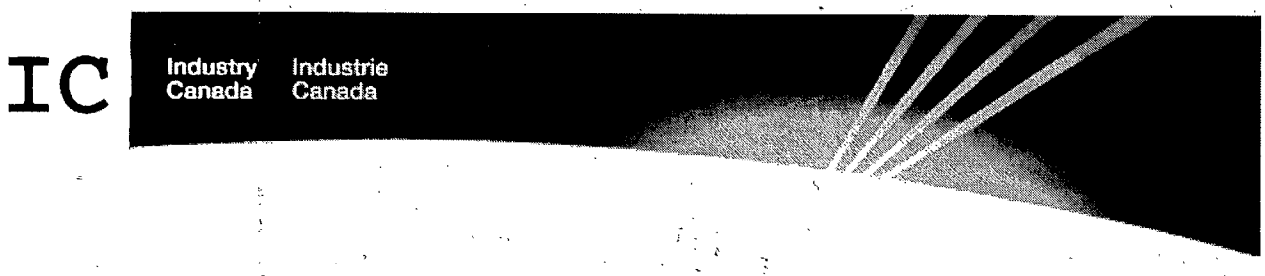

Guide to Establishing an Investment in Canada's Medical Device Sector

March 2001

Canada

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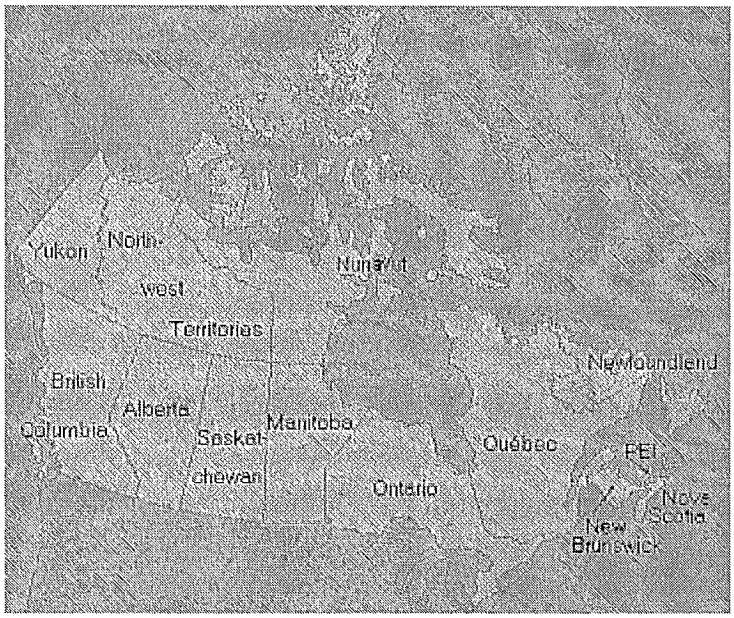
Introduction

This document is intended to be an information tool for foreign medical device companies to

help introduce Canada as a potential investment opportunity. The topics covered are not meant to be all encompassing but are intended to cover the critical first-line questions that must be addressed prior to considering Canada as a place to invest.

1.0 Canadian Demographics



Canada is made up of 10 Provinces and three Territories with a landmass of 10 million km^2. It is interesting to note that, although Canada geographically is the second largest country in the world, 80% of the total population of 30.7 million lives within 257 km of the border with the United States.

1.1. Population by Province / Territory

Province	Population / millions
Ontario	11.7
Quebec	7.2
British Columbia	4.1
Alberta	3.0
Manitoba	1.2
Saskatchewan	1.0
Nova Scotia	0.9
New Brunswick	0.8
Newfoundland	0.5
Prince Edward Island	0.2
Territories	
Yukon	0.05
North West Territories	0.03
Nunavut	0.03
Total	**30.7**

Statistics Canada 2000

1.2. Population – Major metropolitan areas

Metropolitan areas	Population / million
Toronto	4.75
Montreal	3.48
Vancouver	2.05
Ottawa	1.08
Calgary	0.95

Statistics Canada 2000

As to population density, the corridor stretching from Windsor, Ontario to Quebec City, Quebec (approximately 176,000 km^2) contains about 44% of Canada's population.

