INTERNATIONAL
TRADE
ADMINISTRATION

2016 Top Markets Report Medical Devices
Country Case Study

Canada

The Canadian medical device market was valued at approximately $8 billion in 2014, making it the ninth largest market in the world. Canada's medical device imports totaled approximately $6.3 billion in 2014. The United States is the biggest exporter of medical devices to Canada, accounting for approximately 45 percent of imports or nearly $3 billion.

Overall Rank

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Canada's healthcare industry depends heavily on the demand created by the country's publicly funded and insured health care system. The medical device industry consists of companies that produce a wide range of products used for diagnosis and treatment of ailments, which include the following: medical, surgical and dental equipment (including electro-medical equipment and related software), furniture, supplies and consumables, orthopedic appliances, prosthetics and diagnostic kits, reagents, and equipment.

Country Highlights
Capital: Ottawa
Population: 35.75 million (est. 2015)
GDP (USD): 1.785 trillion (est. 2014)
Currency: Canadian Dollar (CAD)
Language: English, French
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The Canadian healthcare system falls under the jurisdiction of each province and territory. While funding is subsidized through federal transfer payments, the delivery and management of healthcare services are controlled by the provincial governments. Healthcare systems in Canada use various competitive tendering processes for the procurement of medical devices and diagnostics technologies. These change depending on the province but are generally conducted by each hospital and depend on the need and resources available to the hospital.

Imported products constitute 80 percent of the Canadian medical device market. There is particular demand for diagnostic equipment, as well as consumables, patient aids, orthopedic and prosthetic equipment, and dental equipment. The orthopedic and prosthetic equipment subsector is experiencing the strongest growth. The three largest provincial markets in the country are Ontario, Quebec and British Columbia. There are nearly 1,500 manufacturers of medical devices in Canada, employing approximately 35,000 people across the country.

Medical device manufacturers should develop partnerships with Canadian distributors to sell their products. To do this, they must obtain an establishment license and, if necessary, a device license. Imported medical devices are subject to Canadian safety and effectiveness regulations and packaging requirements. Few other barriers exist for U.S. companies looking to sell in Canada.

Market Entry

Health Canada, under the authority of the Food and Drugs Act, regulates the sale of medical devices in Canada. Health Canada is the equivalent regulatory agency to the U.S. Food and Drug Administration (FDA). Medical equipment imports must comply with marking, labeling and packaging requirements as described in the Food and Drug Act. In particular, instructions (operator's manual) accompanying the equipment must be in both of Canada's official languages (English and French).

Current Market Trends

Hospitals and other public health institutions are the principal purchasers of medical equipment and supplies, accounting for about 70 percent of total market demand in Canada. These organizations buy directly from manufacturers for capital equipment and use group procurement and distribution for regular medical equipment, including devices, instruments and supplies.

The demand for diagnostic equipment accounted for approximately 12 percent of the total medical devices imports in 2014, which includes technologies such as nuclear medicine cameras, MRI (magnetic resonance imaging) and CT (computed tomography). Other medical electro-diagnostic and patient monitoring equipment, including ultraviolet or infrared rays and ultrasonic scanners, will also see an increased demand. Other top contributors to the medical device import market in 2014 were instruments and appliances (8.3 percent), bougies, catheters, drains, sondes, and parts (3 percent), and artificial parts of the body (1.7 percent).

Main Competitors

The United States is by far the biggest exporter of medical devices to Canada, accounting for approximately 45 percent of the country's medical device imports. Other key import sources include Switzerland (13 percent), Germany (8.6 percent) and the United Kingdom (5.3 percent).

Current Demand

The Canadian medical device market depends upon imports for about 80 percent of its consumption. The import market is expected to grow at a 4.4 annual percent rate through 2016. Orthopedic and prosthetic equipment imports are projected to expand at a growth rate of 8.3 percent, while demand for all other medical device categories is expected to grow by at least 3 percent per year. Canada's elderly population continues to grow: 15.7 percent of the population is aged 65 and over, and this demographic is expected to increase to 18.2 percent by 2016. This rapid aging of the population presents a key market opportunity for companies in the medical device industry.

Registration Process

Canadian authorities have worked at harmonizing regulations with those of the United States and Europe. In keeping with international trends, medical devices are regulated under the Food and Drugs Act as Class I (low risk), II, III or IV (high risk) devices, subject to Health Canada approval. All medical devices require an establishment license, and Class II, III and IV devices require a device license. All products are subject to safety and effectiveness requirements, including Class I devices, and these requirements must be satisfied with objective, documented evidence.

Barriers

Canada's population is largely along its southern border with the United States, and many areas are geographically remote and therefore difficult to access. The Canadian economy is threatened by debt and a decline in oil revenues and a need to reduce budget deficits, which may limit provincial spending. Furthermore, there is a lack of health policy cohesion between provinces and the potential for provincial healthcare spending cuts and a record of under-investment in medical technology. Economists report market barriers in the form of a potential slowdown in market and import growth and currency weakness hindering import growth.

Trade in the medical device market presents a number of advantages to U.S. companies. U.S. companies benefit from similarities between U.S. and Canadian regulations concerning the safety and quality of medical devices. Other advantages include the similarity between general business practices, the established reputation of U.S. companies in Canada and the close geographic proximity to Canada. Partnerships with the provincial and territorial health authorities responsible for the delivery of health care services are essential for the importing success of medical devices.

Trade Events

HealthAchieve
November • Toronto, Canada • ***healthachieve.com***
The largest health care gathering in Canada. Conference program with educational sessions; exhibition floor hosting 350 exhibitors showcasing health care products, services and technologies. Approximately 9,000 delegates annually.

Resources

Health Canada, ***hc-sc.gc.ca***

*Statistics Canada****, statcan.gc.ca***

Healthcare Procurement
MERX—Canadian Public Tenders, ***merx.com***
SEAO—Official Tendering Site of the Government of Québec, ***seao.ca***

Government Health Plans (by Province)

Alberta—Alberta Health, ***health.alberta.ca***
British Columbia—B.C. Health, ***www2.gov.bc.ca/gov/content/health***

Manitoba—Manitoba Health, Healthy Living and Seniors, ***gov.mb.ca/health***

New Brunswick—New Brunswick Health, ***bit.ly/1Ijh1w4***

Newfoundland and Labrador—Department of Health and Community Services, ***health.gov.nl.ca***

Northwest Territories—Health and Social Services, ***www.hss.gov.nt.ca***

Nova Scotia—Nova Scotia Department of Wellness, ***novascotia.ca/dhw***

Nunavut—Department of Health, ***gov.nu.ca/health***

Ontario—Ministry of Health and Long-Term Care, ***health.gov.on.ca***

Prince Edward Island—Health PEI, ***healthpei.ca***

Québec—Régie de l'Assurance Maladie du Québec, ***www.ramq.gouv.qc.ca/en***

Saskatchewan—eHealth Saskatchewan, ***ehealthsask.ca***

Yukon—Health and Social Services, ***hss.gov.yk.ca***