Archived Content

Health Canada Santé Canada

Therapeutic Products Directorate
Holland Cross, Tower "B"
6th Floor, 1600 Scott Street
Address Locator # 3106B
OTTAWA, Ontario
K1A 0K9

January 25, 2006

06-101090-24

To: Canadian Provincial and Territorial Dental Associations, Dental Regulators, Dental Technicians, Denturists

Subject: Purchase of Licensed Medical Devices for Use in Dental Health Care

This letter is being sent to remind dental health care practitioners that many types of medical devices used to deliver dental care to patients must comply with Canadian *Medical Devices Regulations*.

Many types of medical devices require authorization by Health Canada (by way of a device licence) before they can legally be sold in Canada. The *Medical Devices Regulations* prohibit dental laboratories or dental health care practitioners from importing certain types of medical devices (i.e., Class II, III and IV devices) that are not licensed in Canada. Dental tools, including dental instruments and equipment, dental restoratives and dentures are considered to be medical devices.

The purpose of the 1998 *Medical Devices Regulations* is to improve the safety, effectiveness and quality of medical devices sold in Canada and to bring Canada's regulations in line with those of our major trading partners. An important feature of the regulations was the establishment of device classes and requirements for manufacturers, importers and distributors to obtain appropriate authorization prior to sale of medical devices in Canada.

We ask you to ensure that dental health care staff who have responsibility to purchase medical devices have a good understanding of the requirements of the *Medical Devices Regulations*. Informing staff of regulatory requirements will help to assure that your health care practice complies with all applicable requirements. To assist you, an overview of the requirements of the Medical Devices Regulations is enclosed.

.../2

Specifically, Section 26 of the *Regulations* prohibits the importation and sale, including offering for sale by way of advertisement of a Class II, III or IV medical device, unless the manufacturer of the device holds a medical device licence. Health Canada advises that medical devices that are not licensed for sale in Canada should not be purchased by health care practitioners. Recently, Health Canada has been made aware that some manufacturers may be advertising a device for sale prior to obtaining a medical device licence and that manufacturers may have been informing health care practitioners that the *Regulations* permit them to do so provided they have submitted a device licence application to Health Canada. Please be advised that this is not correct and that advertising a Class II, III or IV medical device for sale prior to obtaining a medical device licence is prohibited. It is strongly suggested that health care practitioners not enter into any contractual agreements with manufacturers to purchase medical devices until they have confirmed that a device licence has been obtained by the manufacturer.

Information on licensed devices can be obtained from the Medical Devices Active Licence Listing (MDALL) available on the Health Canada website at **www.mdall.ca**. This website has been recently enhanced to include a licence history archive. This archive displays devices that were previously licensed for sale but no longer have a valid medical device licence. Further information on the licensing requirements of the *Medical Devices Regulations* may be obtained from:

Manager, Device Licensing Services Division
Medical Devices Bureau
Tel: (613) 957-7285
Fax: (613) 957-6345
Email: mdb_enquiries@hc-sc.gc.ca

Health Canada depends on health care professionals to report adverse incidents related to medical devices. Any serious or unexpected adverse incident related to medical devices should be reported to Health Canada at the following address:

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline 1-800-267-9675

The **Medical Devices Problem Reporting Form** can be found at:
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm_e.html

Yours sincerely

Original signed by

Omer Boudreau,
Director General

Enclosure

Overview: Medical Devices Regulations

Classes of Medical Devices

All medical devices are classified into four classes. There are two separate classification systems, one for in vitro diagnostics and one for all other devices. Class I represents the lowest risk class, and Class IV the highest.

Class I non-in-vitro devices include, among other types, those that make only non-invasive contact with the patient and do not transmit energy to the patient. Classes II, III and IV include devices of increasingly higher risk as determined by such factors as their degree of invasiveness, the hazards of energy transmission, and the potential consequences to the patient in case of device malfunction or failure.

