Santé Canada Health Canada

Medical Devices Special Access Programme

What is the purpose of the Medical Devices Special Access Programme?	The main objective of the Medical Devices Special Access Programme (SAP), administered by the Therapeutic Products Directorate (TPD) of Health Canada, is to allow access to medical devices that have not otherwise been licensed for sale in Canada for emergency use or when conventional therapies have failed, are unavailable or are unsuitable to provide diagnosis, treatment or prevention for patients.
Who can apply for special access to medical devices?	Only health care professionals who are entitled under the laws of their province to provide health services in that province may submit applications to the Medical Devices SAP.
Which medical devices are available through the SAP?	All medical devices that are not licensed for general sale in Canada, in addition to certain custom-made devices, require a special access authorization prior to being imported and/or sold in Canada.
What is a custom-made device?	A custom-made device is one which is made to correspond with a health care professional's specific directions or needs. These devices are usually specifically produced for a particular patient or procedure. Custom-made devices exclude those devices which are generally available from a dispenser such as orthotics or glasses.
Who determines whether or not a medical device is released under the SAP?	Health care professionals could apply if the use of a medical device is necessary in the best interests of the patient and that a licensed device that would meet the needs of the patient is not available in Canada. If it is determined by the Medical Devices Bureau, based on the information submitted, that the potential benefits of using a particular unlicensed device outweigh the potential risks, the device is made available for special access.
Is personal information and patient anonymity protected?	Yes. Personal information provided in the application is protected. Only the patients' initials or identifiers are used to distinguish between applications and avoid duplication. Occasionally, the patient's age may be required in determining the benefits versus the risks of using a particular device. For example, children who are still growing would not be suited for certain types of hip implants.

How quickly can a decision be made on an application?	Special access applications are given top priority. A response is usually provided within 3 working days but failure to provide all information will delay the review time. Devices required for life-threatening or emergency conditions are prioritized.
Who pays for medical devices released through the SAP?	The Medical Devices SAP is not responsible for the device costs or the shipping arrangement. Patients should consult their health services providers as they may be responsible for any costs not covered by the hospital, the provincial health care system or a private insurer.
Are applications ever refused?	Yes. It is the health care professional's responsibility to submit a complete application which explains why a particular unlicensed device is needed and why no other will do. If the Medical Devices SAP determines that the potential risks associated with using the device outweigh the potential benefits or if a similar medical device is already licensed for sale in Canada, the application will be refused.
Is special access required for licensed devices used for off-label indications?	No. It is considered a practice of medicine which is regulated at the provincial level.
For further information	Special Access Programme Device Evaluation Division Medical Devices Bureau Therapeutic Products Directorate Room 1605, Main Statistics Canada Building Address Locator 0301H1, Tunney's Pasture Ottawa, Ontario K1A 0L2 Tel: (613) 946-8711 Fax: (613) 957-1596 sap_devices_mdb@hc-sc.gc.ca or visit our Website at: www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/

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