Industry Canada Industrie Canada

Sector Competitiveness Frameworks

Pharmaceutical Industry

Part 1 – Overview and Prospects

Industry Sector
Health Industries

Secteur de l'industrie
Industries de la santé

Canada

This *Overview and Prospects* is the first of two companion documents on the Canadian pharmaceutical industry in the **Sector Competitiveness Frameworks** series, which is being produced by Industry Canada in collaboration with Canada's key stakeholders in the industry. *Part 2 — Framework for Action* will be prepared in coming months, based on discussions with major industry stakeholders, following study and review of the *Overview and Prospects*.

The **Sector Competitiveness Frameworks** series focusses on opportunities, both domestic and international, as well as on challenges facing each sector. The objective is to seek ways in which government and private industry together can strengthen Canada's competitiveness and, in doing so, generate jobs and growth.

Part 1 — Overview and Prospects is being made available for distribution in printed as well as electronic forms. In all, some 28 industrial sectors are being analyzed.

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FOREWORD

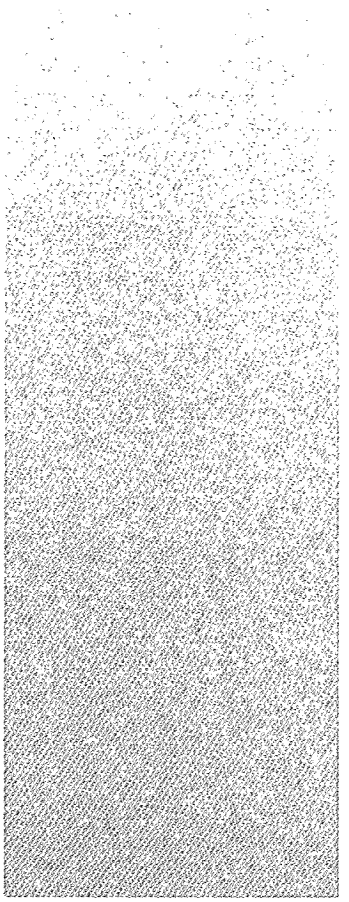
The new Canadian marketplace is expanding from national to global horizons and its economic base is shifting increasingly from resources to knowledge. These trends are causing Canadian industries to readjust their business approaches, and government must respond with new tools to help them adapt and innovate. Industry Canada is moving forward with strategic information products and services in support of this industry reorientation. The goal is to aid the private sector in what it is best qualified to do — create jobs and growth.

Sector Competitiveness Frameworks are a series of studies published by Industry Canada to provide more focussed, timely and relevant expertise about businesses and industries. They identify sectors or subsectors having potential for increased exports and other opportunities leading to jobs and growth. They will cover 28 of Canada's key manufacturing and service sectors.

While they deal with "nuts and bolts" issues affecting individual sectors, the Sector Competitiveness Frameworks also provide comprehensive analyses of policy issues cutting across all sectors. These issues include investment and financing, trade and export strategies, technological innovation and adaption, human resources, the environment and sustainable development. A thorough understanding of how to capitalize on these issues is essential for a dynamic, job-creating economy.

Both government and the private sector must develop and perfect the ability to address competitive challenges and respond to opportunities. The Sector Competitiveness Frameworks illustrate how government and industry can commit to mutually beneficial goals and actions.

The Sector Competitiveness Frameworks are being published sequentially in two parts. An initial *Overview and Prospects* document profiles each sector in turn, examining trends and prospects. The follow-up *Framework for Action* draws upon consultations and input arising from industry–government collaboration, and identifies immediate to medium-term steps that both can take to improve sectoral competitiveness.



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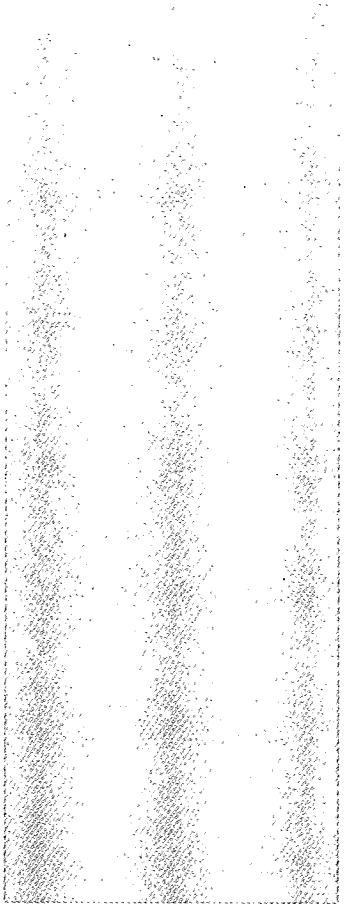


1 HIGHLIGHTS

The pharmaceutical industry is an important contributor to the Canadian economy. It accounts for 1 percent of manufacturing employment and 10 percent of all industry research and development (R&D). It is a competitive, profitable sector with above-average wage rates. The industry is an integral part of the health care system in Canada.

1.1 Major Trends

Structural Change

The pharmaceutical industry is going through a major restructuring worldwide, which is having an impact on the Canadian industry. The restructuring is partly due to downward pressure on the industry's revenue growth. The rising cost of health care in developed countries has caused governments and private sector health care management companies to introduce measures to restrain its growth. This in turn has led to constraints on drug sales volumes and prices.

On the supply side, enhanced productivity is essential for innovative companies to afford the rising costs of discovering, developing and marketing new drugs sold under their brand names (see Annex A — *Glossary of Terms*). Many major pharmaceutical multinational enterprises (MNEs) have engaged in mergers to increase their financial capacity and are shedding manufacturing capacity by closing or selling plants around the world in order to reduce costs.

At the same time, other companies that produce generic drugs have been growing rapidly. This is partly in response to government and private sector measures designed to reduce health care costs by encouraging consumers to switch to lower-priced drugs, where possible, but also in response to the need for inexpensive, effective medications in less developed countries.

The Canadian industry is evolving in response to these global pressures. Canadian R&D expenditures by multinational brand-name companies have been increasing at a time when drug manufacturing capacity in Canada has been falling. The brand-name sector contributes far above the average among Canadian manufacturing industries to R&D funding, dedicating around 12 cents per sales dollar in recent years. Manufacturing by generic drug companies also is on a growth track as the key companies adopt internationally oriented strategies embracing both domestic investment for exports and foreign direct investment. Bio-pharmaceutical R&D is increasingly important in the strategies of both brand-name multinational and generic domestic companies.

International Trade and Capital Flows

Canada's pharmaceutical manufacturers traditionally have not been positioned as exporters. However, this is beginning to change, especially since the 1994 implementation of tariff phaseouts through the North American Free Trade Agreement (NAFTA) and the 1995 implementation of the World Trade Organization (WTO), which embraces most of the world's trading nations. Currently, Canadian producers that are subsidiaries of MNEs export less than 10 percent of their Canadian shipments, whereas Canadian generic drug producers export 40 percent of their output.

There is a growing deficit in pharmaceutical goods trade, which reached $1.8 billion in 1995. (All data shown are the most recent available at the time of writing.) However, as a proportion of total pharmaceutical trade flows (exports plus imports), the deficit is declining slowly in relative terms. Its increase in absolute size comes from the expansion of trade rather than from any serious loss in Canada's competitive position. Because Canada's domestic market is expected to grow less quickly over the next five years than in the past, generic and some brand-name companies are looking to export markets to sustain growth. The U.S. market as well as some of the developing markets are the focus of attention.

The industry's service exports include transfers of information technology expertise, the performance of clinical trials and pharmaco-economic studies. On the import side, management consulting services are sometimes purchased from foreign sources. With respect to capital flows, there is significant inward foreign direct investment among the

brand-name MNEs, and there is some outward foreign direct investment on the part of the generic companies. In addition, the subsidiaries remit dividends and royalty payments for the use of patents to their parent companies.

Technology and Innovation

Canada increasingly fits into global pharmaceutical R&D strategies as a competitive place to perform clinical trials and selected basic research. Pharmaceutical companies in Canada have access to a well-developed infrastructure and specialized expertise, including leading medical researchers outside their organizations. The rise in the R&D-to-sales ratio of patent-holding companies over the past decade is one clear indicator of Canada's growing attractiveness as a site for R&D activities.

Innovation in the industry centres on the discovery and development of new drugs. The Patented Medicine Prices Review Board (PMPRB) reports that pharmaceutical patent holders in Canada in 1995 spent in the order of $620 million on R&D (excluding capital expenditure: see Annex A — *Glossary of Terms* for definition). Since the cost of discovering and developing a single new drug is often in excess of $400 million, it is not surprising that Canadian-based firms have not as yet been solely responsible for many new drug discoveries.

Up-to-date manufacturing technology is also an important aspect of competitiveness. The generic manufacturers have used technologically advanced plants to profitably produce low-priced copies of drugs that are off-patent or still under compulsory licence. The brand-name firms are improving the efficiency of their manufacturing facilities as they restructure their operations and move from branch plant to North American and global product mandates.

Key success factors in promoting R&D include the degree of patent protection available, the R&D tax credit system, the availability of leading researchers in universities and centres of excellence, direct funding of R&D, for example, through the Medical Research Council of Canada, and the ability of Canada's MNE subsidiaries to convince their parent companies that their R&D capabilities (including the use of new information technologies) make Canada an attractive place to invest.

Investment

The global restructuring drive of the MNEs has affected the investment behavior of their subsidiaries in Canada and elsewhere. Worldwide consolidation of major companies has resulted in the sale or shutdown of some manufacturing capacity in Canada. At the same time, new investments, often in R&D facilities, have been made. The generic companies have made a significant contribution to the aggregate investment performance of the industry.

The industry has achieved good levels of profitability over the past several years, partly based on strong growth of sales in the domestic market. Sales growth in Canada is now slowing and, over the next five years, aggregate sales in Canada are expected to continue on a reduced growth track. Although the longer-term outlook for demand growth is favourable, the prospect of reduced profitability over the next several years has caused companies to re-examine their investment plans for the domestic market.

Investment in Canada by MNEs is driven by the allocation of R&D and manufacturing mandates based on corporate judgments about how well Canadian capabilities and opportunities fit into the companies' global strategies. Key success factors in attracting new investments include intellectual property protection, growth in the domestic market (which consumes 80 percent of Canadian shipments), access to foreign markets (including mutual recognition agreements) and the speed of regulatory approval of new products.

A factor in Canada's favour is the existing relative advantage over U.S. locations in the cost of construction and operation of new facilities. Indeed, Canada has recently been chosen for regional/world product mandates by a number of companies. Nevertheless, Canadian subsidiaries face strong competition for investments from sister organizations in countries with fast-growing economies, strengthened patent protection, low wage rates and low taxes (e.g. Brazil, Singapore).

With respect to generics, the decision to invest depends partly on the growth in the domestic market and partly on their ability to serve international markets. Some generic companies are investing in Canada for export while others are making direct foreign investments, particularly in the U.S. market. Recently, foreign-based generic companies have demonstrated an interest in Canadian investments.

A new federal government investment strategy, which seeks to make Canada the NAFTA location of choice, targets the life sciences industry (including pharmaceuticals) as a priority sector.

Human Resources

The pharmaceuticals work force is highly educated, with over 50 percent of personnel having university degrees. The average wage in the industry was $48 000 a year in 1994, which was 30 percent higher than the average in Canada's total manufacturing sector. The human resources available to the pharmaceutical industry are internationally competitive. Skill levels are adequate, and there are enough available people in all key scientific and manufacturing occupations.

While total manufacturing employment in Canada has declined in the 1990s, Canada's pharmaceutical industry has provided some employment growth, and modest growth is projected into the future. Most of the growth has occurred among the generic companies, the smaller brand-name companies and the bio-pharmaceutical sector.

Sustainable Development

The industry has a reputation as being clean and environmentally friendly. The only significant pollution comes from solvents (used on pill coatings) emitted into the air by some major manufacturing plants. While the amount of packaging typically used is large relative to the unit of product sold, the industry feels that it is difficult to reduce because of the requirements by regulatory bodies for product information on labels.

Health Canada has responsibility for ensuring that therapeutic drugs entering the Canadian marketplace are safe for use. Increasingly, however, post-market disposal of unused drugs is becoming an issue. For example, the Province of British Columbia has introduced the idea that pharmaceutical companies bear responsibility for safe disposal of unused drugs, and the Province of Quebec is moving toward a voluntary code of behavior.

Another important factor affecting development of the industry is the *Canadian Environmental Protection Act* (CEPA), which regulates the manufacture and importation of biotechnology products not covered by the *Canada Health Act* or other specialized Acts.

The Public Policy Framework

Policies affecting market conditions include the public funding of health care through reimbursement plans, which reduces access to a portion of the market for some patented drugs, and the control of patented drug prices by the PMPRB.

The marketplace is importantly influenced by the patent protection available. The most recent Canadian legislation on this matter, the *Patent Act Amendment Act, 1992* (commonly referred to as Bill C-91) was introduced in Parliament in 1992 and received Royal Assent on February 15, 1993. This legislation increased effective patent protection available in the Canadian market. A parliamentary review of these amendments was conducted in early 1997.

From the point of view of the MNEs, patent protection in Canada should be seen in an international context. The global profitability of these companies depends on the degree of patent protection in all the markets in which they sell their products. Countries having below-average patent protection tend to be overlooked in the companies' global investment strategies. Although MNE subsidiaries have found the Canadian market to be profitable in the past, they believe that increased patent protection is needed to put Canada on a par with the United States, Europe and Japan, where patent term extensions are available (to make up for long development times and delays in approvals from regulatory bodies).

The generic companies hold the opposite view, citing the fact that the Canadian market is small relative to other key markets and therefore does not account for a large share of MNE profits. The generic companies would prefer less patent protection, which would permit them to enter the market earlier and augment their cash flows by more quickly bringing lower-priced drugs to Canadian and export markets. In their view, higher cash flows are needed in order for them to make the transition into innovative companies.

With respect to bio-pharmaceuticals, the members of the Industrial Biotechnology Association of Canada (IBAC) hold views about patent protection that are similar to those of the MNEs. They feel that strong patent protection has been, and continues to be, a key element in the bio-pharmaceutical industry's growth. However, a few bio-pharmaceutical firms, particularly those who have alliances with or are subsidiaries of generic manufacturers, have views more in line with those of generic companies. A source of some concern to all bio-pharmaceutical companies is the increased time needed by the Canadian Patent Office to examine applications. The growth in applications relative to the number of examiners available is causing delays in Canada, just as it is in other countries.

Another important influence on the effective patent life of drugs is the speed of approvals received from Health Canada. Comparisons between the Canadian and U.S. systems reveal that Canada is slower in granting approvals for both brand-name and generic drugs. In both countries, a shortening of approval times is a goal of the regulatory bodies.

With respect to factor conditions, Canada provides a competitive tax environment through a combination of the R&D tax credit and comparatively low corporate tax levels. Research is promoted through grants to medical institutions and researchers and through the support of the networks of centres of excellence.

1.2 The Bottom Line

The pharmaceutical industry has the potential to make a significant contribution to Canada's economic future.

Companies in Canada are in the process of evolving toward a truly global role. MNE subsidiaries in Canada are no longer strictly branch plant operations mandated to serve only the domestic market. They compete for R&D mandates aggressively and, depending on their competitiveness, attain certain levels of success in obtaining regional or global manufacturing mandates for niche products.

Generic companies have been quite successful in achieving growth in the domestic market. They are moving to penetrate established markets by forging strong alliances and by aggressively targeting emerging markets.

The Canadian pharmaceutical industry:

- develops and markets products that have a strong consumer demand and an increasing consumer base
- has kept pace with or outpaced its U.S. counterpart in recent years, according to the usual industrial performance measures
- is profitable and R&D-intensive
- uses and develops state-of-the-art technology.

A Canadian industry sector with such characteristics could be expected to be on a buoyant growth track into the future. However, some factors unique to pharmaceuticals are causing some concern about the industry's outlook, notably, constraints upon product demand and prices here and elsewhere, global overcapacity and the directions in which global restructuring will carry Canada's pharmaceutical industry.

The future growth of the Canadian-based industry depends on continued efforts by the companies and other stakeholders to maintain and increase international competitiveness. Key issues include how to enhance the export performance of the Canadian industry, how to strengthen the link between the growing R&D expenditures in Canada and manufacturing capabilities, and how to improve the linkages between publicly funded R&D efforts and privately funded activities.

2 KEY POINTS ABOUT THIS INDUSTRY

2.1 Global Context

The pharmaceutical industry is an important contributor to industrial development and employment growth in the global economy. Pharmaceutical employment in the largest industrial countries (United States, Japan, United Kingdom, Germany, France) grew by 9.7 percent from 1981 to 1991, while total manufacturing employment in the same countries showed a 4.3 percent decline. (All data shown are the most recent available in each category at the time of writing.) The pharmaceutical industry worldwide was a centre of growth in shipments and R&D in the 1980s, and Canada participated in this upward trend.

Despite the historical record of steady growth, major changes are taking place, which give rise to questions about the industry's future. To situate the Canadian industry in this broader context, it is useful to consider briefly some of the changes occurring in the health care systems of the world and the global pharmaceutical industry.

The World Health Care System

Rising health care costs force governments to curb drug price increases

In mature developed countries, health care expenditures, which to a large extent are funded from the public purse, have been rising rapidly. Many factors are involved in this increase, including the cost of health services (physicians' salaries, and hospital care and related workers' salaries), the introduction of new and better drugs, and the increasingly sophisticated medical devices needed to care for an aging population. (Informetrica Ltd., a private statistical research firm, estimates that annual health-weighted indexes of population change in Canada will grow by 0.6–0.8 percentage points faster than average population over the next decade or so.) Because of the need to control health care costs, including drug costs, in developed countries, governments have applied downward pressure on drug prices during the 1990s. Government initiatives range from controlling prices and profit margins directly to encouraging the substitution of generic copies of patented drugs. Private health care management companies, which establish reimbursement lists to control expenditures, are a growing force, particularly in the United States.

Drug needs rise rapidly in developing countries

Less developed countries have large, rapidly growing populations in need of basic health care. For example, the lesser developed African and Asian countries and the former Soviet Union are in need of all forms of health care. In the longer term, the potential for sales of drugs in these regions is vast, given the high incidence of diseases that can be effectively treated by currently available products.

In newly developed countries in Asia (e.g. Singapore, Republic of Korea), Latin America and eastern Europe, a rising middle class is demanding better health care than has been available in the past. This trend enhances the export prospects of the drug and other health-related industries that have supply capabilities in developed countries.

