Canada: Pharmaceutical Drugs

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October 09

Summary

The Canadian pharmaceutical market resembles its U.S. counterpart, especially in terms of demand. Much like the United States, Canada is confronted to an aging population, high rate of heart-related diseases, a strong demand for psychotherapeutic medication and other issues, which in all likelihood will ensure a sustained market growth for the pharmaceutical sector for years to come. Canadians receive an average of 14 pharmaceutical prescriptions per year.

In Canada, both federal and provincial governments exercise control over prescription and non-prescription drug prices. The federal government is responsible for the Patented Medicine Prices Review Board (PMBR) through Health Canada's structure under the supervision of the Canadian Minister of Health. Provincial and territorial governments strongly influence non-patented or generic drug prices. They have a certain control over generic medicines by deciding whether or not these drugs are covered by their respective public drug insurance plans. In either case, both the federal and provincial governments generally manoeuvre to prevent drug prices from experiencing increases greater than the inflation rate.

Canada's pharmaceutical research and manufacturing industry hosts the activities of the top ten multinationals in the sector worldwide. According to industry statistics, manufacturer's shipments were valued at $8.8 billion in 2008, of which $6.5 billion worth were exported primarily to the United States. Canadian imports totalled $10.8 billion and fulfilled 82 percent of domestic market demand. Canadian imports from U.S. manufacturers were estimated at nearly $3.5 billion, representing a 32 percent share of total imports of pharmaceuticals.

Distributors and wholesalers are responsible for fulfilling 90 percent of orders placed by the retail and institutional buyers. In the past two decades, they have made spectacular gains in controlling the pharmaceuticals distribution market. Many of these wholesalers are divisions of corporations involved in manufacturing, locally and abroad. These wholesalers are innovative in developing retail sales programs, marketing strategies and computerized management systems used by their clients' marketing and procurement units.

Although highly competitive and highly regulated there is room for new drugs and new opportunities in the Canadian pharmaceutical market place. Key opportunities are apparent for cost-efficient products targeting cardiovascular, gastroenterological and psychotherapeutic treatments as well as new and more efficient anti-inflammatory. Alzheimer's and cancer medications are also sought by an aging and demanding population.

Market Demand

Canada and the United States generally show similar drug consumption records, especially for cardiovascular, psychotherapeutic and cholesterol medications. Canada ranks 36th in the world in terms of population but constitutes the world's 8th largest pharmaceutical market for its sales, accounting for over two percent of the world market. The Canadian pharmaceutical market has experienced strong growth throughout the last two decades, and has continued to grow at the world's fourth fastest rate. The Canadian pharmaceutical market experienced an average annual growth of 8 percent last year. Only China, Mexico and Spain can claim higher growth figures. A number of factors come into consideration to explain such a strong growth, but among the principal factors are Canada's aging population, a higher incidence of heart disease and a growing occurrence of obesity-related diseases.

Interestingly, a study released by The U.S. Department of Commerce, comparing pre and post-NAFTA trade numbers, concluded that American pharmaceutical companies widely benefited from NAFTA. Their Canadian sales jumped more than 150 percent after the enforcement of the agreement, compared to a 125 percent growth achieved with their sales to the rest of the world.

The Canadian pharmaceutical market is controlled by foreign-owned multinationals manufacturing patented brand name drugs with no single company controlling a dominant share of the total market. Among the cluster of major players we find in decreasing order of Canadian revenues, Pfizer, Astra Zeneca, Johnson & Johnson, GlaxoSmithKline, Wyeth, Sanofi-Aventis, Merck Frosst and Brystol-Myers Squibb. Although four times smaller in revenues compared to brand name drugs, the generic drugs industry sector is also vigorous and is dominated by two companies: Apotex and Teva Novopharm.

The degree of consolidation in the pharmaceutical sector clearly exceeds the average of all industries in Canada. The ten largest pharmaceutical companies, of which five are U.S.-owned and only one is Canadian-owned, hold approximately 60 percent of Canadian market share. The Canadian pharmaceutical industry is primarily concentrated in the eastern part of the country, mostly Ontario and Quebec. These two provinces respectively account for 49 and 38 percent of the Canadian pharmaceutical market. Although burgeoning, British-Columbia, is the home of a relatively modest third cluster. In Canada, pharmaceutical companies are largely concentrated in metropolitan areas of Toronto and Montreal.