2.0 Canadian Healthcare System

2.1 The Canadian Healthcare System and the Canada Health Act

The Canadian Healthcare System is built on a socialized framework that aims to provide equal access to therapies, products, and services for all Canadians. However, the Canadian system is not truly "socialized" with doctors working on salary for the government. Most physicians work privately and are paid on a fee-for-service basis. Physicians submit claims to the provincial government to collect payment for services rendered.

The major 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 cost of maintaining a publicly financed healthcare system is spread out among all Canadians by way of provincial income taxes. Many Canadians enjoy the benefits of supplemental health insurance that their employer provides.The Federal Government sets and monitors national policy and delivers transfer payments to each province which manages local service provision.

The flow of money in the Canadian healthcare system begins with the collection of income taxes. The Federal Government transfers a portion of federally-collected tax revenue to each province for use in the provision of healthcare. Each province's government uses the healthcare transfer payments to provide operating budgets for hospitals; payments for claims submitted by healthcare providers, such as doctors; money to operate provincial formularies; access to certain devices, clinical laboratory testing, hospital and clinic infrastructure projects, as well as general health and wellness promotion.

The use of federal healthcare transfer payments can be a contentious issue, resulting in debate (between the Federal and Provincial governments) about how the money should be spent to best serve the public interest. This has led to increased focus, in technology assessments for new devices, on bottom line cost to the healthcare system.

Canada Health Act

The Canada Health Act is the federal legislation that establishes the conditions that provincial health plans must meet to receive full cash contributions under the Canada Health and Social Transfer. The Federal Minister of Health has responsibility for the administration of the Act that is governed by the following five criteria: public administration, comprehensiveness, universality, portability, and accessibility.

The criterion of public administration stipulates that to qualify for a cash contribution, a provincial health insurance plan must be operated on a non-profit basis. The focus on comprehensiveness is intended to ensure that all insured healthcare services, including those provided by hospitals and medical practitioners are covered in each provincial health plan. Universality requires that the healthcare insurance plan of a province must entitle one hundred percent of the insured persons of the province to the insured health services provided for by the plan on uniform terms and conditions. Portability of healthcare is intended to provide access to medical services with no minimum period of residence within a particular province, as well as to ensure that insured persons, while temporarily absent from the province, are still able to gain access to needed treatments and services. Finally, the criterion of accessibility is intended to ensure that uniform terms and conditions are applied to the provincial healthcare plan such that no insured person is impeded or precluded from gaining reasonable access to needed services as a result of extra charges or otherwise. Accessibility also ensures reasonable compensation is provided for all insured health services rendered by medical practitioners and dentists.

Foreign medical device manufacturers must be aware of the criteria established in the Canada Health Act because it governs how provincial healthcare systems operate in order to receive adequate cash transfers from the Federal Government. The operating criteria will then dictate the boundaries and terms that will affect how a manufacturer is able to establish competitive advantage and collect revenue for selling a particular device.

2.2 Hospital Distribution

	Number	Beds
Public	899	120,008
Federal	6	1,428
Private	45	2,907

Guide to Canadian Healthcare Facilities 1999

The Federal hospital group is comprised of Department of National Defense and Corrections Canada establishments. The private sector facilities are units specializing in such procedures as cataract, hernia surgery and drug/abuse rehabilitation. In most cases the services provided by the private sector are not covered by a provincial health plan. Patients must pay for such services directly or through their third party insurer.

2.3 Hospitals by Bed Size

It can be seen from the data below that Canada does not have many large hospitals but a greater proportion of medium size hospitals. This may be seen as an advantage to manufacture's of certain devices, giving a greater market potential.

	Beds							
	1-9	**10-24**	**25-49**	**50-99**	**100-199**	**200-299**	**300-500**	**500+**
Public	38	181	179	143	154	83	80	41
Federal	0	10	15	11	6	2	1	0
Private	0	1	1	0	2	1	0	1

Guide to Canadian Healthcare Facilities 1999

2.4 Hospital Beds by Specialty

	Public	Private	Federal
Extended Chronic Care	35,514	2,045	476
Medical/Surgical	41,061	183	40
General	15,642	15	10
Psychiatric	3,850	0	0
Rehabilitation	6,417	334	0
Paediatric	3,850	0	0
Mental Handicap	2,914	0	0
Isolation	31	0	0

Guide to Canadian Healthcare Facilities 1999

2.5 Long Term Care Centres

As Canada has one of the highest life expectancies in the western world (75 years for men and 82 years for females), the home and long term care sector of the industry is becoming increasingly important.

