



2016 Top Markets Report **Pharmaceuticals** Country Case Study

Canada

Canada is a leading market for U.S. pharmaceutical exporters and among the top 10 pharmaceutical markets globally. The market is supported by a growing elderly population, high per capita pharmaceutical spending and an advanced regulatory system. Shortcomings in intellectual property protection and the lack of uniformity across the country's provinces regarding drug reimbursement policies, however, are causing operational difficulties for U.S. companies.

Overall
Rank

7

Canada is the 10th largest pharmaceutical market in the world and the second largest in North America.¹ Pharmaceutical sales are forecast to grow from \$18 billion in 2015 to \$20.3 billion by 2020, representing an annual growth rate of 2.4 percent.² Per-capita consumption and spending on pharmaceuticals is one of the highest in the world.

As a result of economic growth and an expanding elderly population, healthcare spending in Canada has almost doubled over the last decade or so.³ The total expenditure currently stands at around \$164 billion, or 10.7 percent of GDP, and is projected to reach \$190 billion by 2020. As the population ages, Canada's universal healthcare system will require extensive reforms to address long-term needs in terms of affordability and accessibility.⁴

While Canada's public sector dominates total healthcare spending, federal/provincial/territorial public drug plans account for less than half of total pharmaceutical expenditures. Canada is second among OECD countries, behind the United States, in the participation of private insurers in drug spending.⁵ Because provinces/territories run separate public outpatient drug plans, coverage and eligibility vary tremendously by region.⁶ Navigating

Figure 1: Canada Snapshot

Population: 35.9 million
Population over 65: 5.8 million (16.1%)
Total healthcare expenditure: \$164 billion (10.7% of GDP)
Government healthcare expenditure: \$116 billion (71% of total)
Private healthcare expenditure: \$47 billion (29% of total)
Total pharmaceutical sales: \$18 billion (1.18% of GDP; 10.6% of total healthcare exp.)
Per capita pharmaceutical sales: \$502
Generic sales: \$4.3 billion (24% of total sales)
Patented sales: \$10.8 billion (60% of total sales)
OTC sales: \$3 billion (17% of total sales)
U.S. pharmaceutical exports: \$3.8 billion

through the different pricing regimes and administrative complexity can present enormous challenges for companies.

Sales of generics, which account for 24 percent of the total market and 67 percent of prescription volume, are projected to grow from \$4.3 billion in 2015 to \$5 billion by 2020, representing an annual growth rate of 3 percent.⁷ Canada has some the highest prices for generics in the world, in part

because generics are not subject to the same pricing regulations as their patented counterparts.⁸ The generics market is expected to grow as the government promotes generics usage and as quality perceptions improve among patients. Patent expirations and improved regulatory pathways for biosimilars will also bolster growth in this segment.

Patented drug sales, which account for 60 percent of the total market, are projected to grow from \$10.8 billion in 2015 to \$12.1 billion by 2020, representing an annual growth rate of 2.3 percent. Although Canadian patients have traditionally exhibited a strong preference for patented drugs, government cost containment measures and heavy price regulation has slowed the rate of market growth. Moreover, the approval process for new drugs remains difficult, and both the number of approvals and access to new drugs are below the OECD average.⁹

Disease burden

Typical of a mature economy, non-communicable diseases, such as diabetes, cancer, asthma and cardiovascular conditions, account for 97 percent of the total disease burden in Canada. Over 10 percent of the population has diabetes and 16 percent has pre-diabetes.¹⁰ The number of new cases of cancer is forecast to increase by 182,000 in 2012 to 246,000 in 2025.¹¹ Approximately 8.5 percent of the population has asthma, which has been increasing in prevalence over the past 30 years, and around 4 percent of Canadians have heart disease.¹²

U.S. exports and competitive environment

The United States exported \$3.8 billion of pharmaceuticals to Canada in 2015, representing around 33 percent of Canada's total pharmaceutical imports. Government cost containment measures and patent expiries have slowed U.S. pharmaceutical exports, which declined at an annual rate of 4 percent over the last five years.