Investment in R&D is required to meet growing drug needs worldwide

The ongoing demand for improvements to the level of health care has resulted in devotion of a substantial and growing portion of total R&D expenditures of various countries to the discovery and development of new and better pharmaceuticals. A significant and rising share of medical R&D now is devoted to the discovery of bio-pharmaceuticals, which have the potential to produce breakthroughs in the treatment of world health problems. Canada is an active participant in this field. (Note: statistics regarding bio-pharmaceuticals are not included with the data in this report, but are included in the companion document in the Sector Competitiveness Frameworks series *Bio-Industries: Part 1 — Overview and Prospects.*)

The Pharmaceutical Industry

U.S. accounts for 40% of world drug sales, Canada 2%

Prescription drug sales in 1995 amounted to just over US$200 billion worldwide, while over-the-counter (OTC) drug sales were worth about US$45 billion. The United States is the largest market for drugs, accounting for about 40 percent of the total, while Japan is in second place, and various European countries follow. Canada is a relatively small market, representing about 2 percent of global pharmaceutical sales.

The major firms are headquartered in the U.S., the U.K., Sweden, Germany, France, Japan and Switzerland. In the U.S., pharmaceutical firms developed from retailing concerns, while in Europe they evolved from large chemical or textile-producing companies. Most of the production and R&D capabilities of the key companies remain in the home country. Other markets, including Canada, have been served by subsidiaries of the MNEs or by exports. Countries that are home to major companies typically run significant trade surpluses (Japan is the exception) and other developed country markets run deficits. In the late 1980s and early 1990s, the major companies expanded production and employment in some locations such as Spain, Puerto Rico and Ireland to take advantage of tax incentives and low labour rates, which improved the pharmaceutical trade balance of these jurisdictions.

Market is segmented into therapeutic classes, each providing a few drugs

The global pharmaceutical industry is not highly concentrated. To a large extent, the overall market is segmented into a number of therapeutic classes. Typically, only a few companies have drugs available, and so there is limited price competition for patented drugs. The top 10 companies account for only about 31 percent of prescription drug sales. The largest companies on a worldwide basis include Glaxo Wellcome (U.K.-based), Merck (U.S.), Hoechst Marion Roussel (Germany–France), Bristol-Myers Squibb (U.S.), American Home Products (U.S.) and Novartis (Switzerland).

Multinational Brand-name Companies

R&D costs of new drugs rise faster than prices of patented drugs

Responses on the part of governments to concerns over mounting health care costs have restricted the growth of revenues of brand-name drug companies below what would otherwise have been the case. Prices of patented drugs have not increased as quickly as the costs of R&D for new drugs. New chemical-based drugs are increasingly difficult to find by traditional random search methods. Although companies are moving to more focussed R&D (designer drugs) and toward bio-pharmaceuticals for new discoveries, the higher costs of developing new drugs have convinced many innovative companies that they need at least $1 billion in sales to remain viable. The industry view is that the pipeline leading to the release of new drugs is relatively thinner now than it was in the 1980s.

Companies enlarge operations to gain efficiency and financial strength

The existence of excess manufacturing capacity and the need for scale in production and generation of funds for R&D and marketing have caused a wave of mergers/acquisitions and alliances among drug companies (Table 1). Part of this effort to gain scale and efficiency involves the rationalization of company operations on a global basis. Company activities in both primary and secondary markets have been affected. As an illustration, U.S.-based pharmaceutical companies responding to the annual Pharmaceutical Research and Manufacturers Association (PhRMA) survey reduced their employment worldwide by 3.2 percent or 11 901 employees from 1992 to the midpoint of 1995.

Table 1. Recent Large Mergers and Acquisitions

Former company name	Former company name	New company	Date of merger/ acquisition
Sandoz	Ciba-Geigy	Novartis	1996
Pharmacia	Upjohn	Pharmacia & Upjohn	1995
Glaxo	Wellcome	Glaxo	1995
Hoechst Roussel	Marion Merrell Dow	Hoechst Marion Roussel	1995
American Home Products	Cyanamid	American Home Products	1994
Roche	Syntex	Roche	1994
Sanofi	Sterling	Sanofi	1994
Hoechst	Roussel	Hoechst Roussel	1994

Source: *Financial Times*, March 25, 1996, p. 1.

Many multinationals now have generic divisions or close ties with generic companies. In turn, generic companies in the U.S. and a number of European countries have often actively sought arrangements with multinationals to take advantage of distribution capabilities and to ensure

Many pharmaceutical companies are forming alliances

a place in managed care systems. Indeed, the trend by some majors to move into benefits management opens up the prospect of more alliances as the need to provide a full range of inexpensive products grows.

It is not clear whether the mergers/acquisitions have run their course. It can be noted, however, that present high levels of stock prices in financial markets make company assets expensive, and this may put a temporary damper on this type of activity.

Generic Drug Companies

Generic share of prescription market is rising

The generic sector is growing rapidly in most developed countries. There have been large market share gains by generics in the number of prescriptions written in Canada and the United States over the past five to 10 years. In Canada, prior to 1993, compulsory licensing of brand-name pharmaceuticals provided less expensive drugs to the Canadian population by allowing generic producers to copy and sell drugs still under patent in return for a royalty fee, generally set at 4 percent of sales. A second impetus to the growth of generic companies was the efforts of provinces to encourage substitution toward lower-priced drugs, usually generics. In 1996, the generic sector accounted for 39.8 percent of the total number of prescriptions filled in Canada and 17.4 percent of their value.

In the U.S., the *Waxman/Hatch Act* of 1984 accelerated approval of generic drugs by the U.S. Food and Drug Administration (FDA) with the introduction of the abbreviated new drug application (ANDA). The share of generics in the U.S. prescription market (number of prescriptions filled) is estimated to have exceeded 50 percent in 1995. Generics hold a small but growing market share in Europe. The generic market penetration rate is higher where brand-name prices are above average (e.g. Germany and the Netherlands), as the room for price discounting is greater.

Major drugs are coming off-patent soon

A number of top-selling drugs (market value of around US$30 billion worldwide, although estimates vary) are coming off-patent in traditional markets in the next five years. However, there is a counterbalancing trend toward increased patent protection in a number of countries, including patent term restoration in the U.S., the European Union and Japan, implementation of patent protection in developing countries such as Mexico and Brazil, and the elimination of compulsory licensing in Canada in 1993, all of which restrict the market available for generics.

The rapid growth of health care in newly developed and developing country markets holds potential for generics, particularly because these drugs are less expensive. At the same time, barriers to entry in these markets are low, suggesting that indigenous industries may grow over time.

Services Subsector

Canada extends drug research services

Pharmaceutical companies represent a market for research and other services to varying degrees around the world. Canada has private sector contract research organizations (CROs) that offer integrated packages of all the major services required by pharmaceutical and biotechnology companies to take a new drug through the developmental and regulatory process. Canada also has a strong university medical research base that encompasses 16 medical faculties in Canadian universities affiliated with a network of over 100 teaching hospitals and research institutes. These organizations carry out much of the industry's R&D on an extramural (external to the funding company) basis. Canada's service exports include transfers of information technology expertise, the performance of clinical trials and pharmaco-economic studies. On the import side, management consulting services are sometimes purchased from foreign sources.

2.2 North American Context

Canada and U.S. move to reduce barriers to international trade in drug market

The North American market (defined here as Canada and the United States) is dominated by the U.S.-based pharmaceutical companies. These companies export to Canada and other destinations as well as satisfying the needs of much of their home markets. All the major companies have subsidiaries in the Canadian market to avoid regulatory barriers and for more effective marketing efforts. Tariffs protecting the Canadian market were significant, but were phased out under the Canada–U.S. Free Trade Agreement of 1989, NAFTA and the WTO. Nevertheless, significant non-tariff barriers remain. For example, drugs cannot be traded between the two countries unless they have been approved for sale by the respective regulatory agencies. If approved in both countries, the therapeutic uses for which they are approved could differ, and so limit their availability. Finally, the lengths of patent protection for some products differ in the two countries. These impediments to the free flow of pharmaceutical products across borders can have a negative impact on Canada's ability to attract investment and regional product mandates.

To be consistent with the NAFTA and the trade-related intellectual property rights agreements of the WTO, the effective patent life in Canada was extended through the elimination of compulsory licensing in 1993. This move toward harmonization of intellectual property rights significantly reduced perceived barriers to R&D investment in Canada on the part of MNEs.

Varying patent expiry terms impact on Canadian, U.S. drug exports

Despite this move toward harmonization, patents for a given drug may expire at different times in Canada and the United States. First, the U.S. allows patent term restoration (PTR), which extends exclusive time on the market by up to five years in recognition of the fact that delays in the approval process reduce the effective patent life. Second, companies registering a

patent in a first market, say, the U.S., by international agreement have up to one year to register the same patent in other markets. And third, patents for pharmaceuticals in Canada used to be registered for processes but now are registered for the product, which has caused the patent expiry dates for some drugs to change. When the U.S. patent expires earlier, export of Canadian generic drugs is effectively delayed, since generic drugs cannot be manufactured for sale until the patent expires in Canada. In such cases, U.S. generic firms are more likely to be the first entrant into the market. The opposite occurs, to the benefit of Canadian generics, when the Canadian patent expires first, for example, when drugs receive patent term extensions in the U.S.

Much of Canada–U.S. trade is intra-firm

Canada runs a significant trade deficit with the U.S. on manufactured pharmaceuticals; this represents about 60 percent of the overall Canadian deficit in pharmaceutical goods trade. Much of the trade with the U.S. is between different branches of the same firms.

There are significant inflows of foreign direct investment for drugs into Canada

With respect to capital flows, there is significant inward foreign direct investment in the MNE sector and there is some outward foreign direct investment on the part of the generic companies. In addition, the MNEs remit dividends and royalty payments for the use of patents to their parent companies. Although data on service and capital flows for the industry are not available, there is likely a positive balance on foreign direct investment (net inflow) and a negative balance on dividend and royalty flows. The services account may also be positive, but the small scale of services relative to manufacturing implies that its surplus would be much too small to outweigh the deficit on goods trade.

The Canadian industry's share of Canada–U.S. activity has remained relatively constant between 1983 and 1993, the most recent period for which comparable data for both countries are available. The industries in both countries saw a prolonged period of recovery following the 1982 recession, with expansion lasting into the early 1990s. Latterly, both have experienced declines in employment associated with restructuring activities.

These are the major comparative trends between the Canadian and U.S. pharmaceutical industries in recent years:

- Canada's share of the North American pharmaceutical **market** has remained at about 7 percent over the past decade.
- Canada's share of **shipments** fluctuated between 4.5 percent and 6 percent during 1983–93, with a higher share at the end of the period than in 1983–85. These percentages are lower than the corresponding share of the domestic market because imports supply a larger portion of the Canadian market.

- At the same time, Canada represented about 10 percent of **employment** in the pharmaceutical industry in 1993, up from around 8.5 percent a decade earlier.
- Canada's share of **capital investment** has risen from about 4 percent in 1983 to around 5.5 percent in 1993.
- Canada's average share of **R&D investment** in 1995 was 3.9 percent, made up of about 3 percent of pharmaceutical industry intramural investment and 6 percent of extramural investment.
- The proportion of production that is **exported** is higher in Canada. The export orientation of the Canadian industry has risen to around 17 percent, compared with 10.5 percent in the U.S., largely due to generic exports.

The overall conclusion is that the Canadian industry has performed at a pace that compares well with the benchmarks of the much larger U.S. pharmaceutical sector. A few areas of note lie behind these relatively positive overall trends:

Canadian drug firms keep pace with U.S. benchmarks

- While Canada's share of employment is high relative to the size of the markets, the quality/mix of jobs has been less desirable than in the U.S. The average compensation rate (wages and salaries) is about 30 percent lower in Canada than in the U.S.
- Canadian subsidiaries concentrate more heavily on labour-intensive activities, such as market development and R&D, and use less-capital-intensive manufacturing technologies than their U.S. counterparts (which contributes to a higher employment share).
- Canada's low shipments share and high employment share suggest that labour productivity (manufacturing output per employee) was significantly lower in Canada than in the U.S. over the period examined.
- Drug prices are significantly lower in Canada than in the U.S. (which contributes to a lower measured share of consumer purchases).

2.3 Canadian Industry Snapshot

Canadian drug firms pay high wages, make high R&D investments

The importance of the pharmaceutical industry lies in its strong scientific orientation and state-of-the-art technology, its high wages, its potential for export growth and its contribution to the health and welfare of Canadians. The average wage in the industry is $48 000 a year, which is 30 percent higher than the average in the total manufacturing sector. Pharmaceutical R&D performed by, or on behalf of, companies accounts for 9 percent of total R&D carried out by all industry, in spite of the fact that pharmaceutical shipments and employment represent

only 1.0 and 1.2 percent of manufacturing activity, respectively (Table 2). The high concentration of intramural R&D is augmented by the somewhat lower level of expenditures that finances work by medical researchers in universities and hospitals.

Table 2. Snapshot of the Canadian Industry, 1994

	Employees	Shipments	Average wage	Total R&D[a]
Number	19 564	$4.45 billion	$48 000	$536.6 million
As a share of total manufacturing industry (%)	1.2	1.0	130	—
As a share of all industry (%)	—	—	—	9.0

[a] The estimate for R&D is derived by dividing total pharmaceutical R&D (intramural plus extramural) by total intramural R&D of industry. As other industries perform comparatively little extramural R&D, the estimate is considered reasonable, although it is somewhat overstated.

Source: Statistics Canada, *Industrial Research and Development*, Catalogue No. 88–202, annual; and CANSIM, D662147, D667757, D667760 and D667762.

Brand names and generics engage in many similar activities, but maintain contrasting policy viewpoints

The Canadian pharmaceutical industry consists of two major components: the subsidiaries of multinational brand-name drug producers on one hand, and the largely Canadian-owned generic drug producers on the other (Table 3). A third component, made up primarily of Canadian-owned small and medium-sized bio-pharmaceutical firms, is also emerging. There is some tendency toward convergence of the generic and brand-name sectors, in the sense that generic companies now conduct some innovative research and both groups of companies have an interest in bio-pharmaceutical development. Nevertheless, patent drug producers and generics remain distinct in terms of their views about appropriate policy stances for government (e.g. strength of patent protection) and many other issues.

Table 3. Ranking of Pharmaceutical Companies by Sales, First Half of 1996

Company name and country of control	Rank Canada	Share of Canadian market
		(%)
Glaxo Wellcome (U.K.)	1	5.8
Merck Frosst (U.S.)	2	5.7
Apotex (Canada)	3	5.3
Johnson & Johnson (U.S.)	4	5.3
Hoechst Marion Roussel (Germany)	5	5.1
Astra (Sweden)	6	4.5
Bristol-Myers Squibb (U.S.)	7	4.4
Novopharm (Canada)	8	4.2
Bayer (Germany)	9	3.6
Abbott (U.S.)	10	3.5

Source: Data provided by IMS Canada, 1996.

About half of the Canadian market revenues of brand-name producers comes from selling new prescription drugs under patent protection. The other half of their revenues is derived from over-the-counter (non-prescription) drugs as well as drugs whose patents have expired and now sell for a lower price than when patented (sometimes referred to as pseudo generics). Beyond producing brand-name pharmaceuticals under patent, the companies engage in a considerable amount of R&D directed toward bringing new drugs to market.

OTCs are growing revenue source for brand names

The Canadian-owned generic companies (the two largest of which are Apotex and Novopharm) use highly efficient manufacturing processes to produce and sell lower-priced copies of drugs that have come off-patent or are under compulsory licence. Some of their revenues are also derived from over-the-counter products.

The closely related bio-pharmaceutical industry is in its formative stages in Canada and worldwide. Companies perform a considerable amount of R&D, but few products have been marketed. The risks in developing new products are high. Connaught Laboratories is a well-known vaccine manufacturer, and a number of smaller companies such as Allelix Biopharmaceuticals and Biochem Pharma are active in the Canadian market. Canadian strengths are in therapies for certain cancers, and neuro-degenerative diseases, bone disease, viral infections and specialty plasma proteins (for details, see the companion volume in the Sector Competitiveness Series on *Bio-Industries: Part 1 — Overview and Prospects*). Biochem Pharma's 3TC for the treatment of acquired immune deficiency syndrome (AIDS) is the most successful drug developed in Canada on the market at present.

Canadian bio-pharmaceutical companies seek market specialties, e.g., for AIDS

The pharmaceutical industry shipped approximately $4.7 billion (at factory gate prices) worth of domestically produced product in 1995, up from $4.5 billion in 1994. Approximately $878 million of 1995 shipments were exported.

Canadian firms export 17% of production value . . .

Canada's domestic pharmaceutical market was worth $6.5 billion in 1995. Of this amount, $3.8 billion (58 percent) was supplied by our own industry, and $2.7 billion was satisfied by imports.

. . . import 40% of domestic needs

Canadian shipments included vitamins, glands and extracts, blood and vaccines, medicaments in bulk, medicaments in measured dosage for retail sale, gauze and bandages, and other pharmaceutical goods such as sterile products. Medicaments in measured dosage accounted for 80 to 90 percent of total Canadian pharmaceutical shipments in 1993. Annex Table C-1 provides a breakdown of the patented drugs consumed in the Canadian market.

The main manufacturing input used by the Canadian industry is bulk-form pharmaceuticals (fine chemicals), which represented around 17.5 percent of the value of gross output in 1992. Up to 80 percent of these chemicals are imported. Packaging materials including paper, plastic and glass accounted for about 3 percent of intermediate inputs in 1992, while service inputs including purchased advertising and promotion represented about 7 percent.

Wages, salaries and supplementary labour income accounted for 22.3 percent of the value of gross output in 1992, with direct production workers representing less than half of the wage and salary bill, and sales staff, researchers and administration taking the rest. Annex Table C-2 provides an analysis of the industry's goods and services inputs over a recent period.

Industry maintains strong presence in major metro areas of central Canada

Pharmaceutical companies tend to cluster in large metropolitan areas possessing the required distribution networks and scientific infrastructure. As a consequence, the industry has a strong presence in Ontario and Quebec, with concentration in the regions of Toronto and Montreal (Table 4). The emerging bio-pharmaceutical subsector provides an opportunity for greater participation by other communities, such as Saskatoon.

Table 4. Regional Distribution, 1994

Province/region	Number of establishments	Employment
Atlantic	3	160[e]
Quebec	42	7 806
Ontario	54	10 613
Prairies	3	627
British Columbia	4	300[e]

e = estimate.
Source: Statistics Canada, *Manufacturing Industries of Canada: National and Provincial Areas*, Catalogue No. 31-203-XPB, annual.

