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Guidance for Health Care Professionals on Special Access and Custom-Made Medical Devices

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Health Products and Food Branch

Canada

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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1. INTRODUCTION

The *Medical Devices Regulations (the regulations)*¹ have been established under the authority of the *Food and Drugs Act* and apply to all medical devices imported or sold in Canada. *The regulations* set out the requirements governing the sale, importation, and advertisement of medical devices in Canada.

The Special Access Programme (SAP) administers Part 2 of the *the regulations*, permitting Health Care Professionals (HCP) to obtain custom-made or unlicensed medical devices for emergency use, or when conventional therapies have failed, are unavailable or are unsuitable to provide appropriate treatment for patients under their care.

1.1 Policy Objectives

To ensure that requests from Health Care Professionals (HCP) for special access to unlicensed medical devices or custom-made devices are received, processed and decided upon effectively, consistently, and in accordance with Part 2, sections 69 - 78 of the *Medical Devices Regulations*.

1.2 Policy Statements

The Special Access Programme (SAP) considers requests from Health Care Professionals (HCP) for access to unlicensed medical devices for emergency use, or if conventional therapies have failed, are unavailable or are unsuitable. Additionally, the SAP grants authorizations for custom-made medical devices required for unique patient circumstances.

Section 71 of the regulations outlines the information required for a SAP request. The application form has been designed to allow the HCP to provide all the information necessary for an authorization. Since HCPs should be well-informed about the device they are requesting, they should not have to rely on the manufacturer or distributor to complete an application on their behalf.

Special Access is not intended as an “early market access” route for medical devices that are still undergoing clinical trials, are still in their development phase, or are awaiting licensure. Health Canada expects that manufacturers will pursue investigational testing authorizations and licensure for sale in Canada for devices authorized under the SAP. Furthermore, Health Canada strongly

1 Part 1 of the regulations prohibits the advertising, importation or sale of a Class II, III or IV medical device unless the manufacturer holds a licence for that device. A link to the consolidated version of the regulations is provided for the most up to date version of the regulations:
<http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/>

advises health care facilities and provincial bodies not to change their published standards of care to recommend or reference unlicensed medical devices with the expectation that health care facilities will be able to obtain them on an ongoing basis through the SAP.

Medical devices authorized under Special Access do not undergo the same level of scrutiny required to obtain a medical device licence or an authorization for investigational testing. Accordingly, authorization through Special Access does not constitute an opinion that a medical device has been assessed and found to be safe, effective or of high quality for general use.

According to section 27 of the regulations, no person shall advertise a Class II, III or IV medical device unless the medical device is licensed, or only when the advertisement is placed in a catalogue with a clear and visible warning that the device advertised in the catalogue may not have been licensed in accordance with Canadian law. Health Canada considers promotional activity such as solicitation of sales, provision of pre-filled SAP application forms, promotion of a medical device previously authorized through the SAP, placement of promotional information on a Canadian-only website, distribution of medical device information including the term “Available in Canada through Special Access” and other such activities as advertising activity.

1.3 Scope and Application

This guidance document is intended for Health Care Professionals seeking Special Access to a medical device. It is intended to clarify the mandate, intent and scope of the SAP and outline the responsibilities of the HCP, manufacturers and Health Canada in the process.

Medical devices that fall within the scope of the SAP include certain Class I devices (where the manufacturer does not hold a valid Establishment License), unlicensed medical devices of Classes II, III, and IV and custom-made medical devices. This guidance document is not intended to exhaustively cover industry roles and responsibilities, but may prove useful for industry members.

A Special Access Authorization is not required for devices intended for veterinary use.

1.4 Definitions

Batch Authorization

A batch request can be issued when a HCP requires access to a device for anticipated emergency cases for a one month period, where licensed medical devices are unavailable, and where shipping delays would result in adverse patient outcomes.