Canada has been a significant manufacturing base for pharmaceutical companies. The domestic industry is made up of about 140 companies, of which over 50 are research-based, with the 10 largest multinational companies accounting for an estimated 60 percent of total sales.¹³ The industry

employs over 26,000 people and indirectly employs more than 100,000 people.¹⁴

Due to intense competition from lower-cost foreign manufacturers, domestic pharmaceutical production has been declining at a 2.5 percent annual rate since 2008, and employment in pharmaceutical manufacturing has fallen by an average annual rate of 1.4 percent since 2006.¹⁵ The country is increasingly reliant on imported medicines, and drug imports overall are expected to maintain steady growth. Pharmaceutical trade between Canada and the EU, in particular, is expected to increase as they move toward a more unified regulatory environment. The U.S.-Canada Regulatory Cooperation Council (RCC) Pharmaceutical and Biological Products working group provides opportunities for greater regulatory harmonization between Health Canada and the U.S. Food and Drug Administration.¹⁶

From 2011 to 2013, pharmaceutical R&D in Canada declined by 29 percent. In 2014, innovative companies spent a mere 5 percent of their Canadian revenues on R&D in Canada.¹⁷ Despite government efforts to encourage R&D investment through financing and tax incentives, rising operational costs and uncertainty regarding the IPR environment continue to create headwinds. Canada has one of the weakest pharmaceutical IPR regimes of any developed economy, and its unwillingness to reform or implement stricter intellectual property laws undermines the country's attractiveness as a location for investment.¹⁸

Health insurance, drug coverage

Despite its universal healthcare system, Canada does not offer universal, public outpatient prescription drug coverage. Employers often provide private drug plans, and federal/provincial/territorial drug plans are available to certain elderly and low-income populations. Around a quarter of the population, most of whom are unemployed or self-employed, lack access to either public or private drug plans and must pay out-of-pocket for medicines.¹⁹

Coverage and amounts of co-payments, deductibles and premiums in public drug plans vary tremendously by province, which have different funding levels and formulary and reimbursement systems. For example, elderly patients in British

Columbia, New Brunswick, Prince Edward Island and Newfoundland pay between 0 and 35 percent of their annual prescription costs, but in Alberta and Nova Scotia, they pay between 35 and 100 percent. Over half a million Canadians, mostly in the Eastern provinces, have difficulty accessing necessary drugs, and 6 million people have inadequate access to pharmaceuticals or may struggle to pay for expensive treatments.²⁰

Regulatory approval, pricing, and reimbursement

The Health Products and Food Branch (HPFB) within Health Canada is the federal health agency responsible for approving and regulating drugs. The HPFB reviews new drug submissions for the purposes of safety, efficacy and manufacturing quality and issues marketing authorizations, also known as Notices of Compliance (NOC). Following the issuance of an NOC, HPFB's role is limited to post-market surveillance, inspections and investigations of the safety and efficacy of the drug.²¹ NOC reviews take on average over 13 months for chemical compounds and 21 months for biologics.

The pricing and reimbursement process for innovative pharmaceuticals is controlled at three levels: by the Patented Medicine Prices Review Board (PMPRB), by the Common Drug Review (CDR) and by the many federal and provincial/territorial bodies operating separate formulary and reimbursement regimes.

The PMPRB is a federal body designed to prevent excessive pricing by regulating the ex-factory price of patented medicines.²² Innovative pharmaceutical companies are required to submit pricing information to the PMPRB before introducing a new product and on a semi-annual basis. The PMPRB first conducts a review to categorize a product based on its level of therapeutic improvement.²³ It then applies a price by comparing it to other medicines in the same therapeutic category; reference prices from France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States; and rates of inflation.²⁴ If it finds prices to be excessive, as it routinely does, the PMPRB can order a price decrease and even retroactive or punitive payments from the manufacturer.