2.4 Recent Performance

Shipments

Drug shipments grow faster than those of total manufacturing

In 1983, shipments of the Canadian pharmaceutical industry (not including bio-pharmaceuticals) were $2.8 billion (in constant 1995 dollars). By 1995, the figure had risen by 69 percent to $4.7 billion, for an average annual growth rate of 4.5 percent. This rate of gain outstripped, by a significant margin, the growth of shipments in the total Canadian manufacturing sector as well as the performance of the U.S. pharmaceutical industry.

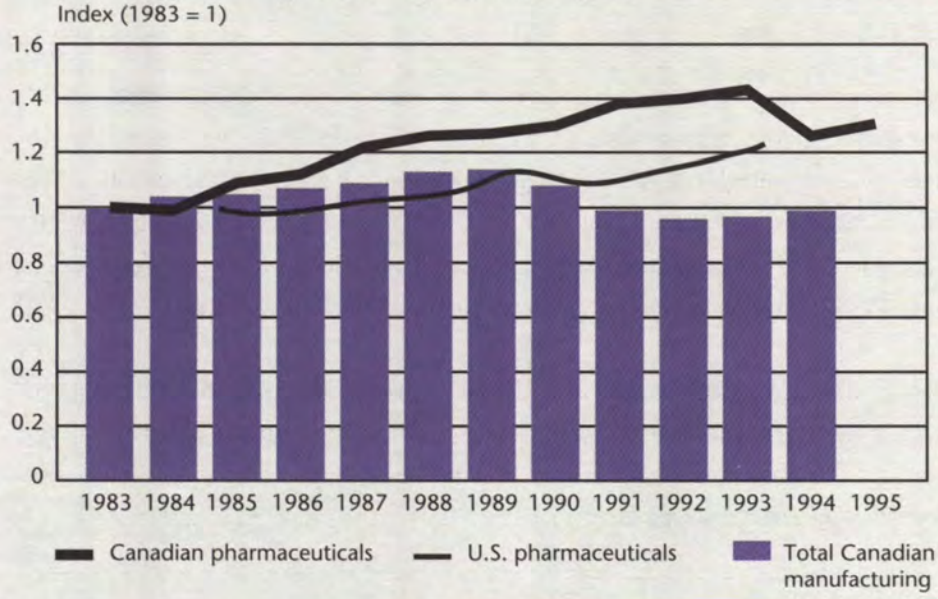
Employment

Overall employment grows, despite MNE rationalization

The pharmaceutical companies support employment through their intramural R&D, manufacturing, marketing and administration activities. Expenditures on extramural R&D also underwrite significant employment of medical researchers and technicians in universities and hospitals.

Between 1983 and 1995, employment in the industry (excluding extramural R&D) grew at an average annual rate of 2.1 percent, rising from 15 268 to 19 657 (Figure 1). This growth was significantly above the rate recorded by the Canadian manufacturing sector, and outstripped the growth recorded in the U.S. counterpart industry as well. In the early to middle 1990s, the aggregate employment level of the Canadian pharmaceutical industry was relatively stable, albeit with significant underlying shifts. Employment in some of the larger brand-name firms fell, while employment in generic companies and smaller brand-name firms (including bio-pharmaceutical firms) increased (see Annex E).

Figure 1. Employment Growth



Source: Statistics Canada, CANSIM, D662150 and D667760; U.S. Department of Commerce, National Economic, Social and Environmental Data Bank, Series 51-SIC 283; 1996.

Productivity

Productivity growth is solid

Over the 1983–93 period, productivity (manufacturing output divided by the total number of employees) grew at approximately the same rate on both sides of the border. Although there was virtually no growth in productivity in the pharmaceutical industry in the 1983–91 period, the indexes have been trending upward since then. It is likely that the new investments in both

R&D and manufacturing facilities associated with restructuring will contribute to productivity growth in the future.

The generic sector in Canada is in a growth phase. It has not needed to restructure because its technology is up-to-date and it is able to compete with its U.S. counterpart.

Wages and Salaries

Wages trend up . . .

Total wages and salaries in Canada increased significantly faster than in the U.S. pharmaceutical industry from 1983 to 1994. Most of the differential in growth is related to faster employment gains in Canada, as wage rates in the two countries have tended to rise at approximately the same rate.

. . . gap with other sectors widens

Throughout the period, wages in the Canadian pharmaceutical industry increased faster than those of the Canadian manufacturing sector. The gap has opened up most quickly since the late 1980s.

Unit Labour Costs

Canada's cost competitiveness position is steady

Combining productivity and wage rates produces a measure called unit labour costs, which is often used in analyses of competitive position. Essentially, relatively fast wage growth can be offset by correspondingly fast productivity growth to maintain an industry's international cost position. Because wages and productivity in the Canadian pharmaceutical industry have grown at about the same rate as those in the U.S., Canada's cost position in aggregate (expressed in terms of U.S. currency) has not changed significantly over the 1983–94 period.

Superior therapeutic benefits and early market penetration are key success factors for drugs

Although unit labour cost is an important competitiveness indicator, the industry appears to attach greater importance to a product's qualities, such as the therapeutic benefit of a drug, and to a firm's ability to be first to market, as being the key success factors (see Section 3.4 — *Firm Strategy, Structure and Rivalry*).

Capital Investment

The Canadian pharmaceutical industry invested a total of $267.8 million in 1994, about evenly split between construction and machinery plus equipment. The vast majority of this capital investment was in manufacturing facilities. Anticipated investment for 1995 was $350.9 million, representing an annual gain of 30.6 percent.

Growth in investment in the Canadian pharmaceutical industry kept pace with the growth of investment in the counterpart U.S. industry and with that in total Canadian manufacturing

over the 1983–88 period. However, since 1988, Canadian pharmaceutical investment has been on a stronger upward track, significantly outpacing the other two types of investment activity.

R&D Investment

Canada's R&D investment is increasing

Canada's R&D investment performance is narrowing the gap with international norms. An R&D-to-sales ratio of 11.8 percent in 1995 was achieved by the patent-holding companies reporting to the PMPRB, up from 10.6 percent in 1993. This compares with an R&D-to-sales ratio of 15.7 percent in 1995 posted by 24 leading international patent-holding companies, and an estimated ratio of 19.1 percent in 1995 by U.S.-based patent companies responding to an annual PhRMA survey. Canada moved from an R&D-to-sales ratio that was one third of the level reported in the PhRMA data in 1988 (6.1 versus 18.8) to well over half by 1995 (11.8 versus 19.1). Thus, commitments by brand-name companies made following the 1993 elimination of compulsory licensing to reach and maintain an average R&D-to-sales ratio of 10 percent have been exceeded.

Intramural R&D for drugs outstrips that for total manufacturing

From 1988 to 1995, total current R&D expenditures by companies reporting to the PMPRB grew from $159 million to $596 million (Table 5). Indeed, intramural R&D in the Canadian pharmaceutical industry (in current dollars) has risen quickly since 1983 (Figure 2), much faster than intramural R&D in total Canadian manufacturing.

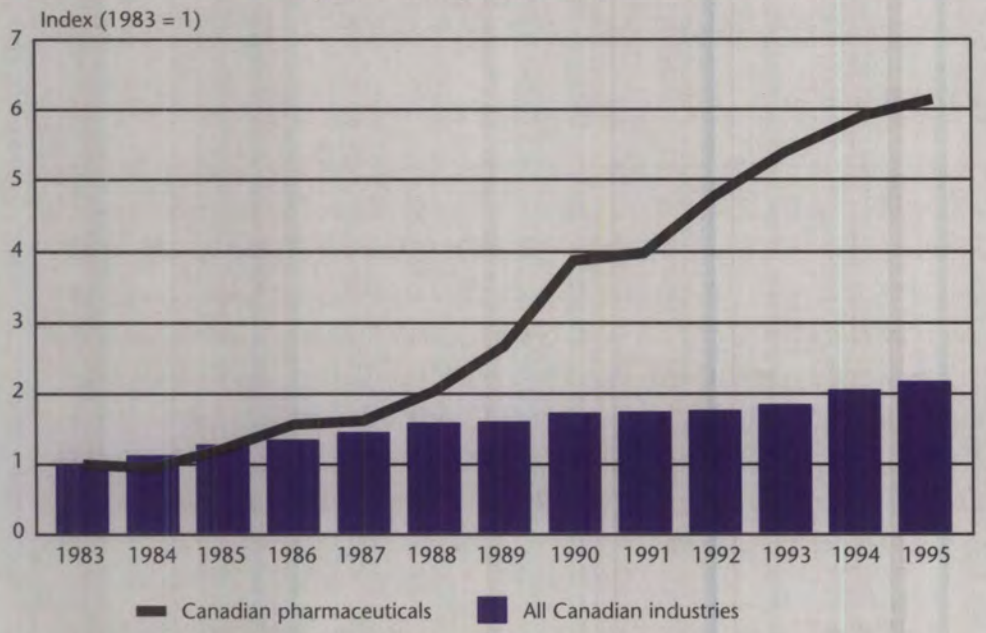
Table 5. Total Current R&D Expenditures, by Type of Research[a]

	Basic research		Applied research		Other qualifying research		Total	
Year	Value	Share	Value	Share	Value	Share	Value	Annual change
	($ millions)	(%)	($ millions)	(%)	($ millions)	(%)	($ millions)	(%)
1988	30.3	19.1	106.6	67.2	21.7	13.7	158.6	—
1989	53.5	23.4	143.3	62.7	31.8	13.9	228.6	44.1
1990	78.4	27.2	167.2	58.0	42.8	14.8	288.4	26.2
1991	94.2	26.5	203.4	57.3	57.6	16.2	355.2	23.2
1992	103.7	26.4	224.1	57.1	64.9	16.5	392.7	10.6
1993	120.7	25.3	288.3	60.3	68.8	14.4	477.8	21.7
1994	117.4	21.9	336.5	62.7	82.7	15.4	536.6	12.3
1995	132.2	22.2	369.3	61.9	94.7	15.9	596.2	11.1

[a] Current expenditures exclude capital equipment and depreciation expenditures. See Annex A — *Glossary* for definitions of basic, applied and other qualifying research and development (R&D).

Source: PMPRB, *Annual Reports*.

Figure 2. Intramural R&D



Source: PMPRB, *Annual Reports*; Statistics Canada, *Industrial Research and Development*, Catalogue No. 88–202, annual.

Canadian firms focus on applied R&D

Intramural R&D expenditures (excluding capital and equipment) by patent-holding companies were $339.8 million (6.7 percent of sales) in 1995. An additional $256.4 million of extramural R&D (5.1 percent of sales) was performed by universities, hospitals and other companies through partnerships and alliances with pharmaceutical companies and associated funding. In Canada, 22 percent of R&D in 1995 was classified as basic or discovery-oriented and about 62 percent was classified as applied. Although R&D statistics are difficult to compare across countries because of differences in definitions, it may be useful to note that in the U.S. in 1994 (the latest year available), the U.S. share of R&D classified as basic was 29.5 percent for companies that reported to the PhRMA. Thus, basic discovery R&D as a proportion of total R&D appears to be similar to, but not quite as strong as, that of the U.S.

Canadian discoveries of new drugs have been few

Although Canada's effort in basic R&D is improving relative to the U.S., Canada has not historically been a discovery centre. Of the 522 new chemical entities introduced to world markets between 1981 and 1989, Japan accounted for 117, the U.S. 106, Italy 42, Germany 37, Switzerland 34, France 31 and the U.K. 21. In contrast, Canada did not discover/introduce any new drugs over this period. According to the brand-name companies, part of the reason

for low expenditures on basic research over this period was the existence of compulsory licensing, which limited the economic return in the Canadian market available to the discovering company. Nevertheless, research efforts in Canada have made important contributions to the discovery of such medicines as 3TC, Photophrin, Timolol and Theratope. Canada's increased activity in basic R&D may hold out the promise of future discoveries (see Annex D).

R&D investment undertaken by bio-pharmaceutical firms is extensive and at present exceeds revenues. Even in the U.S., where some firms have positive cash flow, the R&D-to-sales ratio is very high (about 67 percent in 1994).

International Trade

Trade between countries is growing faster than markets

With respect to international trade in goods, both exports and imports are growing quickly and at about the same rate. As trade is rising faster than the market in general, the trade intensity of the industry is increasing over time. Similar information about trade in services is not available at the present time.

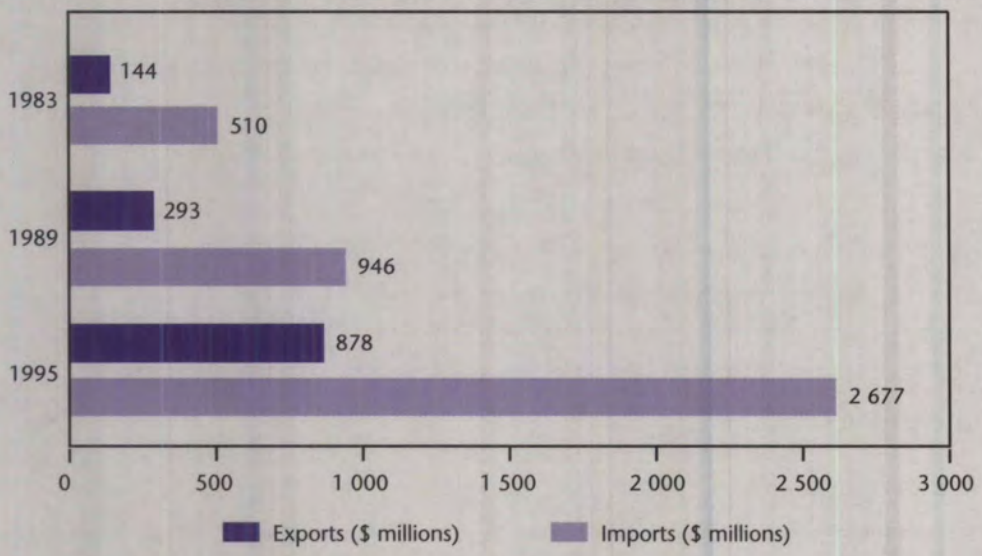
Drug exports lead shipments growth . . .

Exports have contributed to rising shipments. From 1983 to 1987, the export orientation of the Canadian industry was declining. However, since 1987, exports as a share of shipments rose rapidly, from 6.9 percent to 18.5 percent. Propensity to export is much higher in the generic sector of the Canadian industry than for brand-name companies. Import penetration of the Canadian domestic market has risen from about 20 percent in 1987 to about 37 percent in 1993. Import penetration into the U.S. market is only about 10 percent. Much of Canada's imports are fine chemicals needed for the manufacture of drugs.

. . . while imports are taking larger share of domestic market

The absolute size of the trade deficit is increasing (Figure 3). In 1995, Canadian imports at $2.7 billion exceeded Canadian exports at $878 million by a large margin, leaving a trade deficit of $1.8 billion. In addition to being large, the trade deficit has grown over two-and-a-half times since 1989. The growth in the deficit has caused some observers to wonder whether the Canadian industry is experiencing declines in its competitive position.

Figure 3. Canadian Trade in Pharmaceuticals



Source: Statistics Canada, On-line Industrial Monitor database.

However, the deficit as a share of total trade is shrinking slowly; that is, growing slightly less negative (Figure 4). Therefore, it appears that the competitiveness of the Canadian industry is not changing dramatically. Although pharmaceutical exports and imports are growing at about the same rate, the large historical imbalance between them is generating an increasing deficit.

Figure 4. Trade Deficit as a Share of Total Trade

Source: Industry Canada, based on Statistics Canada's On-line Industrial Monitor database.

Bio-pharmaceutical imports in 1995 were estimated at around $85 million. Production of 3TC, a drug developed in Canada, is contracted to offshore manufacturing facilities.

3 CHANGING CONDITIONS AND INDUSTRY RESPONSE

3.1 Market Conditions

Market conditions refer to the size, growth and degree of competition in the domestic market. In his book, *The Competitive Advantage of Nations* (New York: The Free Press, 1990), Michael E. Porter notes that where industries can respond positively to overcome difficult market conditions, competitive advantage may result.

Distribution and Marketing

Traditionally, prescription drugs were bought by hospitals and by individual patients. The greatest influence on which drug was chosen was exercised by the doctor writing the prescription. The decision of the doctor was based on the effectiveness of the drug, rather than on its price, since public and private drug plans reimbursed the patient or the hospital for the medication. As a consequence, brand-name companies focussed their marketing efforts on doctors.

In 1995, 86% of Canadian drug sales were distributed through drug stores, 14% through hospitals — *IMS Canada*

Beginning in the early 1970s, in an effort to limit rapidly rising health costs, provincial and private drug plans established lists of prescription drugs approved for maximum reimbursement (e.g. provincial formularies) based on judgments about the effectiveness of medicines in relation to their costs. These lists potentially segmented the Canadian market (a particular drug may be approved for reimbursement in some provinces and not others); they also introduced a more price-sensitive selection process. The move to approved lists has worked to the benefit of generic companies in many cases, as they offer off-patent and compulsory licensed drugs at lower prices than brand-name companies offer their drugs.

Prescribed drugs accounted for 71.6 percent of the total retail value of drug expenditures in Canada in 1992 (latest year for which such data are available). Just under half of these drugs were funded by the public sector (the vast majority by the provinces) and just over half were funded by private insurers and individuals.

Prescriptions account for over 70% of drug consumption value, half funded by public sector

In the over-the-counter market, where the consumer purchased drugs directly with little reimbursement, the price sensitivity of the market has remained relatively strong. This market represented 28.4 percent of the total retail value of drug expenditures in 1992.

Domestic Consumption

In current dollars (at factory gate prices), the market for pharmaceuticals in Canada, at about $6.5 billion in 1995, is relatively small, representing around 7 percent of the combined

Value of Canadian drug use is low relative to major developed countries, due to low prices

Canada–U.S. market. This share is smaller than the approximately 10 percent share of population because Canada's per capita expenditure on drugs is relatively low. Canadians on average consumed $264.90 worth of drugs in 1994, which was slightly less than half the rate of U.S. consumption (valued at $541.25 in Canadian currency). Canada's per capita consumption was similar to that of Italy ($260.16) and the U.K. ($228.03) but well below Germany ($376.05) and France ($514.49. Much of the difference between the Canadian and U.S. figures is accounted for by lower prices for pharmaceuticals in Canada. After adjusting for the different price levels, Canadian expenditure per capita is about 40 percent lower than that in the U.S.

Drug price increases are slowing . . .

In Canada, annual increases in aggregate drug prices (including prices of patented and off-patent prescription drugs and over-the-counter drugs) have slowed considerably over the past decade. In the middle to late 1980s, annual drug price inflation was in the 6–8 percent range. The rate of increase fell into the 3–5 percent range in the 1989–92 period and eased into the 0–2 percent range in 1993 and 1994.

