IN BRIEF

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The Pharmaceutical Industry, Prices and Access to Medication: A Balance Under International Stress

In Canada and around the world, prescription drug consumption is growing rapidly. Governments, as the primary payers, are therefore making significant efforts to reduce the costs associated with this trend.

At the same time, governments, for industrial policy and economic development reasons, are trying to make their countries more attractive to pharmaceutical research companies and drug manufacturers.

At the international level, the drug industry generates important research and employs a highly qualified workforce in order to respond to a rapidly growing global market, where competition is increasingly intense. Canada is in a difficult situation: with considerably higher drug prices and a much larger market in the United States, U.S.-based producers have an undeniable advantage.

Today, the price gap between prescription medications sold in Canada and those sold in the United States has created a boom in cross-border trade over the Internet,(1) with substantial economic gains ($695 million to $1 billion in 2003, depending on the source). However, this could pose an important challenge to maintaining Canada's drug pricing control system.

A PUBLIC FINANCE ISSUE

To limit rising health care costs, which are largely influenced by the type, price and quantity of drugs consumed, governments control the list of insured drugs, regulate the price of patented drugs(2) and impose a prescription drug reimbursement plan through public programs, which are requiring consumers to absorb a progressively larger share of the cost.

As payers, most governments tend to favour the prescription and consumption of supposedly less costly generic drugs over patented drugs. This has led to a fierce battle for market share between generic drug manufacturers and patented drug manufacturers, which are responsible for most pharmaceutical research.

AN INDUSTRIAL POLICY AND PUBLIC HEALTH ISSUE IN A KNOWLEDGE-BASED ECONOMY

The pharmaceutical industry is a key sector of our knowledge-based economy. According to Industry Canada, the pharmaceutical and drug industry is the fifth-largest and fourth-fastest-growing of the knowledge-intense manufacturing industries in Canada. The pharmaceutical industry is one of the most dependent on R&D spending. In 2002, Canada's brand-name drug manufacturers spent almost $1 billion on R&D.

The industry employs a large, highly skilled and well-paid workforce: approximately 23,000 people are employed by the brand-name sector, 7,000 by bio-pharmaceutical firms, and 6,000 by the generic drug manufacturers.

Maintaining a domestic drug industry is also a public health asset. Geographic proximity and good interaction among research, clinical trials and the health care system, as well as timely access to pharmaceutical innovations, are all factors essential to quality health care.

However, many manufacturers believe that in the future drugs will be increasingly "co-manufactured," meaning that they are manufactured and administered to the patient in tandem. It is therefore desirable to maintain, as far as possible, the integrity of the

complete "drug chain" in Canada. However, an integrated drug industry entails costs, which are caused by tax incentives and higher drug prices, themselves a result of patents.

THE PATENT SYSTEM

A. What is a Patent?

A patent confers an exclusive right to an *invention*, which is a *product* or a *process* providing a new way of doing something or a new technical solution to a problem. The patent guarantees *protection* of the *holder's* right to the invention.

B. Why Have a Patent System?

Patents perform an important function, in that they encourage the development of essential medicine by making companies want to invest in costly, long-term programs to carry out research and create new pharmaceutical products. Without patents, most medication that exists today would never have been developed.

Patents are also an excellent way of sharing knowledge, since the patent application describes how the product or process is new or unique. All patent applications are made public 18 months after the patent is filed, and anyone can access and read them. This information is published to promote the sharing of knowledge and to help those interested find out about progress made in their field.

In Canada, the standard patent term for all inventions is 20 years from the date of filing. However, it takes on average more than 10 years to develop and approve a novel pharmaceutical product before it can be put on the market. The effective term of a pharmaceutical patent is therefore less than 10 years.

Canada's laws compare favourably to those of its trading partners in certain essential aspects such as the basic term of patent protection (20 years). However, Canada's legislation does not provide for extensions to the patent term, an advantage that the United States, certain European Union countries, Australia and Japan confer on their patent holders for periods of up to five years.[(3)]

Pharmaceutical research companies feel that Canada compares unfavourably to its competitors when investors are choosing where their future research and development projects should be located. Adopting measures to prolong Canadian pharmaceutical patent terms would improve Canada's competitiveness in obtaining new investments in the high-tech sector.

GLOBALIZATION CHALLENGES

The pharmaceutical industry is one of the high-tech industries that contribute the most to improving a country's competitiveness through innovation and quality. However, like all industries, it is susceptible to production costs and the range of environmental factors influencing competitiveness. Today, pharmaceutical research and production sites in Canada are constantly at risk because of intense price competition.

The "drug chain" can be broken into various links, and the parameters of competitiveness are not necessarily the same at each stage of the production process (research activities, clinical trials, production, packaging, etc.). The emergence of new global players (China, India, Eastern Europe and North Africa) could encourage some of the labour-intensive segments (final production, packaging) of the production process to be separated and completed elsewhere in the world, where competition by low-wage countries is strong. As well, the development of information technologies has made it possible for some services to be delocalized.

Globalization has also led to new competition (Ireland, Asia) in the development of knowledge-based activities requiring intense R&D efforts and involving maximum product differentiation (which would allow for a temporary monopoly during the patent term, avoiding price competition at the same time) and a high rate of innovation.

Globalization could also directly affect consumers. The cross-border trade over the Internet of Canadian prescription medicines to the United States may be just the first step toward free trade in prescription medicine between the two countries. Greater Canada-U.S. trade (in addition to trade between businesses) could have a major impact on Canada's drug pricing control system for patented medications and create rising prices for Canadian consumers.

Some drug multinationals have already scaled back, or even suspended, their supplies to Canadian on-line pharmacies that sell their products to the United States. They have also increased the cost of drugs to reduce the price gap between the two countries and protect American price levels. Pharmaceutical

companies are aiming to put an end to the cross-border trade in medication before the imminent passage by the U.S. Senate of a bill legalizing the import of Canadian prescription medication to the United States. Such legalization would have an untold impact on prices, access to medication, and the activities of North American pharmaceutical companies.

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(1) See Philippe Le Goff, *On-line Pharmacies and the Sale of Canadian Prescription Medications to the United States*, PRB 03-24, Parliamentary Information and Research Service, Library of Parliament, Ottawa, 18 December 2003.

(2) For further information on price regulation in Canada, see the Patented Medicine Prices Review Board Web site (http://www.pmprb-cepmb.gc.ca).

(3) Since several years can pass between obtaining a patent and the approval of a drug for sale, only a few years may remain between a drug's launch on the market and the expiry of the patent. The "effective" term of the patent is therefore considerably reduced. This is where the *patent term extension process* comes into play, which takes into account the length of the clinical development stage and the delay in obtaining regulatory approval.