Demand Growth and Shift

Industry forecasts indicate that Canada's aging population will dramatically drive demand for prescription medication upwards over the next decade, which will guarantee a sustained growth. It is established that per capita drug expenditures is directly proportional with age. The Canadian Government estimates that seniors (age 65 and over) will make up roughly one fifth of the population by 2026. This older population will be more susceptible to cancers, Alzheimer's disease, hormonal issues, and a wide range of other pathologies. However, demand for over-the-counter drugs is not necessarily linked to aging population. It may even be affected negatively to some extent as seniors in Canada tend to change from non-prescription to prescription drugs when they become entitled to advantageous public insurance coverage for prescribed medication at age 65.

Drug expenditures generated by seniors constitute a very significant portion of the demand. These expenditures are dramatically higher than other cohorts in the Canadian population, certainly due to unimpeded access to public provincial drug plans, but also combined to a more fragile health condition. Several studies bring to light other factors likely to increase demand, namely the current increase of pollution creating several pathologies that are set to increase in frequency. Scientists have made links showing that atmospheric pollution is directly responsible for several respiratory, hormonal and foetal pathologies. While this progression is unfortunate, but real, the demand for such disease treatments will surely increase with the current absence of significant progress in pollution reduction in Canada.

Canadians' intake of prescription drugs is one of the highest in the world. In a recent study by IMS Health, a leading provider of pharmaceutical and health care industry market intelligence reported that number of drug prescriptions grew 7.1 percent in 2008. IMS also reported that Canadians spent over CAN$21.4 billion on prescriptions last year, up from CAN$20.2 billion in 2007, a 6 percent increase. In all, Canadian pharmacists dispensed 453 million prescriptions in 2008, an average of nearly 14 prescriptions per Canadian.

For a first time in 2008, the number of prescription filled by generic drugs surpassed brand-name drugs, 51.6 vs. 48.4 percent. This trend is likely to continue as it represents significant savings for the insured prescription drugs system in each of the provinces. The economic slowdown that prevailed throughout 2008, in Canada, seems to have not affected the demand for prescription drugs.

End-users of pharmaceutical drugs, who up until now favoured brand-name drugs, are gradually shifting to generic drugs. This shift is influenced by the fact that there was a 15% growth in the number of Canadian physicians' prescriptions for generic medication vs. a nearly flat (0.3%) growth for prescribed brand-name drugs.

Among Canadian provinces, New-Brunswick has led the way in 2008, with 58.9 percent of all prescriptions filled by generic drugs. Only in the province of Quebec has the number of prescription for brand-name drugs continue to exceed generics with a ratio of 46 percent generics to 54 percent brand name drugs.

Cardiovascular medications continued to lead demand as Canada's most prescribed drug class (up 7.8 percent over 2007). Nearly 71 million prescriptions for cardiovascular medications, accounting for more than $3 billion in sales, were dispensed in 2008, followed by psychotherapeutics and gastrointestinal / genitourinary drugs. Sales of prescription drugs to Canadian hospitals and pharmacies in 2008 grew 6.6 percent compared to a 6.2 percent growth in 2007.

Demand for vaccines is also on the rise in Canada, particularly with the new worldwide H1N1 pandemic alert in 2009. Demand for H1N1 inoculation has now surpassed in urgency the seasonal flu vaccine. Canada's provincial and territorial health authorities are responsible for the delivery of vaccination to their respective populations. However, federal health authorities are responsible for the ordering of H1N1 vaccines with pharmaceutical companies.

At this time, Canada has a supply contract with GlaxoSmithKline for a quantity of 50 million doses with an acquisition cost established at around US$ 7 per dose or US$ 350 million. GlaxoSmithKline owns a flu vaccine plant in Quebec province, to produce the necessary quantities. That plant is capable of producing 3.5 million to four million doses per week. Supply of these vaccines, in all likelihood, should come from local production in 2009 and 2010. Nonetheless, there are significant Canadian imports of vaccines, which were valued at US$ 345 million in 2008. Imports from the United States were estimated at about US$ 135 million for that same year, representing an import market share for U.S. vaccine suppliers of nearly 40 percent.

For 2009, IMS predicts lower pharmaceutical drugs sales growth in the 4.5 – 5.5 percent range, reflecting the impact of cost containment efforts across the provinces, including increasing use of best price policies, hospital cost containment and pressure to lower the prices of generic medications.