Custom-made Medical Device

A custom-made device, as defined in the regulations, means a medical device, other than a mass-produced medical device, that (a) is manufactured in accordance with a HCP's written direction giving its design characteristics; (b) differs from medical devices generally available for sale or from a dispenser; and (c) is for the sole use of a particular patient of that professionals, or, is for use by that professional to meet special needs arising in the course of his or her practice.

Emergency

An emergency is a situation that poses an immediate risk to a patient's life or long term health.

Health Care Professional (HCP)

A health care professional, as defined in the regulations, means a person who is entitled under the laws of a province to provide health services in the province.

Health Care Facility

A health care facility, as defined in the regulations, means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.

In-Vitro Diagnostic Device

An in-vitro diagnostic device, as defined in the regulations, means a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body.

Medical Device

A "device", as defined in the *Food and Drugs Act*, and a "medical device" as defined in the regulations, means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in: diagnosing, treating, mitigating or preventing disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals; restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals; diagnosing pregnancy in human beings or animals; caring for human beings or animals during pregnancy or at or after birth of the offspring, including caring for the offspring, or; preventing conception in human beings or animals.

However, it does not include such an instrument, apparatus, contrivance or article, or component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

Special Access Programme (SAP)

The Special Access Programme permits health care professionals to obtain custom-made medical devices or unlicensed medical devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable to provide appropriate treatment for patients under their care, under Part 2 of the regulations.

Special Access Unit (SAU)

The Special Access Unit is the group within the Medical Devices Bureau of Health Canada that administers the Special Access Programme under the regulations.

Serious Adverse Event

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

2. GUIDANCE FOR IMPLEMENTATION

2.1 Roles and Responsibilities under the Special Access Programme

2.1.1 Special Access Unit (SAU)

The Medical Devices Special Access Programme (SAP) is administered by the Special Access Unit (SAU), part of the Medical Devices Bureau in the Therapeutic Products Directorate of Health Canada. The SAU receives applications and reviews them on a case-by-case basis, considering the medical rationale and supporting information provided with the application. If an application is incomplete or references previous Special Access applications or regulatory submissions under review for additional clinical or technical information, the application will be rejected and the applicant will be notified accordingly.

Upon receipt of a completed application, the SAU works with scientific reviewers and medical experts in the Bureau to determine whether an SAP authorization can be granted on the basis of the medical rationale provided and other information available at the time of

the application. To this end, the SAU undertakes the following risk assessment and management activities prior to issuing a letter of decision:

- Emphasizing to the applicant that conventional therapies or licensed alternative medical devices should be considered prior to applying for Special Access;
- Ensuring that the applicant is fully aware of the health-related risks and benefits of the requested device, in comparison to conventional therapies or licensed alternatives;
- Ensuring that the applicant is knowledgeable about available safety and effectiveness information in respect of the requested device;
- Monitoring adverse event reports, recalls and other post-market information on medical devices that have been made available through the SAP;
- Reviewing clinical and technical documentation concerning the safety and effectiveness of the requested device prior to its first release through the SAP;
- Conducting periodic reviews of the risk-benefit profile and continued clinical need for devices that have been made available under SAP for an extended period of time, typically one year or more; and
- Encouraging manufacturers and importers to submit applications to Health Canada for an Investigational Testing authorization or a medical device licence to make the device available to the entire Canadian health care system.

It is important to note that the SAP authorization is not required for a licensed medical device. Oversight for new, off-label uses of licensed medical devices is performed under Part 3 of the regulations, the Investigational Testing requirements.

2.1.1.1 Hours of Operation of the SAU

The Medical Devices SAU can be reached 24 hours a day, 365 days a year.

Regular business hours are weekdays from 8:30 am to 4:30 pm Eastern Time. Outside of regular business hours and during statutory holidays², an after-hours service is available.

2.1.1.2 After-Hours Service

To place a request for emergency access outside of the regular office hours described above, applicants should call the Medical Devices SAP On Call number at 613-410-9186.

An officer will either answer directly or will return telephone messages within 20 minutes.

