rwanda became bogged down in the morass of confused and unnecessary steps. Three different companies held patents on the product, and each put forward numerous conditions for issuing a voluntary license. The companies were ultimately unwilling to issue a voluntary license, and the federal government finally issued a compulsory license to Apotex in September 2007.

As Médecins Sans Frontières (MSF) has noted, **"such a convoluted and drawn-out system can never respond to the urgent needs of patients in developing countries who are dying each day from preventable and treatable diseases."**

A company wishing to manufacture and export a generic version of a brand-name drug to apply for a separate licence for every drug order it receives. There is no assurance that the patent holders will not again attempt to delay the supply of these vital generic medicines. The law should only require one licence per drug.

Even streamlining CAMR to track the requirements of the Decision may not be sufficient to ensure that low-cost medicines are distributed. MSF has noted the WTO Decision is **"overly cumbersome"** and has proved unworkable; **"it is incomprehensible that the Canadian government included additional requirements in [CAMR] that increase the complexity of the process."**

CGPA POSITION

The Government of Canada must address the fundamental flaws in CAMR by removing all unnecessary and counterproductive steps that are not required by the WTO Decision. Minor amendments implied by the questions in the Government of Canada's November 24, 2006 consultation paper on CAMR are insufficient to make necessary improvements to the regime.

Using its experience as a world leader in implementing the WTO Decision, the Government of Canada should work to remedy the constraints of the WTO rules governing the delivery of generic medicines to those in need.

Canada's generic pharmaceutical industry remains committed to working with government officials, NGOs and aid organizations to improve CAMR and the WTO Decision so they may ultimately deliver on their intended goals.