Health Canada Santé Canada

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Health Canada's Special Access Programme (SAP) Instructions for Making a Special Access Future Use Request FORM B

Future use requests are made in circumstances where non-marketed drugs are required in anticipation of patients faced with a medical emergency. The practitioner should include a rationale as to why the drug is required on hand as opposed to requesting it on a patient specific basis.

Background on the Special Access Programme

The SAP considers requests from practitioners for access to non-marketed drugs for treatment, diagnosis or prevention of serious or life-threatening conditions when conventional therapies have been considered and ruled out, have failed, are unsuitable, and/or unavailable. The regulatory authority supporting the programme is discretionary and a decision to authorize or deny a request is made on a case-by-case basis by taking into consideration the nature of the medical emergency, the availability of marketed alternatives and the information provided in support of the request regarding the use, safety and efficacy of the drug. This authority however, does not extend to covering the cost of drugs and does not take into consideration the cost of marketed alternatives. If access is granted, the physician agrees to report on the use of the drug including any adverse events encountered with such use, and must account for all quantities received to both the SAP and the manufacturer.

The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. Drugs considered for release by the SAP include pharmaceutical, biologic, and radiopharmaceutical products.

The SAP does not authorize the use or administration of a drug. This authority falls within the practice of medicine, which is regulated at the provincial level. A SAP authorization does not constitute an opinion or statement that a drug is safe, efficacious or of high quality. The SAP does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations of the manufacturer respecting safety, efficacy and quality. These are important factors for practitioners to consider when recommending the use of a drug and in making an appropriate risk/benefit decision in the best interests of the patient. The SAP strongly encourages practitioners treating individuals with drugs obtained through the SAP to seek informed consent before treatment.

Practitioners are encouraged to contact individual manufacturers to confirm the availability of a drug as well as to obtain the most up-to-date drug information such as prescribing information and other data supporting the use of the drug. In all cases, the manufacturer has the final word on whether the drug will be supplied. The manufacturer also has the right to impose certain restrictions or conditions on the release of the drug to ensure that it is used in accordance with the latest information available. For instance, they may restrict the amount of drug released, request further patient information, restrict the indications for which it is released, etc. Inquiries concerning the shipping, cost and/or payment should be directed to the manufacturer of the drug.

Please refer to the SAP guidance document for further information.

Instructions for completing the Special Access Request Form

The request form consists of two pages containing five sections. Practitioners are required to complete all five sections of the form each time a request is made, including renewal requests. The five sections are as follows:

SECTION A: PRACTITIONER AND SHIPPING INFORMATION
Practitioner's Name: First and last name of the requesting practitioner.
Note: Practitioner is defined as a person authorized by law of a province of Canada to treat patients with any drug listed or described in Schedule F of the Regulations as a drug substance intended for human use and requiring a prescription to be sold in Canada.

Hospital or Clinic Name: Full name of clinic or hospital where drug is to be sent- if applicable.
Address: Full name and address of the practitioner's office/clinic or hospital pharmacy where the drug is to be delivered, including the city, province and postal code.
Contact Person: Full name and position (e.g. Pharmacist, Nurse, Resident, etc.) of the person completing the form, if other than the requesting practitioner
Contact Tel. # /Fax#: A telephone and fax number including an area code and extension (if applicable) where the practitioner or contact person can be reached if further information or follow-up is required.
Send Drug c/o: Check the box that applies to where the drug is to be sent: a hospital in-patient pharmacy, the practitioner's office, a nuclear medicine department or blood bank
Note: A drug cannot be sent to retail or out-patient pharmacy.
Contact's email address: An email address for the contact person should they need to be reached if further information or follow-up is required. This is an optional field.
Practitioner's email address: An email address for the requesting practitioner should they need to be reached if further information or follow-up is required. This is an optional field.

SECTION B: DRUG AND MANUFACTURER INFORMATION
Trade Name/Other Name: Full name of drug, including when possible, both trade and generic name or company designated code.
Name of Manufacturer: Full name of the manufacturer and location if applicable (i.e. Canadian office.) **Note:** For new drugs if the requesting practitioner has spoken to a representative at the company regarding their request, please provide a note indicating this including a name and number for the contact person.
PO#: An optional field that can be used by hospitals or other institutions to specify a purchase order number
Route of Administration/Dosage Form: Check the boxes that apply, or specify "other" if applicable.

