MED THREE INSURANCE GROUP | Insurance Newsletter
A Three Holdings Company

Heavily-Regulated Medical Device Distributors Need Specialist Brokers on Their Side

October 27, 2021

Canada is the eighth largest market for medical devices in the world and one of the largest economies in the world. There are plenty of opportunities for foreign manufacturers in Canada since 80% of the market is made up of medical device imports. (1) Most in demand are diagnostic products, monitoring equipment for patients, consumables, medical tools, orthopedic and prosthetic items, and dental products.

Canadian regulations are also well established. This means FDA-cleared manufacturers can transition to the Canadian market more easily.

Challenges and Changes in the Canadian Medical Device Distribution Industry

In the Canadian market, companies based outside North America will face fierce competition from US companies. Because of the close proximity to the United States and similarities in quality and safety standards, the United States controls more than half of the Canadian market. The Canadian market is also attractive to exporters from China, Mexico, and Germany.

Types of Medical Device Distribution Licenses

If a device is approved for distribution in Canada, it will need to receive the necessary medical device license. Canada issues two types of licenses: medical device licences (MDL) and medical device establishment licences (MDEL).

MDLs are issued for Class II, III and IV medical devices, while MDELs are issued to companies that import (Class I to IV), distribute (Class I to IV) or manufacture (Class I) medical devices.

Applications for a license for these high-risk medical devices must demonstrate that they are clinically effective. Among these types of evidence are clinical trials, review articles, meta-analyses and reviews from real-world instances.

How Medical Devices are Regulated and Monitored

Medical devices are regulated in Canada under one of the most stringent systems in the world. The Canadian regulatory system requires all medical devices to be reviewed scientifically, monitored, and checked for compliance and enforcement. This includes:

- Noting changes that may affect the expected benefits and risks of a device
- Verifying compliance with the Food and Drug Act and the Medical Device Regulations by inspecting a company
- Keeping track of recalls, complaints, and problem reports from consumers, health care professionals, and industry stakeholders

Medical devices, like all health products, have benefits and risks. In addition to reducing risks to the maximum extent possible, the licensing system helps to ensure that benefits outweigh the risks.

What Can Happen in Cases of Non-Compliance

In cases of non-compliance, the government takes action against the distributor based on the level of risk posed.

For example, Health Canada may:

- 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

Distributors can be suspended, their products cancelled, and their business licenses can be revoked in the most severe cases. Additionally, the distribution company may be prosecuted. (2)

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.

Content is current as of the date of broadcast and is subject to change without notice.

Sources:

1. https://www.emergobyul.com/resources/market-canada
2. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/about-medical-devices.html