Although the PMPRB has jurisdiction over an extremely broad range of pharmaceutical products,²⁵ which remains a point of concern for U.S. companies, it cannot regulate prices throughout the distribution chain (i.e. from the wholesaler to pharmacies to patients),²⁶ nor can it participate in price negotiations with federal and provincial drug plans.

The Canadian Agency for Drugs and Technologies in Health (CADTH) Common Drug Review (CDR) is intended to centrally harmonize the reimbursement review process among the provincial/territorial drug plans.²⁷ The CDR requires manufacturers to submit extensive data regarding the clinical and economic benefits of medicines seeking inclusion in public formularies. After a panel reviews the information and conducts pharmacoeconomic and cost containment assessments, the CDR issues a recommendation for inclusion on formularies and the level of reimbursement. The CDR process takes on average 8 to 9 months or around 6 months for biologics.

The CDR is often criticized over a lack of transparency, a poor appeals process and the absence of a specialized review pathway for orphan drugs. Because orphan drugs treat rare diseases in small patient populations, they often lack extensive data for traditional review and cost effectiveness analysis. However, the CDR does not allow for significant exceptions in the review requirements for such products.

After the CDR review, companies must then negotiate separately with each provincial and federal drug plan for inclusion in the formularies. Although public drug plans typically follow and implement a CDR recommendation 90 percent of the time, manufacturers are still required to file separate and often duplicative submissions addressing issues specific to each plan. It generally takes around 6 to 7 months for a provincial body to decide whether or not to act on a CDR recommendation.

Challenges and Barriers to U.S. Exports

Heightened utility requirements

From 2005 onwards, Canadian courts began invalidating patents that failed to demonstrate "utility" because the original applications lacked

evidence in the form of data from long-term clinical studies in patients. In Canada, innovators are now required to “demonstrate” or “soundly predict” the utility of a pharmaceutical as “promised” at the time of filing, meaning that a drug must be useful for exactly the purpose that is specifically promised at the date of patent filing.²⁸ This is impractical because companies must file for a patent early in the development process, usually well before clinical trial data is available.²⁹ Moreover, companies have no way of knowing what will be required to establish utility because it is interpreted subjectively and courts have set conflicting opinions on the matter. Moreover, Canada does not permit companies to submit post-filing data or evidence to demonstrate utility. The practical result is that pharmaceutical innovations have largely become un-patentable in Canada.

This “heightened” utility standard, which is unique to the world and applied only to pharmaceutical products, has caused 24 patents to be revoked over the last decade. All of the products affected were significant commercially, and damages from the premature loss of patent protection are estimated at \$766 million for U.S. companies alone.³⁰

Incongruously, every patent revoked on this basis had been approved by Health Canada and had been benefiting patients for years, undermining Canada’s justifications surrounding its ‘usefulness’.³¹

Right of appeal in Patented Medicines (PM) Notice of Compliance (NOC) proceedings

Under Canada’s PM NOC regulations, generic drug companies are allowed to challenge innovators’ patents through a summary judicial review process in which patent owners have limited ability to dispute evidence or provide arguments. Moreover, only generic manufacturers are allowed to appeal an unfavorable outcome. The innovator instead has to file a separate patent infringement case after the generic product enters the market, essentially restarting the process. It might take years before such patent infringement cases are tried, during which time injunctions to prevent generic market entry are rarely granted. Additionally, if a patent holder tries to prevent a generic manufacturer from obtaining market approval but ultimately loses, the generic manufacturer can claim compensation for lost profits and is often awarded damages from the innovator that are punitive in nature.

Standard for the Disclosure of Confidential Business Information (CBI)

Certain amendments in the recently enacted Bill C-17, *An Act to Amend the Food and Drugs Act*, appear to allow the Minister of Health to disclose confidential business information (CBI), such as clinical trial data submitted for market approval, without confidentiality protections. The language describing both the threshold for disclosure and the potential recipients is very broad, requiring only that “the Minister believes that the product may present a serious risk of injury to human health.” Although Health Canada released a guiding document in July 2015 that provided some reassurance to industry on the matter, the guidance remains non-binding.