. . . especially for brand names . . .

According to the PMPRB, patented drug prices in Canada are currently lower (about 47 percent) than those in the U.S. and are similar to prices found in a number of European countries (U.K., Sweden, Germany). Although discounting from listed prices occurs to a greater extent in some markets (e.g. the U.S.) than others (e.g. Canada), a significant price differential remains. Indeed over the past two years, patented drug prices in Canada have declined, and the increase in patented drug prices has been below the rate of inflation for the past eight years. Provincial efforts to contain health expenditures (e.g. formularies) and PMPRB monitoring are important restraining influences; private plans are also attempting to control costs. Moderate drug price increases are expected in Canada in the future.

. . . while volumes of all drugs consumed grow steadily

The volume of all drugs consumed in the Canadian market has grown at an average annual rate of about 5 percent. The volume growth rates on an annual basis are volatile, ranging from small negative numbers in 1989 and 1994 to 9 percent and above in 1987 and 1993. The outlook for volume gains is for growth in the 3 percent range. (Analysis in the eighth annual PMPRB report, December 1995, indicates that for patented drugs only, most of the increase in expenditures in the 1988–95 period was due to increased volume usage per capita.)

Export Markets

Exports increase faster than sales worldwide

Worldwide exports, at $57.9 billion in 1994, represented about 22 percent of worldwide drug sales. Exports have been increasing much faster than sales over the past decade and a half. Canada's pharmaceutical exports represent about 0.9 percent of the world total, far behind those of Germany, the leading exporter with 15 percent of world exports.

About 62 percent of Canada's exports are destined to the U.S., 7 percent to Japan (mostly diagnostic reagents) and 6 percent to Germany (mostly human vaccines, bulk hormones). The majority of Canada's exporting activities are concentrated in a few firms. The six largest exporters accounted for between $450 million and $500 million in export sales in 1995. Much of these sales are between related companies. Most of the firms that do export still derive the majority of their revenues from sales in the domestic market.

Few firms in Canada export

3.2 Factor Conditions

In the Porter framework for analysis of competitiveness, factors of production include financial, human and knowledge resources necessary for the production, discovery and approval of pharmaceuticals. The issues relevant to competitiveness include availability of such resources and their quality relative to other jurisdictions. In Canada, there appears to be no scarcity or quality problems that would detrimentally affect the growth of the industry. Indeed, in the areas of clinical trials and medical research expertise, Canada ranks highly enough on a global basis to confer competitive advantage. Canada also has a cost advantage in constructing and operating new manufacturing and R&D facilities.

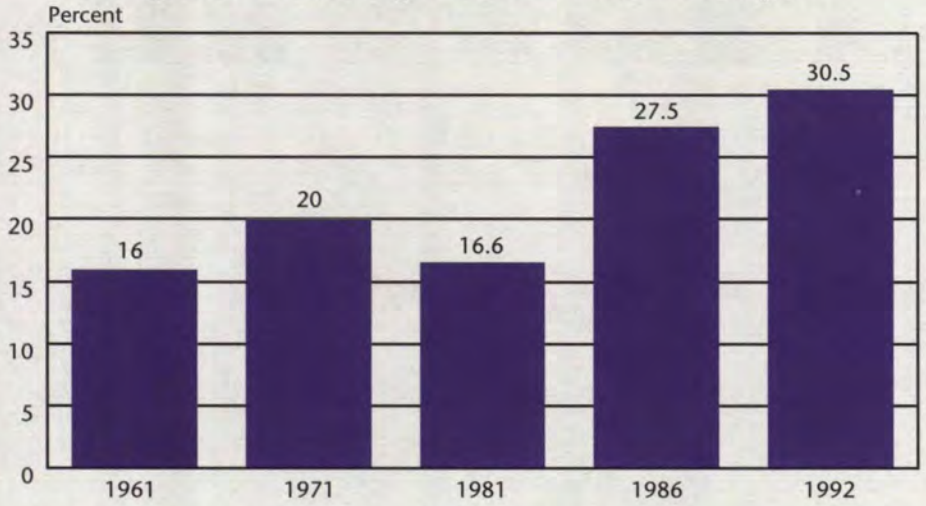
Many factors contribute to Canadian competitiveness

Investment and Financing

The Canadian industry recorded higher rates of profit during the late 1980s and early 1990s than during the previous two decades. The gross operating profit margin, which is calculated as revenues less cost of goods sold (before income taxes) divided by gross output, was in the order of 30 percent in both 1986 and 1992 (Figure 5).

High gross operating profit margins for drugs . . .

Figure 5. Profit Margin as a Share of Gross Output



Source: Statistics Canada, Input-Output tables, special run.

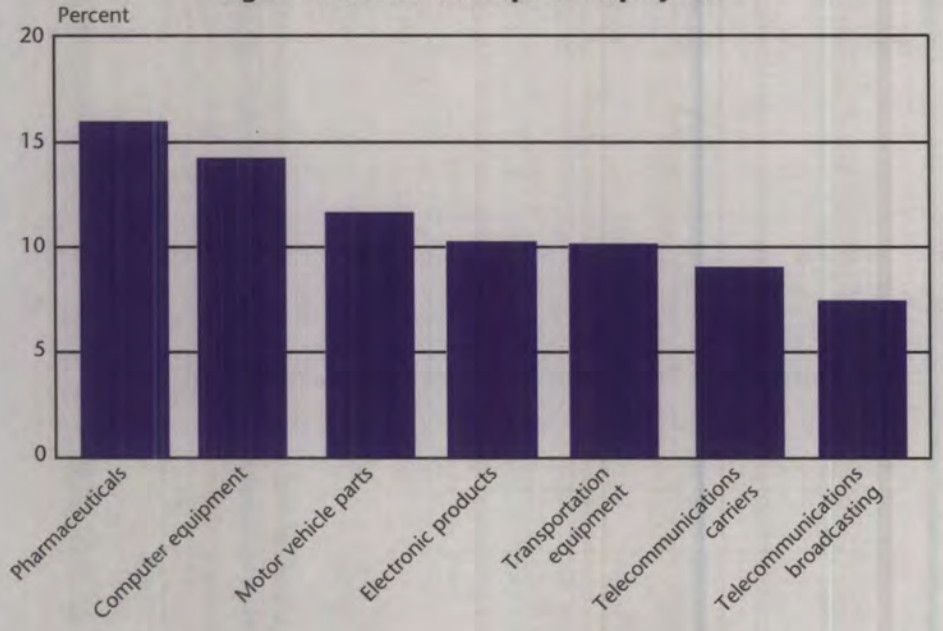
. . . and good net profits on sales . . .

In 1992, another measure, net (after tax) profit on sales, was 9.3 percent for the median firm among large companies in the industry, and 3.2 percent among medium-sized firms. These ratios for median firms in 1995 were 6.6 and 6.3 percent, respectively.

. . . generate sufficient internal capital for R&D-intensive firms to expand drug discovery programs . . .

Standard industry accounting measures of profit rates do not give a complete picture of the profitability of innovative pharmaceutical firms because their R&D intensity (viewed as intangible capital) and their long lead times for product development tie up large amounts of capital. Nevertheless, a comparison with other R&D-intensive sectors (Figure 6) is of some interest. The return on capital (before interest expense) in the Canadian pharmaceutical industry (comprising both brand-name and generic firms) was higher than that in other R&D-intensive industries in 1994. (Since pharmaceutical companies expense R&D whereas the other industries mentioned in Figure 6 capitalize R&D, the relative profitability of pharmaceuticals may be even greater than that shown.) These data suggest that Canadian pharmaceutical companies generally have sufficient internal capital to expand and to finance their R&D programs.

Figure 6. Return on Capital Employed



Source: Statistics Canada, *Financial Performance Indicators for Canadian Business*, Catalogue No. 61F0058XPE, 1996.

. . . except for bio-pharmaceuticals

The exception may be bio-pharmaceutical companies, which to this point do not have internally generated funds to finance their R&D. Moreover, they do not have as much access to venture capital as their U.S. counterparts and therefore have relatively high debt levels. These firms are

increasingly forming joint ventures with large pharmaceutical firms, partly to ensure access to capital. Although a number of bio-pharmaceutical firms have suffered large losses, the few success stories so far indicate potentially high rates of profit.

Knowledge Resources

The knowledge resources available to the pharmaceutical industry in Canada are a recognized strength. The extramural R&D infrastructure includes universities, research institutes and Networks of Centres of Excellence. Canada's medical researchers are highly regarded, and there is a growing contract research organization capability upon which pharmaceutical companies can draw.

The **Medical Research Council of Canada** (MRC) is the federal funding agency for a network of biomedical and clinical scientists in Canada. The agency promotes and supports basic, applied and clinical research in the health sciences. Training is carried out in universities and health care institutes (mainly teaching hospitals and research institutes).

MRC is instrumental in developing partnerships for drug discoveries . . .

In 1995–96, the MRC's budget from the federal government was $251 million, most of which was used for grants in support of specific research projects and awards in support of specific researchers. As part of its work, the MRC has developed partnerships with industry, governments and non-profit organizations. These partnerships facilitate investment in research and training programs through a peer review process. For example, an agreement between the MRC and the Pharmaceutical Manufacturers Association of Canada (PMAC) committed the latter to spending $200 million over a five-year period. Generic companies also engage in joint projects with the MRC. For example, Apotex has contributed to a fund worth up to $1 million in the first year and $50 000 in each of four subsequent years for the Toronto Cell Cycle Group.

. . . with commitments from PMAC . . .

. . . and generic companies . . .

Within the federal government, the **National Research Council of Canada** (NRC) is active as a research partner with industry in biomedical research in life sciences, including biotechnology. Collaborative research is concentrated in five institutes dedicated to specific sectors of life sciences/biotechnology, namely, the Biotechnology Research Institute, the Montreal Joint Centre for Structural Biology, the Institute for Biological Sciences, the Steacie Institute for Molecular Sciences and the Institute for Biodiagnostics.

. . . collaboration in life sciences research by NRC . . .

Established by the federal government, **Networks of Centres of Excellence** (NCEs) provide the pharmaceutical industry with a link to leading basic, applied and clinical researchers throughout Canada on key projects organized around a common area of interest.

. . . links through six NCEs . . .

The six NCEs of particular importance are the Canadian Bacterial Disease Network, the Canadian Genetic Diseases Network, the Neuroscience Network, the Protein Engineering Network, the Respiratory Health Network (Inspiraplex) and HEALnet. Participation in a network leverages the effectiveness of all members.

. . . as well as medical faculties and teaching hospitals

Canada has a strong **university medical research** base that encompasses 16 medical faculties in Canadian universities that are affiliated with a network of over 100 teaching hospitals and research institutes. Leading research is conducted in specialized therapeutic areas such as Alzheimer's, cardiovascular, central nervous system and gene-based diseases.

Canadian research publications have worldwide impact

Canada's research performance as measured by the publication record of Canadian scientists and the impact of their work on other scientists worldwide is noteworthy. The majority of Canada's pharmaceutical–medical sciences publications arise from university research supported by extramural programs of the government through its granting councils.

The Canadian biotechnology industry is concentrated in centres with a strong university and hospital research base. The biotechnology/university relationship is expected to strengthen as university technology assessment and transfer agents take a more active role in negotiating alliances among their institutions, pharmaceutical and biotechnology companies, and industry.

CROs package services required by firms . . .

Canada has private sector **contract research organizations** (CROs) that offer integrated packages of all the major services required by pharmaceutical and biotechnology companies to take a new drug through the developmental and regulatory process. Depending on their clients' requirements, these CROs can design and conduct some or all aspects of the development process.

. . . and facilitate clinical trials

Canada has a well-developed capacity to perform **clinical trials**. Since full-scale medical examinations are covered by Canada's health care system, the costs to the companies of such research are reduced. As well, innovative clinical trial networks provide industry with a direct entry into the drug delivery system for new pharmaceutical products.

Human Resources

Employment is distributed 74% among brand names, 15% among generics, 11% among OTCs

In 1995, the industry employed approximately 21 000 people. In 1995, 45 percent of pharmaceutical company employees were located in Ontario, 32 percent in Quebec, 20 percent in the western provinces and 4 percent in Atlantic Canada. Roughly 74 percent of these employees were accounted for by brand-name companies (PMAC members plus Abbott Laboratories), and about 15 percent by generic companies (member firms of the Canadian Drug Manufacturers

Association (CDMA) and the Quebec-based Groupement provincial de l'industrie du médicament (GPIM)). The remaining employees worked for companies producing OTC products that were not members of the above-named industry associations.

Increasingly, bio-pharmaceuticals are an important source of employment growth. In 1996, the top 45 bio-pharmaceutical companies employed close to 4 000 people, of whom 1 574 were engaged in R&D activities. Ten of these companies are PMAC members and three are CDMA members.

Manufacturing/ production jobs dominate structure of generics . . .

In 1991, some 45 percent of the pharmaceutical industry's workers were in manufacturing/ production occupations. Since that time, and in line with the restructuring of manufacturing facilities in the brand-name sector, the proportion of direct production workers has declined. This has reinforced the structural difference whereby production workers are a significantly higher proportion of the labour force in the generic sector than in the brand-name sector.

. . . while sales/marketing and R&D jobs dominate that of brand names

Sales and marketing personnel account for a much higher proportion of employment in the brand-name sector than is the case for generic companies, including GPIM members based in Quebec. The share of R&D personnel in both the brand-name and the generic sectors has increased significantly over the past five years.

The work force is highly educated, with over 50 percent of personnel having university degrees. Degree-holding individuals are concentrated in sales, marketing and R&D occupations, while manufacturing workers are likely to be less highly educated. Unionization is not a significant factor in the industry.

Restructuring and slow market growth curtail job growth

The demand for employment is expected to grow slowly at about 1 percent per year over the next five years, which is only about half the growth rate of the previous five-year period. This moderate growth is likely to result from the effects of continued restructuring and a slower rate of increase in the market for pharmaceuticals. Employment growth that does occur is likely to be in the areas of sales and marketing and R&D.

Skills mix undergoes adaptation to strengthen fit to markets . . .

Brand-name companies are putting increased emphasis on productivity-enhancing skills such as informatics, communication, leadership and the ability to motivate. The generic companies and some of the smaller innovative companies may also need expertise in product development, specialized marketing, quality control and regulatory affairs as well as skilled production workers.

. . . few skills gaps

The skill levels of pharmaceutical employees appear adequate for the future scientific and manufacturing needs of the companies, despite small supply gaps in a few areas. The industry

has identified regulatory and government affairs as the one area in which the supply of personnel is a problem. The fact that pharmaceutical companies tend to recruit from within the industry may be one reason this supply shortage has persisted.

Overall, the state of human resources available to the industry would not appear to confer any special competitive advantages or disadvantages.

Plant Construction and Operating Costs

Canada has 17% lower facilities costs, 14% lower operating costs, 26% lower labour costs than U.S.

A comparison of location-sensitive costs in eight Canadian cities with those in seven U.S. cities (using a financial model estimating costs of new facility start-up plus 10 years of operation, based on current tax rates, cost factors, construction, labour, transportation and exchange rates) indicates that the initial cost of a new facility would be 17 percent lower in Canada, while annual total operating costs would be about 14 percent lower in Canada. Labour costs, the largest component of location-sensitive operating costs, would be 26 percent lower. Electricity costs also would be lower in Canada, while transportation and distribution costs would be about the same (a lower cost of transportation per mile from Canadian locations is offset by the greater distances to major U.S. population centres). Higher costs of financing only partially offset the labour and electricity cost advantages.

These comparisons assume that the facilities on both sides of the border, in terms of size (minimum efficient scale), technology and productivity of factors of production, are the same. The results also hold for a range of exchange rates.

3.3 Related and Supporting Industries

Modest contribution to competitiveness of drug firms comes from other industries

According to Porter, a strong competitive position in related and supporting industries (those that supply goods and service inputs or produce related products) may enhance the competitive position of an industry, partly through clustering effects. On balance, the mixed capabilities that now exist in industries related to or supporting the Canadian pharmaceutical industry are not sufficiently strong to confer competitive advantage.

For example, on one hand, production of the key input for the industry, fine chemicals, is extremely limited in Canada. Most fine chemical needs (of both the brand-name and generic companies) are met by imports. On the other hand, there is a rapidly evolving biotechnology industry in Canada, which may eventually contribute synergistically to a stronger Canadian pharmaceutical industry. Many relatively small bio-pharmaceutical companies are on the Canadian scene and are increasingly partnering with brand-name MNEs in their research efforts.

Advertising and promotion services available in Canada tend to be competitive, but capabilities in packaging are mixed. Distribution networks are fairly well developed, and the information technology industry, which comes into play in many ways (consumption/production/education), is keeping pace with rapid worldwide changes in the way that business is done.

3.4 Firm Strategy, Structure and Rivalry

Firm strategy, structure and rivalry, according to Porter, refer to the way that firms are created, organized and managed and the degree of interfirm rivalry. According to Porter, a good match between firm strategies and the other sources of unique advantage in the domestic economy enhances competitiveness.

Patents protect discoveries, sustain profits and generate funds for future R&D

Competitive conditions among the pharmaceutical companies are strongly influenced by the proportion of the market accounted for by products that are patented. Patents, normally held by brand-name companies, confer a product-specific monopoly for the effective life of the patent in return for public disclosure of the discovery. With this exclusive market position comes higher prices and profits to offset development costs of the drug itself and costs of unsuccessful research. Although there is competition among patented producers, it generally is in the form of trying to be first to market with new breakthrough drugs and marketing efforts to disseminate information on the therapeutic benefits of their medicines. This competitive behavior does not result in significantly lower prices for consumers. Cost of research into new drugs makes entry into the innovative section of the industry difficult.

Market harmonization puts end to compulsory licensing

Between 1969 and 1993, Canada had a more competitive market for drugs than many other countries because of its compulsory licensing regime. The removal of this system as part of the harmonization of intellectual property rights under the NAFTA and the WTO has reduced the potential for new generic competition in the Canadian market. As a counterbalance, the PMPRB was given added powers to control introductory drug prices (in addition to limiting price increases of existing drugs under patent).

Competition in the generic segment of the market also revolves around the ability to be first to market with a lower-priced substitute for brand-name products. There is evidence that the ratio of generic prices to brand-name prices is much higher in Canada than in the U.S. It is not clear, however, how significant the implications are for the competitiveness of the Canadian generic market. Brand-name prices are much lower in Canada than in the U.S., which means that Canadian generics have less room to discount from brand-name prices than their counterparts in the U.S. while still making a profit.

