

OH CANADA, Land of Pharma Opportunity

A research leader with a strong healthcare network, a stable democracy, and a rich talent resource, Canada remains a powerful draw for the pharma industry.

The second largest country in the world, based on land mass, Canada enjoys a strong economy and extensive democratic advantages, including among the highest measures in education, government transparency, civil liberties, quality of life, and economic freedom.

A parliamentary democracy with a constitutional monarchy, Canada has a population of around 35 million people, is officially bilingual, and is multicultural.

Canada boasts one of the highest life expectancies and lowest infant mortality rates in the industrialized world.

In 2012, Canadians spent a total of CAD\$207 billion (\$197 billion) on healthcare, or a per capita expenditure of CAD\$5,948, representing 11.6% of GDP. Hospitals consumed about 30% of total expenditures, prescription drugs 16% and physicians 14%, says Paul Crotty, VP Canadian Operations, TGaS Advisors.

“On a per capita basis, and as a percentage of GDP, Canadian healthcare expenditures rank among the top half dozen OECD countries with only the United States, at \$8,233 per capita and close to 17% of GDP, having a dramatically higher expenditure level,” he says.

Pharma Status

According to 2010 data, Canada has around 180 private and public biopharmaceutical companies, mostly small to medium-sized companies located in Montreal, Toronto, and Vancouver. There were 500 new products in development by Canadian biopharma firms. The top three therapeutic classes in development were oncology (41%), neuroscience (14%), and infectious diseases and vaccines (11%).

The number of people employed in Canada’s pharma industry totaled around 28,000 in 2010, and the industry had annual sales of CAD\$21 billion (\$20.14 billion), exported products worth \$7 billion, and conducted more than \$1.3 billion in R&D.

Canada has been considered a strategic market for many pharmaceutical companies, says Mark Omoto, general manager Canada, Cegedim Relationship Management, not only because its commercial healthcare environment is considered a blend of both U.S. and European market influences, but also because of its trendsetting approaches and impact on the global market in pricing and reimbursement.

“In recent years, established companies have started entering the Canadian market,

Canada at a glance

Total Population: 34,838,000

Gross national income per capita (PPP international \$): 39,660

Life expectancy at birth m/f (years): 80/84

Probability of dying under the age of 5 (per 1,000 live births): 6

Probability of dying between the ages of 15 and 60 years male/female (per 1,000 population): 84/53

Total expenditure on health per capita (CAD\$, 2012): 5,894*

Total expenditure on health as % of GDP (2012): 11.6*

Source: Global Health Observatory. Figures are for 2009 unless otherwise indicated

* Canadian Institute for Health Information (C.I.H.I.), provided by TGaS Advisors

and setting up shop versus licensing their products, as the search for revenue becomes more and more elusive,” Mr. Omoto says.

Canada’s multicultural commercial environment has also provided a strong talent

management opportunity for pharma company executives to acquire internationally recognized professionals, Mr. Omoto says.

“By the same token, Canadian pharmaceutical executives have been sought after for key global assignments because of their success and experience in dealing with complex healthcare and regulatory systems,” he says.

Mr. Crotty describes Canada’s pharma market as somewhere between the United States and Europe in terms of pricing and access, although the market is becoming more like Europe in both respects.

“That said, Canada continues to be a very attractive market for pharma companies; it remains the number seven or eight market in the world and one of the most politically and economically stable countries in the world,” he says.

Research & Development

Canada’s world-class health research centers, academic centers, hospitals, and government laboratories play an integral role in helping to elucidate ideas and concepts. Canadian research centers are recognized in many therapeutic fields, including cardiovascular, metabolic disorders, neuroscience, oncology, and infectious diseases and vaccines, a Canadian government website notes. Canada is also a leader in the development of key technology platforms including stem cells and regenerative medicine, genomics, and antibody technologies.

Canada’s pharma and biotech industries have been experiencing consistent R&D growth, as federal and provincial governments are offering programs and tax breaks to try to entice companies to boost their R&D investments, especially at the early stage, Mr. Omoto says.

Among the programs aimed at bolstering industry are the Scientific Research and Experimental Development (SR&ED) Tax Incentive Program, administered by the Canada Revenue Agency to encourage Canadian businesses to conduct R&D in Canada. The National Research Council’s Industrial Research Assistance Program (IRAP) provides advisory services and financial support to small and mid-sized companies conducting R&D of technological innovations. Among IRAP initiatives is the Canadian HIV Technology Development Program (CHTD), which is contributing to global efforts to develop safe, effective, affordable, and globally accessible HIV vaccines.