Future potential for U.S. exports

The United States, as a country, remains the largest single exporter of pharmaceutical drugs to Canada. However, its market share, which is currently about 33 percent, has declined by nearly 5 percent over the last three years. Approximately 60 percent of Canada's pharmaceutical imports originate from countries of the European Union. This group has been steadily increasing its market share over the recent years. The EU's main exporting countries to Canada are Germany, Ireland, United Kingdom and France.

Generally speaking, the best prospects for the Canadian market are innovative new drugs or treatments that represent therapeutic advances. In order to be successful, new drugs seeking to compete with existing ones in an already saturated market must be cost effective to obtain a reimbursement status from provincial drug plans.

Price Changes & Regulations

Federal and provincial governments play a major role in the regulation of drug prices. Prescription drug prices are subject to direct control by the Patented Medicine Prices Review Board (PMPRB), a federal government agency, under the banner Health Canada, (the Department of Health of Canada). Created under the *Patent Act of Canada,* manufacturers' drug prices are limited for all patented medicines, whether or not they're available by prescription or over-the-counter. The PMPRB acts as an independent, quasi-judicial tribunal which has both a regulatory role, as it ensures that consumers can access their medications at a reasonable price, as well as a reporting agency which monitors R&D spending and pharmaceutical trends. However, even though the PMPRB has no authority over unpatented medicines, and therefore does not regulate prices of generic drugs, there is a possibility that the board's jurisdiction could be broadened to regulate non-patented drugs prices, which would require provincial cooperation.

At the provincial level, most provincial drug reimbursement plans have adopted the policy of the “best available price” in Canada. The “best available price” policy not only applies to purchases by covered patients but to virtually all drug sales in the province. The outcome of most provinces demanding the best available price is that there is one price across Canada and therefore the lowest price is also the highest price. Provincial pharmaceutical plans limit price increases for patented and non-patented medicines to less than inflation rate increases. It is highly unlikely that financially-stretched provincial drug plans would be willing to endure prices increases higher than inflation, as they will generally be encouraging price freezes or decreases. Therefore, the only prescription medicines prices that can increase at a rate faster than inflation are the unpatented drugs that are not covered by provincial drug plans.

Industry Projections

The pharmaceutical industry comprises a major sector of the Canadian economy. As of 2008, approximately 40,000 Canadians were directly employed by pharmaceutical firms, and 60,000 additional jobs were indirectly supported by the pharmaceutical industry. In terms of R&D spending, a recent report indicated that 32 of the top 100 R&D investors in Canada pharmaceutical companies. Industry Canada also estimates that the private sector funds two-thirds of Canadian pharmaceutical R&D, while local, provincial, and federal governments fund the remaining other third.

Changes in Market Structure

The percentage sales reinvestment into R&D varies according to patent protection laws. Before 1988, companies reinvested approximately 4 percent of sales in R&D. After Royal Assent was granted to Bill C-91, which ensured greater patent protection, that R&D increased to 11 percent of sales. Important factors affecting R&D reinvestment are the degree of patent protection available, the R&D tax credit system, the availability of research centers, renowned researchers and direct government funding.

It is estimated that one fifth of Canada’s health expenditures, which amount approximately to 10% of Canada’s GDP, is allocated to pharmaceuticals. While drug prices are government-controlled, Canada offers competitively lower R&D and clinical trial costs than most western countries. It is important to note that the Canadian Government receives a large number of requests for product approvals, therefore it is very important to file for these formulary approvals as early as possible and to follow the process on a regular basis. A formulary is the list of drugs funded by the government through its drug insurance plans. These formularies strongly influence the prescribing habits of physicians.

Market Data

The pharmaceutical industry is among the most innovative, promising and lucrative industries of the Canadian economy. Employing almost 100,000 Canadians, directly and indirectly, the pharmaceutical industry is one of the largest private employers in the country. According to Statistics Canada, labour productivity and growth in the pharmaceutical industry was 4.5 times higher than the overall of all other industries in recent years. The pharmaceutical industry injects $5 billion annually in the Canadian economy and accounts for $660 million worth of capital investment, in terms of buildings and engineering construction. This industry employs a highly educated workforce and offers highly competitive conditions for research and development including clinical trials.