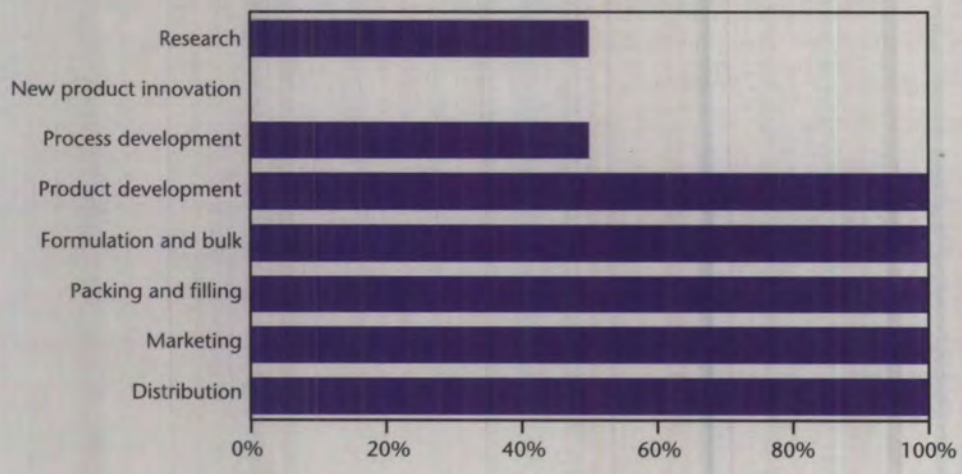
MNE Manufacturing, Trade and R&D

Historically, multinational enterprises have tended to locate R&D and product mandates in home markets, leaving their subsidiaries, including those in Canada, to serve smaller, secondary markets by engaging in final formulation, packaging and marketing functions. The subsidiaries typically import finished product and fine chemical inputs from their parents. This pattern of activity leads to surpluses in pharmaceutical trade for countries where the major MNEs' headquarters are located, and deficits for countries where subsidiaries are located. For example, the 1993 export-to-import ratio in the U.S. was 1.34, and higher in many European countries. In contrast, Canada as a secondary market runs a significant trade deficit (export-to-import ratio of 0.24).

Canadian MNEs focus on production/ marketing, conduct little innovation

The Canadian subsidiaries still have limited scope for value-added activity (Figure 7). The subsidiaries rarely engage in new product innovation, and process development is usually carried out by the parent in the home market. The focus of the manufacturing operations is on product formulation, packing and filling, marketing and distribution.

Figure 7. MNEs Reporting Selected Activities as a Focus of Operations in Their Canadian Subsidiaries, 1996



Source: Coopers & Lybrand Consulting, "Best Practices Benchmarking Study of the Manufacturing Function in the Canadian Pharmaceutical Industry," Toronto, 1996.

Location in Canada is perceived by MNEs to be a handicap in making/marketing sophisticated, differentiated products. Disadvantages cited include inferior product features, lack of detailing, lack of sales support and relatively poor shelf life control. Maintaining consistent quality and high overhead costs were also problem areas in the Canadian context. Given the global rationalization occurring in the industry and the fact that Canadian subsidiaries have to compete with their sister organizations for the right to produce, the gaps identified may account for the fact that world product mandates are infrequently given to Canadian subsidiaries. Another part of the story is that the business environment (regulatory requirements, selling price in Canada, market access) is perceived to be less favourable than in some other jurisdictions such as the U.S.

Canadian subsidiaries have few world product mandates for large-scale production . . .

Nevertheless, Canadian operations are acknowledged to be good at smaller-scale, flexible manufacturing requiring short lead times. This along with the construction and operating cost advantage for new facilities in Canada versus the United States has led companies such as Merck, Glaxo, Astra and Novartis to award production mandates for specific products to Canada.

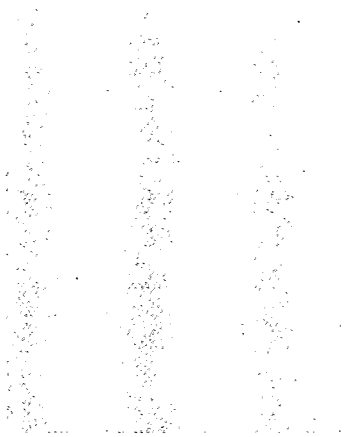
. . . but excel at small-scale manufacturing

Exports have not been a focus of the Canadian subsidiaries, which is consistent with the historical lack of world/regional product mandates. In fact, at present, less than 10 percent of finished output is destined for foreign markets. Seventy-five percent of the fine chemicals making up the drugs are imported from abroad, often from plants operated by the same corporate entity. Part of the reason that fine chemicals are not produced in the Canadian market by brand-name companies is a perception that financial returns can be maximized by importation. In addition, about 30 percent of the finished product sold in Canada is imported from parents or affiliates of the subsidiary.

Only 10% of finished products are exported, 75% of main inputs are imported

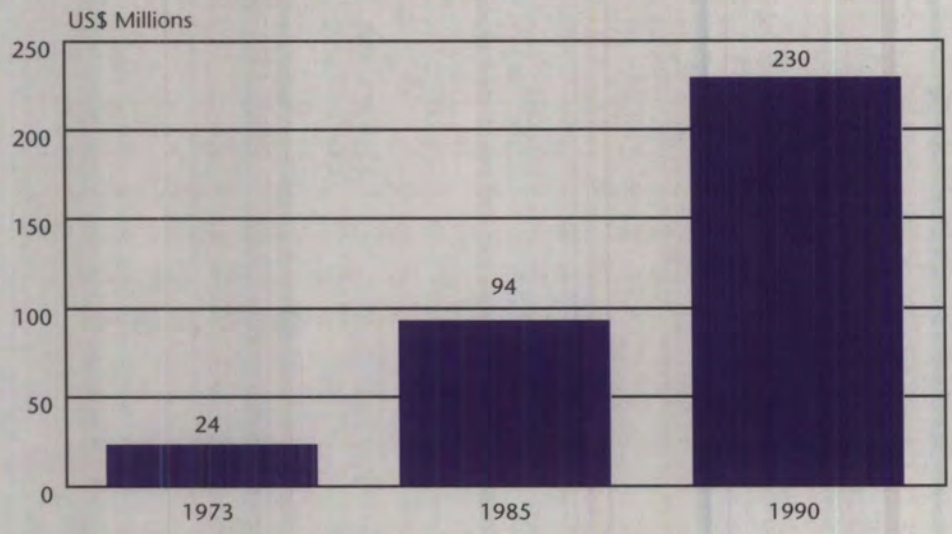
Innovative companies depend on a continuous stream of new products coming to market to maintain revenue growth and market share. However, new drug discovery and development is increasingly costly (Figure 8). This has caused R&D-to-sales ratios to rise in most countries, including Canada. One of the reactions of companies has been to engage in mergers in order to be able to afford the scale of research required. There is also increased attention to discovery of new pharmaceutical products based on biotechnological processes. Canada has done well in this field with a considerable number of bio-pharmaceutical companies seeking to discover new drugs that would be eligible for the extended patent protection now available.

R&D-to-sales ratios are rising in Canada and other countries



Cost of finding new drugs rises sharply

Figure 8. New Drug Development Costs



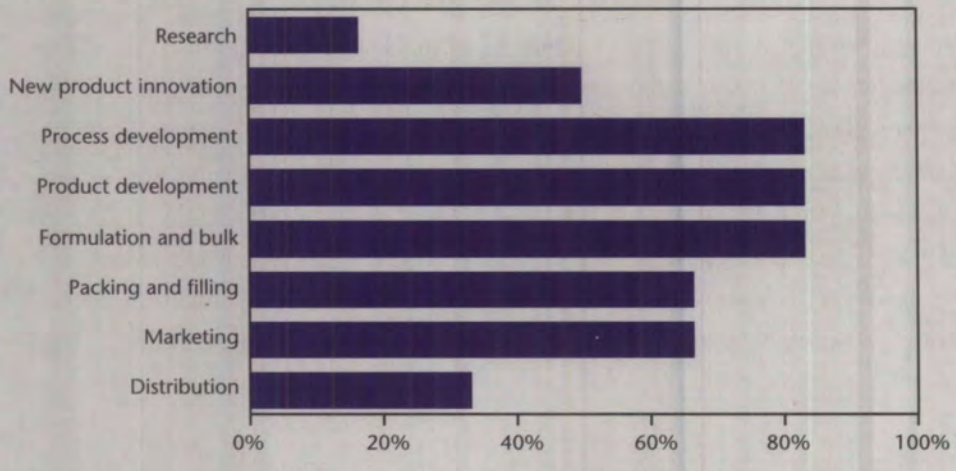
Source: Coopers & Lybrand Consulting, "Assessment of Current Competitiveness of Canadian R&D in the Pharmaceutical Industry," Toronto, 1996.

Generic Manufacturing, Trade and R&D

Canadian generics focus on production

The Canadian generic companies engage in a full span of value-added manufacturing activity (Figure 9). These companies engage in a certain amount of basic research, but the primary focus of their upstream activity is new product innovations largely directed to making generic

Figure 9. Generics Reporting Selected Activities as a Focus of Operations in Their Canadian Plants, 1996



Source: Coopers & Lybrand Consulting, "Best Practices Benchmarking Study of the Manufacturing Function in the Canadian Pharmaceutical Industry," Toronto, 1996.

copies of brand products that are off-patent or subject to a compulsory licence. Process and product development, and formulation and bulk using competitive technologies are integral parts of the generic companies' operations. Marketing is also less important than to brand-name companies because generics follow a low-price strategy.

There is limited competition within the generic market segment, as there are two dominant Canadian-owned firms. Nevertheless, there are approximately 15 to 20 firms operating solely in the generic market in Canada, although up to an additional 20 manufacture or sell some generic products along with their other lines (OTC, private labels, brand names).

Several firms have niche markets, limited interfirm competition, generics face mixed bag of competitiveness factors

Location in Canada is perceived by generics as a moderate handicap. Important gaps in the business environment (regulatory requirements, selling price), overhead costs and global market reach are cited by the companies as significant problem areas. Canadian location is viewed as an advantage with respect to reliable delivery and supply chain management.

On one hand, early working of patented products (i.e. manufacturing for the purpose of obtaining regulatory approval and for stockpiling) is allowed in Canada prior to patent expiry. On the other hand, a notice of compliance cannot be granted to a generic company until relevant patents have expired.

The main generic companies export almost 40 percent of their finished product while importing about 17 percent of the goods sold in Canada. Over 80 percent of fine chemical inputs are imported because of the lack of sufficient domestic supply.

40% of finished products are exported, 80% of main inputs are imported

The value of generic exports may roughly balance the value of imports because the finished goods that are exported have higher unit prices than the fine chemicals imported.

3.5 Sustainable Development

The industry has a reputation as being clean and environmentally friendly. The only significant pollution comes from solvents (used on pill coatings) emitted into the air by some major manufacturing plants. There is also a need to reduce packaging, although the industry believes such action is inhibited by regulatory requirements for more public information on drugs sold.

Little pollution arises during production . . .

Health Canada has the responsibility of ensuring that therapeutic drugs entering the Canadian marketplace are safe for use. Increasingly, however, post-market disposal of unused drugs is becoming an issue. The Province of British Columbia has introduced the idea that pharmaceutical companies bear some responsibility for the safe disposal of unused drugs, and the Province of Quebec is moving toward a voluntary code of behavior.

. . . but post-market disposal poses concern

CEPA is on watch for toxic substances in environment

Another important factor affecting sustainable development in the industry is the *Canadian Environmental Protection Act* (CEPA), which was proclaimed in June 1988. The Act regulates the manufacture and importation of biotechnology products that are not covered by the *Health Act* (e.g. non-living substances). The domestic substances list is used to determine if a substance is new to Canada. If so, it is considered potentially risky and is subject to notification. Before manufacture or importation, an assessment must be undertaken to ensure that "toxic" substances are not introduced into Canada's environment.

Issues with respect to the environment include the cost to companies of the regulations and how compatible Canada's regulations are with those of other jurisdictions. If Canada's regulations are more stringent than others, this could be viewed as a competitive disadvantage from the perspective of the cost of doing business, but could be an advantage in the area of consumer acceptance and ultimately in applying best-practice techniques.

3.6 The Public Policy Framework

Public policies are important in setting the framework for industrial development and sometimes in directly influencing private sector decision making. This section brings all of these influences together in one place, where the full impact on company decision processes can be more easily assessed.

Policies Affecting Market Conditions

Provincial formularies dictate reimbursements for drugs . . .

Public funding of health care through reimbursement plans makes the fiscal situation of governments a major influence on aggregate market growth. Reimbursement levels can be adjusted, for example, and the market for individual drugs can be significantly affected, depending on whether a drug is included or excluded from provincial formularies or other reimbursement lists.

. . . while prices of patented drugs are controlled federally

Prices of patented drugs are monitored/controlled at the federal level. This contributes to holding the line on drug expenditures but, at the same time, restricts the revenues and profits of the companies who in turn may view the market as less attractive for new investments. For example, a recent study by the PMPRB found that the prices of top-selling patented drugs, in 1994, were 47 percent higher in the U.S. than in Canada, while the prices for such drugs were lower in Italy, France, Sweden and the U.K. than in Canada. With respect to generic drugs, reimbursement prices allowed by formularies have been static for a number of years.

Policies Affecting Factor Conditions

Tax incentives enhance Canada as R&D location . . .

With respect to **financial resources**, Canada provides a competitive tax environment (Table 6). With the exception of Germany, tax incentives available to large companies make the after-tax cost of $1 of R&D in several Canadian provinces less costly than in most other jurisdictions. To the extent that revenues are earned from the R&D in the same locality, the corporate income tax must be taken into account (see figures in parentheses). By this measure, Canadian locations are much more attractive. All Canadian provinces lead both Germany and Japan, with the closest competitor being California.

Table 6. After-tax Cost of $1 of R&D Expenditures,[a] 1995

	Large company	Small company
	(in dollars)	
Germany	0.456 (1.051)	0.456 (1.051)
Manitoba[b]	0.439 (0.717)	0.452 (0.585)
Nova Scotia[b]	0.446 (0.717)	0.479 (0.583)
New Brunswick[b]	0.462 (0.755)	0.482 (0.616)
Quebec	0.493 (0.714)	0.407 (0.502)
Japan	0.501 (1.014)	0.579 (0.935)
Ontario	0.507 (0.784)	0.455 (0.586)
California	0.527 (0.893)	0.527 (0.893)
Italy	0.492 (1.051)	0.192 (0.410)
Illinois[b]	0.544 (0.902)	0.544 (0.902)
North Carolina	0.558 (0.932)	0.558 (0.932)
Michigan[b]	0.607 (0.934)	0.607 (0.934)
France	0.616 (0.923)	0.616 (0.923)
United Kingdom	0.670 (1.00)	0.670 (1.00)

[a] Before-tax revenue needed to cover the R&D expenditure if earned in the same locality in parentheses.

[b] 1994 data.

Source: Jacek Warda, *Canadian R&D Tax Treatment, An International Comparison* (Ottawa: Conference Board of Canada, 1994), Report 125-94 (for 1994 data); Jacek Warda, *Members' Briefing — R&D Tax Incentives in OECD Countries: How Canada Compares* — Report 190–97 (for 1995 data).

Nevertheless, companies do report some difficulties in accessing Canada's R&D tax credit, particularly when the expenditures are on clinical trials (e.g. pharmaco-epidemiology).

. . . assisted by ample knowledge resources . . .

The government promotes **knowledge resources** by making grants to medical institutions and researchers and supporting the Networks of Centres of Excellence. For example, faculties of medicine spent $835 million on biomedical and health care research in 1994–95. Approximately 33 percent of the funding came from the federal government (26 percent from the MRC and the rest from Health Canada and NSERC), 16.4 percent from provincial governments, and about 4.6 percent from the universities themselves. Private industry contributed $129.6 million, representing 15.5 percent of the total funding in 1994–95. The share of funding from private industry has grown (from 8.3 percent in 1989–90) as public funding has been reduced.

The Canadian Foundation for Innovation (CFI) provides grants for the modernization, acquisition and development of R&D infrastructure in post-secondary institutions, research hospitals and certain other not-for-profit organizations.

. . . and adequate skills and human resources

In the opinion of the pharmaceutical companies, there are no glaring gaps in the skills available to the industry. As such, there are no government programs particular to developing **human resources** suitable for the pharmaceutical industry.

Policies Affecting Related and Supporting Industries

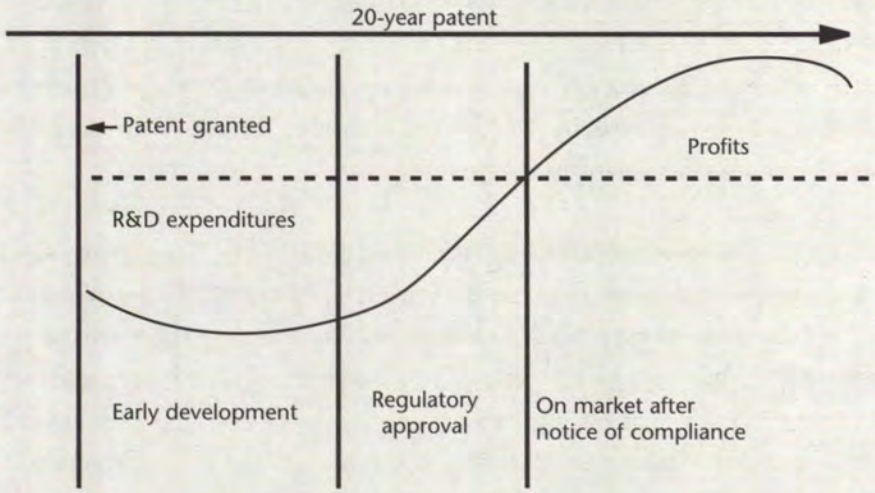
Environmental regulations cover the location of toxic chemicals, particularly in the vicinity of population centres, which can affect whether companies decide to locate fine chemical plants in Canada. Many companies view Canada's environmental laws as less favourable than those of some other jurisdictions. This is one of the factors behind the high level of importation of fine chemicals used to manufacture drugs.

Policies Affecting Firm Strategy, Structure and Rivalry

Longer patents boost profitability

Patent terms are a key factor in company strategies. Patents in pharmaceuticals are viewed as essential for the discovery to take place in a higher percentage of cases than in other industries. Other things being equal (e.g. drug approval times), a longer patent term means more exclusive time on the market for a drug and therefore is an important determinant of the profitability of operating in a specific country (Figure 10).

