Dear HMEDA Member

RE: HEALTH CANADA MEDICAL DEVICE ESTABLISHMENT LICENSE (MDEL)

A number of HMEDA members attended the recent Health Canada Medical Devices roadshow held recently in Coquitlam. As a service to all members, Darryl Mackie (SelfCare Home Health Products) has summarized some of the more important points coming out of the roadshow. Note that this communication is only for informational purposes and not to be construed as advice on any particular Member’s situation; each Member must undertake their own measures to ensure that they are in compliance with the legislation and regulations covering medical devices.

What Are Medical Devices?

Medical devices are used in the diagnosis, treatment, mitigation or prevention of a medical condition. They include a vast range of equipment, from a cane, crutch or tongue depressor to highly sophisticated magnetic resonance imaging (MRI) machines or robotically assisted surgical equipment. Not everything that a typical HMEDA member sells will be deemed to be a medical device by Health Canada, however, a significant proportion of durable medical equipment is used in the treatment and mitigation of medical conditions.

How Are Medical Devices Classified?

Medical devices are classified according to a number of rules. The rules can be grouped into four sets:

- invasive devices
- non-invasive devices
- active devices
- special rules
If a device can be categorized under more than one rule, the classification of highest risk applies.

Class I devices are exempt from device-licensing requirements; manufacturers are required to obtain an establishment licence if they import or distribute through an entity that does not already hold a licence. The manufacturer is required to confirm that the facility has documented procedures for the distribution of records, as well as the handling of complaints and product recalls.

Class II, III and IV devices require a medical-device licence from Health Canada prior to being imported, sold or advertised for sale. It is the responsibility of the manufacturer or importer to obtain this license. Unlicensed Class II, III and IV products cannot be offered for sale in Canada.

**Information Sources on Classification of Medical Devices**

On the Health Canada website you may look up, by keyword search, various medical devices to determine which, if any, class they fall into. This is a tool provided by Health Canada to assist manufacturers in determining the Class of product that they are proposing to market in Canada; it does not take the place of the risk based assessment procedures required by the legislation.

The keyword search is found by going to the Health Canada website home page and typing “keyword medical device” into the search field. The search will bring you to a list of documents – select the document entitled “Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices”, this will bring you to a PDF document which is searchable by product type.

**MDEL – Does My Company Need One?**

The short answer, for most members of HMEDA is yes, an MDEL is required if the company is selling Class I devices to a healthcare facility or to a third party funder that retains ownership of the device for subsequent distribution to another end user (such as MCFD and the Red Cross operated CMERLS). If the HMEDA member is only selling Class I devices as a retailer then a MDEL is not required. Following is an excerpt from the Health Canada website:

**2.0 Legislated Requirements**

Any person who imports into Canada, or sells in Canada, a medical device for human use requires an establishment licence with the exception of

- a retailer
- a healthcare facility,
- a manufacturer of Class II, III or IV medical devices that only sells:
  - medical devices for which they hold a valid licence,
  or
medical devices subject to Parts 2 and 3 of the Regulations,
- a manufacturer of a Class 1 medical devices who imports or distributes solely through a licensed establishment,
- a person solely selling medical devices subject to Parts 2 and 3 of the Regulations
- a dispenser.

For manufacturers who are also involved in sales of other medical devices (for which they are not the manufacturer), the MDEL requirements are as follows:

a. If they are involved in any distribution activities, such as sales to healthcare facilities, they are acting as a distributor for these other medical devices and require a MDEL for these activities. If they are solely selling these medical devices to consumers for their own use, and not for resale, the establishment is a retailer of these other medical devices and are exempt from the MDEL requirements.

b. Manufacturers of Class I medical devices who sell their devices solely to individual members of the general public for their own use do not require a MDEL. As indicated above retailers are exempt from holding an establishment licence.

c. For persons who provide medical devices to consumers for their own use but are paid by a third party, such as a health insurer, the following applies.
   1. If the consumer becomes the owner of the medical device, the person is considered a retailer for this activity and does not require a MDEL.
   2. If the consumers does not become the owner of the medical device, because the third party retains ownership of the device (i.e. the third party retains the right to recover the device from a user and provide it to other users), the person providing the medical device to the third party is acting as a distributor and requires a MDEL.

d. The person that sells to re-sellers is not a retailer.

e. A site is a building in where one or more of the procedures attested to are in place and where activities listed for the primary licence address are conducted. If there no additional sites, the primary licence address should be listed.

**MDEL – Fees and Remission**

MDEL fees are now $7200 per annum. The fees are payable in respect of the regulated activities of the license holder. If the license holder’s revenues from the distribution of Class I products (excluding retail sales) is less than $720,000 then the license applicant will qualify for a remission of the MDEL fees. There are some important points to note about this:

1. For calculation one uses the gross revenues from the license activities of the prior calendar year. For the application due April 1, 2012 the calendar year used will depend
upon the date the application is made; if made prior to Dec. 31, 2011 one uses the revenues from the year ended Dec. 31, 2010; if the application is made in 2012, then one uses the revenues from the year ended Dec. 31, 2011.

2. The application must be accompanied by a certification of the company’s responsible financial officer, along with supporting documents

3. Health Canada reserves the right to request a 3rd party audit of the revenue amounts – the cost of audit to be borne by the license holder.

Fees can be paid by cheque, Visa, Mastercard, American Express or by wire transfer. There is a document “How to Pay Fees” which contains a form to fill out if paying by credit card. The URL is:


**MDEL – Expect an Audit**

Your MDEL application requires you to provide attestations on the documented procedures in respect of distribution records, complaint handling, and recalls (for all holders of MDEL). In addition if the holder of the MDEL is an importer, documented procedures in respect to mandatory problem reporting. This is all in relation to Class I devices.

If the establishment is an importer or distributor of Class II, III or IV devices there must also be documented procedures for the following:

- Handling, storage and delivery
- Installation
- Corrective action
- Servicing

The attestation is not a mere formality. Part of the rationale behind the increase in the MDEL fees to $7200 is that Health Canada, through the Inspectorate branch, will be able to conduct more frequent field audits of all license holders. Auditors will determine the adequacy of the documentation and efficacy of the procedures in place.

**MDEL – More Information**

The Health Canada website has all the information that you will need although it is not organized in a very logical, user friendly fashion. A good initial source is the MDEL Application form and Guidance document found at the following URL:


In addition, CADA has prepared a summary document found at the following URL:

http://www.cadaonline.ca/pdf/ppt_health_canada_MDEL.pdf