The following chart shows long term care centers that are licensed by the Provincial Governments.

	Beds							
	1-9	10-24	25-49	50-99	100-199	200-299	300-500	500+
# Centre	188	324	602	385	408	115	34	2

Guide to Canadian Healthcare Facilities 1999

Total number of beds = 299,141

2.6 Medical Schools

Canada has a total of 16 medical schools graduating approximately 2400 medical practitioners annually. The following data from the Royal College of Physicians and Surgeons of Canada and Canadian Dental Association indicates the number of specialists from some of the major medical disciplines.

Medical disciplines	Number of specialists
Family Physicians	26,000
Dentists	16,400
Psychiatric	3,524
Internal Medicine	3,420
General Surgery	2,529
Paediatric	2,174
Obstetrics & Gynaecology	1,935
Gastroenterology	327
Rheumatology	264
Thorasic Surgery	103
Medical Biochemistry	73

RCPSC / CDA 2000

Other approximate annual number of graduates of paramedical disciplines:

Paramedical disciplines	Number of graduates
Nursing	4070
Physical Therapy	635
Pharmacy	975
Occupational Therapy	568

Statistics Canada 2000

2.7 Reimbursement Options for Medical Devices

In Canada there are basically four (4) types of reimbursement for Healthcare products and services:

- Government Reimbursement: Paid for through provincial health plans such as OHIP (Ontario Health Insurance Plan).

- The product/service is paid for by the Hospital as part of their yearly budget.
- The product/service is paid for by a Third Party Insurer.
- The product/service is paid for privately by the actual patient.

When Canadians need medical care, in most instances, they go to the physician or clinic of their choice and present the health insurance card issued to all eligible residents of a province. Canadians do not pay directly for insured hospital and physicians' services, nor are they required to fill out forms for insured services. There are no deductibles, co-payments or dollar limits on coverage for government insured services.

Every medical service that is covered by a provincial reimbursement plan is given a code number and a fixed billing rate; example 1 below. In some cases the reimbursement may be broken into several components such as "P" for the professional component (the physician) and "T" for the technical component (technician time); example 2 below.

Example 1: General Assessment by Family Physician

Code	Description	Reimbursement
A003	General Assessment	$ 52.50

Example 2: Continuous ECG Monitoring

Code	Description	Reimbursement
G650	Professional Component (P)	$ 45.60
G651	Technical Component (T)	$ 25.25

In example 2, the monitor that would be used for the ECG recording would be paid for through the hospital's capital budget. Hospitals basically have control of the day-to-day allocation of financial resources (both capital and operating) provided they stay within the operating budgets established by the regional and/or provincial health authorities.

In addition, his or her provincial Ministry of Health issues each patient a health care number. At the end of each month, the physician sends the Provincial Health Insurance Plan a billing statement, which lists the patient health care number and the code for the service provided.

The provinces and territories also provide additional public coverage for specific groups within the population (e.g., seniors, children and welfare recipients). These supplementary health benefits often include dental care and prescription drugs through the provincially-run drug formulary programs.

Most provinces have an Assistive Devices Program (ADP) where the program will fund some 1,500 types of equipment under the following categories – prostheses, mobility aids, visual and communication aids, diabetic supplies etc. To become eligible for the program, patients must have a valid Provincial Health Card and have a physical disability of six months duration or longer. The Program will only pay for equipment that is purchased from vendors who are registered with the provincial assistive devices branch.