SECTION C: PATIENT-PRODUCT TRACKING INFORMATION.
Indication: The indication for which the drug is anticipated to be used for.
Strength: Required strength or combination of strengths.
Quantity: Precise number of tabs, vials, etc. requested to keep on hand.
1st future use request:

If YES, then proceed to the clinical rationale section of the request form- Section D.

If NO,
1) then the requesting practitioner has had a previous future use request authorized for this product. In order for the SAP to consider another request, the practitioner will need to provide a list of patients on whom the previous supply authorized was used. This information is to be provided in the table found in section C. If additional fields are required, extra copies of page 2 of the form should be attached.

Or

2) If drug has expired prior to being used, please check off the corresponding box.

Initials: First, middle (if applicable) and last initials of the patient.
Note: To ensure the patient's confidentiality, please do not indicate the patient's full name.
DOB: Specify the date of birth in order of date, month, year order (i.e. DD/MM/YYYY).
Sex: Check off the applicable box for the specified patient- **M**ale or **F**emale.
Indication: Exact medical indication for which the drug is being requested for.
New or Repeat Patient: Check the applicable box indicating whether this represents an initial (i.e. new) treatment or a repeat treatment for the patient for the specified drug via the SAP.
Quantity Released: Specify the amount of drug released for each patient. (i.e. # tabs, vials, bottles).
Date Administered: Specify the date the drug was administered to the identified patient in the format date, month and year (i.e. DD/MM/YY).

SECTION D: CLINICAL RATIONALE

Question 1a):

Specify the circumstances in which the drug will be used or is being requested for including, information on conventional therapies considered, failed or that are unavailable to achieve an adequate response. Explain with details why this drug is being requested as a future use supply.

Question 1b):

With details, explain what about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s).

Question 2) References:

Provide **specific** data/references with respect to the safety and efficacy of the product that support the requesting practitioner's decision to prescribe the drug for the specified indication. This can be in the form of medical literature, clinical protocols, investigator brochures etc. If copies of the reference(s) are appended to the request form, please check off the box. Otherwise provide a complete citation including journal/article titles, author(s), volume, issue, date and page information.

SECTION E: PRACTITIONER ATTESTATION

Section E consists of three attestations for the requesting practitioner to acknowledge and sign off on before requesting a non-marketed drug through the SAP.

Practitioner's Signature: Requesting practitioner's signature.
License #: Requesting practitioner's licence # (i.e. license to practice medicine or dentistry as issued by a provincial licensing authority).
Date: Date when request was signed and submitted to the SAP.

Processing of Requests and Hours of Operation

Completed forms should be faxed to the SAP without an accompanying cover sheet. Telephone calls should be reserved for urgent requests requiring immediate attention.

A complete form does not guarantee that a request will be authorized and additional information may be required during the consideration process. Every effort is made to process requests within 24 hours of receipt. However, given the mandate of the Programme and the volume of requests received, the SAP adopts a triage system to ensure that requests for drugs for life-threatening conditions take precedence over less urgent requests. If a drug is new to the Programme, the total processing time may be extended, although every effort is made to contact the practitioner within 24 hours to discuss the process for handling new drugs.

After consideration of a request, an authorization may be granted. The manufacturer is notified by fax. A Letter of Authorization is sent to the manufacturer and copied to the practitioner. Practitioners will be notified in the event that a request is denied.

The SAP operates 24 hours a day, 365 days a year. Regular business hours are weekdays from 8:30 am to 4:30 pm Eastern Standard Time. Outside of regular business hours and during statutory holidays, an on-call officer is available. The on-call officer can be reached by calling the regular business line, (613) 941-2108 and pressing 0. The officer will either answer directly or return the phone call within 20 minutes. Should an authorization be provided, practitioners will be required to submit a completed request form to the SAP, by fax, the following day.

