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The Importance of working with Health Canada Certified Vendors

Purpose of This Memo

From time to time, HMEDA receives inquiries from our members and prescribers asking how durable home medical devices are treated under the Health Canada Act. The purpose of this memo is to provide an overview and some guidance on this topic.

Medical device prescribers and Home medical equipment dealers have a responsibility to ensure equipment they recommend and provide is in conformance with Health Canada rules. This memo will help you understand the steps needed in meeting this responsibility.

What is a Medical Device?

The term "medical device" covers a wide range of products used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Some examples include pacemakers, artificial heart valves, hip implants, synthetic skin, medical laboratory diagnostic instruments, test kits for diagnosis and contraceptive devices.

Durable medical products such as wheelchairs and hospital beds (to name a few) fall under the term “medical device” in Canada and fall under Health Canada legislation.

What is required to manufacture, distribute and/or sell a medical device in Canada?

There are two types of licences issued by Health Canada for medical devices sold in Canada. The first is a licence for the actual device itself, called a Medical Device Licence (MDL). The second licence type is needed for the establishment (company) who manufactures and/or distributes these devices. The establishment licence is called a Medical Device Establishment Licence (MDEL).

When do you need a medical device license (MDL)?

An MDL is issued to the manufacturer of class II, III, or IV devices by the Medical Devices Bureau (MDB) of the Therapeutics Products Directorate based on review of scientific evidence for quality, safety and efficacy. For information on medical device licences, please contact the MDB:

- E-mail: device_licensing@hc-sc.gc.ca
- Telephone: (613) 957-7285
- Fax: (613) 957-6345

In Canada, certain devices must have a Medical Device Licence before they can be sold. To determine which need a Licence, medical devices have been categorized based on risks associated with their use. This approach

means that all medical devices are grouped into four classes with Class I devices presenting the lowest potential risk (e.g. a thermometer) and Class IV devices presenting the greatest potential risk (e.g. pacemakers).

Prior to selling a medical device in Canada, manufacturers of Class II, III and IV devices must obtain a Medical Device Licence. Although Class I devices do not require a Licence, they are monitored through Medical Device Establishment Licences (MDEL).

When do you need a Medical Device Establishment Licence (MDEL)?

A Medical Device Establishment Licence is separate from a Medical Device Licence and is issued for the activities of manufacturing, importing and/or distributing medical devices for human use in Canada. A MDEL is issued by the Inspectorate based on an establishment certifying that they meet certain requirements and are then inspected for compliance.

Medical device manufacturers and distributors must have a MDEL license to import/sell Class II, III and IV devices in Canada. If a manufacturer or distributor wishes to sell a class I device that does not have a MDL, that manufacturer or distributor must have a MDEL license.

Classes of Health Canada Certified Products

The *Medical Devices Regulations* (Regulations) utilize a risk-based approach to regulating products within its scope. The safety and effectiveness evidence required to support a medical device licence application is proportional to the risk of the device, which is determined by applying the Classification Rules for Medical Devices detailed in Schedule 1 of the Regulations.

The Medical Devices Regulations separate medical devices into the following 4 risk categories:

1. Class I: Low risk devices such as wound care and non-surgically invasive devices.
2. Class II: Low-to-medium risk devices including contact lenses and the majority of surgically invasive devices (e.g., surgical gloves, needles, magnetic resonance imaging equipment).
3. Class III: Medium-to-high risk devices such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, and surgically invasive devices that are intended to be absorbed into the body or that are intended to remain in the body for at least 30 consecutive days.
4. Class IV: High-risk devices such as pacemakers and surgically invasive devices that diagnose, control, or correct a defect in the central cardiovascular system. The device manufacturer, importer, or distributor is responsible for classifying the device.

Nearly all medical devices retailed by HMEDA members generally fall into class I. For most HMEDA members, the only class II devices they are likely to sell will be air flotation and/or alternating pressure mattresses. **When a retailor sells a device to an end-user, that retailor will not require a MDEL. When a manufacturer or distributor sells a Class I device to a retailor, that manufacturer or distributor must have a MDEL.**

Many manufacturers of Class I devices in Canada will have a MDL for each device they manufacture, thereby allowing retailors to provide these products to end-users without the retailor needing a MDEL:

- Class I medical device examples
    - Wheelchairs (stroller, adaptive, mechanical, powered, stand-up) & wheelchair seating
    - Hospital beds (ac-powered adjustable hospital, pediatric open)
    - Mattresses (non-powered flotation therapy)
    - Cushion, flotation; pad, pressure, gel

    - Walker, mechanical
    - Canes
    - Slings (overhead suspension, wheelchair)
    - Standers

- Class 2 medical devices examples
    - Mattress, air flotation, alternating pressure

For Class II devices, manufactures must have a MDL for each device. Manufactures and distributors must have a MDEL when supplying these devices to retailors who provide the products to end-users.

Why is this important for Prescribers?

Prescribers need to ensure the equipment they are prescribing and the companies providing these products meet all Health Canada requirements. Many medical device products falling under Class I and all products falling under Class II will have a MDL.

If you find yourself working with a Class I product that does not have a MDL, it can be provided so long as the product manufacturer or distributor has a MDEL.

Health Canada licencing is in-place primarily to protect the public. When dealing with an unlicensed product or vendor, there may be other added risks such as a lack of product liability insurance, the product may not be CSA approved, a mobility product may not have been crash tested, or a bed product might not meet Canadian Bed Manufacturing standards.

Is the product manufacturer/distributor covered by General Product Liability Insurance

When providing General Product Liability Coverage, insurers will normally confirm the manufacturer/distributor can supply evidence the product has a MDL for products and/or MDEL for distributors.

When in doubt, ask the supplier to provide a copy of their General Product Liability Coverage. If proof of coverage can be attained, the companies and products are likely in compliance with Health Canada requirements.

Other product quality standards you may want to consider

In Addition to Health Canada legislation, here is a list of other standards that must be adhered too:

- Equipment must have been in the North American market for a minimum of one year (Alberta only)
- Manufacturer must carry a minimum two+ million dollars in comprehensive general liability insurance
- Materials must meet the CA 117 Fire Retardancy Standard
- RESNA ISO Standards are available for wheelchairs and some other mobility products
- Testing at Provincial centres such as Ottawa Rehab in Ontario
- Children's in Alberta to be approved for funding
- Canadian Bed Manufacturing standards
- Engineering specs and testing results required before funding approval by some Provincial Programs
- Insurance liability certificates required to 10 million + in some cases

- Crash testing required on Mobility products with Test results
- Engineering Specs required on some approvals

Resources

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/annual-review-documents/frequently-asked-questions-medical-device-establishment-licensing-fees.html#a1

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-medical-device-establishment-licensing-medical-device-establishment-licence-fees-guide-0016.html

Find a Medical Device Licence number, Active or Inactive Licences
https://health-products.canada.ca/mdall-limh/index-eng.jsp

Find a Medical Device Establishment, Active or Inactive
https://health-products.canada.ca/mdel-leim/index-eng.jsp