Domestic production, estimated at over $9.2 billion for 2009, is relatively important and export oriented. Almost three quarters of local production is exported, $6.8 billion, and more than $5 billion worth shipped to the United States.

Canadian Pharmaceutical Market
($US Millions)

	2007	2008	2009 (Forecast)	% Growth
Canadian Imports	10,256	10,828	11,694	+8%
Local Production	8,881	8,801	9,241	+5%
Canadian Exports	6,525	6,462	6,785	+5%
Total Market	12,612	13,167	14,150	+7.5%
Imports from the U.S	3,613	3,468	3,504	+1%
U.S. Imports Share	35%	32%	30%	

Note: All HS numbers included in data generated with Global Trade Data: 190590,293390,293391,293490,293491,293710,293711,293712,293719,293721,293722,293723,293729,293731,293739,293740,293750,293790,293791,293792,293799,293810,293890,293910,293911,293919,293920,293921,293929,293930,293940,293941,293942,293943,293949,293950,293951,293959,293960,293961,293962,293963,293969,293970,293990,293991,293999,294110,294120,294130,294140,294150,294190,3001,3002,3003,3004,051000

In Canada, imports of pharmaceutical drugs account for more than 80 percent of the total market demand. It is worthwhile noting that this proportion has been quite stable over the last few years. Domestic production therefore fulfills roughly 20 percent of Canadian market demand. The proportion of Canadian imports from the U.S. is currently estimated at 30 percent, a 5 percentage point decline from two years ago.

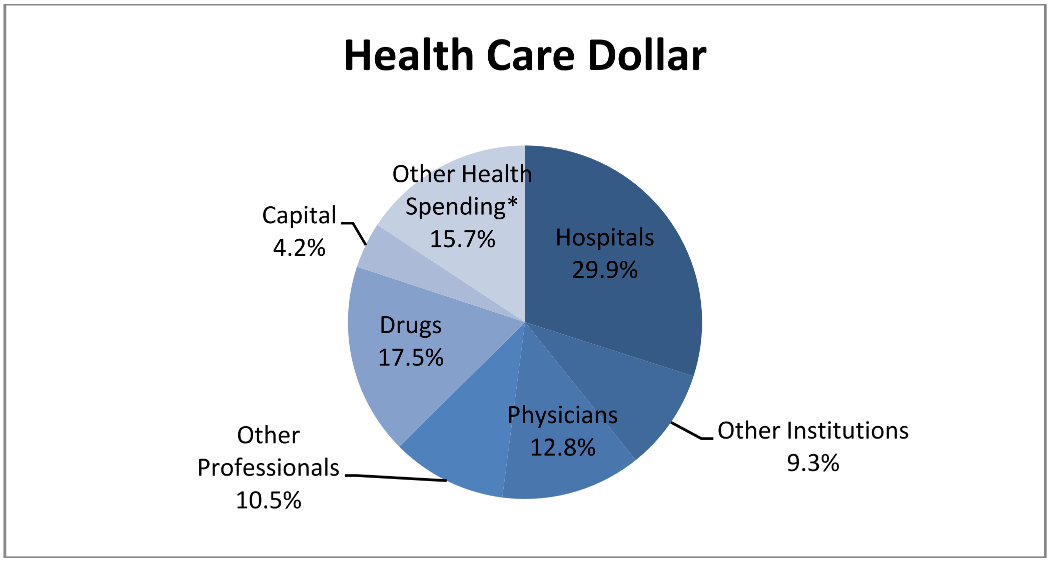
Wholesalers are used to distribute pharmaceutical products to health institutions and pharmacies, which account for 90% of the Canadian market. Over the past ten years, wholesalers-distributors have made spectacular gains in controlling the pharmaceuticals distribution market as demand for prescription drugs rose. Many of these wholesalers are divisions of corporations involved in manufacturing or research and development, as well as subsidiaries of foreign manufacturers distributing their products in Canada.

These wholesalers have built their stronghold on distribution pharmaceuticals as well as for other pharmacy supplies by developing innovative support and logistical services such as developing retail sales programs, marketing strategies and computerized management systems. They also offer support in coordinating the client's procurement unit's activities, organizing joint advertising programs and collecting and presenting highly valuable market data and analysis to them.

