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# Medical Devices Distributors

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For medical device startups, Canada has been a growing market. Demand for innovative products has propelled R&D and medical technology development forward. Canada is also widely seen as a prime environment for this kind of innovation. With a highly educated population and top-notch research being done by Canadian universities, the country has substantial capacity to support both medical device industry growth and medical device innovation. (1)

Canada has well-established regulations as well. This makes it easier for FDA-cleared manufacturers to transition to the Canadian market.

However, there are many challenges for this industry such as complex regulatory processes, reimbursement restrictions, and the costly development of advanced technologies. A solid insurance policy combined with in-depth knowledge of this growing market is vital for ensuring the success of medical innovation for many years to come.

## Canada's Medical Device Market Expected to Grow

Canada spends an increasing percentage of its wealth on health care as the demand for services and the costs of delivering healthcare services continue to rise. Revenues in the Medical Device industry in Canada are projected to reach $10,839 million USD by 2026. (2)

Moreover, Canada's aging population will result in increased health care costs over the next few years, placing greater demands on health systems and increasing the demand for medical devices like imaging systems, artificial hip replacements, pacemakers and blood pressure monitors.

Cutting-edge medical devices, although often seen as an unaffordable cost for hospitals operating on limited budgets, offer significant long-term savings, improve patient outcomes, and create more efficient and effective health practices. As compared to other health care treatments, medical devices can be very cost-effective. This has led to medical devices being viewed as an important tool for innovation and sustainability within health care systems.

## What are Medical Devices?

The Food and Drug Act in Canada defines medical devices as: any article, instrument, apparatus, or contrivance, including any component, part, or accessory thereof, manufactured, sold or represented for use in:

1. The diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical condition, or its symptoms, in humans or animals,
2. The restoration, correction, or modification of a body function or a body structure in humans or animals,
3. The diagnosis of pregnancy in humans or animals,
4. The care of human or animal beings during pregnancy and at or after delivery, including the care of the offspring, and the use of contraceptive devices, but not drugs.

According to the Medical Devices Regulations, a medical device is one that is within the meaning of the Act, but excludes devices intended for use on animals. Software is a medical device if it is sold for the purposes specified in the definition of a medical device or if it is used as a component of a medical device. (1)

## Medical Device Distribution Licence Types

Device classification is the responsibility of the manufacturer, importer, or distributor. Depending on the risk classification of a product, Canadian law requires different levels of proof for quality assurance. Health Canada classifies medical devices into four risk categories:

- **Class I:** Low-risk devices like wound care and non-surgically invasive devices.
- **Class II:** Low-to-medium risk devices such as contact lenses and the majority of surgically invasive devices (e.g., surgical gloves, needles, magnetic resonance imaging equipment).
- **Class III:** Devices with moderate to high risks, such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, and surgically invasive devices that are intended to be absorbed into the body or remain in the body for more than a month.
- **Class IV:** High-risk devices such as pacemakers and surgically invasive devices used to diagnose, control, or correct a defect in the central cardiovascular system.

Class I devices are exempt from licensing and do not require approval from Health Canada. Applications for Class II devices require that applicants assert their device's safety and efficacy without having to provide evidence to support their claim. Devices in Class III and IV require more documentation and evidence proving their safety and effectiveness.

The medical device industry generally refers to Class III and IV devices. More often, these are the innovative devices that have a significant impact on how healthcare services are delivered (such as robotic surgery, pacemaker implants), which impact the patient care outcomes, improve treatment options and outcomes, replace surgeries with less invasive procedures, and reduce patient recovery time and hospital stays. Often, class III and IV medical devices require expertise in software, signal processing, engineering, and any number of other disciplines to ensure safety, efficacy, and cost-effectiveness.

## How Medical Devices are Regulated and Monitored

Medical devices in Canada are regulated by Health Canada, which has the legislative mandate to protect patients by ensuring the quality of medical devices. The Medical Device Regulations, enacted in 1998, replaced preceding regulations from 1976. (1) Canada's Medical Device Regulations are based on the European Medical Device Directives (MDD).

In Canada, medical devices are regulated under one of the most stringent systems in the world. Under the Canadian regulatory system, all medical devices must be reviewed scientifically, monitored, and checked for compliance and enforcement. These requirements include:

- Taking note of changes that may affect a device's benefits or risks
- Inspection of a company to determine compliance with the Medical Device Regulations and the Food and Drug Act
- Tracking recalls, complaints, and problem reports from consumers, health care professionals, and industry stakeholders

Like all health products, medical devices have benefits and risks. A licensing system helps to ensure that benefits outweigh risks in addition to reducing risks to the maximum extent possible.

## What Can Happen in Cases of Non-Compliance

Depending on the level of risk, the government takes action against the distributor in cases of non-compliance. Health Canada may, for example:

- Recall the medical device
- Seize an unlicensed device
- Request a label change
- Issue a stop-sale letter
- Refuse importation of the device
- Control the distribution of the device

In the most severe cases, distributors can be suspended, their products can be cancelled, and their business licenses can be revoked. In addition, distribution companies may also face prosecution. (3)

## The MedThree Advantage

With specialized experience in the healthcare industry, MedThree Insurance Group can help by providing tailored policies for medical device distributors and other professionals in healthcare. Our coverage options make it easy for brokers to find the right policy for their healthcare clients. Visit our website to get started or for more information: www.medthreeinsurance.com.

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