2 New Year's Day - January 1; Good Friday - Friday before Easter Sunday; Easter Monday; Victoria Day - Monday on or before May 24; Canada Day - July 1; Civic Holiday - first Monday in August; Labour Day - first Monday in September; Thanksgiving Day - second Monday in October; Remembrance Day - November 11; Christmas Day - December 25; Boxing Day - December 26

The officer will request the same information that would be required of a routine paper application and will make a determination over the telephone. If authorization is granted, the officer will endeavor to contact the manufacturer, by e-mail or telephone, immediately to facilitate shipment and transfer of the medical device; if the manufacturer contact is not available after normal hours, the on-call officer will follow up the next business day.

If an authorization is granted after-hours, the HCP must always follow up by submitting a signed, completed Special Access application, indicating that verbal authorization was provided and the date when the verbal authorization was granted.

The On Call number is reserved for after-hours emergency requests from HCPs and may not be answered during business hours. Requests made via this number for guidance on policy or the regulations will be deferred to the next business day.

2.1.2 Health Care Professionals

Individuals who are entitled under the laws of their province to provide health services are considered HCPs under the regulations and are eligible to apply for Special Access. HCPs are responsible for initiating a Special Access application for situations where unlicensed medical devices are required for emergency situations, or when conventional therapies have failed, are unavailable or are unsuitable. Recall that importation and sale (including distribution) of an unlicensed medical device without authorization from the SAP is prohibited, therefore, coordination of purchasing/importation and surgical date planning is important to consider during the application process. Furthermore, in the case where device training is required prior to use, HCPs are reminded to consider the timing requirements for training prior to submitting their application.

It is expected that, in accordance with good medical and clinical practice, the HCP will become familiar with all relevant available information about an unlicensed medical device prior to requesting access to it.

The HCP, in submitting an application for Special Access, must also undertake to inform the patient for whom the device is intended of the risks and benefits associated with its use. Furthermore, the HCP agrees to report all serious adverse events associated with the device, within 72 hours of their occurrence, to Health Canada and to the manufacturer or importer of the device.

The HCP assumes responsibility for the medical device upon its receipt at the health care facility identified in the authorization letter. The device is authorized for use only by the applicant and cannot be used by anyone else. Each HCP at a facility who wishes to access

an unlicensed medical device must submit a separate application; the SAP does not allow department heads to apply for batch releases of medical devices for further distribution to their staff.

HCPs should be aware that a positive decision by the SAU to a special access request should not lead to an assumption that subsequent requests for the same medical device (by the same HCP, within the same facility, or within the country) will lead to a similar decision. The SAU reviews every application on a case-by-case basis, considering the medical rationale and supporting information provided with each application.

2.1.3 Manufacturers and Importers

While this guidance is written explicitly for HCPs, it is important for HCPs to understand what industry members are, and are not allowed to do regarding the SAP. Since the SAP is designed to address the needs of the HCP, it is not appropriate for manufacturers and importers to be involved in initiating a request for authorization. Additionally, manufacturers and importers cannot advertise or sell unlicensed medical devices, even if they have previously been released under the SAP, because this activity is prohibited under the regulations. Health Canada considers the distribution by manufacturers of pre-filled SAP application forms to HCPs to be promotional activity, and subject to compliance measures.

Manufacturers and importers may supply administrative information to HCPs at their request [for example (e.g.) catalogue numbers, regulatory contact details, Instructions for Use], however, they may not provide any medical or clinical rationale to support the application process.

During the review of an application for Special Access, the SAU may request additional technical or administrative information from the manufacturer or importer to complement the content of the HCP's application.

Although Health Canada may issue a Special Access authorization, there is no regulatory obligation on the manufacturer to sell a device for Special Access and Health Canada cannot compel a manufacturer or distributor to do so. Additionally, there is no requirement for the manufacturer to provide the device at no cost to the applicant.

2.2 Initiating a Special Access Request

HCPs can apply to obtain an unlicensed device under Special Access after determining that the device is required to treat a patient in an emergency, or if conventional therapies have failed, are unavailable, or are unsuitable. The application form and associated instructions may be accessed

and downloaded from the Health Canada website (<http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/index-eng.php>).