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SPECIAL ACCESS PROGRAMME

FORM B – FUTURE USE REQUEST

SECTION A: PRACTITIONER INFORMATION		
Practitioner's Name:		
Hospital or Clinic Name: (if applicable)		
Address: (shipping address only)		
City:	Province:	Postal Code:
Contact Person: (if other than practitioner)		Send Drug c/o: In-patient Hospital Pharmacy ☐ Practitioner's Office ☐ Nuclear Medicine ☐ Blood Bank ☐
Contact Telephone #:		
Contact Fax #:		
Contact's Email Address: (optional)	Practitioner's Email Address: (optional)	

SECTION B: DRUG AND MANUFACTURER INFORMATION	
Trade Name:	Other Name:
Manufacturer:	PO#:
Route of Administration: ORAL ☐ I.V. ☐ I.M. ☐ TOPICAL ☐ S.C. ☐ OTHER:	
Dosage Form: TAB ☐ CAP ☐ LIQUID ☐ POWDER ☐ CREAM ☐ OINT. ☐ PATCH ☐ OTHER:	

SECTION C: PATIENT-PRODUCT TRACKING INFORMATION

INDICATION _____ **STRENGTH**_____ **QUANTITY**_____
(I.E. SPECIFIC NUMBER OF VIALS/TABS)

1ST FUTURE USE REQUEST: YES ☐ NO ☐

IF NO,

1. PLEASE PROVIDE A LIST OF PATIENTS WHO RECEIVED THE PREVIOUS SUPPLY IN THE TABLE BELOW.

2. IF REPLACING EXPIRED STOCK PLEASE CHECK HERE ☐

PATIENT INITIALS (E.G. A.B.C.)	DOB (DD/MM/YYYY)	GENDER	INDICATION FOR USE OF DRUG	NEW OR REPEAT PATIENT VIA THE SAP FOR THIS DRUG?	QUANTITY RELEASED (E.G. ## TABS)	DATE ADMINISTERED (DD/MM/YY)
	: :	M ☐ F ☐		N ☐ R ☐		: :
	: :	M ☐ F ☐		N ☐ R ☐		: :
	: :	M ☐ F ☐		N ☐ R ☐		: :

PATIENT INITIALS (E.G. A.B.C.)	DOB (DD/MM/YYYY)	GENDER	INDICATION FOR USE OF DRUG	**N**EW OR **R**EPEAT PATIENT VIA THE SAP FOR THIS DRUG?	QUANTITY RELEASED (E.G. ## TABS)	DATE ADMINISTERED (DD/MM/YY)
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		
		M ❑ F ❑		N ❑ R ❑		

SECTION D: CLINICAL RATIONALE
1a) Please specify the circumstances in which the drug will be used including information on conventional therapies considered, failed or that are unavailable to achieve an adequate response. Explain why this product is needed on a future use basis.
b) What specifically about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s)? Please explain.
2) Please provide **specific** data, references and/or resources in your possession, with respect to the use safety and efficacy that support your decision to prescribe this drug. For citations please include journal/article titles, author(s), volume, issue, date and page information. Check here if reference(s) is/are attached ☐

SECTION E: PRACTITIONER ATTESTATION	
I, the practitioner, am accessing this non-marketed drug for use in the emergency treatment of a patient under my care in accordance with the *Food and Drug Regulations* C.08.010.	
I, the practitioner, am aware that by accessing this drug through the SAP, the sale of the drug is exempt from all aspects of the *Food and Drugs Regulations* including those respecting the safety, efficacy and quality.	
I, the practitioner, agree to provide a report on the results of the use of the drug including information on Adverse Drug Reactions and, on request, to account for quantities of the drug received.	
Practitioner's Signature:	**License #:**
	Date:

Special Access Programme Therapeutic Products Directorate c/o Health Canada AL 3105 A Tunney's Pasture Ottawa, ON K1A 0K9	**FAX all requests to (613) 941-3194** For urgent requests requiring immediate attention please follow up with a call to the SAP at: **(613) 941-2108**	**AUTHORIZATION ONLY VALID WITH SIGNATURE & SAP STAMP**
website: http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index_e.html **email: sapdrugs@hc-sc.gc.ca**		