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The Canadian Special Access Program for Medical Devices

Health Canada regulates the safety, efficacy and quality of therapeutic products, including medical devices under the *Food and Drugs Act*. Before a medical device receives market authorization from Health Canada, access is usually limited to investigational testing involving human subjects, which is sponsored by a manufacturer and authorized by Health Canada through an investigational testing application. When an unlicensed medical device is not available in Canada through enrolment in investigational testing, Health Canada may authorize a health care professional's access to the device through its Special Access Program. This bulletin describes Canada's Special Access Program for medical devices, which is governed by Part 2 of the *Medical Devices Regulations made under the Food and Drugs Act*.

The Program

Class III or IV custom-made devices and Class II, III or IV medical devices that have not been approved for use in Canada require special access authorization from the Medical Devices Bureau of Health Canada before being imported or sold in Canada. A "custom-made device" is "*a medical device, other than a mass-produced medical device, that: (a) is manufactured in accordance with a health care professional's written direction giving its design characteristics; (b) differs from medical devices generally available for sale or from a dispenser; and (c) is (i) for the sole use of a particular patient of that professional, or (ii) for use by that professional to meet special needs arising in the course of his or*

her practice". Special access authorization is not required for the importation and sale of Class I and II custom-made devices; however, the special access labelling requirements must still be observed.

Canada's Special Access Program allows health care professionals to gain access to Class III or IV custom-made devices and Class II, III or IV medical devices that have not been approved for use in Canada on a narrow and discretionary basis. Health care professionals may access such devices for emergency use or if conventional therapies have failed, are unavailable, or are unsuitable to provide a diagnosis, treatment or prevention for patients under their care. "Health care professional" is defined as "a person who is entitled under the laws of a province to provide health services in the province". This broad definition enables a wide scope professionals to request a medical device for special access – not just physicians.

Application for Authorization

A health care professional is responsible for submitting a complete application for authorization to Health Canada under the Special Access Program. The information to be submitted includes, among other things:

- information about the device and its manufacturer or importer,
- the medical rationale for the use of the device, including:
    - the diagnosis, treatment or prevention for which the unlicensed device is required,
    - a list of the licensed devices available for sale in Canada that were considered and a rationale as to why they would not adequately meet the requirements of the patient,
    - the reasons the unlicensed device was chosen for the diagnosis, treatment or prevention,

  - the risks and benefits associated with the use of the unlicensed device,
  - the known safety and effectiveness information in respect of the device, and
  - in the case of a request for a batch release, a description of the emergency condition requiring treatment, and the number of devices required for one month (a batch release authorization can be issued for a one-month supply to devices to treat patients on an urgent basis if shipping delays would result in adverse patient outcomes),

- the name and address of each health care facility at which the device is to be used by the health care professional and to which the device is to be shipped, and
- a written undertaking by the health care professional that the professional will inform the patient for whom the device is intended of the risks and benefits associated with its use.

While Health Canada's regulatory authority under the Special Access Program is discretionary Health Canada must issue an authorization to a manufacturer or importer if it determines that:

- the benefits that may be obtained by the patient through the use of the device outweigh the risks associated with its use,
- the health or safety of patients, users or other persons will not be unduly affected,
- a licensed device that would adequately meet the requirements of the patient is not available in Canada, and
- the authorization is not being used by the manufacturer or importer to circumvent the requirements of Part 1 of the *Medical Devices Regulations*.

Health Canada provides a decision within three working days for non-emergency requests, and the same day for emergency

requests. Health Canada also has the discretion to cancel an authorization after it has been issued.

Issues for Consideration

In considering the special access request, Health Canada does not conduct a comprehensive evaluation on the validity of medical device information or assertions from the manufacturer with respect to safety, efficacy and quality. Therefore, the authorization given for any medical device does not constitute an opinion that it is safe or efficacious. Health care professionals must ensure their decision to recommend the unlicensed medical device is made after an appropriate risk/benefit analysis in the best interests of the patient and is supported by credible evidence found in the medical literature or provided by the manufacturer. Further, as is the case for any treatment, the health care professional must obtain the patient's informed consent to the use of the medical device.

A health care professional must within 72 hours after the occurrence of any incident that comes to his or her attention occurring inside Canada and involving a medical device for which a special access authorization has been issued and that:

- is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in the directions for use, and
- has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur,

report the incident to Health Canada and to the manufacturer or importer of the device, and specify the nature of the incident and the circumstances surrounding it.

This mandatory problem reporting requirement applies to incidents occurring outside Canada if the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred,

the manufacturer's intention to take corrective action, or if the regulatory agency has required the manufacturer to take corrective action.

A manufacturer or importer must ensure the unlicensed device is labelled with the name of the device and manufacturer, and whether the device is custom-made or imported or sold for special access, and maintain a distribution record for the device in accordance with sections 52 through 56 of the *Medical Device Regulations*. The implant registration requirements of sections 66 to 68 of the *Medical Devices Regulations* apply in respect of an implant that is imported or sold for special access.

The Special Access Program is responsible only for permitting the import and sale of a medical device to a health care professional. Funding for the delivery of health care is under provincial jurisdiction. Patients will need to determine if the costs of the medical device will be funded by the province, by a private insurer or by the patients themselves.

Health Canada has stated that the Special Access Program is not intended to promote the early use of medical devices and should not be used to circumvent the regulatory review and authorization process for new medical devices in Canada. Because only health care professionals can initiate access requests, it cannot and should not be used by manufacturers or importers to achieve this result.

A manufacturer or importer that advises health care professionals that its medical devices are available by special access may be exposing itself to regulatory action by Health Canada. The *Food and Drugs Act* provides that no person shall advertise any medical device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding the medical device's design, construction, performance, intended use, quantity, character, value, composition, merit or safety. A Class II, III or IV medical device cannot be advertised for the purpose of sale before the medical device has been licensed by Health

Canada. An exception to this advertising prohibition is available if the advertisement is placed only in a catalogue accompanied by a clear and visible warning that the advertised medical device may not have been licensed in accordance with Canadian law.

Manufacturers and importers might be tempted to view the Special Access Program as a means to market unlicensed medical devices in Canada. Given the strict conditions of the Special Access Program that must be fulfilled before access is authorized, it is not a viable way to circumvent the regulatory review and approval process. However, in situations where health care professionals believe that access to these unlicensed medical devices is beneficial, the Special Access Program could potentially provide promising alternatives for patients who may otherwise be precluded from benefitting from certain devices.

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a cautionary note