2.2.1 Completing the SAP Application

All fields on the application form must be completed. The first portion of the application form deals with the administrative requirements of applying and requests information such as the contact details for the applicant, information about the health care facility, the name and model number of the device and the quantity required, and contact information for the manufacturer or distributor.

The second portion of the application form requests the medical rationale for requiring the unlicensed device. This rationale forms the basis of Health Canada's assessment, and it is therefore important for the applicant to be transparent about the intended use of the device and to provide clear and detailed information about the patient to be treated, such as the patient's age, diagnosis, conservative treatments, co-morbid medical conditions, plan of care or other pertinent details. Copying marketing or advertising information from a manufacturer's brochure is insufficient to justify an authorization. In some cases, HCPs will provide their consultation notes, which are very helpful in reviewing the request. However, please ensure that patient confidential information is not included as part of the application. Further, we do not require the patient's name.

According to Part 2 of the regulations, the application must provide the following information:

- The diagnosis, treatment or prevention for which the device is required,
- The reasons the device was chosen,
- The risks and benefits associated with its use,
- The clinical reasons why the procedure could not be accomplished using conventional treatment or a licensed device that is available for sale in Canada,
- The known safety and effectiveness information in respect of the device,
- A written undertaking by the HCP that the professional will inform the patient for whom the device is intended of the risks and benefits associated with its use,
- The manufacturer's directions for use of the device. In the case of a custom-made medical device, a copy of the HCP's written direction to the manufacturer giving the design characteristics of the device.

2.2.2 Patient-Specific or Batch Requests

A Special Access request can be made for a device to treat one specific patient, or for a limited batch of devices that may be feasibly required to treat future patients in the short term. A patient-specific request should be made for treatment of an identified patient for immediate single-patient use.

A batch request is appropriate when the HCP requires access to the device for anticipated emergency cases where licensed medical devices are unavailable, and where shipping delays would result in adverse patient outcomes. In this case, the HCP must estimate the number of devices that may be required for emergency treatments for one month. The restriction to a one-month supply of devices is intended to provide sufficient quantities for true emergency cases in the short term, bearing in mind that a suitable licensed device may become available in the near future. The SAP maintains the ability to use discretion in enforcing this one month restriction.

2.2.3 Submitting a Special Access Application

The Special Access Unit is continuing its transition to an exclusively electronic procedure for receiving and processing applications. While our preference is to receive applications and supporting documentation electronically, completed forms can be faxed, emailed or sent by letter mail to:

Medical Devices Special Access Programme
2934 Baseline Road, Tower B
Address Locator 3430A
Ottawa, Ontario K1A 0K9

Telephone: 613-946-8711
Fax: 613-957-1596
E-mail: sap_devices_mdb@hc-sc.gc.ca

A cover sheet is not required for applications sent by fax. Telephone requests should be reserved for life-threatening situations requiring immediate attention. When making telephone requests, HCPs should be prepared to provide all of the required information using the application form as a guide. If an authorization is granted, the HCP will be required to submit a completed and signed application form as soon as possible. For after-hours service, please refer to section 5.1 of this document.

The SAU experiences a high volume of requests and follow-up communications. Please wait 3 business days before contacting us to determine the status of any non-urgent applications.

2.3 Processing Special Access Applications

2.3.1 Screening

The priority for processing a Special Access application is determined by the date of the planned procedure. Requests in which a clear urgency is indicated take precedence over less urgent requests. While the target response time for all applications is 3 business days, in most cases, a preliminary response is provided within 24 hours. Applicants should not submit the request at the last minute for a scheduled procedure.

After determining the date of procedure, the applications are screened to ensure that all sections of the form are complete, the application is signed, the required supporting documents are available and the application, if handwritten, is legible. Given the large volume of applications reviewed by the unit, incomplete or illegible applications are automatically rejected, with an explanation of the deficient areas returned by fax to the applicant. Every Special Access application is assessed individually on its own merits and content; an applicant cannot refer to a previous application or a regulatory submission under review for any of the required information. Such references will result in an automatic rejection.