Patent term restoration (PTR)

Despite a relatively long regulatory approval timeline for new medicines, Canada is one of the only developed nations providing no form of patent term restoration.³² Although Canada has agreed to PTR provisions in the EU-Canada Comprehensive Economic and Trade Agreement (CETA) and the Trans-Pacific Partnership (TPP), statements made by the government suggest that PTR for unreasonable delays in the marketing approval process will be

capped at two years, which is less than half of the maximum protection period in the European Union or the United States. Further, during this period, Canadian generics manufacturers may be permitted to make and sell patented products for export. The government has not yet issued any formal proposals for changes to the Patent Act or Rules to implement patent term extensions in CETA or TPP.

¹ Figure 1: Canada Snapshot:

Pharmaceutical sales, Pharmaceutical sales per capita: Canadian Generic Pharmaceutical Association (CGPA), Patented Medicine Prices Review Board (PMPRB), Association of the European Self-Medication Industry (AESGP), BMI

OTC medicine sales: Association of the European Self-Medication Industry (AESGP), BMI

Generic drug sales, Patented drug sales: Canadian Generic Pharmaceutical Association (CGPA), Patented Medicine Prices Review Board (PMPRB), BMI

Health spending, Govt. health spend, Private health spend: World Health Organization (WHO), BMI

Population, Population over 65: World Bank/UN/BMI

See also: BMI, *Canada Pharmaceuticals & Healthcare Report*, March 2016 (referenced throughout)

² The overall market for pharmaceuticals in Canada includes U.S. patients who travel north to purchase patented drugs in Canada, which are comparatively cheaper for U.S. consumers. Although the U.S. Food, Drug and Cosmetic Act prohibits re-importation, the federal government has not strictly enforced the law for personal use for humanitarian reasons. BMI

³ Healthcare spending in Canada rose from \$85 billion in 2003 to \$164 billion in 2015.

⁴ JAMA Internal Medicine, David U. Himmelstein, Steffie Woolhandler, *Cost Control in a Parallel Universe: Medicare Spending in the United States and Canada*, December 2012, <http://archinte.jamanetwork.com/article.aspx?articleid=1387588>

⁵ Federal plans account for around 3 percent of total pharmaceutical expenditure and provincial/territorial plans account for around 40 percent of total pharmaceutical expenditure.

⁶ The Canadian Federation of Nurses Unions, Marc-André Gagnon, *A Roadmap to a Rational Pharmacare Policy in Canada*, https://nursesunions.ca/sites/default/files/pharmacare_report.pdf