Much like manufacturing, pharmaceutical wholesale activities are dominated by large establishments with international presence. McKesson Canada, AmerisourceBergen Canada, and Kohl & Frisch Limited are among the major wholesaling players in Canada. By their sheer size and geographical distribution of outlets, some pharmacy chains are self-distributing, like The Jean Coutu Group, Shoppers Drug Mart and Sobeys Pharmacy Group (150 in-store pharmacies across Canada, in addition to the 70 Lawton's Drug Stores that operate in the Atlantic Provinces). U.S. pharmaceutical manufacturers aspiring to enter the competitive Canadian market must consider approaching the above mentioned wholesale or self-distributing firms.

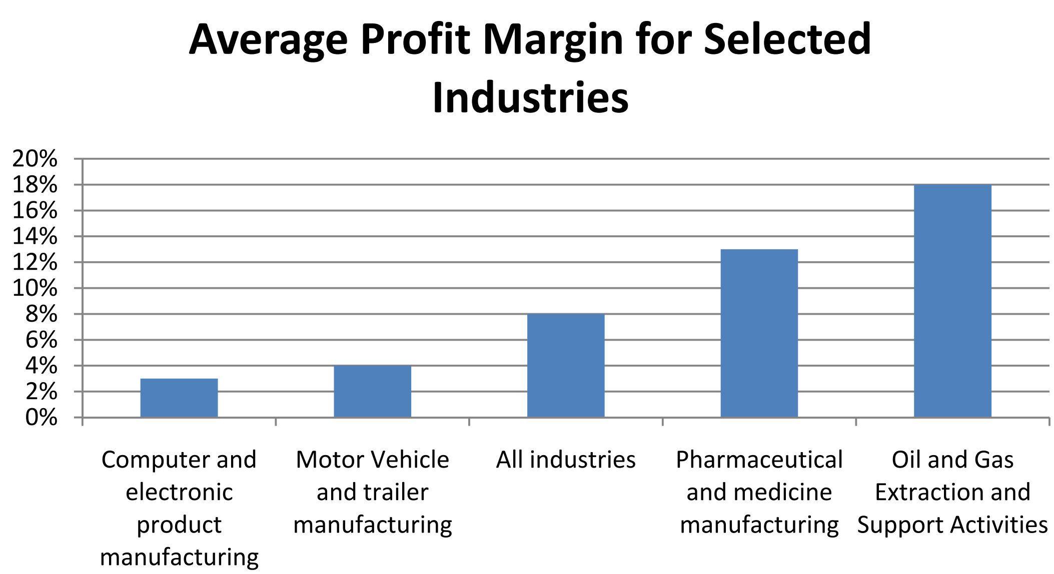
In recent years, pharmaceutical drugs expenditures moved ahead of physicians' fees and other health spending categories to become the second largest health care expenditures category in Canada's healthcare budget. Of the total expenditures reported nation-wide for health care, only hospital operational expenditures exceed pharmaceuticals.

The following pie chart illustration of Canada's health care spending dollar distribution is showing the result of a shift from hospitalization to home treatment and changes in medical technology. Ten years ago, physicians' costs represented a 17% of the budget and pharmaceuticals, only 13%. Today, the situation has practically reversed.



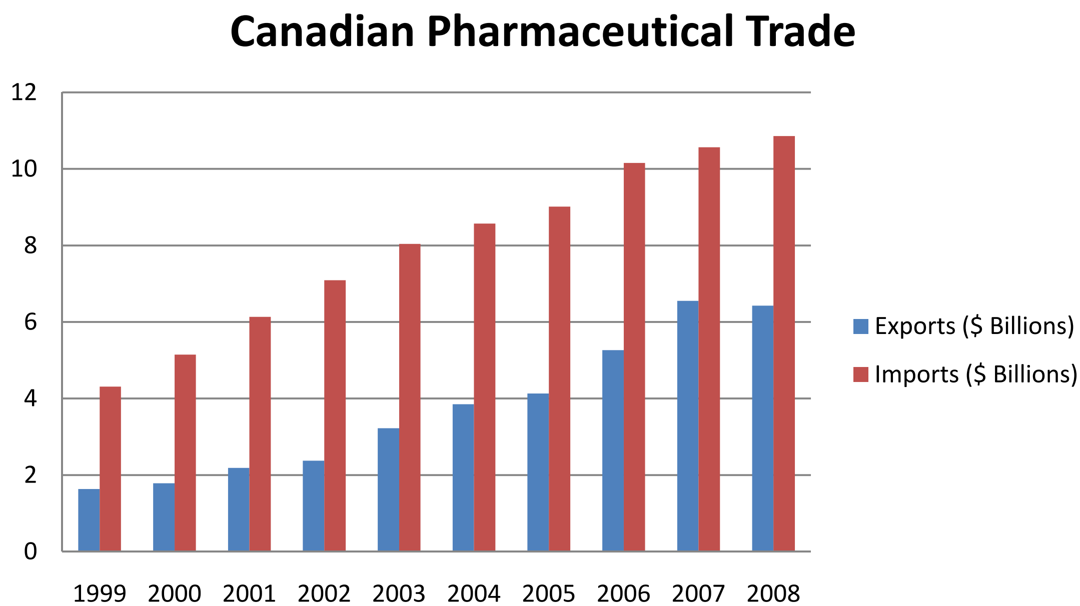
Source: Canadian Institute for Health Information, National Health Expenditure Trends