2.3.2 New Medical Devices

The SAU frequently receives requests for new medical devices and new technologies not previously reviewed within the Medical Devices Bureau. These requests will often require technical information and data from the manufacturer to support the application to facilitate a review by Medical Devices Bureau technical and medical experts. While the SAU endeavors to provide a response to the applicant as soon as possible, a contributing factor in the speed of the response is the willingness and ability of the manufacturer to provide the requested information in a timely manner.

2.3.3 Review and Consideration

After initial screening of an application, the SAU reviews the content of the application to determine whether the request satisfies all the requirements of section 72 of the regulations. Specifically:

- a) The benefits that may be obtained by the patient through the use of the device outweigh the risks associated with its use;
- b) The health or safety of patients, users or other persons will not be negatively affected;
- c) A licensed device that would adequately meet the requirements of the patient is not available in Canada; and

- d) The authorization is not being used by the manufacturer or importer to circumvent the requirements of Part 1 of the regulations, specifically the requirement to obtain a medical device licence.

Each request for Special Access represents a unique set of circumstances and is supported to varying degrees by information provided by the applicant, by the manufacturer, in the public domain, from our international counterparts or already in the possession of Health Canada. Health Canada carefully considers each Special Access request while ensuring that our responsibility to protect the health and safety of Canadians is upheld.

After verifying that the application is complete, the SAU may consult scientific reviewers and medical experts in the Medical Devices Bureau to determine whether an authorization can be granted based on the medical rationale provided and other information available to Health Canada at the time of application. In most circumstances, elective cosmetic procedures are unlikely to meet the regulatory criteria for approval, particularly considering the requirement that the benefits obtained by the patient outweigh the risks associated with the use of a SAP device.

2.3.4 Transparency of the Application

When submitting an application for Special Access, it is imperative that the content of the application is true, correct and complete to the best of applicant's knowledge; Health Canada expects that the patient's plan of care and the intended use for the medical device is clearly described in the application. Unsubstantiated claims should not be included in the application.

2.3.5 Conventional Therapies and Licensed Alternative Devices

The regulations state that an unlicensed medical device may be obtained under the SAP if the device is required for emergency use or when conventional therapies have failed, are unavailable or are unsuitable. Health Canada will not issue an authorization when suitable licensed alternative medical devices are available. Therefore, it is the responsibility of the applicant to clearly demonstrate that conventional therapies have failed, are unavailable or are unsuitable. Note that a "conventional therapy" does not necessarily mean a medical device, but could be a device, drug, surgical procedure or other therapy. A searchable database of medical devices licensed in Canada can be found on the Health Canada website (www.mdall.ca).

2.3.6 Risks and Benefits of the Requested Device

The SAP requires a discussion of the risks and benefits related to the use of the requested device. While the instructions for use of a device will usually discuss general risks and

benefits, it is important that the discussion of risks and benefits provided in the application clearly present the specific condition of the patient for whom the device is requested, as well as the risks and benefits for that particular patient.

For example, a HCP may wish to use a device to treat a pediatric patient even though it is specifically indicated only for adults. The applicant should provide a discussion of the risks and benefits of using the device on a pediatric patient.

2.3.7 Safety and Effectiveness of the Requested Device

The regulations require a discussion of the known safety and effectiveness information in respect of the device. Any of the following information would be acceptable in fulfilment of this requirement:

- Published clinical trial results
- Published case studies
- History of device usage and regulatory status internationally
- Summary of data presented at an international conference
- Summary of previous personal use and experience with the unlicensed medical device
- Discussion of the clinical specificity and sensitivity of the in vitro diagnostic device.

Including a statement to the effect of “This medical device is safe and effective” is insufficient to meet the regulated requirements to provide evidence of safety and effectiveness. Note that some additional information may be requested from the manufacturer of the device to address these issues, but information must be provided by the applicant outlining the applicant’s knowledge of the safety and effectiveness of the device.

