

HEALTH CANADA'S MEDICAL DEVICE REGULATIONS

Health Canada

The Canadian Medical Devices Regulations set out the requirements governing the sale, importation and advertisement of medical devices. The Regulations ensure that medical devices distributed in Canada are safe and effective. Medical Device manufacturers, importers and distributors are responsible for ensuring that the medical devices they sell in Canada are compliant with the Medical Devices Regulations. In July, 1998, new Medical Devices Regulations were implemented in Canada to improve the safety 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 new regulations was the establishment of device classes and licensing requirements.

CLASSES OF MEDICAL DEVICES

The Regulations define four classes of medical devices. Class I is the lowest risk class, and Class IV is the highest. Class I devices include, for example, 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.

All Class II, III and IV medical devices sold in Canada must have a valid Medical

Device Licence issued by Health Canada before they may be imported or sold. Class I devices do not require a licence.

RESPONSIBILITIES OF MANUFACTURERS AND DISTRIBUTORS

All manufacturers must obtain a device licence before importing, advertising or selling any Class II, III or IV device. Manufacturers of Class I devices must also hold an Establishment Licence unless they import or sell through a person who holds an Establishment Licence. Importers and distributors of all classes of medical devices are required to obtain an Establishment Licence in order to import or sell medical devices in Canada. Device and establishment licensing provides a framework for the sale of safe and effective medical devices in Canada.

Health Canada recommends that when dealing with importers and distributors of medical devices, hospitals ask to see a copy of the Establishment Licence (where Class I devices are involved) or the Device Licence (for Class II, III or IV devices) issued to them by Health Canada. They should not buy from those who do not, and should advise Health Canada if they encounter an unlicensed distributor or device.

WHY IS IT IMPORTANT TO REPORT DEVICE PROBLEMS TO HEALTH CANADA?

Medical device problem reporting is an essential element in the continued efforts of Health Canada to protect the health and safety of Canadians. Manufacturers and importers are required by the Regulations to report medical device problems. Health Canada encourages anyone purchasing, using or maintaining these products to do so as well. Failure to notify the manufacturer and Health Canada could place patients at risk.

Health Canada investigates problem reports in cooperation with users, manufacturers and its own laboratories. It has a range of options for regulatory action to assure that problems are addressed and similar problems prevented. The outcome may involve issuance of a warning or Medical Device Advisory to users, product modifications, redesign, recalls, or improvements in directions for use. In general, medical device problem reporting leads to an increased level of device safety, effectiveness and quality.

Problem reports may be submitted using the Health Products and Food Branch Inspectorate website problem report form or you may call our toll-free number.

WHAT TYPES OF PROBLEMS SHOULD BE REPORTED?

Any concerns that relate to the safety, effectiveness or quality of a medical device that have been detected during use, testing or other device examination should be reported. The problems include deficiencies in the design of the device, defects arising from

the manufacturing and inadequacy or errors in labeling such as directions for use.

WHAT ARE THE BENEFITS OF REPORTING INCIDENTS?

The HPFBI acts as a central clearing house for problem report data, and can link isolated reports to identify problems that would otherwise go unnoticed or be dismissed as an isolated incident. Once assessed by the manufacturer in consultation with the HPFBI, all affected facilities and professionals can be promptly informed of the situation and required actions. In addition, the HPFBI:

- ! monitors the manufacturer's investigation and steps taken to correct the problem to ensure they are adequate to establish the safety and effectiveness of the device;
- ! provides assistance from scientific, medical and engineering staff to identify the cause of problems and possible solutions, which may include testing of devices; and
- ! provides access to Health Canada's expertise in risk identification and management.

**Inspectorate Number:
1-800-267-9675**

**Inspectorate website:
www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate**

**TPD website:
www.hc-sc.gc.ca/hpb-dgps/therapeut**