Look Before You Leap: Pre-Canadian Launch Regulatory Considerations for U.S. Companies

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Deciding whether or not to launch a food, drug, medical device, dietary supplement or cosmetic product in Canada involves a number of considerations, including:

- whether regulatory approval is needed for the product;
- if regulatory approval is required, timing the approval with the launch of the product and the Canadian operations;
- whether to establish a business corporation in Canada or to outsource or partner for the distribution of the Canadian product;
- how to price the product;

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- how to protect your brand and market in Canada; and
- whether your U.S. agreements, labeling and product support will suffice for the Canadian market.

Regulatory Approvals

In Canada, food, drugs, medical devices, dietary supplements (in Canada, known as "natural health products" or NHPs), and cosmetics are regulated federally by Health Canada (Canada's version of the U.S. Food and Drug Administration) and governed by Canada's Food and Drugs Act and Regulations.

For drugs, including over-the-counter and NHPs, and most medical devices[1], a manufacturer must obtain a license from Health Canada before the product may be sold. Cosmetics and certain classes of foods are subject to notification and must be manufactured and marketed in accordance with detailed legislation and government policies.

There are differences between licensing requirements in Canada and the U.S. For example, NHPs, generally akin to dietary supplements in the U.S., are regulated as a type of drug in Canada and are subject to "drug"-related standards rather than "food"-related standards. Medical devices are categorized into four different risk classes in Canada, so a manufacturer cannot assume that a device will have the same risk classification in Canada and the U.S.

Timing to obtain regulatory approval is a key consideration for your Canadian launch. The time required to obtain a product license varies according to a product's classification and its complexity. Lower-risk medical device licenses typically take one to two months to obtain, while higher-risk medical device licenses typically take four to six months or more. The approval process for new drug submissions can take several years. The time required to receive a natural health product license in Canada is typically three months for standard submissions, but can be significantly longer for products with several active ingredients.

Coordinating the timing of the regulatory approval with the launch of the Canadian product and Canadian operations can be tricky. To minimize the risk of costs associated with operations before a product has regulatory approval, usually there is a lag between regulatory approval and launch. Most manufacturers want the certainty of the Canadian regulatory approval before the other operational processes required for the launch of the Canadian product—hiring employees, leasing space, etc..

A regulatory application filed with the U.S. FDA is usually a good start for preparing a corresponding product license application for Canada, although some changes to the U.S. application will likely be needed, particularly with respect to the mandatory label requirements.

In addition to product licensing requirements, Canadian facilities may also require an establishment or site license to permit the manufacture, sale, import or distribution of regulated products. Although the obligations of a license holder vary depending on the class of product, these facility licenses generally require that internal policies relating to good manufacturing practices, recall procedures, complaint handling and record keeping be in place at each facility where products are handled.

Where the product is manufactured outside of Canada, and after the product has its regulatory approval, most manufacturers will test their import, warehousing and distribution in Canada through a trial run to ensure that the product is not held up at the border and that distribution of the product through the supply chain is smooth.

Establishing A Business In Canada

Many options exist for structuring your business operations in Canada, including: establishing a relationship with a Canadian partner that will be responsible for regulatory approvals, sales, marketing and distribution in Canada; establishing a Canadian subsidiary of a U.S. corporation; or handling most operations from the U.S. and running Canadian operations from the U.S. office, with outsourcing to Canadian third parties where required.

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 (Scientific Research and Experimental Development, or SRED, credits) for certain operating expenses and capital expenditures, which, depending on the province, can be as high as 60%.[2] Many other provincial grants are provided for early-stage companies. For example, there are loans and grants specially geared to companies operating in the food, drug and medical device spaces, as well as grants available to companies that create at least 100 jobs or invest C$25 million locally.

In Canada, taxes on goods and services can apply at both provincial and federal levels. It is important

to understand how Canadian sales taxes apply and who is responsible for collecting them. For example, the manufacturer, importer, distributor, reseller or end user may be required to remit the applicable tax, depending on your particular situation. Establishing a business presence in Canada may require your Canadian operation to file a Canadian income tax return with the Canada Revenue Agency (CRA).