2.3.8 Undertaking

The regulations require the applying HCP to provide a written undertaking to inform the patient for whom the device is intended of the risks and benefits associated with its use. In some cases, a discussion regarding risks and benefits cannot be performed; in such cases, the HCP must attest that institutional policies and guidelines related to informed consent will be followed.

Due to the nature of in vitro diagnostic testing, it may be impracticable to advise a patient during sample collection that the test kit to be used is unlicensed. In such cases, applicants performing in vitro diagnostic testing using unlicensed medical devices should undertake to indicate on any laboratory results that testing was performed, in whole or in part, with an unlicensed medical device obtained under Special Access. The same risk/benefit

determination previously presented to Health Canada during the application process should be included in the laboratory report, so that the primary health care provider can use this information to inform their patient.

2.3.9 Requests for additional information

The SAU may contact the requesting HCP or manufacturer (or their designated representative) for clarification on clinical, technical or administrative information. Applications where additional information requests are outstanding after 3 business days will be refused; in such cases, applicants can re-apply when the requested information is available.

2.4 Decision

2.4.1 Authorization

If the SAU determines that Special Access can be granted, a letter of authorization will be issued to the manufacturer or importer with a copy to the applicant. The letter states the number of units of the device authorized to be imported or sold and the name of the HCP at a particular health care facility to whom the device can be sold. Note that the manufacturer may not import or sell more than the number of devices authorized, or to distribute the devices to a HCP or health care facility other than the one named in the letter of authorization. Any distribution outside the provisions in the letter of authorization is prohibited.

2.4.2 Request for Amendment

If an amendment due to a clerical error or a change in patient status is required, and the importation and/or sale of the device has not yet taken place, contact the SAU via telephone or email to request an amendment to the letter of authorization.

If the importation or sale of the device has already taken place, and the applicant would like to include new devices on the request, please submit a new application detailing the new devices required under Special Access. Letters of authorization cannot be amended after the importation or sale of a Special Access device.

2.4.3 Expiration of Letter of Authorization

A letter of authorization does not expire based on the date that the letter was issued however, once all medical devices have been imported or sold under the authorization, the letter is no longer valid.

In some cases, surgical interventions are postponed, rendering the date on the letter as “stale” (e.g. a letter issued in excess of 6 months from the surgical date). In such cases, the SAU can issue an amendment to the authorization, provided the medical devices have not yet been imported or sold, to facilitate transfer of the medical devices across the border, or to reflect hospital patient records. Please refer to the section above for guidance on requesting an amendment.

2.4.4 Refusal

If the SAU determines that the application must be refused, a letter of refusal will be sent to the applicant with a copy to the manufacturer, stating the reasons for the refusal.

In some cases, Health Canada has access to confidential information obtained from other sources, which indicates a concern with the safety or effectiveness of the medical device. This information will be considered in a decision to refuse an application under Special Access.

Please note that an authorization will not be given if the application is received after the procedure has taken place.

2.4.5 Cancellation

A letter of cancellation may be issued by Health Canada if new information is brought to the attention of the SAU indicating any of the following:

- the device could be unsafe to patients or users,
- the patient’s clinical condition has changed so that the benefits no longer outweigh the risks,
- the SAU becomes aware of licensed alternative devices which could be considered suitable for treatment,
- the SAU has reasonable grounds to believe that the manufacturer is using the SAP to circumvent licensing requirements
- the device is no longer needed to treat the patient, or
- the manufacturer refuses to supply the authorized medical device.

A letter of cancellation means that the product can no longer be imported or sold to the HCP who was originally authorized.

2.4.6 Automatic Rejection

Given the large volume of requests handled by the unit, if the SAU determines that the application is incomplete, it will be automatically rejected. The applicant will receive a

letter stating which information needs to be included in a future submission. At this stage, the content of the medical rationale has not been reviewed, and therefore, future submissions may require clarification of content.