Authorizations to Sell

In Canada, there are three mechanisms by which medical devices can be legally sold: Device Licensing; Investigational Testing; and Special Access.

Licensing Requirements

For the purposes of general marketing, all Class II, III, and IV medical devices sold in Canada after July 1, 1998, must have a valid Medical Device Licence issued by the Therapeutic Products Directorate of Health Canada before they may be sold. Class I devices, because of their relatively low risk, do not require a device licence. Medical devices which were legally sold in accordance with the *Medical Devices Regulations* prior to July 1, 1998, did not require a licence.

Medical Devices for Investigational Testing Involving Human Subjects

Where the safety and effectiveness of a medical device has not been fully established, and the medical device is therefore not yet ready for general marketing, manufacturers can apply for and obtain authorization to conduct Investigational Testing in Canada. This requirement applies to all Class II, III and IV medical devices.

Medical Devices to be Imported or Sold for Special Access

Special access refers to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable. Where a medical device has not received authorization for general marketing through the device licensing requirements, a health care professional can apply to Health Canada for authorization that would permit a manufacturer or importer to sell the device for use by that professional.

Responsibilities of Manufacturers, Importers and Distributors

A manufacturer must obtain a licence before importing, advertising or selling any Class II, III, or IV device for general marketing. A distributor or importer of medical devices cannot legally sell an unlicensed device.

Additionally, importers and distributors of medical devices are required to obtain an Establishment Licence from Health Canada to ensure that proper distribution records are kept and complaint handling, mandatory problem reporting and recall procedures are in place. Note that medical devices sold by foreign manufacturers directly to health care facilities are also required to have a valid Canadian Medical Device Licence.

Health Care Facilities

The Regulations prohibit the sale in Canada, or the importation into Canada, of a medical device unless the manufacturer of the device has obtained a device licence, Investigational Testing authorization, or authorization to sell under the Special Access provisions.

It is the manufacturer's responsibility to ensure that the medical devices they sell are properly authorized. However, a hospital who directly imports an unauthorized medical device is in contravention of the Regulations.

Health Canada strongly advises that health care facilities verify that all Class II, III, and IV devices have valid licences before entering into a contractual arrangement, purchases or using them. Manufacturers, importers or distributors can provide you with copies of the licence issued to the manufacturer by Health Canada.

Directions for Use and Performance Specifications

All medical devices are required to have information related to the device's performance specifications and directions to use it in the manner it was intended by the manufacturer. Health Canada has reviewed this information for Class III and IV medical devices, and in part, forms the basis of granting authorization to sell the device. It is extremely important to remind users of medical devices to follow manufacturer's instructions for use to ensure that the device will be used in a safe and effective manner, and to minimize risk of harm to either the user or patient.

The Register of Licensed Medical Devices

The Therapeutic Products Directorate maintains a searchable list of all licensed medical devices on its Internet web site at:

www.mdall.ca

This website has been enhanced to allow healthcare facilities to search devices that have an active Medical Device Licence or were previously licensed at one time. This objective is to expand the search capability to include previously licensed devices. To implement this feature a new window was designed to prompt for a search mode: Search Active Licences or Search Archived Licences. The Issue Date of the previous version of MDALL is replaced with the First Licence Date field to indicate when a product was initially authorized for sale. It is available at the Licence, Device and Device Identifier level.

Health care facilities contemplating the purchase of a Class II, III or IV device should use this list to verify that the manufacturer has a valid licence. As medical device licences can be suspended by Health Canada, cancelled during the annual renewal of licences by Health Canada, or discontinued by the manufacturer, it is important to conduct this verification each time the purchase of a medical device is considered.

Further Information

Further information on licensed devices or the licensing requirements of the *Medical Devices Regulations* may be obtained from:

Manager, Device Licensing Services Division
Medical Devices Bureau
Tel: 613-957-7285
Fax: 613-957-6345
Email: mdb_enquiries@hc-sc.gc.ca