Product Pricing

Because of the proximity of Canada to the U.S. market, an important consideration is the pricing of your regulated product. Differential pricing, whether through product pricing or through currency exchanges, can create gray marketing or can result in cross-border sales that may interfere with your plans for product distribution and sales. Pricing of certain products may be reviewed and controlled by federal bodies, including the Competition Bureau and the Patented Medicine Prices Review Board (PMPRB). The PMPRB is unique to Canada and regulates the price for which patented drugs are sold, based in part on the price that an equivalent drug is sold in other jurisdictions.

Advertising And Promotional Activities

Drugs, medical devices and NHPs require regulatory approval before you can advertise their availability for sale in Canada. Prescription drug product advertising varies greatly in the U.S. and Canada, with Canadian promotion to the general public being very limited with no therapeutic claims.[3] There are also restrictions on advertising of any product as a treatment for certain diseases, such as diabetes, cancer and hypertension[4].

Food advertisements and label claims are also regulated. Canada has relatively strict rules with respect to the types of disease-reduction claims (for example, "a healthy diet low in sodium and high in potassium can reduce risk of high blood pressure"), and functional claims (for example, "calcium aids in the formation and maintenance of bones and teeth"). Products that are promoted for use in a "healthy" lifestyle can be subject to greater scrutiny.

Marketing and promotional practices at conferences or trade shows are subject to specific Canadian rules. For example, the distribution of drug and natural health product samples to the general public is not permissible.[5] When food samples are provided free to consumers, labeling must comply with the *Food and Drug Regulations, such as the inclusion of a* Nutrition Facts table, if applicable.

Because of the unique advertising regulations, your company website may require some changes to promote your product to Canadian residents. For example, you may need to create a Canadian-specific portion of your main website if your approved Canadian claims differ from the U.S. claims, or if you have products that are not yet approved for sale in Canada but are available in other jurisdictions. Additionally, if you plan to sell your product in Quebec as well as support its sale in the province (e.g., having a French language website) you may wish to consider French language compliance rules.

It can be advantageous to obtain a Canadian domain name, with the ".ca" suffix. According to the Canadian Internet Registration Authority, over 60% of Canadians prefer using a domain with a .ca suffix for online shopping[6]. To obtain this domain name, the registrant must have a connection to Canada, meaning that the registrant must be a Canadian citizen, a permanent resident or a Canadian corporation—so this should be a consideration for establishing a business presence in Canada. Provided the requirements to obtain a .ca domain name are met, the name can be purchased from a domain name registrar approved by the Canadian Internet Registration Authority.

Canadian Marketing Standards And Codes

With respect to prescription drugs, most oversight of the marketing practices of manufacturers has been undertaken by the pharmaceutical industry itself, through complaints to bodies such as: (i) the Pharmaceutical Advertising Advisory Board (PAAB), which reviews advertising directed at health care professionals under its Code of Advertising Acceptance; (ii) Rx&D, the innovator industry trade association, which has established a Code of Ethical Practices; and (iii) the Canadian Generic Pharmaceutical Association (CGPA), through the administration of the Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical Products in Canada. There are several other industry associations that have developed ethical codes and guidelines, including the national medical technology industry group MEDEC, Food Beverage Canada and BIOTECanada.

These codes are considered to be "industry standard" and therefore many Canadian companies will voluntarily adhere to the codes, whether or not they are actually members of the applicable organizations.

Canadian advertising industry bodies, such as Advertising Standards Canada (ASC) and the Television Bureau of Canada (TVB) provide pre-clearance services for various types of consumer advertising presented through Canadian media, including radio, TV, newspapers, magazines, billboard, flyers and internet. These bodies will review advertisements for compliance with the Food and Drugs Act, as well as their own compliance codes. Although pre-clearance by these bodies is generally not a legal requirement, in practice broadcasters will not run advertisements, particularly for NHPS, drug and medical device products that have not been approved by these bodies.

Branding – Selecting Your Trademark

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. Obtaining a Canadian trademark registration provides trademark protection across all Canadian provinces and territories. Obtaining Canadian protection as soon as possible can minimize the possibility of a competitor aware of your brand in the United States filing for a registration in Canada, which would preclude your registration and restrict how you may be able to use your brand in Canada.

An application for a trademark in Canada is filed with the Canadian Intellectual Property Office (similar to the U.S. Patent and Trademark Office) and in some situations, priority claims can be made to an earlier U.S. trademark application.