2.4.7 Letter of Exemption

If the SAU determines that the requirements of Part 2 of the regulations do not apply to the application, the applicant will be issued a letter of exemption, stating that a Special Access Authorization is not required in order to purchase the device. An example of an exemption is when an unlicensed medical device may be sold for research use only provided they will not be used to treat, diagnose or prevent disease in patients. The device must be clearly labelled as “Not for use on humans”.

2.4.8 Appeals

The SAP does not have a formal appeal process, as defined in the regulations. If a HCP wishes to appeal a refusal of their application for Special Access, they may re-submit a new application, providing additional information and addressing any inconsistencies or missing information from the refused application.

2.5 Special Considerations

2.5.1 Custom-made medical devices

The process for applying for a custom-made medical device is essentially the same as applying for Special Access. The HCP must, however, include documentation which describes his or her written direction to the manufacturer for the design and construction of the custom-made medical device. Additionally, while only Class III and IV custom-made medical devices require an authorization for importation and sale, labelling requirements outlined in section 75 of the regulations, do apply to Class I and II custom-made medical devices.

2.5.2 Cost savings of requested devices

While Health Canada recognizes that health care costs can be a concern, reduced cost of an unlicensed device compared to a licensed device is not a rationale that satisfies the regulatory criteria within which the SAP can provide an authorization.

2.5.3 Contractual Obligations

A hospital or health care facility or purchasing group may enter into a binding contract that requires them to purchase medical devices from a particular manufacturer. Occasionally,

the manufacturer will stop marketing a device specified in the purchasing contract but will not yet have a license for the device that replaces it. This is insufficient rationale to support the requirements for authorizing a medical device under Special Access.

In some cases, a health care facility or purchasing group may issue a Request For Proposal (RFP), to supply devices to a hospital. A manufacturer may respond to the RFP by offering to provide a device that is not yet licensed. However, if the hospital or purchasing group enters into a contract with that manufacturer, the manufacturer will not be permitted to sell the device under that contract until it has received a Health Canada medical device licence. A SAP application from a health care facility to support contractual obligations is not appropriate.

2.5.4 Application for a device while it is under licensing review by Health Canada

A manufacturer who has submitted an application for a new or amended medical device licence, may not use the SAP to obtain early market access for their new medical device in Canada. Special Access applications for medical devices under licensing review receive the same prioritization and must meet the same criteria as any other Special Access request.

2.5.5 Incremental improvements to licensed medical devices

The SAP often receives applications for medical devices which are considered an incremental improvement over their licensed predecessor. Unless there is a clear, significant and demonstrated clinical benefit to the patient in using this new device, innovation in product development is an insufficient rationale to meet the regulatory requirements for Special Access.

2.5.6 Software updates

Software updates for licensed software must be reviewed through the medical device licence amendment process, and should not be requested under Special Access, unless there is a clear and significant patient benefit to doing so. Manufacturers may not mandate software upgrades for licensed medical devices and advise users to request them through the SAP.

2.5.7 Requests for Recalled Devices or Devices Refused for Licensing

The SAU monitors international and domestic recalls, corrective actions or other evidence of a safety concern, as well as domestic licensing refusals of devices that have been previously authorized under Special Access. Depending on the reason for the recall or licence refusal, the SAU may refuse the SAP request, or ask the manufacturer to disclose

the reason for recall or licence refusal to the requesting HCP. If authorization is granted, this information must be given to the patient when the HCP discusses the benefits and risks of the unlicensed medical device.

2.5.8 Requests for off-label use of licensed medical devices

Health Canada does not regulate the way HCPs use a medical device after sale. Therefore, the SAP will not authorize a health care professional to use a licensed device ‘off-label’, that is (i.e.), in a manner or for a purpose not indicated in the manufacturer’s instructions for use.

2.5.9 Use of Special Access to conduct physician-sponsored clinical trials

Occasionally, HCPs request a device under Special Access in order to conduct a clinical trial with the device. Part 3 of the regulations sets out the requirements for conducting a clinical trial (referred to as ‘investigational testing’) of a medical device. According to the regulations, clinical trials using unlicensed devices must be sponsored by the manufacturer or importer and cannot be solely initiated by the physician.