Figure 10. Product Cycle of New Drug



Intellectual property protection in Canada is consistent with international treaty obligations. Canada's compulsory licensing system for drug patents was eliminated with passage of the *Patent Act Amendment Act, 1992* (commonly referred to as Bill C-91). The amendments also strengthened the powers of the PMPRB, and established exceptions to patent infringement for the purposes of regulatory approval and for stockpiling.

Bill C-91 strengthened legislative protection for drugs, in line with treaties . . .

At the same time, regulations were developed with regard to the stockpiling exception and to prevent patent infringement by parties using the exceptions:

. . . with regulations designed to prevent abuse

- The Manufacturing and Storage of Patented Medicines Regulations allow a six-month period for stockpiling prior to patent expiry.
- The Patented Medicines (Notice of Compliance) Regulations prohibit Health Canada from issuing a safety and efficacy approval (NOC) for a generic drug product until the expiry of the relevant patents (this provision has proved contentious in practice, as generic and brand-name companies have frequently engaged in litigation).

From the point of view of the MNEs, patent protection in Canada should be seen in the international context. Because of increasing R&D costs, the global profitability of these companies depends on the degree of patent protection in all the markets in which they sell their products. Countries that have below-average patent protection tend to be overlooked in the companies' global investment strategies. Although MNE subsidiaries have found the Canadian market to be profitable in the past, they believe that increased patent protection is needed to put Canada on a par with the U.S., Europe and Japan, where patent term extensions are available (to make up for long development times and delays in approvals from regulatory bodies).

MNEs rely on patent protection to raise R&D funds, which influence their location decisions

Generics favour short patent period to enter markets earlier

The generic companies hold the opposite view, citing the fact that the Canadian market is small relative to other key markets and therefore does not account for a large share of MNE profits. The generic companies advocate less patent protection, which would permit them to enter the market earlier and augment their cash flows by more quickly bringing lower-priced drugs to Canadian and export markets. In their view, higher cash flows are needed in order for them to make the transition into innovative companies.

With respect to bio-pharmaceuticals, the members of the Industrial Biotechnology Association of Canada (IBAC) hold views about patent protection that are similar to those of the MNEs. They feel that strong patent protection has been, and continues to be, a key element in the bio-pharmaceutical industry's growth. However, a few bio-pharmaceutical firms, particularly those who have alliances with or are subsidiaries of generic manufacturers, have views more in line with those of generic companies. A source of some concern to all bio-pharmaceutical companies is the increased time needed by the Canadian Patent Office to examine applications. The growth in applications relative to the number of examiners available is causing delays in Canada, just as it is in other countries.

Approval process ensures drug safety but delays market entry, impacts on competitiveness

Before drugs can be offered for sale, they must be approved as safe for use (i.e. by Health Canada). Fast approvals mean that drugs will have more time on the market to earn profits before new or copy drugs appear and begin to take market share. Thus, drug approval times are an important factor in determining the profitability of operating in country markets. Drug approval times can also influence the attractiveness of exporting from Canada, since drugs cannot be manufactured for export prior to their approval for sale in the domestic market. Recent figures from Health Canada show that actual review times for new chemical entities in Canada are diminishing, from an average of 710 days in 1995 to 531 days in 1996, which exceeds the 1996 performance target of 540 days. This compares favourably with actual total review times in the U.K. (547 days) and Australia (507 days). Canada still lags behind the U.S.; the most recently published figures there show an actual average review time of 483 days.

Approval fees and performance standards may speed process

Health Canada is implementing a program to recover the costs of drug approvals from the applicants. The payment of such fees by companies is to be linked to increased efficiency in the approval procedures of Health Canada. The U.S. FDA already charges such fees, but the funds are being used to augment the agency's resources devoted to approvals.

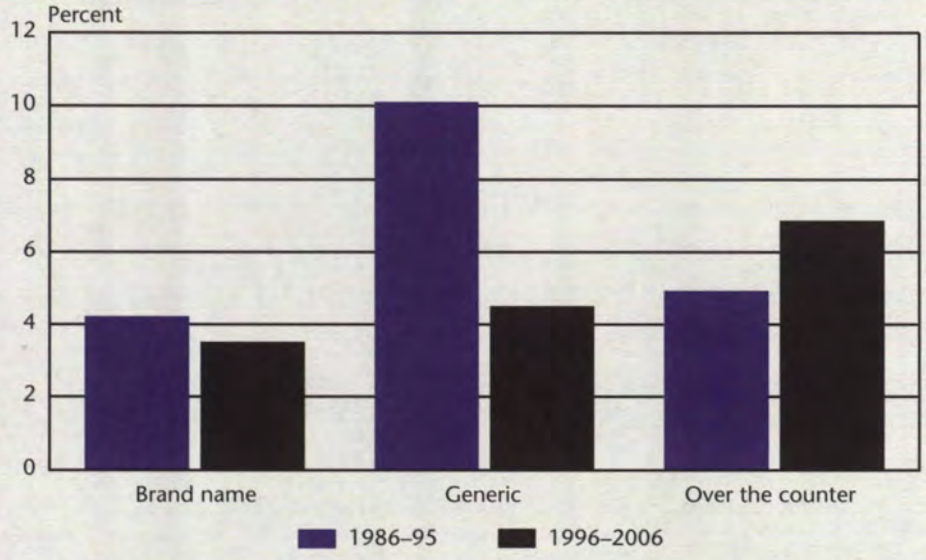
4 GROWTH PROSPECTS FOR THE INDUSTRY

4.1 Demand Outlook

Overall spending on drugs slows . . .

The growth of Canada's pharmaceutical market is expected to be slower over the next 10 years than it was over the past decade; this is similar to the situation in the United States. While the rate of growth for pharmaceuticals is projected to be slower than in the past, it will remain high relative to that for other consumer categories. As Figure 11 shows, total real growth (in constant 1986 dollars) of prescription brand-name drug sales is likely to be 3.5 percent a year from 1996 to 2006, compared with 4.1 percent during the 1986–95 period.

Figure 11. Annual Consumer Expenditure Growth in Pharmaceuticals (constant 1986 dollars)



Source: W. N. Palmer & Associates, "Demand Outlook for Pharmaceuticals in Canada," Ottawa, 1996.

. . . as pipeline of new products to market thins

The slower growth over the next five years will be mostly due to an anticipated reduced rate of new drug introductions (although some companies do have a strong roster of new drugs awaiting introduction). This effect will outweigh the demand stimulus from the aging of the population. A constrained ability to pay for drugs, especially those with higher prices, also will moderate growth in sales. The slower growth projected is in line with the reduced willingness of both public and private drug plans to freely reimburse rising drug expenditures. Over the longer term, as the fiscal position of Canadian governments improves and the aging of the population

intensifies the demand for drugs, the growth rate of the market is likely to rise. At that time, chronic diseases of aging are expected to lead to higher drug sales in a number of therapeutic areas, including Alzheimer's, osteoporosis, cancer and cardiovascular diseases.

Spending on generics moderates

The buoyant market conditions for generics witnessed in the recent past are now waning. Generics gained value share (growing from 9 percent in 1986 to 17.4 percent in 1996) mostly because of blockbuster drugs coming off-patent, compulsory licensing and increased use of provincial formularies. Expected growth in the next 10 years for generics is more moderate at about 4.5 percent a year, but some gain in share of the prescription market is anticipated. In the longer term, the growth rate of the market for generics is likely to be increased as a consequence of the aging of the population.

OTCs continue strong

The growth prospects of over-the-counter (OTC) products are relatively strong. OTC drug sales are likely to grow at 6.8 percent a year over the next 10 years, compared with 5.1 percent from 1986 to 1995, because of personal income growth and a switching away from prescription drugs (partly because of a trend toward more home-based care). Some important prescription drugs will soon be available over the counter in Canada.

Bio-pharmaceuticals contend with price cuts, low discovery rates

With respect to bio-pharmaceuticals, growth of the market was high in the early 1990s (10 percent a year) but had slipped to half that rate by 1994. The outlook is for relatively slow growth for the foreseeable future because of pressure for price cuts in existing products and the low rate of successful discovery/approval of new products.

Export markets of interest to Canadian companies show mixed growth prospects. The U.S. market is expected to grow relatively slowly, while emerging markets in Asia, Latin America and eastern Europe are likely to increase their consumption of drugs rapidly.

Large size makes U.S. prime target market for brand names, with other markets to follow as patent protection there takes hold

Many firms in the Canadian industry are interested in penetrating the vast U.S. market in spite of its relative maturity and moderate growth prospects. Brand-name companies focus on the U.S. for export growth to the relative exclusion of other markets, because the lack of patent protection in countries such as China, Brazil and India serves as a disincentive to brand-name exporting. As developing countries move toward implementation of patent protection, they will become more attractive sites for new brand-name investments. Until then, the expected increase in export sales ranges from 0 to 5 percent per year over the 1995–2000 period. Along with the low projected growth, there is a downside risk because of ongoing company rationalization, which may potentially restrict the supply capabilities of Canadian-based subsidiaries of MNEs. In general, the export activities of MNE subsidiaries in Canada are strongly affected by the policies of the parent companies with respect to world or regional product mandates.

Export interests of Canadian generic producers are much more diverse than those of brand-name companies. The generics show significant interest in Latin America, eastern Europe and East Asia in addition to the U.S. market. They expect 10–15 percent growth per year over the next five years, partly because a number of major drugs are coming off-patent in the U.S. The companies believe their export prospects would be even better if there were an export exception provision in Canadian patent legislation that allowed them to export drugs that are no longer under patent in the target market but remain under patent in Canada. Generic companies also believe competition is increasing in their market segment with the rise of low-cost supply from countries such as India and China. A number of developing countries also encourage foreign direct investment inflows as a preferred alternative to importing generic and other products. If expected export growth rates are achieved, export orientation could increase significantly in the future.

Generics favour opportunities in fast-growing markets, face competition from low-cost suppliers

OTCs also have diverse export interests, with the East Asian market drawing more attention than even the United States. Latin America and eastern Europe are also viewed as attractive export markets. Because seven MNEs account for three quarters of OTC export revenues, the allocation of regional product mandates has an important bearing on export growth prospects. Expected annual growth of exports of OTC products is in the 10–11 percent range in the near term, with analgesics, cough and cold preparations, and vitamins having the most sales potential.

OTCs favour East Asia, Latin America, eastern Europe over U.S.

One of the major issues in achieving higher export levels is the existence of non-tariff trade barriers. One important barrier to exporting is gaining registration approval of products in foreign markets (including the U.S.). As a consequence, there is strong support among all companies for greater harmonization of product approval procedures among countries. Although tariffs are not a major difficulty in most cases, some companies encounter tariff barriers in the Indian and eastern European markets.

All firms favour greater harmonization of approvals among countries

4.2 Industry Strengths

The Canadian industry has a number of key strengths. In manufacturing, the costs of constructing and operating new facilities are relatively low, the work force is competitive and technology used by generic firms and some MNEs is in line with international practice. For R&D, a wide range of resources are available to the industry, including highly qualified health researchers, excellent infrastructure (universities, institutes, the National Research Council and the Networks of Centres of Excellence), an established capacity for contract research and clinical trials and special funding programs (Scientific Research and Experimental Development tax credit, Medical Research Council). As well, the tax system in Canada is very competitive with respect to R&D incentives.

Tax credits, tax system help attract R&D to Canada

4.3 Competitiveness Challenges

Industry faces mixed bag of competitiveness factors

The strategies of firms must continuously evolve to meet changing circumstances of the marketplace. This process may at times favour industrial development in Canada and at other times be to Canada's disadvantage, as summarized in Table 7.

Table 7. Summary of the Competitiveness Assessment

	Manufacturing		R&D	
	Pro	**Con**	**Pro**	**Con**
Market conditions	• growing export markets • aging population • rising demand for OTC	• slowing domestic market growth for brand and generics • relatively low brand-name prices vis-à-vis U.S. • fragmented market (access)	• critical mass in specific areas (e.g. cardiovascular)	• slowing domestic market growth for brand products • R&D efforts sometimes weakened by being spread too thinly
Factor conditions	• cost advantage (e.g. labour, facilities and operations) • profitability	• efficiencies of scale are available in larger markets	• favourable tax regime • comprehensive health system • R&D networks • strong medical researchers	• links between public and private R&D efforts are not strong enough
Related and supporting industries	• growing biotechnology capacity	• lack of fine chemical supply	• dynamic bio-pharmaceutical companies • health information technologies	
Firm strategy, structure and rivalry		• home market favoured • slow regulatory approval times • export trade barriers		• home market favoured • slow regulatory approval times • lack of PTR for brand

MNEs in Canada

MNEs cope with need for continuing rationalization . . .

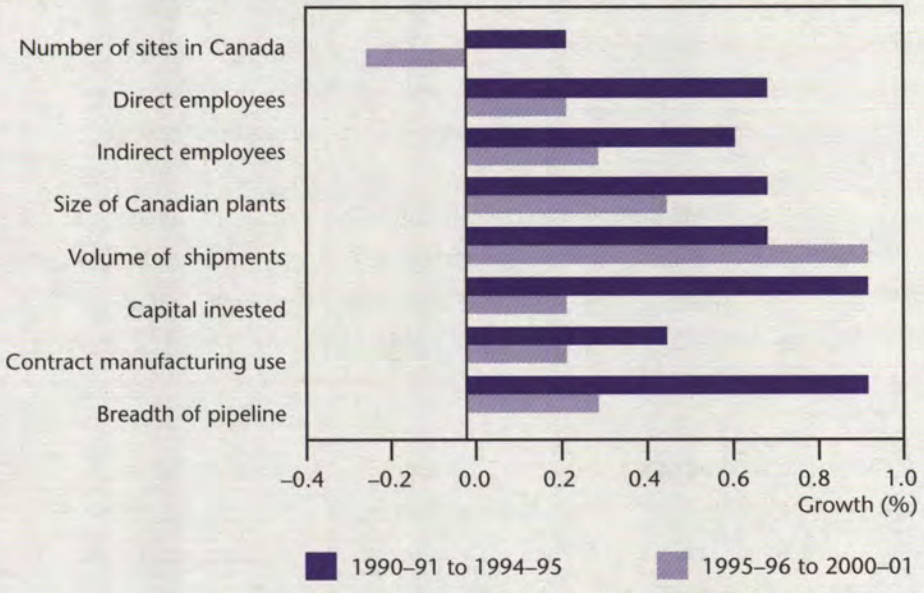
Global rationalization decisions are being made based on corporate needs for increased financial resources to carry out R&D and to support global marketing networks. MNEs face slowing market growth, which makes the market for prescription drugs less attractive than in the past. Restraints on the domestic prescription market include a tightening up of provincial and

private drug plan formularies, a switch by consumers from prescription to OTC medicines, and growing concern by the public about high drug usage. There is also a perceived risk of changes to the business climate, which can potentially affect new investment decisions.

Part of the drive to enhance financial capacity involves increasing the efficiency of manufacturing processes. Many plants in Canada are old and their capacity utilization is low. The question for MNEs is whether it makes economic sense to upgrade the supply capability in Canada or to move toward providing a higher share of the market's needs through imports.

Over the next five years, the number of manufacturing sites in Canada is expected to fall, while the size of plants will expand, but less than in the first half of the 1990s (Figure 12). Consistent with this outlook, the growth in capital investment from 1995–96 to 2000–01 is projected to be much reduced from the rates of the previous five-year period. The breadth of product line could also grow less quickly than in the past five years.

Figure 12. Areas of Growth among MNE Subsidiaries



Source: Coopers & Lybrand Consulting, "Best Practices Benchmarking Study of the Manufacturing Function in the Canadian Pharmaceutical Industry," Toronto, 1996.

Shipments are expected to increase faster than in the previous five years in spite of the projected slowing in demand growth. This suggests that the brand-name companies will look more to

export markets for growth than in the past. Productivity is likely to increase significantly, as shipments growth is expected to outstrip employment growth.

. . . although business and regulatory climates remain uncertain

Future R&D commitments will depend importantly on the domestic business climate and on Canada's perceived place in diverse company strategies. Today, the brand-name sector views the business and regulatory environments in Canada as difficult.

Achieving mutually beneficial collaborations in the R&D field is particularly important. For example, bio-pharmaceutical companies in Canada, now in the invention stage, may well look to established pharmaceutical companies in the future for help in development and marketing of new drugs. Collaboration can also occur between academic researchers, who are increasingly interested in patenting their work, and pharmaceutical firms that have the capability to aid in developmental activities.

Generics in Canada

Generics face slowing domestic market, rising export opportunities . . .

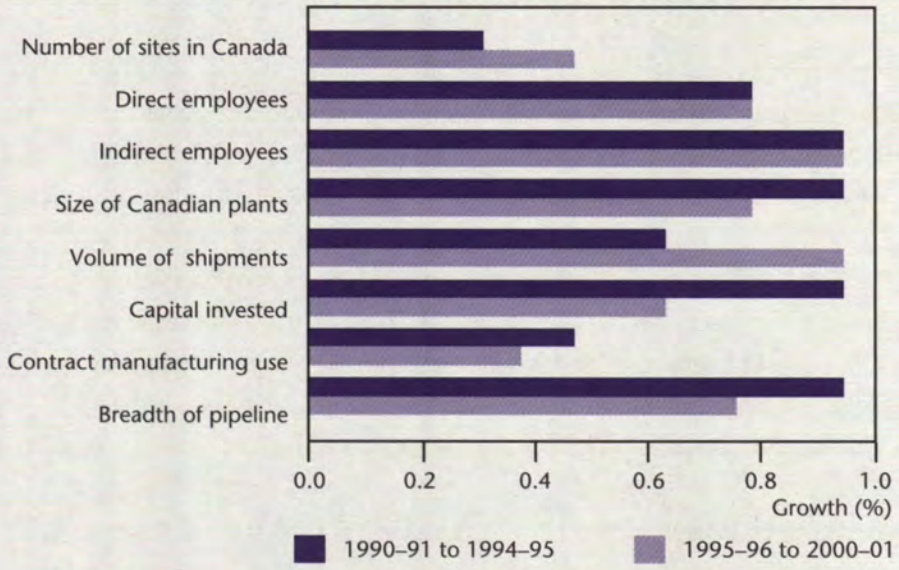
The largest generics in Canada grew quickly during the era of compulsory licensing and the establishment of provincial formularies. They now rank in the top 10 pharmaceutical companies in terms of sales. Their growth prospects within the Canadian market are less favourable now than in the past, and their attention is shifting to foreign markets.

