

MEDICAL DEVICES REGULATIONS OVERVIEW

Life Sciences British Columbia NRC-Industry Research Assistance Program

Health Canada Regulations on Medical Devices

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Nancy Shadeed
A/Manager, Device Licensing Division
Medical Devices Bureau (MDB)
Therapeutic Products Directorate (TPD)

GOALS OF THE REGULATORY SYSTEM IN CANADA

- Risk based approach
- Post-market surveillance
- Global Harmonization
- International standards
- Quality systems approach
- Transparency and communication

DEFINITION OF A DEVICE

“DEVICE” means any article, instrument, apparatus of 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, in human beings or animals,
- b) Restoring, correcting or modifying a body function or the body structure of human beings or animals.

DEFINITION OF A DEVICE (CONT'D)

- c) The diagnosis of pregnancy in human beings or animals, or
- d) The care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.

“MEDICAL DEVICE” means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals

REGULATORY PROVISIONS:

- Health Canada regulates the manufacture and sale of medical devices in Canada
- The Food and Drugs Act and Medical Devices Regulations are the tools used to ensure that safe and effective devices are available
- Manufacturers of devices apply to Health Canada to receive either a Licence or an Authorization to sell their devices.

REGULATORY PROVISIONS: ESSENTIALS

- In general all devices offered for sale in Canada must comply with the Food and Drugs Act in that they:
 - cannot advertise or represent by label a treatment for a Schedule A disease or disorder;
 - Cannot sell or advertise a device that may cause harm; and
 - Cannot sell or advertise a device in a misleading or deceptive way.
- All medical devices (those used on human beings) must also comply with the Medical

REGULATORY PROVISIONS: ESSENTIALS

- A manufacturer in the Regulations:
 - Sells a medical device under their own name, trade-mark, design, trade name or other name owned or controlled by the person
 - Is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, assigning it a purpose
 - Performs or has someone perform on their behalf

Manufacturer = Name on the label

REGULATORY PROVISIONS: ESSENTIALS

- The Regulations apply to:
 - The sale and advertising for sale of a medical device
 - The importation of a medical device for sale or for use on individuals, other than importation for personal use
- The Regulations are divided into five Parts, with three Schedules attached

FOUNDATION OF THE MEDICAL DEVICES REGULATIONS

- Degree of pre-market scrutiny based on the risk of a device
- Balance of pre-market, post-market and quality system
- Harmonize as much as possible with the regulatory approach of Canada's international trading partners

PARTS AND SCHEDULES

- Interpretation “Definitions” (Section 1)
- Part 1 General (Sections 8-68)
- Part 2 Custom-Made Devices
and Medical Devices
Imported or Sold for
Special Access
to be (Sections 69-78)



PARTS AND SCHEDULES (CONT'D)

- Part 3 Medical Devices for Investigational Testing Involving Human Subjects (Sections 79-88)
- Part 4 Export Certificates (Sections 89-92)
- Part 5 Transitional Provisions (Sections 93-97)

PART 1 GENERAL (SECTIONS 8-68)

- Safety and Effectiveness Requirements
 - Sections 8-20
- Labelling Requirements
 - Sections 21-23
- Advertising Contraceptive Devices
 - Section 24

PART 1 GENERAL (SECTIONS 8-68)

- Class 1 Medical Devices
 - Section 25
- Class II, III and IV Medical Devices
 - Section 26-32
- Foreign Manufacturers – MRA
 - Section 33
- Amendments
 - Section 34



PART 2 CUSTOM AND SPECIAL ACCESS DEVICES

- Custom-made devices other than a mass-produced medical device, must:
 - Be manufactured in accordance with written instructions from a health care professional;
 - Differ from devices generally available from a dispenser; and,
 - Be for the sole use of a particular patient or professional
- Special access to devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable can also be

PART 2 CUSTOM AND SPECIAL ACCESS DEVICES

- Applications in a prescribed format must be received from a health care professional.
- Authorization for sale will be granted to the manufacturer of the device.
- Mandatory problem reporting still applies to these devices.

PART 3 INVESTIGATIONAL TESTING

- Grants the authorization to conduct clinical trials involving human subjects.
- Allows manufacturers to acquire evidence of effectiveness as required by Section 12 (Part 1) of the Regulations.
- Is applicable to *in vitro* diagnostic devices when:
 - effectiveness has not been adequately established for clinical use; or,
 - Additional evidence of safety and effectiveness can only be obtained using target populations.

PART 3 INVESTIGATIONAL TESTING

- Applications are received from the manufacturer, including a risk assessment and detailed protocol.
- Authorization for sale is granted to the manufacturer.
- Additional problem reporting requirement, to submit mandatory reports within 72 hours to the Bureau.

PART 3 INVESTIGATIONAL TESTING

- CLASS 1 Device
 - Manufacturer attestation of possession of required documents, no application required.
- CLASS II, III, and IV
 - Requires written authorization following successful application.
- SECTION 81
 - Detailed information required.