Medical Device Distributors: Medical Supplies, PPE, Defibrillators, Diagnostic Machines

March 9, 2021

Over the last year, the Canadian healthcare industry has had to quickly pivot as the provincial governments called for greater manufacturing capacity to meet the urgent lack of personal protective equipment (PPE) and medical equipment. Companies across the country have innovated to fill in the gaps in medical supplies and PPE: brewing companies have shifted production to hand sanitizer; clothing brands have converted their manufacturing plants to make masks, gowns, and scrubs; while other companies have employed 3D-printing technology to make face shields.

Meanwhile, the Minister of Health issued an interim order for Health Canada to issue expedited authorizations for the sale of medical devices. In addition, the Department of Public Works and Government Services has published specifications for specific COVID-19 medical devices or products on its website. The Federal Government has also pledged $2 billion to purchase medical supplies and PPE and the Ontario Government has committed $50 million to Ontario companies to shift their manufacturing operations to COVID-related products and supplies.

The COVID-19 pandemic has challenged Canada's medical device distributors in unprecedented ways, and it won't be the last time the healthcare sector will be forced to adapt. That is why medical device suppliers should only rely on insurers with deep expertise in healthcare. If you are a broker looking to represent medical device distributors, MedThree Insurance can help.

Overview of Canada's Medical Device Industry

In Canada, medical devices are regulated under the Food and Drugs Act as a Class I, II, III, or IV. Class I represents devices that present the lowest risk and Class IV the highest. The Food and Drugs Act provides a definition of a regulated medical device.

Examples of medical devices include:

- Pacemakers
- artificial heart valves
- diagnostic and imaging equipment
- in-vitro diagnostics

- dialysis equipment
- hip and knee implants
- synthetic skin
- surgical tools
- infusion pumps
- life support machines
- catheters
- bandages
- some information and communications technologies.

In 2017, the key business segments of the global medical device market were:

- diagnostic imaging, such as MRI and CT-scan (24% of the world market)
- consumables (16%)
- patient aids (such as hearing aids and pacemakers) (13%)
- orthopedic products (12%)
- dental products (8%), and
- other medical equipment (28%). (1)

Firms in the medical device sector are highly R&D intensive, technology-based, and driven to continually innovate through developing new products and enhancing features on old ones. Further, medical device products are becoming increasingly complex with the inclusion of multiple technologies into a given product. Technologies such as advanced materials, microelectronics, biotechnology, and software and informatics are now routine technologies featured in medical devices.

Safety of Medical Devices After Licensing

Medical devices need to be re-evaluated as important new information about the safety, effectiveness, and quality of a device may need to be (re)considered. As such, medical devices licensed in Canada are monitored for their ongoing safety, effectiveness, and quality in various ways. Health Canada watches for any changes to the expected benefits and risks of licensed medical devices by assessing:

- scientific literature;
- reports of medical device problems;
- information shared by international regulators;
- input from health care professionals and users;
- information that we have requested from the manufacturer; and
- other relevant information that becomes available. (2)

Consumers are also encouraged to report problems with medical devices, including the sale of unauthorized devices, even if they're uncertain of all the specific details needed.

When a safety issue related to the use of a medical device arises, Health Canada takes appropriate action, which might include:

- informing health care professionals and consumers about complaints;
- requiring the manufacturer to update the device's design or label;
- restricting the use of a device for people who are considered to be at higher risk; and
- stopping the sale of the medical device.

Medical device suppliers could be named in lawsuits where a medical device or product is found to be faulty or harmful.

The MedThree Advantage

If you are a broker looking for tailored coverage and advice for medical device suppliers, MedThree Insurance can help. Our deep expertise in underwriting Canada's healthcare sector makes it easy for brokers to find the right coverage their clients need to safeguard their organizations. Visit our website to learn more about our tailored insurance products.

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Sources:

1. https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html
2. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/about-medical-devices.html