July 2013

mcmillan Health Law Bulletin

From Tooth-Brushes to Insulin Pumps – The Regulation of Medical Devices in Canada

Industry Updates

The Canadian market surrounding the advertisement, importation and sale of medical devices is far from insignificant. According to the Government of Canada's Medical Device Industry Profile for 2013, there are over 1,000 medical device manufacturers in Canada, a value that does not include companies engaged solely in the distribution of devices. In 2011, the Canadian medical device market was valued at $6,300 million. The value of exports in 2011 was $1,835 million, and imports were valued at $6,499 million.

Medical devices range from simple latex exam gloves to complex insulin pumps and diagnostic kits, and while already diverse, it is expected that the variety of medical devices that will require regulation will continue to grow. This is partly due to an increasing shift to deliver care, where appropriate, out of hospitals and into the community as a response to restrictive hospital budgets. The demand for more IT-centric medical devices that can help to serve those individuals who are increasingly accessing health care remotely in their homes and communities will likely expand.

The new mandate of Ontario's Senior Strategy, and the release of geriatric specialist Dr. Samir Sinha's report *Living Longer, Living Well* on January 11, 2013, are further indications of an increase in community-centric care. The report, among other things, recommends greater collaboration among hospitals, Local Health

Integration Networks, Community Care Access Centres and other community care agencies to deliver more integrated and seamless care to seniors as they navigate the health care system. As well, Dr. Sinha calls for the expansion of home and community care and the use of Assistive Living and Supportive Housing regimes.

These new priorities and a growing Canadian market for medical devices provide an opportunity for medical device manufacturers, importers and distributors to launch a wide range of products and related services.

Medical Device Regulation

The regulation of the advertisement, importation and sale of medical devices in Canada is governed by the *Food and Drugs Act* (the "**Act**") and the *Medical Device Regulations* ("**Regulations**") made under it. The obligations of manufacturers, distributors and importers vary under the Act. Furthermore, while the *Act* and *Regulations* provide the foundation for the regulation of medical devices, there is a host of other requirements, complexities and considerations at play when a medical device enters the Canadian market. The following is a brief glimpse at some of these intricacies.

1. Classification Rules

The definition of "device" under the *Act* is broad and covers any article, instrument, apparatus or contrivance used in: a) the diagnosis, treatment, mitigation, prevention of a disease, disorder or abnormal physical state in human beings or animals; b) restoring or modifying a body function or structure in human beings or animals; c) the diagnosis of pregnancy in human beings or animals; or d) the care of human beings or animals during pregnancy and at and after the birth of the offspring, including care of the offspring.

After confirming that a product qualifies as a medical device, manufacturers must determine the class of the device. Medical devices are categorized as Class I, II, III or IV depending on the

level of risk involved in their use. Class I represents the lowest risk and Class IV represents the highest risk. If a medical device can be classified into more than one class, the class representing the highest risk applies. There are 25 classification rules for determining the appropriate class for a medical device under the *Regulations*.

2. Licensing Requirements

The *Regulations* set out licensing requirements to be met by manufacturers, importers and distributors, which vary depending on the role to be assumed and the classification of the device.

a) Medical Device Licence

A manufacturer of a Class II, III or IV device must hold a valid medical device licence. The Minister of Health will issue a licence only after the Minister is satisfied that the device meets the requisite safety and effectiveness requirements. When submitting an application for a medical device licence, a manufacturer must attest that it has objective evidence establishing the safety and effectiveness of the device, and that the device meets the labelling requirements as set out in the *Regulations*.

b) Medical Device Establishment Licence

The *Regulations* also require that any person who imports or sells a medical device must obtain a medical device establishment licence ("**MDEL**"), subject to a few exceptions. The application for a MDEL requires specific detailed information as well as attestations from a senior official of the establishment that the requisite procedures are in place.