The pharmaceutical industry in Canada is the second most profitable after oil and gas extraction.



Source: Industry Canada

The pharmaceutical trade has show exceptional growth and vitality in the past 10 years. Although exports regressed in value for a first time in 2008, the following chart illustrates the spectacular growth of this industry in Canada.



Source: Statistics Canada

Best Prospects

Some of the current and future best prospects products for the Canadian market should be for new and improved medications in the following six treatment categories:

Cardiovascular (including cholesterol reducers, hypertension controllers and blood pressure controllers)
Gastroenterological (including proton pump inhibitors or gastric acid control)
Psychotherapeutic (including antidepressants, tranquilizers and hypnotics)
Anti-Inflammatory Medication (including Systemic Anti-arthritic)
Alzheimer’s disease medication
Cancer Treatment Medication (including chemotherapy as well as antiparasitics, antineoplastics and immunomodulating agents)

The above best prospects can be found under the following listing of HS 30 – Pharmaceutical Products:
HS 3003 – MEDICINES NOT PACKAGED IN MEASURED DOSES OR PACKED FOR RETAIL USE
HS 3004 – MEDICINES PACKAGED IN MEASURED DOSES
HS 3006 – PHARMACEUTICAL GOODS

Key Suppliers

The ten largest pharmaceutical drugs makers in Canada hold 60% of market share in terms of pharmaceutical sales while the top five companies hold a market share of nearly 40 percent of all pharmaceutical sales in Canada. Pfizer Canada, the largest pharmaceutical company in Canada, has

13.4% of the Canadian drug market while Canadian-owned Apotex, and Novopharm, owned by Teva Pharmaceuticals of Israel dominate the Canadian generic drug market.

Source: IMS Health: Canadian Drug Stores and Hospital Purchases Audit

Links to Pharmaceutical Companies in Canada - Main Regions

Quebec

- **Adherex Technologies Inc.**
- **Aeterna Zentaris Inc.**
- **Axcan Pharma Inc.**
- **Labopharm Inc.**
- **Neurochem Inc.**
- **Merck Frosst Canada**
- **Paladin Labs Inc.**
- **Prometic Life Sciences Inc.**
- **Theratechnologies Inc.**

Ontario

- **Astrazeneca Canada Inc.**
- **Bayer Inc.**
- **Bioniche Life Sciences Inc.**
- **Biovail Corporation**
- **Cangene Corporation**
- **Dimethaid Research Inc.**
- **Draxis Health Inc.**

- **Glaxosmithkline Inc.**
- **Hemosol Corp.**
- **Lorus Therapeutics Inc.**
- **Pangeo Pharma Inc.**
- **Patheon Inc.**
- **Systems Xcellence Inc.**
- **Transition Therapeutics Inc.**

British Columbia

- **Angiotech Pharmaceuticals, Inc.**
- **Cardiome Pharma Corp.**
- **Inex Pharmaceuticals Corporation**
- **Migenix Inc.**
- **Stressgen Biotechnologies Corporation**

Prospective Buyers

Buyers of pharmaceutical drugs and products include hospitals, drug stores, long-term care facilities, medical and dental clinics, nursing homes and the Canadian public. Prospective buyers of pharmaceutical drugs, particularly drug stores, often use group-purchasing organizations to negotiate better prices, in order to enhance their buying power. On a smaller scale, health product stores and retailers are important buyers of non-prescription drugs.