3.0 Medical Device Regulatory Framework

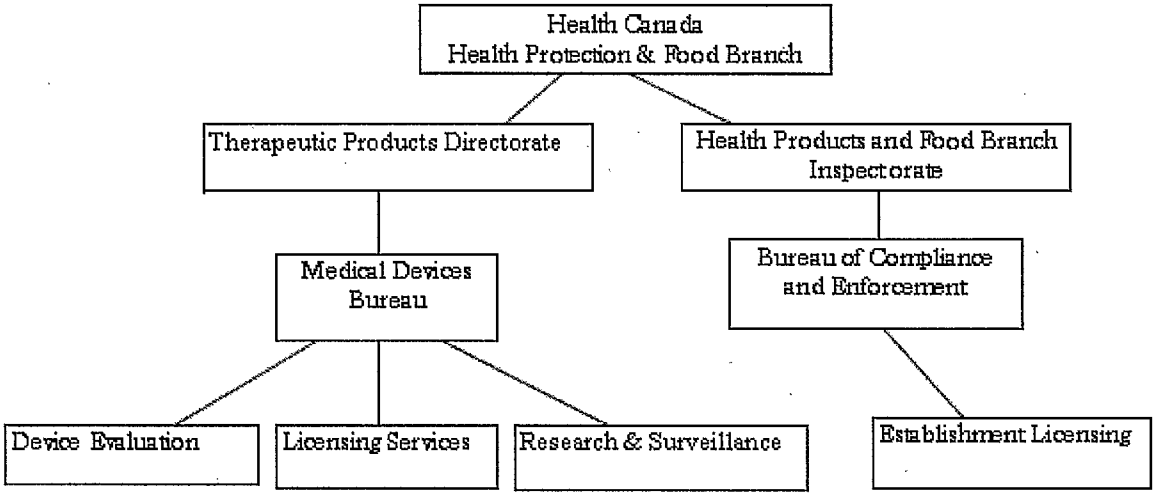
3.1 Overview

Medical devices in Canada are subject to the *Medical Devices Regulations* under the *Food and Drugs Act*. In July 1998, a new regulatory framework was implemented that brought Canada's regulatory requirements closer to those of its major trading partners as a risk-based system. This regulatory framework is based on two major principals:

- The level of regulatory scrutiny is dependent on the risk the device affords
- The safety and effectiveness requirements are met through a balance of
  - Quality System Requirements
  - Device Licensing
  - Establishment licensing

Therapeutics Products Directorate (TPD) of Health Canada undertakes this regulatory role.

The organization structure is depicted below:



3.2 Device Licensing

Manufacturers of Class II, III and IV medical devices must obtain a license for their devices from TPD, prior to selling or advertising them in Canada. (It is not permitted to advertise with a rider "not approved by Health Canada").

Device licensing is undertaken by TPD, based on submitted information only. License requirements are directly proportional to the risk classification of the device.

3.3 Device Classification System

Under the *Medical Devices Regulations*, a risk-based classification system has been implemented to categorize medical devices as to their potential risk.

The Canadian classification rules were developed with a view to their harmonization with the device classification systems of the European Union and United States.

The system is based on four classes (Class I, II, III and IV) representing increasing degrees of risk. Assignment of products to each risk class is based on factors such as degree of invasiveness, duration of contact with patient, energy transmission hazard and consequences

on device malfunction or failure.

	Risk	Examples
Class I	Lowest risk	Surgical Instruments, culture media
Class II	Low risk	Contact lenses, epidural catheters, pregnancy test kits, surgical gloves, ultrasound scanner
Class III	Moderate Risk	Orthopaedic implants, glucose monitors, dental implants, haemodialysis systems.
Class IV	High Risk	HIV test kits, pacemakers, angiographic catheters.

In order for manufacturers to establish the classification of their devices TPD has three documents that could be of valuable assistance:

1. "Keyword Index To Assist Manufacturers In Verifying The Class of Medical Devices" http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guid es/meddev/keyword_e.pdf
2. Guidance for the risk based classification system of in vitro diagnostic devices http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/meddev/ivdd -rsk_e.pdf
3. TPD posts on their web site all the Class II, III and IV licenses that have been issued; therefore manufacturers can establish their product's class by comparing it to similar or competitive devices. http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/md_lic.html

3.4 Quality System Requirements

The quality system requirements of the *Medical Devices Regulations* do not come into force until January 1, 2003, when manufacturers will have to attest compliance. For licenses in existence prior to December 31, 2002, manufacturers will be required to demonstrate compliance when those licenses become due on November 1, 2003. The requirement will be for all devices (except Class I) to be manufactured under a quality system:

- Class II ISO 13488
- Class III, IV ISO 13485

The auditing must be undertaken by independent registrars accredited by the Standards Council of Canada (SCC) and recognized by them and Health Canada under the Canadian Medical Devices Conformity Assessment System (CMDCAS).