The Canadian Innovation Commercialization Program was established to help Canadian companies bridge the pre-commercialization gap. Several other federal support and regional programs exist to promote R&D.



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MARK OMOTO

Cegedim Relationship Management

Mr. Omoto says Canada as with many countries, has been competing within the pharmaceutical company affiliate infrastructure for internal research investments, whether it be at the commercial or clinical trial level.

“Canadian research quality, and the ability to successfully recruit and conduct clinical trials, has been a main reason why Canada has always been a key site for global pharmaceutical trials,” he says.

Rx&D, which represents Canada’s research-based pharmaceutical companies, reported in a May 2013 survey of its companies that a total of CAD\$832 million was invested in scientific research and experimental development in 2012. The organization estimates that there are about 3,000 clinical trials ongoing in Canada across a multiple of therapeutic areas and all phases of trials.

“Canada’s ability to deliver strong results in the clinical trials area is a reflection of a number of positive factors, including the quality of researchers, a diverse population with strong health and disease networks, and of course the overall strength of Canada’s innovative pharmaceutical companies,” Mr. Omoto says.

Regulatory Environment

Many of the challenges companies face in bringing drugs to the market are those seen in

other industrialized nations. Notice of compliance (NOC), common to all countries, takes around 14 months, Mr. Crotty says. Companies filing in Canada also face the Common Drug Review, which takes around seven months. While the CDR isn’t seen in the United States, it is standard in Europe, Australia, and New Zealand. Other steps are the Patented Medicine Prices Review Board (PMPRB), also not seen in the United States, which takes place in parallel with other access steps and continues throughout the life of the patent, and the formulary review by the provinces, which takes about eight months.

All in all, Mr. Crotty says from submission of a new drug to Health Canada to its listing on a provincial formulary can take up to 30 months. Mr. Crotty says the CDR, handled by the Canadian Agency for Drugs and Technologies in Health (CADTH), is a pan-Canadian process for conducting objective, rigorous reviews of the clinical, cost-effectiveness, and patient evidence for drugs. The pan-Canadian Oncology Drug Review (pCODR) reviews cancer drugs.

“CDR also provides formulary listing recommendations to Canada’s publicly funded drug plans — except Quebec,” he says. “Since its inception the CDR has recommended listing for about half of the drugs that it has reviewed.”

In Quebec the Institut national d’excellence

Supporting Canadian R&D

PROGRAMS AND INITIATIVES TARGETED AT INDUSTRY

» Scientific Research and Experimental Development (SR&ED) Program

Administered by the Canada Revenue Agency, the SR&ED Tax Incentive Program is the largest single source of federal government support designed to encourage research and development in Canada. The program includes cash refunds and/or tax credits for expenditures on eligible R&D work done in Canada.

» Business Development Bank of Canada

BDC supports the creation and development of Canadian businesses through financing, subordinate financing, venture capital, consulting, and securitization, with a focus on small and medium-sized enterprises.

» National Research Council's Industrial Research Assistance Program

NRC-IRAP provides a range of technical and business-oriented advisory services, as well as financial support for small and medium-sized enterprises engaged in research and development of technological innovations. NRC-IRAP started delivering the Canadian HIV Technology Development Program (CHTD) as of April 1, 2011. The CHTD will contribute to global efforts to accelerate the development of safe, effective, affordable and globally accessible HIV vaccines.

» Canadian Innovation Commercialization Program

Launched in 2010, CICP uses procurement as a tool for innovation. The program aims to help Canadian companies, with a focus on SMEs, bridge the pre-commercialization gap.

REGIONAL ECONOMIC DEVELOPMENT AGENCIES AND ORGANIZATIONS

» Atlantic Canada Opportunities Agency

ACOA is dedicated to the economic development of

Atlantic Canada. It supports enterprise and community development, policy, advocacy and coordination. ACOA puts special emphasis on initiatives that encourage productivity, commercialization, competitiveness, and skills development.

» Canada Economic Development for Quebec Regions

CED provides support to small and medium-sized enterprises and non-profit organizations in Quebec. Financial assistance involves repayable and non-repayable contributions through its various programs and initiatives.

» Federal Economic Development Agency for Southern Ontario

FedDev Ontario supports the competitiveness, innovation, and diversification of southern Ontario's economy by directing investments to businesses, nonprofit organizations and communities; engaging in collaborative partnerships with key economic stakeholders; and advocating for the region's interests at the national level.

