



Considerations for Medical Device Software Companies Entering the Canadian Market

By Eileen McMahon and Jason Gilman

Canada has one of the world's largest medical device markets, estimated at C\$6 billion in 2010, with sales of almost C\$3 billion taking place in Ontario. The medical device industry in Canada, not taking into account medical imaging and assistive devices, employs over 35,000 people in about 1,500 companies, the bulk of which are small or medium-sized companies.¹

With the growth of the medical software industry, software development companies that wish to market their products in

Canada may be faced with considerations they may not have encountered in the past—specifically, regulatory approval. The influx of medical software in recent months, such as software that can remotely monitor the health status of a patient, has led Canadian regulators to turn more attention to the regulation of software as a medical device.

This article deals with a number of topics relevant to companies considering launching a medical device software product in Canada. It describes how regulatory approval, pricing and



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reimbursement can affect your decision on whether to launch in Canada; it then goes on to discuss whether the market can be tested before the launch, and concludes with an overview of relevant marketing issues and product support.

How should you launch a medical device software product in Canada?

Deciding how to launch a medical device software product in Canada involves a number of considerations, including these:

- Should you establish a business presence in Canada?
- Do you require regulatory approval for your product?
- Are there reimbursement options for your product and how will you get paid?
- Is it possible to conduct research or testing of your product prior to any regulatory approval?
- What can be done to protect your brand in Canada?
- Are there any restrictions or requirements related to advertising and product support in Canada?

Should you establish a business presence in Canada?

Several options exist for structuring a U.S. business wishing to operate in Canada. These include

- creating a Canadian division;
- establishing a relationship with a Canadian partner;
- establishing a Canadian subsidiary of a U.S. corporation
- starting a standalone business in Canada.

A business presence in Canada can provide significant advantages for your company. For example, there are federal and provincial refundable tax credits

for basic science and clinical research conducted in Canada, which can be as high as 60 percent. These Scientific Research and Experimental Development, or SRED credits, are claimed from the Canada Revenue Agency (CRA) at the time of filing a Canadian income tax return. Banks will often advance loans on the basis of estimated refundable SRED credits.

There are also government loans and grants specially geared to companies operating in the medical device space as well as grants available to companies that create at least 100 jobs or invest C\$25 million locally.

Does your software require regulatory approval?

In Canada, medical devices are regulated federally by Health Canada's Medical Devices Bureau (Canada's version of the United States Food and Drug Administration) and governed by Canada's Food and Drugs Act and Medical Device Regulations.

The Medical Devices Bureau assigns medical devices to one of four risk classifications on the basis of the device's functionality: Class I is the lowest perceived risk and Class IV is the highest perceived risk. In Canada, software that has a medical application can be regulated as a medical device. This can include software that displays data or that generates alerts using data from a patient monitoring device. Medical device software is typically assigned a Class I or Class II rating; however, if the software is embedded in a medical device, it can receive a higher classification. Canada's rules for classifying medical device software differ from those of FDA and some of these differences can result in software being regulated differently in Canada.

Each classification of medical devices has certain regulatory obligations, not

unlike the requirements under U.S. laws. These include obtaining licenses to sell, advertise and offer the software for sale in Canada, as well as labeling requirements, problem-reporting obligations and the need for documented policies and procedures in place to deal with recalls.

Class I medical devices are exempt from the requirement to obtain a medical device license; however, these devices require a medical device establishment license before you can sell or advertise for sale any such medical device in Canada. The application for a medical device establishment license, which typically takes five to 10 business days to obtain, requires that certain internal policies related to recall procedures and complaint-handling are in place at your facility and that you comply with medical device labeling requirements under Canadian law.

For other classifications (II, III or IV), the classification of your device will determine the information and details required in your medical device application. For example, Class III and Class IV medical device license applications require data from clinical studies. In addition, the Medical Devices Bureau requires the ISO 13485 Quality Management Systems certificate of your facility before it will approve any application for a Class II, III or IV medical device.

If you are planning to launch your medical software in Canada, one key question is timing. The time required to obtain a medical device license varies according to your device's classification and its complexity: Class II medical device licenses typically take one to two months, and Class III and IV medical device licenses typically take four to six months or more.

Other regulatory approvals

If your product includes both software and hardware, other regulatory approvals may be required. For example, medical devices that include radio frequency devices – for example, medical telemetry devices or Bluetooth devices – may require additional regulatory approval from Industry Canada. Additionally, electrical components of a medical device must meet provincial electrical safety requirements before they can be used in Canada, requiring Canadian Standards Association or comparable approval.

For devices that meet Canadian standards and approvals, Industry Canada provides technical acceptance certificates in a typical turnaround time of 14 calendar days. Failure to obtain this technical acceptance certificate can result in fines. When reviewing technical acceptance certificate applications, Industry Canada will generally accept reports that were provided to the U.S. Federal Communications Commission (FCC) for similar approvals; however, the application must indicate how the FCC standards for the product compare with the Canadian standards.

Are there reimbursement options for your product?

