Health Canada Santé Canada

Instructions for Completing the Application Form for Custom-Made Devices and Medical Devices for Special Access

Please type or print legibly. Illegible applications can not be processed. The form can be completed online and faxed to **1-613-957-1596** or e-mailed to **sap_devices_mdb@hc-sc.gc.ca**. For questions or emergency requests call **613-946-8711** during business hours Eastern Time.

Health Care Professional Information

A "Health Care Professional" (HCP) means a person who is entitled under the laws of a province to provide health services in the province. Please include all contact information so that we can contact you if clarification is required. Two or more HCPs submitting requests for the same device must each complete a separate application even if they work at the same institution.

Health Care Facility Information

"Health care facility" means the facility where the diagnostic or therapeutic services are to occur. This is the address to which the device is to be shipped. Additional facilities where the device is to be used by the HCP can be listed.

Date of Procedure

The date of the planned procedure is requested to help us prioritize Special Access Programme (SAP) requests. Our performance standard is to provide a decision within three working days for non-emergency requests, and the same day for emergency requests. For breast implants, the procedure date is required. The procedure date does not apply to batch release requests. Requests submitted after the procedure has taken place will be refused.

Clearly indicate whether this is an emergency request. Emergency requests will also be accepted by telephone.

Information Regarding the Unlicensed Device

Each item in this section must be completed. Check the "custom made device" box only if the device satisfies this definition:

> A "custom-made device" means 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.

For custom-made device applications a copy of the HCP's written direction to the manufacturer giving the specific design characteristics of the device either in writing or by diagram is required.

Manufacturer and Importer (Distributor) Information

The Manufacturer and the Importer (or Distributor) may be the same entity. If they are not the same, the Importer or Distributor is the entity that holds an Establishment Licence to import and sell the device. Do not enter the name of the Health Care Facility as the Importer or Distributor.

Medical Rationale

The medical rationale should include the following:

1. The diagnosis, treatment or prevention for which the unlicensed device is required.
2. A list of the licensed devices considered and a rationale as to why they would not adequately meet the requirements of the patient. Providing this information will expedite the review of your application. A list of licensed devices can be found on the Health Canada website (http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp).
3. A discussion of the risks and benefits associated with the use of the unlicensed device.
4. A summary of the known safety and effectiveness information in respect of the device.
5. In the case of a request for 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 of devices to treat patients on an urgent basis if shipping delays would result in adverse patient outcomes. In the case of *in-vitro* diagnostic devices, an authorization is issued for a one-month supply of the assay. An exception to this policy can be made if the assays or kits are available only in packages that contain more than a one-month supply and cannot be broken down for shipping.

Undertaking and Declaration

The HCP must indicate whether the application is for an individual patient (and if so, provide the patient's initials or another identifier) or for Batch Release. Please do not provide the patient's name. In the case of Batch Release, the HCP must complete part 5 of the Medical Rationale.

If informed consent cannot be obtained, please indicate that institutional policies will be followed. Type or clearly print your name under the signature. Electronic signatures are acceptable.

Problem Reporting

Serious adverse events associated with the use of the device must be reported by the HCP within 72 hours of occurrence to the SAP Unit (sap_devices_mdb@hc-sc.gc.ca) and to the manufacturer or importer. Please use the *Mandatory Problem Reporting for Medical Devices - Preliminary Report Form (FRM-0237)* and *User Problem Reporting for Medical Devices (GUI-0060)* guidance found on the Health Canada Compliance and Enforcement website.