» FedNor

FedNor, the Government of Canada's regional development organization for Northern Ontario, works with various partners to promote economic development, diversification, and job creation and encourages sustainable, self-reliant communities in Northern Ontario.

» Western Economic Diversification Canada

WD works to improve the long-term economic competitiveness of the west by supporting initiatives that enhance innovation, business development, and community economic development.

FEDERAL GRANTING COUNCILS

» Canadian Institutes of Health Research

CIHR is the Government of Canada's agency responsible for funding health research in Canada. It supports nearly 14,100 researchers and trainees in universities, teaching hospitals, and

other health organizations and research centers in Canada.

» National Sciences and Engineering Research Council of Canada

NSERC supports basic university research through discovery grants, project research through partnerships among post-secondary institutions, governments, and the private sector, as well as the advanced training of highly qualified people.

OTHER FEDERAL SUPPORT TO LARGE-SCALE RESEARCH PROJECTS AND RESEARCH INFRASTRUCTURE

» Genome Canada

Genome Canada is a nonprofit organization with a mandate by the Government of Canada to implement a national strategy for supporting large-scale genomics and proteomics research projects.

» Canadian Foundation for Innovation

CFI aims to establish the nation's capacity to undertake world-class research and technology development through investments in state-of-the-art facilities and equipment, universities, colleges, research hospitals, and nonprofit research institutions.

» Networks of Centres of Excellence of Canada

The NCEs Program fosters multi-disciplinary, multi-sectoral partnerships between universities, industry, government and non-governmental organizations to conduct leading-edge research in strategic areas and accelerate the commercialization of innovations. Three network programs have been established under the NCE Secretariat: the original Networks of Centres of Excellence (seven networks are biomedical-related); Centres of Excellence for the Commercialization of Research (11 networks are biomedical-related); and Business-Led Networks of Centres of Excellence (one network is biomedical-related). In addition, the Industrial Research and Development Internship Program supports research internships contributing to a highly skilled research and managerial talent pool in Canada.

en santé et en services sociaux (INESSS) fills the roles that CDR and pCODR play in the rest of Canada, he adds.

Managing Reimbursement

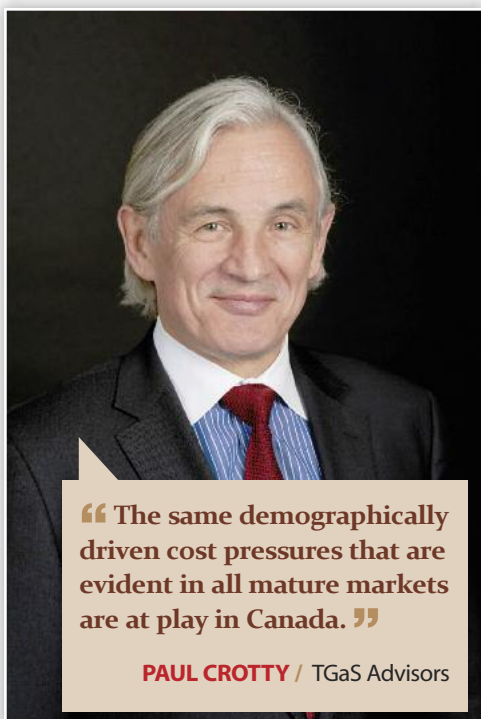
The reimbursement environment in Canada is quite different from that of most

other countries, Mr. Omoto says, noting that its provincial and territorial healthcare systems have tended to each have its own pricing and reimbursement opportunities and challenges.

Efforts to ensure that the price charged for patented medicines sold in Canada are not excessive are overseen by the Patented Medicine Prices Review Board.

The PMPRB is an independent quasi-judicial body established by Parliament in 1987 under the Patent Act, Mr. Crotty notes. The PMPRB reviews the prices that patentees charge for each individual patented drug product in Canadian markets. If a price is found to be excessive, the Board can hold public hearings and order price reductions and/or

Source: Industry Canada, www.ic.gc.ca



the offset of excess revenues. The PMPRB regulates the “factory gate” prices.

Mr. Crotty says all 10 provinces make their own listing decisions and, in the vast majority of instances, implement the CDR recommendations. There are moves under way to establish greater coordination of negotiations between the provinces under the umbrella of the Pan Canadian Pricing Alliance.

Mr. Omoto says efforts to contain costs are also impacted by the fact that Canada has universal healthcare coverage. For example, there have been recent government initiatives to expand the use of generic pharmaceuticals, while at the same time imposing mandatory generic pricing reductions and formulary changes.