The two dominant companies have adopted different approaches to accessing foreign markets, with one exporting from the home base (Apotex has obtained FDA approval for its manufacturing facilities so that it can export into the U.S. market) and the other beginning to set up operations abroad (Novopharm has built a facility in North Carolina to serve the U.S. market). Apotex also engages in alliance building in foreign markets.

. . . with production site expansion . . .

The number of generic drug production sites in Canada is expected to grow more quickly over the 1995–96 to 2000–01 period than in the previous five years, and the size of Canadian plants will expand almost as quickly (Figure 13). Capital investment of companies is not expected to grow quite as rapidly as in the previous five years.

Figure 13. Areas of Growth among Generics



Source: Coopers & Lybrand Consulting, "Best Practices Benchmarking Study of the Manufacturing Function in the Canadian Pharmaceutical Industry," Toronto, 1996.

Productivity of generic manufacturing is expected to increase moderately, as shipment growth will exceed employment growth over the next five years.

. . . and moderate productivity increases

Both major companies (i.e. Apotex, Novopharm) aim to become innovators in the long term. They are moving toward this goal by entering the biotechnology field and increasing R&D aimed at discovering new drugs.

Bio-pharmaceuticals

Almost 50 percent of Canada's 200 biotechnology companies are involved in the health care field, developing bio-pharmaceuticals, diagnostics and vaccines. The biotechnology industry has credited the *Patent Act Amendment Act, 1992* (Bill C-91) for contributing to its growth in recent years. Most bio-pharmaceutical companies are still at the R&D stage. They often rely on alliances with larger firms for investments in later-stage drug development, regulatory approval and marketing. These alliances will undoubtedly change the composition of Canada's pharmaceutical industry from its past simple division into patent and generic drug producers, since both of these groups are taking an interest in bio-pharmaceuticals.

Bio-pharmaceuticals claim boost from Bill C-91, await expected drug development from current R&D

4.4 Future Opportunities

Drug sector outperforms manufacturing sector, contributes jobs and wealth

The pharmaceutical industry in Canada has contributed to employment and income growth in the Canadian economy. The industry outperformed the total manufacturing sector over the past decade on various measures such as employment, income, investment, exports and R&D. Can a similar performance relative to total manufacturing be achieved over the next five to 10 years?

Domestic market growth for pharmaceuticals has been about 20 percent higher than for total manufacturing over the past 10 years, which fueled the industry's growth and led to strong relative performance. The moderating of the domestic market growth rate for pharmaceuticals suggests that to outperform manufacturing in the future with respect to shipments and job creation, pharmaceutical exports will have to grow relatively quickly.

There is significant growth potential for drug exports . . .

There seems to be a reasonable prospect that pharmaceutical exports will grow. For example, 17 companies responding to a recent survey of pharmaceutical companies indicated they are planning or have begun to upgrade or expand their production capabilities in Canada, of which 10 are projecting that the new or upgraded production facilities will have a significant impact on the value of their export sales (seven of these 10 companies are multinationals). Several respondents noted that to be cost-effective, these plants would have to serve both domestic and export markets.

. . . and R&D investment

The Canadian pharmaceutical industry has increased its R&D expenditures significantly faster than the total manufacturing sector. Canada is recognized as a prime location for clinical trials, and this form of R&D could show significant future growth. Although clinical R&D does not have to be tied in with basic R&D to be valuable, the potential for synergies could be explored. More focussed and synergistic research, both basic and applied, in the private and public sectors, could make a significant contribution to health and economic development in Canada.

A vision for the future would include the prospect of substantially increased export activity and a greater share for Canada of international R&D expenditures. It would include:

- an innovative bio-pharmaceutical sector designing and developing new drugs for the world market
- an active and growing contract research capacity for conducting clinical trials and for developing new chemical entities
- MNE centres of excellence with world mandates for specialized R&D and for marketing and product management; with efficient, flexible manufacturing facilities for niche products

- growing generic manufacturing and marketing capacity, with subsidiaries or alliances in developed country markets, and aggressive strategies in emerging markets, as well as increased innovative activity, especially in the bio-pharmaceutical field
- greater activity by specialized manufacturers of over-the-counter products in global consumer markets.

Industry has many strengths to build on

Key success factors in the effort to build a more export-oriented, R&D-intensive industry include:

- increased emphasis on excellence in drug utilization, including more public and private sector use of pharmaco-economic data and the development of large-scale health information systems
- strengthening of the Canadian "clusters of excellence" (e.g. cardiovascular, respiratory, genetic, neuroscience and radiopharmaceuticals) to deepen research capacity and to improve the relationship between the medical/public R&D communities and private sector firms
- better access to U.S., European, Japanese and other markets (e.g. through mutual recognition agreements) to enhance the export performance of firms in Canada
- a legislative environment (i.e. following completion of the parliamentary review of the 1992 amendments to the *Patent Act*), which reduces uncertainty for corporate decision makers
- a competitive business environment for R&D (e.g. tax credits, MRC funding, infrastructure) and the generation of earnings to finance R&D and global marketing programs
- improvement in the time frame for regulatory approval of new drugs to make Canada more competitive in attracting regional/world product mandates
- alliances and easier access to venture capital for smaller pharmaceutical and bio-pharmaceutical firms.

4.5 The Bottom Line

The Canadian pharmaceutical industry:

- has kept pace with or outpaced its U.S. counterpart in recent years according to the usual industrial performance measures
- is profitable and R&D-intensive
- utilizes and develops state-of-the-art technology
- develops and markets products that have a strong consumer demand.

Some concerns remain

A sector with such characteristics would normally be expected to be on a buoyant growth track into the future.

However, some factors unique to the pharmaceutical sector are giving rise to some concern about the industry's outlook, notably, constraints upon product demand and prices, global over-capacity, and the ways in which corporate decision makers can affect Canada's pharmaceutical industry, including the impact of their decision on the level of R&D and manufacturing taking place here, as they cope with the need to restructure on a worldwide basis.

Prospect for more jobs and growth is significant

There are many issues to address, but the pharmaceutical industry holds significant potential for contributing to jobs and growth in the Canadian economy, while continuing to play a key role in maintaining and improving the health of Canadians.

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Annex A
GLOSSARY OF TERMS

Active Ingredient: The chemical responsible for a claimed pharmacological effect of a drug product.

ATC: Anatomical Therapeutic Chemical classification system, which divides drugs into different groups according to their site of action and therapeutic and chemical characteristics. This system is used as a guide for selecting comparable medicines for purposes of price review.

Bill C-22: The *Patent Act Amendment Act, 1987*, which provided for a period of market exclusivity for patented medicines of seven to 10 years and established the Patented Medicine Prices Review Board.

Bill C-91: The *Patent Act Amendment Act, 1992*, which eliminated compulsory licensing of pharmaceuticals, enhanced the powers of the Patented Medicine Prices Review Board, introduced exceptions to patent infringement for regulatory approval and stockpiling, and introduced the Patented Medicines (Notice of Compliance) Regulations.

Drug Identification Number (DIN): A registration number that the Health Protection Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the Food and Drug Regulations. The DIN is assigned using information in the following areas: manufacturer of the product, active ingredient(s), strength of active ingredient(s), pharmaceutical dosage form, brand/trade name and route of administration.

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s).

Drug Product, Brand-name: A particular presentation of a medicine that is under patent.

Drug Product, Generic: A drug product having the same active ingredient, strength and dosage as a brand-name product but that is not under patent (or is under a compulsory licence).

Formulary: List of prescription drugs approved for maximum reimbursement, from a private or public insurance plan, based on judgment about the effectiveness of medicines in relation to their costs; i.e. provincial formularies.

Licence, Compulsory: A licence granted by the Commissioner of Patents in accordance with ss. 39(4) of the *Patent Act* that has been continued pursuant to ss. 11(1) of the *Patent Act Amendment Act, 1992*, which permits the licensee to import, make, use or sell a patented invention pertaining to a medicine. Royalties payable are determined by the Commissioner of Patents, who sets the terms of licences pursuant to ss. 39(5) of the *Patent Act*. Except for those compulsory licences issued prior to December 20, 1991, which are continued pursuant to ss. 11(1) of the *Patent Act*, licences issued after December 20, 1991, have no effect.

Licence, Voluntary: A contractual agreement between a patent holder and a licensee under which the licensee is entitled to enjoy the benefit of the patent or to exercise any rights in relation to the patent for some consideration (e.g. royalties in the form of a share of the licensee's sales).

Managed Care System: A model of health care delivery that strives to improve patient outcomes at reduced therapeutic cost, usually by reducing the utilization of health care services.

Notice of Compliance: A notice in respect of a medicine issued by the Health Protection Branch of Health Canada under s. C.08.004 of the Food and Drug Regulations. The issuance of a notice of compliance indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the product is approved for sale in Canada.

Patent: An instrument issued by the Commissioner of Patents in the form of letters patent for an invention that provides its holder with a monopoly, limited in time, for the claims made within the patent. A patent gives the patent holder the exclusive right to make, sell or otherwise exploit the invention for the term of the patent.

Research and Development (R&D): Basic or applied research for the purpose of creating new or improving existing materials, devices, products or processes (e.g. manufacturing processes). The definitions of R&D investment used in Canada, its provinces and foreign jurisdictions differ. The PMPRB uses the definition of R&D contained in the *Income Tax Act* as of December 1, 1987.

R&D, Applied: Work that advances scientific knowledge with a specific practical application in view, such as creating new or improved products or processes through manufacturing processes or through preclinical or clinical studies.

R&D, Basic: Work that advances scientific knowledge without a specific application in view.

R&D, Clinical: The assessment of the effect of a new medicine on humans. It typically consists of three successive phases, beginning with limited testing for safety in healthy humans, then proceeding to further safety and efficacy studies in patients suffering from a target disease.

R&D, Extramural: Research carried out by sources such as universities, hospitals and contract research organizations on behalf of the sponsoring company.

R&D, Intramural: Research carried out by the sponsoring company.

Annex B
PROCESS FOLLOWED

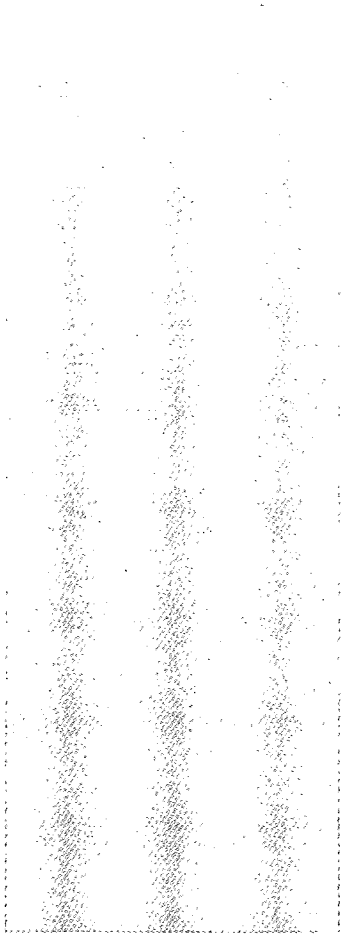
The preparation of this *Overview and Prospects* of the pharmaceutical industry benefited greatly from the input of an active industry advisory group of industry representatives, which was formed in the winter of 1995–96. Members of this group helped establish a process for building the information base necessary for understanding the industry, and also commented on the resulting analysis and conclusions. The members were:

- Terry McCool, Vice President Corporate Affairs, Eli Lilly, on behalf of the Pharmaceutical Manufacturers Association of Canada (PMAC), representing brand-name patent holders
- Jim Keon, Canadian Drug Manufacturers Association (CDMA), representing generic companies
- Pierre Morin, Groupement provincial de l'industrie du medicament (GPIM), representing Quebec-based pharmaceutical companies
- David Skinner, Nonprescription Drug Manufacturers Association of Canada (NDMAC), representing manufacturers of over-the-counter drug products.

David Hoye, Director and Manager of the Health Industries Branch, Industry Canada, served as chair of the committee and oversaw the work of the team of authors of this report. While the helpful contributions of these industry representatives is gratefully acknowledged, responsibility for the findings, as well as for any errors or omissions, rests solely with the Health Industries Branch.

Most of the analysis used in this *Overview and Prospects* of the pharmaceutical industry is based on data supplied by Statistics Canada. Other valuable data were taken from IMS Canada. Comparisons over time involving currency values between Canada and the United States are made using the Purchasing Price Parity, published by the Organisation for Economic Co-operation and Development, rather than the current exchange rate.

In addition, with the agreement of the industry advisory group, six private sector consultant studies were commissioned by Health Industries Branch of Industry Canada to build up the necessary knowledge base and to provide a vehicle for industry participation. The views of the industry associations were sought in choosing consultants to carry out the studies.



The consultants' studies, all completed in 1996, form the basis for important sections of the document. The consultants, and the sections of this document that were based on their reports, are:

- Coopers & Lybrand Consulting, Toronto: "Assessment of Current Competitiveness of Canadian R&D in the Pharmaceutical Industry"; "Best Practices Benchmarking Study of the Manufacturing Function in the Canadian Pharmaceutical Industry"; "Comparative Analysis of Pharmaceutical Manufacturing Development and Trade Balances of Selected Countries in Europe" (bases for Section 3.4 — *Firm Strategy, Structure and Rivalry*, and Section 4.3 — *Competitiveness Challenges*).
- Ference Weicker & Company, Vancouver: "Export Opportunities for Canadian Pharmaceuticals" (basis for subsection on *Export Markets*, beginning page 26, Section 4.1 — *Demand Outlook*, and Section 4.4 — *Future Opportunities*).
- W. N. Palmer & Associates, Ottawa: "Demand Outlook for Pharmaceuticals in Canada" (basis for subsection on *Domestic Consumption*, beginning page 25, and part of the basis for Section 4.1 — *Demand Outlook*).
- Price Waterhouse, Ottawa: "Human Resource Study of the Pharmaceutical Industry" (basis for subsection on *Human Resources*, beginning page 30).

A day-and-a-half symposium was organized by Industry Canada in March 1996 to allow interested parties to see early results of the studies and to provide direction to the consultants with respect to revisions and additional work required. More than 40 people attended the symposium, representing companies, industry associations and federal government departments and agencies (Industry Canada, Health Canada, Department of Foreign Affairs and International Trade, Finance Canada, Human Resources Development Canada, the Patented Medicine Prices Review Board and the Medical Research Council of Canada).

In addition to the private sector consultant studies, in-house analysis and report writing drew together the various pieces of information available into an overall, consistent story line. This work was carried out under contract by Industry Canada's Management Consulting Centre (David Caldwell, Principal Consultant) and by members of the pharmaceutical team of the Health Industries Branch (Maryanne Murphy and Claude-Andrée Ouimet) of Industry Canada.

Annex C
PRODUCTS CONSUMED AND MANUFACTURING INPUTS UTILIZED IN CANADA'S PHARMACEUTICAL INDUSTRY

Table C-1. Canadian Market for Patented Drug Products, by Anatomical Therapeutic Chemical (ATC) Classification, 1995

Major ATC classification		Patented drug products			
		Number	Share of total	Value	Share of total
			(%)	($ millions)	(%)
A	Alimentary tract and metabolism	103	11.4	412	15.6
B	Blood and blood-forming organs	35	3.9	261	9.9
C	Cardiovascular system	99	11.0	419	15.9
D	Dermatologicals	35	3.9	76	2.9
G	Genito-urinary system and sex hormones	32	3.6	112	4.2
H	Systemic hormonal preparations, excluding sex hormones	22	2.4	23	0.8
J	General anti-infectives for systemic use	172	19.1	395	15.0
L	Antineoplastics and immunomodulating agents	58	6.4	134	5.1
M	Musculo-skeletal system	44	4.9	101	3.8
N	Nervous system	65	7.2	396	15.0
P	Antiparasitic products	3	0.3	0	0.0
Q	Veterinary products	115	12.8	86	3.4
R	Respiratory system	59	6.6	170	6.4
S	Sensory organs	23	2.6	16	0.6
V	Various	35	3.9	36	1.4
	Totals	**900**	**100.0**	**2 637**	**100.0**

Source: PMPRB, *Eighth Annual Report*, December 1995.

Table C-2. Canadian Pharmaceutical Industry Inputs (% share of gross output)

Commodities and services	1981	1986	1992
Animal by-products for industrial use	0.84	1.09	0.00
Plastic containers and closures	0.70	1.20	0.93
Paper bags, boxes, plastic bags	1.40	1.28	1.21
Glass containers	1.89	0.70	0.59
Pharmaceuticals	17.62	16.01	17.43
Other industrial chemical preparations	0.28	0.00	0.48
Organic–inorganic compounds	0.77	0.00	1.75
Custom work, miscellaneous	0.77	1.09	0.57
Truck transportation	0.56	0.47	0.36
Wholesaling margins	0.63	0.66	0.62
Other finance and real estate services	2.38	2.48	3.13
Professional service to business management	1.89	1.55	1.34
Advertising and promotion	6.15	6.20	5.67
Other inputs	20.62	16.34	13.10
Wages and salaries	24.62	21.16	19.64
Supplementary labour income	2.24	2.29	2.69
Other operating surplus (gross profit)	16.64	27.48	30.49

Source: Statistics Canada, Input-Output tables, special run, 1996.

Annex D
ADDITIONAL MATERIAL ON R&D IN CANADA'S PHARMACEUTICAL INDUSTRY

Announcements of increased research expenditures in Canada have been made by a number of U.S.-based firms (e.g. Eli Lilly, Bristol-Myers Squibb, Pfizer). As these announcements concentrate on in-house research in Canada, they suggest that alliances by these firms with universities and hospitals performing R&D tend to take place in the U.S. There are, however, prior existing alliances between U.S. firms and Canadian firms in the Canadian market (e.g. Eli Lilly and Allelix).

Significant R&D announcements have also been made by European-based firms (e.g. Astra, Hoechst Marion Roussel, Smith Kline Beecham, Glaxo) and alliances with Canadian firms have been formed (e.g. Glaxo and Biochem Pharma). In contrast to the behavior of the U.S.-based firms, European foreign direct investment is spread between in-house research facilities and alliances with Canadian universities and hospitals.

As an illustration of the growing R&D activities of generic firms, Apotex has funded recombinant DNA research at Canadian universities and is pursuing the discovery of new molecules. Novopharm is focussing on developing biotechnology cancer treatments by, for example, forming collaborative arrangements with Hygeia and Genzyme.