Market Entry

Before pharmaceutical drug is authorized for sale in Canada, Health Canada reviews it to assess its safety, efficacy and quality. These products include prescription and non-prescription pharmaceuticals. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by Canada's Food and Drugs Act and Regulations. In fact, the rule applies for any product that is offered for sale in Canada to treat or prevent diseases or symptoms. Application and submission documents can be accessed at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index-eng.php

Pre-market Submission Requirements for New Drug

A pharmaceutical drug product may be considered a new drug when it bears a drug claim for a single ingredient or combination of ingredients presented to the Canadian market for the first time. In such a case, in addition to the assignment of a DIN, a Notice of Compliance (NOC) with Division 8, Part C of the Food and Drug Regulations must also be issued to authorize the sale of the product. Briefly, these requirements for a new drug application include, but are not limited to, replicate studies conducted to current scientific standards with animals and humans to establish the safety and efficacy of the product for the use proposed.

Health Canada offers a guidance document to be used in the preparation and filing of new drug submissions to Health Canada in the electronic Common Technical Document (eCTD) format established by the International Conference on Harmonization (ICH) of Technical Requirements for Registration of

Pharmaceuticals for Human Use. It is possible to access and download this eCTD guidance document called “Preparation of Drug Submissions in the eCTD Format”

Market Issues & Obstacles

Many factors come into consideration when it comes to set the price of a patented drug in Canada. For instance, when establishing the price of a new drug, two main factors are considered. First, the price of that drug is compared to that of the existing drugs used for a similar treatment. Second, the price of that drug is not to exceed the median price of a certain group of industrialized countries (France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States). Existing drugs' prices cannot increase by more than the Consumer Price Index (CPI), on an annual basis

In addition, the Canadian price of a certain drug is never to be the highest in the world. If the following criteria aren't met, an investigation is opened, which can lead to a legal order to reduce the price, or the seizure of excess revenues. The Patented Medicine Prices Review Board (PMPRB) reports annually to the Parliament of Canada on its activities, price trends and R&D spending reported by pharmaceutical companies.

The Canadian federal Consumer Packaging and Labeling Act and regulations require consumer product packaging to be bilingual in English and French for Canada. However, it does not apply to any product that is a device or drug within the meaning of the Food and Drugs Act. For more complete information, please consult the following link:
Validation Documentation Requirements and Responsibilities for Drug Fabricators, Packagers / Labelers, Testers, Distributors and Importers

Trade Events

The Canadian Association for Pharmacy Distribution Management (CAPDM) – Annual Conference
May 2-6, 2010
The Fairmont Turnberry Isle Resort & Club
Aventura, Florida

Canadian Pharmacists Association - Annual National Conference 2010
May 15 - 18, 2010
Telus Convention Centre & the Hyatt Regency Hotel
Calgary, Alberta, Canada

BioContact Québec – Biopharmaceutical Partnership Symposium
October 7 – 8, 2009
Château Frontenac
Ville de Québec, Québec, Canada

Resources & Contacts

Canadian Association of Chain Drug Stores (CACDS)
Canadian Generic Pharmaceutical Association (CPGA)
Canadian Pharmacists Association
Canada's Research-Based Pharmaceutical Companies
The Canadian Association for Pharmacy Distribution Management (CAPDM)

Food and Drug Association (USA)
Health Canada
Industry Canada
National Association of Pharmacy Regulatory Authorities
Ontario Hospital Association
Patented Medicine Prices Review Board
Pharmaceutical Canada
Pharmaceutical Marketing Club of Quebec
Quebec Consortium for Drug Discovery
Quebec Drug Council
Statistics Canada

For More Information

The U.S. Commercial Service in Montreal, Canada, can be contacted via e-mail at: pierre.richer@mail.doc.gov; Phone: 514-398-9695 Ext: 2261; Fax: 514-398-0711; or visit our website: www.buyusa.gov/canada/en

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Comments and Suggestions: We welcome your comments and suggestions regarding this market research. You can e-mail us your comments/suggestions to: **Customer.Care@mail.doc.gov**. Please include the name of the applicable market research in your e-mail. We greatly appreciate your feedback.