In some situations, HCPs who have treated one or more of their patients with a device obtained through Special Access may wish to publish studies describing the clinical cases and the outcomes using the device. Such publications are permitted, as Health Canada recognizes the benefits of communicating such case studies within the clinical community.

2.5.10 Use of a Special Access device in a different patient

Devices authorized under Special Access to treat a specific patient should be used only for that patient. Health Canada requests that unused devices remaining after the procedure be immediately returned to the manufacturer.

2.5.11 Requests for first-in-human use of a device

The SAU will occasionally receive applications for first-in-human use of an unlicensed medical device for treatment of patients who would otherwise have no clinical options. Such applications are given careful scrutiny and should be supported with very strong pre-clinical data. If a physician anticipates the need to request a device for first-in-human use, please consult the SAU as soon as possible.

2.5.12 Managing devices authorized for batch release

Authorizations can be granted for a batch of devices sufficient for the number of emergency cases anticipated during a one-month period when licensed alternative medical

devices are unavailable and shipping delays may compromise patient outcome. Applicants should apply only for the number of devices that they require for a one month period, and should consider managing their supply by applying for small quantities initially, and then submitting an SAP request to replenish their supply as needed. Requests for large quantities of devices under batch will be scrutinized, and actual quantities authorized by Health Canada may differ from the quantity requested.

2.6 Post Approval

2.6.1 Adverse Event Reporting by Health Care Professionals

Under the regulations, HCPs who receive medical devices through the SAP are required to report serious adverse events within 72 hours of occurrence to the Minister of Health Canada and the manufacturer or importer of the device. This report must specify the nature of the incident and the circumstances surrounding it and should be submitted to MDPR@hc-sc.gc.ca. For the most up-to date problem reporting forms, please go to the Health Canada website (<http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/index-eng.php>).

HCPs must report incidents or events that relate to device failure, deterioration of effectiveness or labelling inadequacies, when the outcome is one of the following:

- Death,
- Serious deterioration in the state of health of a patient, user or other person, or
- Potential for serious deterioration in the state of health of a patient, user or other person.

A serious deterioration in the state of health of a patient means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage.

2.6.2 Voluntary reporting of patient outcomes

While not mandatory under the regulations, the SAU encourages submitting voluntary reports of clinical outcome for patients treated using a device obtained under SAP. These voluntary reports, which may be informal, assist the SAU and the Medical Devices Bureau form the basis of opinion for future release of the particular medical devices under SAP or Investigational Testing, and may be consulted during licence review.

If you wish to report the outcome of a case using a medical device under SAP, please send your report by email to sap_devices_mdb@hc-sc.gc.ca, and ensure that you include the SAP reference number, which appears on each letter of authorization issued by the SAU.

2.6.3 Record Keeping

The manufacturer or importer of a medical device authorized for importation and sale under the Special Access Provisions must maintain distribution records in accordance with sections 52 to 56 of the regulations.

HCPs are encouraged to retain all records related to a Special Access case for a minimum period of 25 years, in a manner that permits rapid retrieval if necessary.

The SAU maintains archives of all requests for Special Access, including letters of decision.

2.6.4 Return of Unused Medical Devices

Health Canada requests that all unused medical devices are returned to the manufacturer or importer after the procedure has taken place. The importer may choose to hold the returned medical devices in quarantine for anticipated emergency cases; however, any future sale of the quarantined medical device is prohibited without prior approval from Health Canada.

2.6.5 Labelling of medical devices authorized under Special Access

A medical device that has been authorized for importation and sale through the SAP requires special labelling prior to importation. This labelling must state the name of the product, the name of the manufacturer, and must specify whether the device is custom-made, or is being imported or sold for special access. Additionally, the letter of authorization should accompany any shipment of medical devices for special access. If labelling is not present prior to importation, the shipment may be held at the border by the Canadian Border Services Agency.