Intramural R&D capabilities and basic R&D mandates for Canadian subsidiaries have been limited in the past but are expanding. Few new chemical entities have been discovered in Canada, partly because the amount of research is simply not yet large enough. There is only about $132 million of basic research done in Canada, according to the PMPRB, and this is spread thinly over different companies and different products. Nevertheless, individual company strategies vary widely, with some companies exhibiting R&D-to-sales ratios in Canada that are comparable with their international headquarters (in Canada, R&D definitions are somewhat more restrictive, which leads to some bias in Canada's R&D-to-sales ratio when used in international comparisons) and others being well below this standard (Table D-1). In addition, the R&D performed by several Canadian bio-pharmaceutical firms is not reported by the PMPRB, since these firms do not yet market products. In 1995, 64 bio-pharmaceutical companies (both marketing and non-marketing) spent $251 million, according to Contact Canada, a private statistical research firm.

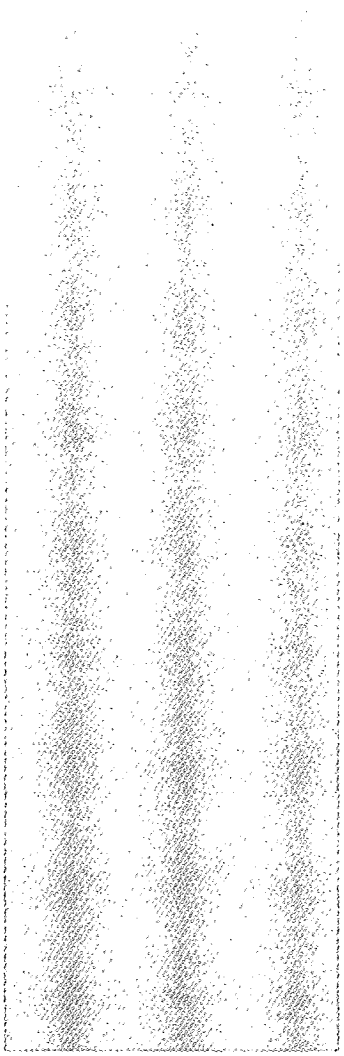


Table D-1. R&D-to-sales Ratios

U.S.-based parent companies	R&D/sales 1993	R&D/sales 1995	Change	Canadian subsidiaries	R&D/sales 1993	R&D/sales 1995	Change
	(percent)				(percent)		
Merck	11.7	11.8	0.1	Merck-Frosst Canada Inc.	10.8	15.6	4.8
Bristol-Myers Squibb	14.8	13.6	–1.2	Bristol-Myers Squibb Group	13.6	13.4	–0.2
Johnson & Johnson	14.8	12.3	–2.5	Johnson & Johnson	9.3	11.0	1.7
American Home Products	n.a.	20.1	n.a.	Wyeth-Ayerst	16.7	16.4	–0.3
Eli Lilly	15.0	16.5	1.5	Eli Lilly Canada Inc.	8.5	11.0	2.5
Pfizer	18.9	18.3	–0.6	Pfizer Canada	8.6	7.7	–0.9
Abbott	n.a.	20.4	n.a.	Abbott Laboratories Limited	3.8	1.8	–2.0
European-based parent companies	**R&D/sales 1993**	**R&D/sales 1995**	**Change**	**Canadian subsidiaries**	**R&D/sales 1993**	**R&D/sales 1995**	**Change**
	(percent)				(percent)		
Astra (Sweden)	n.a.	16.0	n.a.	Astra	9.6	10.1	0.5
Bayer (Germany)	13.9	20.9	7.0	Bayer Inc.	6.2	9.3	3.1
Hoechst Marion Roussel (Germany)	—	14.8		Hoechst Marion Roussel Canada Inc.	—	15.3	
Hoechst (Germany)	14.6	—		Hoechst Roussel Canada	9.8	—	
Marion Merrell Dow (Germany)	14.0	—		Marion Merrell Dow Canada	12.3	—	
Novartis (Switzerland)[a]	—	20.9					
CIBA-Geigy (Switzerland)	15.5	—		CIBA-Geigy Canada Ltd.	8.7	7.9	–0.8
Sandoz (Switzerland)	16.2	—		Sandoz Canada	16.1	12.1	–4.0
Roche (Switzerland)	23.6	n.a.	n.a.	Hoffman-La Roche Ltd.	24.2	16.3	–7.9
Glaxo Wellcome (U.K.)[b]	15.0	15.1	0.1	Glaxo Wellcome Inc.	10.2	n.a.	13.6

n.a. = not available.

[a] CIBA-Geigy (Switzerland) and Sandoz (Switzerland) merged to form Novartis in 1995, but CIBA-Geigy Canada Ltd. and Sandoz Canada operated as separate companies that year.

[b] Glaxo bought Burroughs Wellcome Inc. in July 1995. The 1993 figures are for Glaxo.

Source: *Scrip Yearbook*, Vol. I, 1994, p.54; *Scrip Report*, 1993, Pharmaceutical Company League Tables pp. 86–95; PMPRB, *Annual Reports*, 1994, pp. 37–42, and 1995, pp. 27–28.

Another measure of R&D performance is the importance of pharmaceuticals relative to the gross expenditure in research and development (GERD). By this measure, Canada, at 9.2 percent compares well with the U.S. at 10.5 percent, but poorly relative to other G-7 countries such as France at 12.2 percent, Italy at 14.5 percent and the U.K. at 23.4 percent. However, the high figures in these countries

may be attributed to the tendency to locate R&D close to the company's headquarters or main pharmaceutical production unit.

Merck, one of the largest U.S.-based companies, stands out because of its R&D commitment to Canada. The Canadian subsidiary has increased its R&D-to-sales ratio by 4.8 percentage points between 1993 and 1995, so it is now significantly more R&D-intensive than its parent. BMS already has the same ratio as its parent, while Johnson & Johnson and Eli Lilly have increased their R&D-to-sales ratios but these remain somewhat lower than those of their parent companies. Abbott and Pfizer are examples of U.S. companies that currently have much lower R&D-to-sales ratios in Canada than at U.S. headquarters. However, Pfizer has announced a new R&D facility for Canada.

With respect to European firms, Hoechst Marion Roussel appears to favour R&D in Canada, whereas Bayer exhibits a much lower R&D-to-sales ratio in Canada than internationally.

The majority of R&D expenditures in Canada are devoted to clinical trials. The Canadian subsidiaries have a real competitive advantage in clinical R&D trials, including access to a population with characteristics similar to Americans, comprehensive medical records (annual physicals for patients are government-funded) and relatively low costs of clinical trial personnel, which allows them to compete successfully with sister organizations for mandates. To enhance this activity, the companies need access to more high-quality contract research organizations (CROs). Extramural R&D expenditures are also used to capture specific researchers or institutional expertise. In addition, MNEs often acquire manufacturing and marketing rights of biopharmaceuticals under development in Canadian companies, in exchange for financial support.

A recent study by Statistics Canada for the PMPRB estimates that intramural R&D performed by CDMA members was $66 million in 1994, while extramural R&D amounted to $41 million, most of which is directed to copying brand products. (R&D directed toward copying products is different in character from innovative R&D. For example, the R&D figures quoted in this document for brand-name companies are reported to the PMPRB as being eligible for the Scientific Research and Experimental Development tax credit. Based on Revenue Canada's definition, as set out in bulletin T4052: "The financial support is intended to encourage business . . . to develop new or improved technologically advanced products or processes." Most activities solely directed toward copying would not be eligible.) Nevertheless, there is a small but growing capacity to do innovative R&D, often on an extramural basis, in two areas: monoclonal antibodies for diagnosis and treatment of cancer, and oral chelators for treating thalassemia.

Annex E
DYNAMICS OF EMPLOYMENT AND INVESTMENT WITHIN CANADA'S PHARMACEUTICAL INDUSTRY

Employment

About a third of the employment in the Canadian industry is provided by U.S.-based pharmaceutical companies that are members of PhRMA. Between 1992 and the midpoint of 1995, employment in Canada of companies responding to the PhRMA annual survey fell by 10 percent (8 138 to 7 321). Although the survey data of PhRMA may not capture all the relevant companies because of underreporting, the movements in the data are consistent with employment changes reported by individual companies. For example, Merck Frosst, the largest U.S. firm in the Canadian market in terms of sales (1995), reduced its employment level between 1991 and 1993, but subsequently added employees. (Merck Frosst's employment in Canada has grown by over 40 percent since 1987.)

Johnson & Johnson, the second largest U.S.-based firm in Canada, reduced its employment by 40 percent between 1991 and 1995 (1 671 to 900) with most of the reduction coming in 1995. In contrast, Eli Lilly Canada, the fourth largest U.S. firm in the Canadian market, increased employment by 30.6 percent (450 to 588) over the same period (Source: *Financial Post 500,* annual, 1992–96, and *Canadian Business*, annual, 1992–96). Because a number of these companies have secondary lines of business in addition to pharmaceuticals, these changes to total employment levels may not necessarily be fully accounted for by pharmaceutical operations.

With this proviso in mind, the data show that European-based firms also have had mixed performance on the employment front. Glaxo Wellcome, the largest European firm in the Canadian market (due to a merger in 1995), reduced its work force by 10.3 percent between 1992 and 1995 (1 500 to 1 300). Hoechst Marion Roussel Canada (also the product of a merger), trimmed its work force by 26.8 percent (1 185 to 867) between 1992 and 1995. Bayer reduced its work force by 9.4 percent (2 599 to 2 354) between 1992 and 1995. In contrast, Astra increased employment in the past few years.

The two largest Canadian generic firms, Apotex and Novopharm, have shown significant employment growth throughout the 1990s. According to a Price Waterhouse study ("Human Resource Study of the Pharmaceutical Industry," Ottawa, 1996), employment of CDMA member firms in the generic sector more than doubled over the past five years to stand at 3 630 in 1995. This performance, along with growth of employment in some of the smaller brand-name firms (particularly in the biotechnology sector), generic firms and new entrants to the market,

has offset the employment reductions by the larger multinationals. For example, IVAX, a U.S. generic company, is entering the Canadian market by buying the Montreal manufacturing plant of Glaxo Wellcome, which was made available by Glaxo's decision to consolidate operations in Mississauga, Ontario. This development will allow 120 of the original 210 employees of the Glaxo plant to retain their jobs.

Investment

Significant investments in facilities have been announced by U.S.-based firms (an R&D facility by Eli Lilly and manufacturing facilities by Merck Frosst and Wyeth-Ayerst). European-based companies such as Astra and Glaxo also have recently invested in manufacturing facilities in Canada.

The pharmaceutical industry delayed its restructuring until the early 1990s, when a wave of mergers among major pharmaceutical companies took place. For example, the consolidation of Glaxo Wellcome's manufacturing operations in Mississauga includes building a new plant, which is projected to export 50 percent of its output, and the merger of Pharmacia and Upjohn included the building of a new headquarters facility, also in Mississauga.

The rising trend in Canada's share of **investment** compared with the U.S. may reflect Canada's existing cost advantage in construction and operation of new facilities. At the same time that companies make new investments, older, less efficient plants are being shut down (disinvestment). For example, Searle is in the process of selling its manufacturing plant in Oakville to a U.S.-based firm (Roberts), Hoffman-LaRoche is closing its manufacturing facilities in Mississauga, and Novartis Pharma Canada is putting its Dorval, Quebec, plant up for sale in order to consolidate production in Whitby, Ontario. Similar disinvestment is occurring in the U.S. and other countries.

Generic firms are expanding their capacity in line with their fast-growing sales. For example, Apotex recently built a state-of-the-art manufacturing plant at a cost of $130 million, completed Torpharm Phase 2 at a cost of $15 million and undertook a $10-million expansion of its large industrial pharmaceutical fermentation plant; Genpharm is upgrading its capacity with a $4-million project, and Novopharm expanded its head office facility, acquired Wampole Canada (an OTC company) and invested $54 million in a new manufacturing facility in North Carolina in the past few years.

With respect to bio-pharmaceuticals, there is little investment in production facilities as yet because, with the exception of Connaught, Canadian firms have not moved far enough through the development/approval cycle.

Annex F — ADDITIONAL PERTINENT DATA

Table F-1. Pharmaceutical Industry

Date	Industrial product price index (IPPI), annual average	Gross domestic product (GDP)	Shipments	Profit margin, median large firm[a]	Profit margin, median small firm[a]	Capital investment	Total R&D in pharmaceuticals and medicine (intramural)[b]	Total current pharmaceutical R&D expenditures (intramural + extramural)[c]	Total employment	Total wage bill	Labour productivity	Index of unit labour cost	Canadian apparent market	Total exports[d]	Total imports[d]
	(1986 = 100)	(constant $ millions)	($ millions)	(%)	(%)	($ millions)	($ millions)	($ millions)	(number)	($000)	($000)	(1986 = 1)	($ millions)	($ millions)	($ millions)
1980	58	935		—	—		43	—							
1981	65	992	1 327	—	—		52	—	16 058	338	61.78	0.85			
1982	73	955	1 458	—	—	85.5	58	—	15 260	365	62.58	0.95			
1983	80	1 040	1 662	—	—	65.6	66	—	15 268	390	68.12	0.93	2 028	144	510
1984	87	1 090	1 840	—	—	65.1	63	—	15 184	419	71.79	0.96	2 229	149	538
1985	94	1 290	2 230	—	—	73.3	81	—	16 704	488	77.23	0.94	2 580	158	508
1986	100	1 310	2 489	—	—	91.7	103	—	17 127	527	76.49	1.00	2 950	181	642
1987	107	1 470	2 932	—	—	132.4	107	—	18 578	593	79.13	1.00	3 423	201	692
1988	114	1 550	3 180	9.80	2.90	124.3	134	158.6	19 319	652	80.23	1.05	3 805	287	911
1989	118	1 530	3 257	11.30	1.00	177.2	177	228.6	19 398	679	78.87	1.10	3 910	293	946
1990	124	1 640	3 582	9.20	8.10	249.4	256	288.4	19 876	734	82.51	1.11	4 394	339	1 151
1991	130	1 620	3 797	10.40	4.70	241.1	263	355.2	21 146	815	76.61	1.25	4 734	361	1 298
1992	134	1 690	4 147	9.30	3.20	263.3	314	392.7	21 354	851	79.14	1.25	5 304	545	1 702
1993	135	1 830	4 544	6.80	2.10	295.4	366	477.8	21 872	903	83.67	1.23	6 008	601	2 065
1994	136	1 850	4 453	7.80	4.40	264.8	392	536.6	19 564	938	94.56	1.26	6 066	766	2 378
1995	136		4 749	6.60	6.30	223.4	405 *	596.2	21 069	950			6 548	879	2 675
1996														1 044	2 960
Average				8.90	4.10										

[a] Net profit divided by sales. [b] Including capital expenditures. [c] Excluding capital expenditures. [d] SIC classification 3741. * Intentions.

Source: Statistics Canada, TIERS, STAN Database; Revenue Canada, Economic Reference Table; ISTC, Queen's Health Policy, Industry Profile; Statistics Canada, *Financial Performance Indicators for Canadian Business*; PMPRB, CANSIM M3103.

Annex G
REVIEW OF BILL C-91

In February 1997, the House of Commons Standing Committee on Industry was tasked with undertaking a review of the *Patent Act Amendment Act, 1992* (Bill C-91), as required by the review clause set out below.

Bill C-91 Review Clause

14(1) On the expiration of four years after this Act is assented to, the provisions of the *Patent Act* enacted by this Act shall be referred to such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established for the purpose of the review referred to in subsection (2).

14(2) The committee shall undertake a comprehensive review of the provisions of the *Patent Act* enacted by this Act and shall, within one year after the review is undertaken or within such further time as the House or Houses that designated or established the committee may authorize, submit a report thereon, including such recommendations as the committee may wish to make pertaining to those provisions.

The committee heard over 150 witnesses and received numerous briefs. The evidence presented can be found on the committee's website at http://www.parl.gc.ca.

The committee's report, released in April 1997, titled *Review of Section 14 of the Patent Act Amendment 1992: Fifth Report of the Standing Committee on Industry* and containing numerous recommendations, can also be found at that website. Copies may also be obtained from the Canada Communication Group Inc., Public Works and Government Services Canada, Ottawa, Ontario, K1A 0S9.

The government's press release following the publication of the committee's report is attached to this annex.

NEWS RELEASE

MINISTERS WELCOME CALL FOR CHANGE IN PARLIAMENTARY REPORT ON *PATENT ACT*

OTTAWA, April 25, 1997 – In response to the recommendations contained in the Standing Committee on Industry's report on its review of the *Patent Act Amendment Act, 1992*, Industry Minister John Manley and Health Minister David Dingwall reaffirmed the need to protect intellectual property rights, enhance research and development activities and ensure affordable drug prices.

Ministers welcomed the Committee's report. "It calls for change and gives positive direction for improving Canada's drug patent policy," said Mr. Manley.

"The Committee's report reflects the concerns of Canadians about drug costs and their impact on the health care system," said Mr. Dingwall. "Consistent with the views of the Committee and the National Forum on Health, the government is already taking concrete steps with the provinces and territories to explore the possibility of a national pharmacare program."

Ministers agreed with the Committee on the need to strengthen the Patented Medicine Prices Review Board (PMPRB) and to work closely with the provinces and territories to consider broadening its mandate to include non-patented drugs. They noted that the government is prepared, if asked by the provinces, to make the necessary changes to give the PMPRB authority to administer provincial controls on prices of non-patented medicines. Ministers also agreed to work with the PMPRB to review the mechanisms for regulating the prices of patented drugs and to improve the transparency of the price review process.

Ministers also agreed with the Committee on the need for the pharmaceutical industry to increase significantly research and development expenditures and challenged brand name, generic and bio-pharmaceutical companies to increase their R&D spending in Canada to reach international levels. For its part, the federal government has put in place a framework and programs which encourage and support R&D in the health sector. This framework includes the intellectual property regime, generous tax credit incentives and support for health science infrastructure. In the last budget, the Government also announced a wide range of investments as proof of its commitment to research and development.

"In reviewing Canada's drug patent policy," said Mr. Manley, "the Committee has concluded that Canada must maintain the standard of 20 years of patent protection in order to satisfy our international trade obligations. We agree and we will maintain those obligations."

Ministers noted that the Committee's specific recommendation on the regulatory framework for drug patent policy called for change to address stakeholder concerns to achieve fairness and effectiveness, and reduce unnecessary litigation. Ministers noted that in addressing the need for change, we must be guided by the need to strike the right balance between ensuring effective enforcement of patent rights and ensuring that generic drug products can hit the marketplace immediately after patent expiry. To that end, they endorsed the need to consult on a priority basis with key stakeholders on what changes are required to the regulations and how these changes could be implemented.

Ministers thanked the Standing Committee members for their thorough review of *Patent Act* issues and for providing valuable advice for the future, and thanked Canadians for taking the time to make their views known.