Mr. Crotty says that in just over five years the price of generic drugs has, through legislation, fallen from about 70% of the brand level to, in many provinces, less than 20% today.

“For branded products, especially new ones, the Pan Canadian Pricing Alliance (PCPA), is looking to establish pan Canadian price levels that may be as much as 30% lower than the price approved by the PMPRB,” he says. “Currently, 10 brands have negotiated terms with the PCPA and 17 are under negotiation.”

Healthcare Delivery

Canada’s healthcare system, delivered under the Canada Health Act (CHA) of 1984, comprises a group of socialized insured health services, which are publicly funded and administered on a provincial or territorial basis.

Mr. Crotty says “insured health services” means hospital services, physician services, and surgical-dental services provided to insured persons.

The Act states that the primary objective of Canadian healthcare policy is to protect, promote, and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers.

The federal government places conditions for funding of provinces and territories, including that administration must be carried out by a public authority on a nonprofit basis, that all necessary health services must be insured, that all residents are entitled to the same level of care, that healthcare is portable across provinces and territories, and that all insured people have reasonable access to healthcare facilities.

Mr. Crotty says the CHA’s definition of insured services is largely restricted to care delivered in hospitals or by physicians.

“As care has moved from hospitals to home and community, it increasingly has been moving beyond the terms of the CHA,” he says. “International data show that about 70% of Canadian health expenditures are paid from public sources, placing Canada below the OECD average. However, health insurance covers surgery and services, including psychotherapy, in clinics and doctors’ offices as well as dental surgery at dental offices and laboratory tests.”

The 30% of healthcare expenditures that is funded by the private sector splits reasonably equally between cash out of pocket and private/employee insurance plans, he notes, with the major categories being drugs (30%); dental/vision/other professional care (34%); and some hospital/other institutional care (19%).

“As wait times in the public sector continue to grow — 18 weeks between referral from a general practitioner to delivery of the elective treatment by a specialist across 12 specialties in 2010 — and the number of Canadians without a general practitioner expands beyond 20%, most observers expect to see further steady growth in the private sector,” Mr. Crotty notes. “The federal government has shown little interest in slowing that growth or in providing the funding that might do so.”

He notes that prescription drugs account for about 13.5% of all healthcare expenditures in Canada. The public sector, including the provinces and the federal government, funds roughly 45% of all drug expenditures, while private sector insurance plans and cash payments, around 12%, account for the other 55%.

“At present, private sector health plans are

much more likely to list new drugs on their formularies than are the provinces, regardless of the recommendations issued by CDR,” Mr. Crotty says. “There are, however, signs that this ease of access in the private sector is changing and may become much like public plans.”

Mr. Crotty says drug prices in Canada tend to be around 60% of U.S. levels but per capita annual expenditure on prescription drugs by Canadians, at CAD\$765 in 2010, ranks third highest among 26 OECD countries.

“The same demographically driven cost pressures that are evident in all mature markets are at play in Canada,” he says. “An aging, expanding, more sophisticated, and more demanding population coupled with the availability of more sophisticated treatments is driving healthcare costs well ahead of inflation in Canada, as elsewhere.”

Reaching Patients

While Canadian patients can go where they please for information, what Canadian pharmaceutical companies communicate to patients and physicians is tightly regulated, Mr. Crotty says.

Mr. Omoto says the Canadian marketplace has been successful in maintaining a relatively nongovernmental promotional compliance climate through the adherence to marketing and promotional codes of conduct, overseen by the industry’s self-governing body Rx&D, as well as by the Pharmaceutical Advertising Advisory Board, known as PAAB.

“PAAB is a self-governing board that includes government regulatory oversight around pharmaceutical promotional material and advertising,” he says. “In a sense, the restrictive promotional climate has helped the Canadian pharma industry avoid some of the early pressures that resulted in the dramatic changes and government intervention seen in the United States, and more recently, in Europe.”

Mr. Crotty says the scope of the PAAB includes promotional healthcare product communication for prescription, non-prescription, biological and natural health products to healthcare professionals in all media. PAAB also provides advisory comments on direct-to-consumer materials for prescription drugs.

“This is despite the fact that DTC advertising as seen in the United States is not allowed in Canada,” he says. “Manufacturers may communicate directly with consumers but they may not associate a healthcare claim with a named brand. However, within 100 miles of its 3,000 mile border with the United States — where 90% of Canadians live — a lot of U.S. DTC advertising is seen, uncensored, by Canadians.” **PV**