Health Canada Santé Canada

November 9, 2010

Notice

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Electronic Labelling (e-labelling) of certain medical devices sold or imported into Canada

This Notice is intended to provide the Therapeutic Product Directorate's (TPD) interpretation of the *Medical Devices Regulations* (*Regulations*) with respect to electronic labelling (e-labelling) of certain medical devices sold or imported into Canada.

The scope of this Notice is only for devices that are **not sold to the general public**. The following definitions, as stated in the *Regulations*, apply:

> "directions for use" means full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects.
>
> "near patient *in vitro* diagnostic device" or "near patient IVDD" means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside.

The labelling requirements for medical devices are contained in sections 21 through 23 of the *Regulations*. These sections stipulate that no person shall import or sell a medical device unless the medical device has a label, and they establish the content of such labels, including the language in which the labels must be presented. In particular, section 21(2) of the *Regulations* requires that label information be expressed in a legible, permanent and prominent manner.

For the purposes of this Notice, e-labelling refers to the information required by section 21(1) of the *Regulations* that would ordinarily be found in the directions for use. The directions for use may include a surgeon's instruction manual, operator's manual, or user's manual. At this time, the only acceptable electronic media in which to present information to satisfy the labelling requirements of section 21(2) of the *Regulations* are those described below.

Electronic labelling may be provided on Compact Disc (CD) or Digital Video Disc (DVD), accompanying the device at the time of sale and/or delivery, for devices that are not sold to the general public. The CD/DVD must be packaged with or accompany the device in a manner that alerts the user to its purpose. The information provided on CD/DVD should be easily navigable.

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For the following two categories of devices that are not sold to the general public, this information may, in the alternative, be provided in downloadable format from the internet: Class IV medical devices and *in vitro* diagnostic devices (IVDDs) that do **not** fall within the definition of near patient IVDD. The internet address must accompany these devices at the time of sale and/or delivery, and be displayed in a manner that alerts the user to its purpose. The information provided via internet should be easily navigable.

Manufacturers should ensure that the labelling information provided in electronic format is identical in content to the paper format submitted with the device licence application. A sample Letter of Attestation is provided.

Sample Letter of Attestation

[Manufacturer's Letterhead]

I, as a senior official of the manufacturer, [name of manufacturer], attest that the information contained in the directions for use for [name of the device] matches the information contained in the paper copy. No information has been added, removed or changed.

Title:

Signed:

Upon request, a paper copy of the label information should be provided promptly to the user, without additional cost.

Since this Notice is permissive in nature, it is effective immediately. Please direct any questions or comments regarding the content of this Notice to the following:

Device Licensing Services Division
Medical Devices Bureau
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