3.5 License requirements

An important first step in the process is to determine the device license type; TPD will issue licenses for groups of devices under one license application under certain circumstances, examples are:

Device License Type	Definition	Example
Single Device	A device that is identified with a unique name by its manufacturer and is sold as a distinct packaged entity.	Nebulizer
Medical Device Family	A group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same manufacturing process and that have the same intended use.	Urological catheters differing in size
Medical Device Group	A collection of medical devices, such as a procedure pack or tray that is sold under a single name.	Suture trays
Medical Device Group Family	A collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that only differ in the number and combination of the products that comprise each group.	Suture trays for differing applications
System	A medical device comprising a number of components or parts used together to fulfill all or some of the device's intended functions and which is sold under a single name. This includes an *In-vitro* diagnostic device (IVDD) system, but does not include processing devices that support numerous different assays and may be designated a system by the manufacturer.	Clinical chemistry system that has several assays of the same class with a dedicated analyzer
Test Kit	An in-vitro diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.	Hepatitis EIA kit

What information is required to undertake a license application?

The generalized topics that must be addressed in a medical device license submission for each of the Class II, III and IV are as follows:

Class II

- Manufacturer and Device Identification Information
- Attestation of compliance with
  - Safety and Effectiveness
  - Labeling *
  - Procedures relating to distribution
  - Problem reporting and recalls

- Indications for use
- List of standards used in manufacture
- Attestation by accredited registrar of ISO 13488 (January 2003)

** Labeling of medical devices used by professionals does not require bilingual (French/English) labeling, but devices that are sold directly to the consumer require the label information in both French and English.*

Class III

- Manufacturer and Device Identification Information
- Background Information
  - Device Description
  - Design Philosophy
  - Marketing History
- Summary of Safety and Effectiveness Studies
  - List of Standards
  - Method of Sterilization
  - Summary of Studies
- Bibliography
- Labeling
- Near-Patient *in vitro* Diagnostic Devices (if applicable)
- Attestation by accredited registrar of ISO 13485 (January 2003)

Class IV

- Manufacturer and Device Identification Information
- Background Information
  - Device Description
  - Design Philosophy
  - Marketing History
- Risk Assessment
- Quality Plan
- Device Information
  - Material Specifications

- Manufacturing Process
- Standards used in manufacturing process
- Safety and Effectiveness Studies
  - Preclinical and Clinical Studies
  - Validation Studies
  - Literature Studies
  - Software Validation (if applicable)
- Literature Studies
- Near Patient IVDD information (if applicable)
- Labeling
- Attestation by accredited registrar of ISO 13485 (January 2003)

The following references are for sources of additional information and the application form for a Class II, III or IV device:

"Guidance on How to Complete the Application for a New Medical Device"
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guid es/meddev/lcn_nw4_e.pdf

"Preparation of a Pre-market Review Document for Class III and Class IV Device License Applications"
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guid es/meddev/prmkt2_e.pdf

3.6 TPD Medical Device Filing Fee

	Device	IVDD	Near patient IVDD	Annual Renewal Fee
Class II	$200	$200	$200	$100
Class III	$1980	$1980	$2420	$100
Class IV	$16,730	$10,370	$12,780	$100

Initial device license fees for Class III and IV may vary due to the specific device.

3.7 Review Times

	Average	Median
Class II	13 days	5 days
Class III	88 days	58 days
Class IV	106 days	56 days

3.8 Establishment Licensing

Establishment Licensing allows Health Canada:

- To identify establishments which are selling medical devices in Canada, the identity of the manufacturers of these devices, and the classification of the devices sold.
- To provide assurance that regulations covering post-production and post-marketing are being complied with.

Who must be licensed?

Any importer or distributor of a device that is subject to the regulations, or a manufacturer of **Class 1 devices** who does not sell through a licensed distributor must be licensed.

The identity of a manufacturer of any Class 1 device must appear on an establishment licence whether the manufacturer is selling directly or through a licensed distributor. A distributor may have numerous manufacturers listed on its licence, and is not required to have a separate licence for each manufacturer. Importers /distributors are required to ensure that any device they sell is in compliance with the *Medical Device Regulations*, including that which requires that the manufacturer of any Class II, III and IV device being distributed possess a Medical Device License.

Who does not require licensing?

Certain groups who operate in the medical device sector are not required to hold an establishment license:

- Hospital or other licensed health care facilities
- Retailers who sell directly to the consumer i.e. ultimate user of the device.
- Manufacturers of devices (unless they sell Class 1 devices directly to a retailer / consumer)

The License Application Process:

The licence application form is very simple and requires a senior member of staff to attest that the establishment meets several requirements:

- Labeling
- Distribution records
- Recalls and mandatory problem reporting
- Complaint procedures

The cost of an establishment license:

The establishment license fee (which must be renewed annually) is $2120.00. The time from submission to receipt of a licence is approximately 21 days. There is a fee reduction program in effect, which allows for reduction for limited sales in Canada.

