APPROVAL OF MEDICAL DEVICES IN CANADA

In Canada, medical devices are regulated by Health Canada's Therapeutic Products Directorate ("TPD") and are subject to the *Medical Devices Regulations* under the *Food and Drugs Act*. The goal of the *Medical Devices Regulations* ("Regulations") is to ensure, to the extent possible, that devices offered for sale in Canada are safe, effective, and meet quality standards. The Regulations apply to the sale and advertising for sale of a medical device, and the importation of a medical device for sale or for use on individuals, other than importation for personal use.

The term "medical device" includes any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, (b) restoring, correcting or modifying a body function or the body structure, (c) the diagnosis of pregnancy, or (d) the care of human beings during pregnancy and at and after birth.

Device Classification

Medical devices are classified into one of four classes, based on the risks associated with their use, including the degree of invasiveness, duration of contact with the patient, energy transmission hazard, and consequences of device malfunction or failure. The four classes are very similar to the four classes of devices in the EU Medical Device Directive. Although the device manufacturer, importer or distributor is responsible for classifying the device, classification is subject to verification by Health Canada. The Regulations provide a series of sixteen rules to be applied to correctly classify devices. Where a medical device can be classified into more than one class, the highest class applies.

The four classes of devices are:

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Class I: these devices present the lowest potential risk and do not require a licence. Examples of class I devices include reusable surgical instruments, cell culture media, bandages, toothbrushes, and hospital beds.

Class II: these are low-to-medium risk devices. Examples include magnetic resonance imaging equipment, single-use surgical instruments, catheters, contact lenses, blood pressure monitors, condoms, tampons, and pregnancy test kits.

Class III: these are medium-to-high risk devices, such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, ventilators, cardiac monitors, lasers, 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 thirty consecutive days.

Class IV: these are high-risk devices, such as pacemakers, defibrillators, coronary stents, and other surgically invasive devices that diagnose, control, or correct a defect in the central cardiovascular system. Many of the devices in Class IV would result in serious deterioration of health or death of the patient or operator if they were to fail. Also included in the class are HIV test kits.

Licensing

Most medical devices must have a licence before they can be advertised or sold in Canada.

Class I devices are not subject to any regulatory review and are exempt from device licensing requirements. However, Health Canada requires manufacturers of

class I devices that do not sell through an establishment already holding a licence, as well as importers and distributors of any medical devices for human use, to obtain an **establishment licence** to import, sell or advertise a class I device in Canada. This requirement applies to organizations located in Canada and abroad. Establishment licencing ensures that the TPD is aware of the identity of establishments that are selling or manufacturing devices. In addition, it requires establishments to provide assurances that appropriate recall, problem-solving and complaint-handling procedures have been established and that proper distribution records are maintained.

Class II, III and IV devices require a medical device licence from Health Canada before they can be imported, sold or advertised for sale. All class II, III and IV medical device applications are submitted to the Medical Devices Bureau at the TPD. They undergo an administrative review and application validation. Class III and class IV devices also undergo a technical review.

The basic information required for most applications is the same, namely: name, class, and identifier of the device; name and address of manufacturer; description of the device and its features; a list of the countries other than Canada where the device has been sold, and quantities sold; and a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted. Information requirements increase as the risk level of a device increases.

Applications for class II devices must be accompanied by the attestation of a senior official of the manufacturer confirming that the manufacturer has objective evidence that the device meets the safety and effectiveness requirements and labelling requirements set out in the Regulations.

Class III and IV devices present a greater potential for risk and are therefore subject to greater information requirements and in-depth regulatory scrutiny before licensing and sale. For class III devices, in addition to the basic identification information, the manufacturer must submit a summary of all studies on which it relies to ensure the device meets safety and effectiveness requirements. For class IV devices, the manufacturer must provide: a quality plan specifying quality practices and resources; specifications of the materials used in the manufacturing and packaging of the device; a description of the device's manufacturing process; a list of the standards that have been complied with in the design and manufacture of the device, particularly in regard to safety and effectiveness; evidence from pre-clinical and clinical studies of the device; literature studies relating to the device; and objective evidence of the biological safety of the device.

Manufacturers of class II, III and IV devices must also demonstrate that their devices are manufactured in accordance with internationally recognized quality management system standard for medical devices: ISO 13485:2003 Medical devices - Quality management systems – System requirements for regulatory purposes.

If the information provided in the application meets the requirements of the Regulations and all applicable fees have been paid, a licence will be issued. If TPD decides not to issue a medical device licence, the manufacturer has the opportunity to re-submit the application and supply additional information or to appeal TPD's decision.

Records and Safety Reporting

Manufacturers are required to maintain distribu-

tion records with respect to each medical device. Manufacturers are also required to maintain records of complaints or reported problems regarding the performance characteristics or safety of a device. The manufacturer is required to submit information to Health Canada regarding any (i) failure of the device, (ii) deterioration in its effectiveness, or (iii) inadequacy of labelling or in directions for use of the device, that results in the death or serious health deterioration of a patient, user or other person, or that could do so should the incident recur.

For an event that occurs in Canada, the information must be submitted within ten days after the manufacturer becomes aware of the incident if it results in death or serious deterioration in health. For events that have not led to death or a serious deterioration in health, but could do so should the event recur, the manufacturer has thirty days to report the incident to Health Canada. For an incident that occurs outside Canada, the manufacturer must report the information to Health Canada as soon as possible after the manufacturer has indicated to the appropriate regulatory agency the corrective action that it intends to take.

If a medical device is found to no longer be safe and effective, its licence can be suspended or the manufacturer may be requested to recall or refit the medical device.

Investigational Testing and Special Access Programme

Medical devices that are sold for investigational testing or for custom or special access purposes are the only exceptions to the stipulation in the Regulations that all medical devices sold in Canada must meet the safety and effectiveness requirements set out in the Regulations.

Provided that all required records and documentation are kept, class I devices do not need approval for investigational testing. However, an application for investigational testing must be submitted to Health Canada for class II, III, and IV devices. After successful investigational testing of the device, the manufacturer, importer or distributor must apply for a device licence in order to sell, advertise or import the device into Canada.

Under Health Canada's Special Access Programme (SAP), devices that are not otherwise approved for sale in Canada (and some custom-made devices) can be granted an exception for ‘‘emergency use or when conventional therapies have failed, are unavailable or are unsuitable to treat a patient’’. SAP device requests are generally made by a healthcare professional on behalf of a specific individual. Health Canada must still approve the applications for authorization prior to importation or use of the device in Canada.

Device Portal
1280 Finch Avenue West, 308
Toronto, Ontario
M3J 3K6
Direct: 888 647 9928
Email: info@deviceportal.ca