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- ⁷ The Canadian Generic Pharmaceutical Association (CGPA), *Market Trends*, http://www.canadiangenerics.ca/en/resources/market_trends.asp
- ⁸ Provinces such as British Columbia, Ontario and Quebec are introducing regulations to lower the price of generic drugs.
- ⁹ Canada ranked 20th and 21st out of 25 OECD countries in access to new small molecule and biologic drugs. Canada's Research-Based Pharmaceutical Companies prepared for RX&D by Wyatt Health Management, *The 2008/2009 RX&D International Report on Access to Medicines*, <http://www.wyatthealth.com/wp-content/uploads/IRAM/iram-2008-2009.pdf>
- ¹⁰ International Diabetes Federation, *Canada*, <http://www.idf.org/BRIDGES/map/canada>
- ¹¹ International Agency for Research on Cancer/World Health Organization, *Globocan 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012*, "Population Fact Sheets," http://globocan.iarc.fr/Pages/fact_sheets_population.aspx
- ¹² Public Health Agency of Canada, *2009 Tracking Heart Disease and Stroke in Canada*, <http://www.phac-aspc.gc.ca/publicat/2009/cvd-avc/index-eng.php>
- ¹³ Government of Canada: Industry Canada, *Pharmaceutical and Medicine Manufacturing (3254)*, <http://www.ic.gc.ca/app/ccc/sld/cmpny.do?lang=eng&profileId=201&naics=3254>
Government of Canada: Innovation, Science and Economic Development Canada, *Canada's Pharmaceutical Industry and Prospects*, <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html>
- ¹⁴ Government of Canada: Innovation, Science and Economic Development Canada, *Pharmaceutical industry profile*, <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01703.html>
- ¹⁵ The number of jobs in the Canadian pharmaceutical industry went from 29,900 in 2006 to 26,300 in 2014.
- ¹⁶ International Trade Administration, *Regulatory Cooperation Council – Work Planning Format*, <http://www.trade.gov/rcc/documents/a1-hc-fda-wp-pharmaceuticals-bio.pdf>
- ¹⁷ The Canadian Generic Pharmaceutical Association (CGPA), *The Real Story: Research & Development Spending by Brand-Name Drug Companies in Canada: 1988-2014*, http://www.canadiangenerics.ca/en/advocacy/docs/TheRealStory_2015_Web_Eng_FINAL.pdf
- ¹⁸ The Canadian Chamber of Commerce, *Innovation for a Better Tomorrow*, <http://www.chamber.ca/download.aspx?t=0&pid=01c1b24c-9bae-e211-8bd8-000c291b8abf>
- ¹⁹ There are over forty separate federal and provincial/territorial pharmaceutical coverage programs in Canada (but nineteen main ones.) Quebec is the only province to mandate universal coverage and public or private insurance is compulsory.
- ²⁰ BMI, *Canada Pharmaceuticals & Healthcare Report*, "Market Overview," March 2016
- ²¹ Health Canada, *How Drugs are Review in Canada*, http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php
- ²² The "ex-factory price" is the price at which patentees or their licensees sell patented medicines to wholesalers, hospitals or pharmacies or retail outlets.
Patented Medicine Prices Review Board (PMPRB), *2014 PMPRB Annual Report*, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1217>
- ²³ Therapeutic improvement categories include: breakthrough, substantial improvement, moderate improvement, or slight or no improvement.
- ²⁴ The categories and price tests are set out in the following document, which, though not binding on the Board or patentees, are rigidly adhered to by Board staff: Patented Medicine Prices Review Board (PMPRB), *Compendium of Policies, Guidelines and Procedures – Updated June 2015*, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492>
- ²⁵ Patented Medicine Prices Review Board (PMPRB), *The Scope of the PMPRB's Jurisdiction: When Does a Patent Pertain to a Medicine?*, <http://www.pmprb-cepmb.gc.ca/cmfiles/Ref%20Docs%20Patentees/scopeofjurisdiction-e38MLR-8182006-4914.pdf>
- ²⁶ Drug prices can still be marked up throughout the distribution chain. In Canada, wholesale mark-ups average around 10 percent, pharmacy markups average around 30 to 40 percent and consumer taxes average around 13 percent or more, depending on the locality.
- ²⁷ Except Quebec.
- ²⁸ Language sourced directly: Information Technology & Innovation Foundation, *The Worst Innovation Mercantilist Policies of 2015*, <http://www2.itif.org/2016-worst-innovation-mercantilists.pdf>
- ²⁹ Innovators cannot simply defer filing until clinical data is available because performing clinical tests can negate the patentability of a product as novel and inventive.
- ³⁰ The Canadian Patent Utility Coalition, *2016 Special 301 Review*, http://www.canadianpatentutility.org/sites/default/files/uploads/public_cpuc_2016_special_301_review_comment.pdf
- ³¹ National Association of Manufacturers, *2016 Special 301 Comments*, http://documents.nam.org/IEA/NAM_2016_Special_301_Comments.pdf?_ga=1.90986714.1956537913.1455028354
- ³² Fraser Institute, Mark Rovere and Brett J. Skinner, *Access Delayed, Access Denied 2012: Waiting for New Medicines in Canada*, April 2012, <https://www.fraserinstitute.org/sites/default/files/access-delayed-access-denied-2012.pdf>
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