Additional information on the process and the Medical Devices Establishment License Application Form may be obtained from Health Canada's web sit at:

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guid es/meddev/md_interpret_e.pdf

and;

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/form s/md_elap_e. pdf

Examples:

A US company manufactures implantable orthopaedic devices and wishes to sell directly to hospitals in Canada.
The company will not require an establishment licence but must have a valid Class III Medical Device Licence to sell its products in Canada.

A Canadian manufacturer of microbiological culture media sells to laboratories directly and also through a licenced distributor.
The company will need an establishment licence as it is acting as both a manufacturer and distributor of a Class 1 medical device.

A French company sells urological catheters and surgical instruments to a distributor in Canada.
The company will not require an establishment license for the surgical instruments which are classified as Class I devices (it must check that the distributor holds a valid establishment license), but will require a medical device license for the catheters which are Class II devices.

A company imports many different class 1 devices from a variety of manufacturers who produce at many different sites in the world.
The company will be required to have only a single establishment license for all its activities in Canada, but must define each manufacturer and their different sites on the application.

4.0 Medical Devices not requiring Formal Licensing

Certain medical devices are not required to undergo the formal licensing process as described above.

4.1 Custom-Made Devices

Devices that are manufactured according to the specific written instructions of a health care professional and differ from any medical device that is generally available for sale in Canada.

The device should be for a specific patient or for practioners, to meet special needs arising in their practices.

4.2 Special Access Devices

Where access to a device is for emergency use or in situations where all conventional therapies have failed.

The above devices do not require manufacturers to have an establishment license or a medical device license. The health care professional requesting the device must complete a specific application form and forward it to TPD for review. There is no charge for this process and the timing for approval is flexible, depending on the particular situation.

Additional information and the Application Form for Custom-made Devices and Medical Devices for Special Access are available at:

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html

5.0 Market Data

Canada ranks fourth among the G8 nations for health spending as a percentage of gross domestic product, behind the United States, Germany and France.

	Estimated #
Total Number of Employees in the Canadian Medical Device Industry	18,000
Canadian Manufacturers	800
Medical Device Sector – total (2000)	
Estimated Domestic Production	$3.1 billion
Domestic Usage	$4.9 billion
Exports	$1.6 billion
Imports	$3.4 billion
Home Care and Mobility Equipment Market (1999)	
Domestic Usage	$226 million
Domestic Production	$126 million
Exports	$55 million

Data obtained from Canadian government publications, medical device industry associations and opinions of industry leaders.

6.0 Marketing and Distribution

Marketing

Marketing strategies can be very complex in nature, and in most cases, a manufacturer will have to tailor a specific strategy to suit an individual market.

In the medical device marketplace it is important to remember that manufacturers must satisfy the needs of three separate parties to influence one single buying decision. This is unlike traditional marketing, where a company can focus a marketing program on one end-user to sell one or more units of product. To be successful at selling one medical device or one unit of medical product, a manufacturer must, through marketing programs, satisfy the needs of a patient who benefits from the therapeutic outcomes of the product and is interested in a higher quality of life, a physician who prescribes the use of the product, and a healthcare insurer who pays for the use of the product and is interested in cost-effectiveness. Although each party is essential for one purchase to take place, separate marketing approaches and tactics must be employed to be successful.

Distribution

As one of the major pillars of a successful marketing strategy, distribution logistics must be carefully thought out to achieve adequate penetration of the Canadian medical device market. Manufacturers may distribute either directly, through a dedicated sales force, or indirectly, through a third party. Companies that manufacture a highly technical and complex product may wish to hire their own sales staff to maintain a proprietary control over the dissemination of information and ensure adequate delivery of specialized training that may be required to use the new device. However, in most cases, rapid and cost-effective market penetration can

be easily achieved by contracting to a distribution partner.

- Third-party distributors may be focused on local markets or on providing national coverage. Choosing a national distributor over a local one is a matter of accommodating specific marketing objectives. For example, national distributors may have more resources at their disposal and be able to access more healthcare facilities across the country, but normally charge more. National distributors can also be more bureaucratic, thus making it more difficult to quickly sign a deal to represent a foreign manufacturer's products. This would be a major problem if a rapid market entry were required to capitalize on a restricted window of access.