Patents – Don't Forget Canada

For companies whose products are innovative, the innovations relating to the products are typically covered in patents and patent applications. There can be strategic issues associated with the filing and prosecution of your Canadian patent applications, regulatory approvals and launch. In the pharmaceutical and biotechnology section, regulations provide for the listing of

patents on Health Canada's patent register (the Canadian counterpart to the U.S. Orange Book). However, if the patent application is filed in Canada after the date of the regulatory submission, the patent is not listable against that regulatory submission, even if the patent meets the other criteria for listability. In all sectors, failing to proactively prosecute the Canadian application to issuance will have the result that the patent is not enforceable against competitors until the patent issues. The result can be that competitors are on the market and your patents cannot be leveraged until they are issued. For that reason, it is helpful to dovetail the patent strategy with the preparation and launch of the Canadian product.

Adverse Reaction Reporting And Product Liability

Your company should be aware of its obligations under the Food and Drugs Act, and its regulations, to report adverse reactions related to your product. The regulations for each product class differ and a manufacturer selling in Canada may also be required to report adverse reactions to Health Canada that occur in other jurisdictions.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada, including drugs and medical devices. The Canadian Food Inspection Agency and Health Canada's **Consumer Product Safety Directorate** manage recalls for foods and cosmetics, respectively. Information relating to adverse reactions and recalls is available through the Canadian government's online resources.

As in other jurisdictions, the sale of your product in Canada may place your company at risk for product liability claims, including class-action proceedings which are on the rise. To succeed in a product liability suit, a consumer would need to show that the product in question was in some way defective, either in its manufacture or design. An assessment of whether the product is defective will typically involve a review of the risks and benefits of the product. This review can subsequently form the basis for the determination of other issues, such as the appropriate warnings that the manufacturer had a duty to convey. Accordingly, to reduce the likelihood of product liability claims, you should ensure that any applicable product documentation, package labeling and instruction materials transparently inform the user of any risks or deficiencies inherent in the product and its use or consumption.

Privacy Protection For 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 you have in place with Canadians comply with Canadian law. Canada has both federal and provincial privacy laws, and it can be a challenge to determine which law applies in a particular situation.

In general, organizations must obtain the knowledgeable consent of an individual for the collection, use and disclosure of his or her personal information. The Canadian Privacy Commissioner has voiced concern over the personal information of Canadians being transferred outside Canada, where Canadian privacy laws may no longer apply (especially regarding storing personal information in the United States). An organization should therefore consider whether additional measures must be taken if personal information is to be transferred from within Canada to another jurisdiction, for example, for processing or cloud storage.

In addition, Canada has recently enacted "anti-spam" legislation that applies to commercial electronic messages, including emails, text, instant messaging, and social media notifications. This legislation will be in force July 1, 2014, and non-compliance could result in monetary penalties of millions of dollars per violation.

French Language Requirements

Canada has two official languages: English and French. English is the dominant language throughout most of Canada; French is the official language of the province of Quebec, and the province of New Brunswick is officially bilingual. With very limited exceptions, Quebec's provincial laws require advertising, packaging, instruction manuals, customer support and troubleshooting, as well as other services to be made available in French. For example, if a product is offered for sale in Quebec, labeling must include French content, and if a product is advertised on the manufacturer or vendor's .ca website, the website must also be available in French. Quebec is one of Canada's largest provinces, so these provincial laws may have an important impact not only on advertising, but also on how you provide support and other services to residents of Quebec.

This article is a general overview of some of the issues you will want to

consider before launching a product in Canada. Answers will differ, depending on each company's circumstances. For more information, contact any one of the authors.

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1. Class I medical devices, the lowest risk class for devices in Canada, are exempt from the requirement to obtain a medical device license; however, manufacturers of these devices require a medical device establishment license before they can sell or advertise for sale any such medical device in Canada.
2. Moreover, banks will advance loans on the basis of estimated refundable SRED credits. Claims for SRED credits are made to the Canada Revenue Agency (CRA) at the same time as filing a Canadian income tax return.
3. Promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Food and Drug Regulations).
4. For a complete list, see Schedule A of the Canadian Food and Drugs Act available at <http://www.canlii.org/en/ca/laws/stat/rsc-1985-c-f-27/latest/rsc-1985-c-f-27.html>.
5. Section 14 of the Food and Drugs Act prohibits the distribution of drug samples other than to a physician, dentist, veterinary surgeon or pharmacist (a "health care professional"). Accordingly, it is not permissible to distribute NHP samples direct to consumers.
6. See http://www.cira.ca/why-ca/?lang=en.