The Canadian healthcare system, unlike that of the United States, is mostly publicly funded and is typically free at the point-of-care for Canadians. In Canada, the federal and provincial governments share the responsibility for Canada's healthcare system, the federal government providing funding to the provinces to finance their healthcare insurance plans. However, the cost of medical devices is typically not directly reimbursed by the provinces. Some Canadian provinces provide reimbursement for specific categories of assistive

devices, such as communication devices and diabetic supplies, that enable people with physical disabilities to become more independent.

Reimbursement options for your medical device as you enter the Canadian market may include reimbursement directly from hospitals, physicians, private clinics, the patient or third-party supplemental health insurance.

All hospital expenditures, including operating costs and the purchase of all drugs and medical devices required by the hospital, come directly out of the hospital's operating budget, handed down by its provincial government. The cost of any additional medical devices must be paid for by the patient; however, some medical devices may be reimbursed by the patient's supplemental third-party health insurance plan.

The cost of medical devices used by physicians or private clinics must come out of the physician's or private clinic's budget. These costs can either be absorbed or be passed directly on to the patient (who may then either pay for the devices themselves or be reimbursed through the patient's supplemental third-party health insurance).

How do physicians get paid?

Physicians and private clinics are paid by the province for insured services that they provide and that are covered under the provincial health insurance plans. These insured services and the amounts paid by the province are set by each province, and physicians and private clinics cannot charge patients extra to perform these insured services. Since the cost of medical devices purchased by physicians and private clinics comes out of the physician's or private clinic's operating budget, physicians will be less willing to use the product if they are not paid by

the province for the services performed when diagnosing or treating patients using your product.

Can you conduct research or test your product before regulatory approval?

You can test your medical device in the Canadian market without approval through investigational testing (clinical trials), research use and the special access program for medical devices (similar to the compassionate use of unapproved medical devices in the United States). In all three instances, you cannot promote or market an unapproved medical device in Canada.

You can apply to the Medical Devices Bureau for authorization to conduct investigational testing with your medical device before obtaining the license. Application details differ according to the risk classification of your medical device and the complexity of the medical device and investigational testing.

Your medical device can be used in Canada for research purposes only without a medical device license provided that the product will not be used for treatment or diagnosis of a patient. Medical devices must be accurately labeled and appropriate agreements must be in place to ensure that your "For Research Use Only" devices comply with Canadian laws and regulations.

Through the Canadian special access program for medical devices, you can sell your medical device in Canada for use with a specific patient. Under this program, a Canadian physician or other healthcare professional is responsible for initiating the request on behalf of a specific patient and must provide the rationale to the Medical Devices Bureau to justify the use of your medical device over an already licensed medical device.

What can be done to protect your brand in Canada?

It is important to take steps to protect your trademark in Canada, especially if you have already invested efforts to protect your brand in the United States. A Canadian trademark registration, filed with the Canadian Intellectual Property Office (similar to the U.S. Patent and Trademark Office), provides trademark protection across Canada, regardless of where it is being used. Obtaining Canadian protection can minimize the possibility that someone who is aware of your brand in the United States may file in Canada first, restricting your use of the brand in Canada. In some situations, trademark priority claims can be made to an earlier U.S. trademark application.

Are there any restrictions or requirements related to advertising and product support in Canada?

In addition to the regulatory approvals required to advertise your medical device software for sale in Canada, there are also advertising restrictions for medical devices related to certain diseases, such as diabetes, cancer and hypertension. These rules may require changes to your

website or other advertising or promotional materials to ensure compliance with Canadian laws and regulations.

Although you are not permitted to advertise your medical device in Canada without a license, there are certain narrow exceptions relating to exhibiting your device at trade shows or in catalogs (assuming that the appropriate disclaimers regarding lack of regulatory approval are in place) and showing it to physicians or other healthcare providers who may be interested in conducting clinical trials. In all instances, it must be clear that the device is not for commercial sale or diagnostic or treatment use.

Website and product support

Your company website may require some changes to comply with Canadian laws and regulations. For example, you may need to create a Canadian portion of your website if your medical device is approved for use in Canada but makes different claims for use from your corresponding U.S. medical device approval. Additionally, you may need to include Canadian pricing and you may wish to consider having a French language section if you plan to sell and support the product in Quebec.

Accounting for French language

Canada has two official languages, English and French. English is spoken throughout most of Canada, and French is spoken in the province of Quebec. If you are planning to make the product available in Quebec, you should consider the implications of Quebec French language laws and regulations, which require advertising, packaging, instruction manuals, customer support and troubleshooting, as well as other services, to be made available in French.

Privacy protection for Canadians

Canada has privacy laws in place to protect the personal and health information of Canadians. If you are planning to obtain personal information or personal health information from Canadians, it is important to ensure that your privacy policy, websites and any contracts or other agreements that you have in place comply with Canadian privacy laws. Δ

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1. All statistics from Medical Devices Canada <www.medec.org/content/about-our-industry> (last accessed: 2011-04-28).