The advantage of dealing with a local distributor is simplicity. Each province manages its own healthcare system, creating some inconsistencies in delivery of services across the country. Therefore, even if a manufacturer contracts with a national distributor, there may be delays in acceptance of the product by individual provinces, due to the specifics of the different healthcare bureaucracies. A manufacturer may pay for national distribution but achieve market penetration in only some provinces, while waiting for others to approve the product. For new devices, it is generally recommended to start with the simplicity of a local distributor that is specialized in the logistics of one particular province.

7.0 Access to the North American Market

The North American Free Trade Agreement (NAFTA), between Canada, the United States and Mexico, came into effect on January 1, 1994. The agreement focuses on the elimination of tariffs and other trade barriers to facilitate the cross border movement of goods and services. Under NAFTA, all tariffs on medical devices traded between Canada and the United States were eliminated in 1998. Tariffs on many medical devices traded between Canada and Mexico have already been eliminated. The agreement states that all tariffs will be eliminated on products or services, moving between Canada and Mexico, by January 1, 2003.

For more information on the North American Free Trade Agreement go to:

www.dfait-maeci.gc.ca/nafta-alena/menu-e.asp

Another interesting point to note in looking at the North American market is that both Canada and Mexico use the metric system, while the USA still uses the imperial system.

8.0 Investment Options

When considering expansion into new markets, it is essential to carefully plan financing strategies to fund the multitude of corporate activities. While there are a variety of sources of financing, each comes with its own advantages and disadvantages.

Venture Capital

Manufacturers who require more financing than a private investor is able to provide may look to a venture capital fund. Venture capital companies are small to medium sized, high-risk funds that invest in emerging technology companies in return for a relatively sizable piece of equity. Venture capital companies may invest as little as a million to as much as several hundred million dollars. However, for their investment, venture capital companies frequently demand an equity stake of at least 40-50%, and require that some of their own representatives are placed either on the board of directors or on the senior management team. The management coaching offered by most venture capital companies comes from seasoned executives who have had a number of successes developing other technology efforts. This type of financing is best for manufacturers who have relatively well-developed products but

either an undeveloped organizational structure or inexperienced managers.

- Some of Canada's venture capital companies that have investments in the healthcare sector:

Business Development Bank of Canada (BDC) Venture Capital
www.bdc.ca/venturecapital

Canadian Medical Discoveries Fund Inc.
www.cmdf.com

The Canadian Science & Technology Growth Fund Inc.
www.cstgf.com

MDS Capital Corp.
www.mdscapital.com

Sofinov
sofinov.lacaisse.com

Ventures West Management. Inc
www.ventureswest.com

Working Ventures Canadian Fund Inc.
www.workingventures.ca

Public Equity Financing

- Manufacturers may wish to finance their operations with an initial public offering (IPO) where shares are issued on the open market for trade by ordinary investors. In this case, a manufacturer who wishes to raise money publicly will work with an investment bank that will represent and sell the stock for an underwriting fee.

Many complex rules apply to an application to have a listing on a Canadian stock exchange and are beyond the scope of this report. One of the most important implications of a public stock issue is the requirement to comply with disclosure regulations. Public disclosure regulations require manufacturers to share all material corporate information with shareholders. Given that many medical companies experience negative effects when they have to publicly announce bad clinical trial or product failure results, this form of financing is not recommended for most emerging medical companies.

Canada's major stock exchanges:

Toronto Stock Exchange
www.tse.com/

Montreal Exchange (Bourse de Montréal)
www.me.org/

Canadian Venture Exchange (formed by the merger of the Alberta and Vancouver Stock Exchanges):
www.cdnx.com

Debt Financing

- It is sometimes less risky for emerging companies to seek a loan from a stable, accredited financial institution. While the money is guaranteed, a borrower is subject to interest rate risks that may impact on cash flow. During the past several years, the Canadian economy has

maintained low interest rates making borrowing an inviting way to finance operations. The Conference Board of Canada, in its annual forecast for 2001, predicted that interest rates should remain low for the foreseeable future. Manufacturers can seek short-term or bridge loans to finance specific projects, such as a clinical trial patient recruitment. Alternatively, long-term loans can be used to finance new infrastructure projects or large capital expenditures such as new equipment. It is important to note that certain restrictions may apply to foreign companies seeking debt financing from a Canadian institution. Any manufacturer wishing to pursue this type of financing should contact individual lending companies and banks to inquire about specific borrowing regulations.