3. Advertising Restrictions

a) General Advertising Under the Act

The Act establishes the criteria for acceptable advertising of medical devices in Canada. At a threshold level, the *Act* provides that no person shall advertise any medical device in a manner that is false, misleading or deceptive or is likely to create an erroneous

impression regarding the medical device's design, construction, performance, intended use, quantity, character, value, composition, merit or safety. The legislation also sets out more specific rules on certain types of advertising. For instance, there is a prohibition against advertising any medical device to the *general public* as a treatment, preventative or cure for a listed number of diseases, disorders or abnormal physical states.

b) Advertising Under the Regulations

A Class II, III or IV medical device cannot be advertised for the purpose of sale before the medical device is licensed by Health Canada. An exception to this advertising prohibition is available if the advertisement is placed only in a catalogue accompanied by a clear and visible warning that the advertised medical device may not have been licensed in accordance with Canadian law.

4. Interactions with Health Professionals

Canada's Medical Technology Companies ("**MEDEC**") *Code of Conduct* ("**Code**") is a voluntary guideline that establishes industry standards concerning interactions between member companies that manufacture, design, develop and/or market medical technologies/services and health professionals. Under the Code, health professionals includes those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe medical technology products in Canada. The Code sets out the standards for different types of interactions between companies and health professionals, including company-sponsored training sessions, promotional and business meetings, and the provision of modest gifts. All such interactions are assessed against MEDEC's overarching mandate of encouraging ethical business practices and socially responsible industry conduct to ensure health professionals make independent product-related decisions.

5. Public Procurement Practices

When engaging public sector organizations in the course of their business operations, medical device manufacturers, importers and

distributors should also be aware of legislation and policies governing public procurement activities. In Ontario, the *Broader Public Sector Accountability Act* and certain of its directives is relevant to medical device manufacturers, importers and distributors where such companies interact with designated broader public sector organizations, such as hospitals, or publicly funded organizations ("**public sector organizations**") when providing products or services. In particular, there are rules that govern the planning, sourcing, procurement, moving and payment processes of public sector organizations to ensure that these organizations act and are perceived to act with integrity and professionalism. Similar public procurement legislation and policies apply in some of the other Canadian jurisdictions.

6. Privacy Obligations

Manufacturers, distributors and importers of medical devices must also be aware of the applicability of certain privacy laws in situations where such companies might collect, use or disclose personal information in the course of commercial activities, such as in the case of selling medical devices online through a website. A related issue is the cross-border transfer of personal information that originates in Canada but is collected, accessed, used or disclosed in another jurisdiction. Such a situation is especially relevant where the parent or affiliate of a medical device company that intends to do business in Canada, is located in the United States and is involved in the sale, importation or distribution process.

7. Assistive Devices Program

Certain medical devices in Ontario may also be subject to the Assistive Devices Program("**ADP**") of the Ministry of Health and Long-Term Care if they are devices necessary to assist Ontarians with long-term physical disabilities. The ADP provides funding assistance to consumers for eligible medical devices, subject to the requirements and restrictions established in the applicable device-specific policies and procedures. The ADP will only provide funding assistance for devices that are purchased from vendors

registered with ADP. In order to be properly registered with ADP, vendors of medical devices must also comply with the applicable policies and procedures established by the Ministry of Health and Long-Term Care. The assistive devices regime may become even more relevant with the growing shift towards community- based health care.

How We Can Help

The advertisement, importation, distribution and sale of medical devices in Canada involve the interplay of a number of different legal regimes. McMillan LLP is a full-service law firm, with offices in Toronto, Vancouver, Calgary, Ottawa, Montreal and Hong Kong, and is well-positioned to provide both broad comprehensive legal advice, as well as industry-focused assistance based on client needs.

by Lydia Wakulowsky and Ratika Gandhi

For more information on any of the issues set out above, please contact:

Toronto Ratika Gandhi 416.865.7795 ratika.gandhi@mcmillan.ca

a cautionary note

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.