Contacting private investors, attracting venture capital, or applying for a loan is a complex but crucial process for any company looking to expand operations in Canada. The best way to access quick and thorough advice may be to contact an incubator company. Incubators are set up, in some cases, with Federal government support or by groups of private individuals. Most incubators are affiliated with major Canadian universities, governmental organizations such as the National Research Council, or local business associations and boards of trade. The objective of a typical incubator is to act as a central contact point to access sources of financing, to receive regulatory and general management advice, or for a manufacturer to out-source any of the variety of corporate functions.

9.0 Company Experiences

This section presents brief descriptions of the experiences of some companies which have entered the Canadian market successfully. In each case, the company began with a modest commitment and, after gaining experience and knowledge of the Canadian healthcare market, grew and evolved along with their level of success in the market. The examples given below show that initially, some companies choose to work with local distributors. Others have approached the Canadian market by establishing an office and developing from within their own company. Both routes have led to successful market penetration and growth.

1. A Scandinavian manufacturer's diagnostic kits had been distributed throughout Canada for several years by a Canadian distributor. The company's market share had progressively increased over this period. The company decided to purchase the distributor and make it a wholly-owned subsidiary. It subsequently expanded the facility. The president of the distribution company stayed on in that position with the new Canadian entity and played an important role in providing intelligence to the corporate headquarters on the Canadian market.

2. An American manufacturer of orthopedic implants and accessory products decided to enter the Canadian market through an agent. It was decided that, due to the support required to market such a product range and the success which the agent had achieved, the manufacturer would acquire the agent. The agent has since grown to become a major force within the company, acquiring the world manufacturing mandate for certain product groups.

3. The product line of a British manufacturer of Class 1 devices was being distributed by a national distribution organization. The company decided to set up a Canadian distributor in order to have an organization dedicated to the distribution of its products. This operation has grown to be one of the most profitable (per capita population) of all the manufacturer's worldwide subsidiaries. Manufacturing of some of the product range for the North American market was transferred to Canada.

4. An American cancer diagnostics company had their products distributed in Canada by a third party. The company decided to establish its own distributor in order to ensure that its products' distribution was given the highest priority and to fully exploit the Canadian market potential. A subsidiary company was formed, that was only the second such

operation in the world (the other is located in the United Kingdom).

10.0 Further Information

Additional information on Canada as a potential area for investment in the medical device sector can be obtained at your local Canadian Embassy, High Commission or Consulate.

A directory of Canadian posts abroad can be found at:

Department of Foreign Affairs and International Trade
http://webapps.dfait-maeci.gc.ca/InternetPhoneDirectory/Direc tory.asp

11.0 Links to Canadian Healthcare Resources

Useful World Wide Web links to useful sites where addition information may be found on the Canadian healthcare sector.

Health Canada
www.hc-sc.gc.ca

Industry Canada
http://strategis.ic.gc.ca/sc_indps/sectors/engdoc/hind_hpg.ht ml

Department of Foreign Affairs and International Trade
http://www.dfait-maeci.gc.ca

Canadian Healthcare Association (CHA)
http://www.canadian-healthcare.org/

Canadian Telehealth Association
http://www.cst-sct.org/

Canadian Institute for Health Information
http://www.cihi.ca

Centres of Health Evidence
http://www.cche.net

Institute of Health Economics
http://www.ihe.ab.ca

CSA International (Canadian Standards)
www.csa-international.org

Standards Council of Canada
www.scc.ca

Canadian Health Network
http://www.canadian-health-network.ca

Medical Devices Canada
http://www.medec.org

Quebec Association of Medical Technologies and Devices Manufacturers
http://www.aqfim.com/en/index.asp

Association of Ontario Medical Manufacturers
http://www.aommcanada.com

Association des Physiciens et Ingénieurs Biomédicaux du Québec (in French only)
http://www.apibq.org/index.php3

Canadian Venture Capital Association
http://www.cvca.ca/

Ontario Hospital Association
http://www.oha.com

Association des hôpitaux du Québec (in French only)
http://www.ahq.org

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