Health Canada Santé Canada

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Special Access Program
Form A - Patient specific request - C08.010(1)

Section A: Practitioner information		
Practitioner's name: (First Last)		
Hospital or clinic name:		
Practitioner's address:		
City:	Province:	Postal Code:
Telephone #:	Fax #:	
Email:		
If alternate contact is available complete section below		
Alternate contact name: (First Last)		
Telephone #:	Fax #:	
Email:		
Shipping information		
Send drug c/o: O In-patient hospital pharmacy O Blood bank	O Practitioner's office O Government agency depot	O Nuclear medicine O Community Pharmacy
Shipping address:		
City:	Province:	Postal Code:
Telephone #:	Fax #:	

Section B: Drug and manufacturer information							
Manufacturer: (name and location)							
Trade name:							
Other name(s):							
PO#:							
Route of administration:	O Oral	O I.V.	O I.M.	O Topical	O S.C.	O Other:	
Dosage form:	O Tab	O Cap	O Liquid	O Powder	O Cream	O Oint.	O Patch	O Other:

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Section C: Transfer of supply

Note: Authorization by the SAP and the manufacturer is required prior to transfer of supply to another patient.
Transfer to another patient must be for the same medical emergency.

Do you have a supply of the drug on hand and would like to transfer it to another patient? ○ Yes ○ No

If no, please move to Section D.

1) Please specify the request number of the initial request and the original patient initials being transferred:

2) Please specify to where the supply is being transferred:

3) Please specify the patient initials of the patient to whom the supply is being transferred:

4) Please specify the total quantity of stock being transferred: (e.g. #tabs, vials, bottles, etc.)

Section D: Patient information

Note: To ensure the patient's confidentiality, please do not indicate the patient's full name

☐ Please check this box if your patient is critically or terminally ill.

Patient initials (First .Last) (e.g. J.S)	Unborn child?	Date of birth (mm/dd/yyyy)	Sex	Exact indication for use of drug	Dosage form	New or Repeat patient via the SAP for this drug	Dosage and duration (e.g. #mg bid x #days)	Strength (e.g. #mg)
	○ Yes ○ No		○ Male ○ Female ○ Other			○ New ○ Repeat		
	○ Yes ○ No		○ Male ○ Female ○ Other			○ New ○ Repeat		

Please specify the **exact amount** of drug requested (e.g. number of tabs, vials, units, etc.) for each patient.

The SUM of the quantities for all patients must also be specified. The SAP will not calculate quantity.
Total:

Please specify the date at which you plan to administer / dispense the drug:

Section E: Clinical rationale

i.e.: details concerning the medical emergency for which the new drug is required

1) For **new** patients:
    a) Provide below any relevant clinical information on the patient's current condition, medical history and co-morbidities. What specifically about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s)?

b) Specify all treatments tried and/or failed, including details on dosage, duration and clinical response. For treatment options that have been ruled out on clinical grounds, please specify and explain.

☐ I, the practitioner, have verified that the drug & indication that I am requesting is authorized by the European Medicines Agency or the United States Food and Drug Administration.

In the case of other drugs

c) Please provide recent and relevant data, references, and/or resources in your possession with respect to the use, safety, and efficacy of the drug. The supporting evidence must be directly relevant to the medical emergency specified, be from credible medical/scientific information sources. For citations, please include author(s), title, journal, volume, issue, date, and page information.

☐ Check if reference(s) is/are attached

2) For **repeat** patients:

a) Describe your patient(s)'s response to the drug relative to the initial treatment goal(s);

b) Provide a rationale for requesting continued access.

Section F: Practitioner attestation & signature

I, the practitioner, attest that I 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 and I attest that the patient's condition is considered to be serious or life-threatening.

I, the practitioner, attest that other therapies have been tried and failed or are considered medically inappropriate or are unavailable on the Canadian market at this time.

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.

I, the practitioner, attest that the drug supply will be administered to identified patients and will maintain records of those patients including the indication, quantity released, and the date the drug was administered and will provide them to Health Canada upon request.

By signing below, I certify that all information is true and correct to the best of my knowledge.

Practitioner's signature:	Practitioner licence # or College licence #:
	Date:

Special Access Program, Therapeutic Products Directorate
c/o Health Canada, AL 3105 A, Tunney's Pasture, Ottawa, ON K1A 0K9

Regular business hours are weekdays from 8:30 am to 4:30 pm Eastern Standard Time (EST) **Fax** all requests to **(613) 941-3194**

For after hours and urgent requests requiring immediate attention please follow up with a call to the SAP at: (613) 941-2108

Website: www.healthcanada.gc.ca/sap **Email:** hc.sapd-pasm.sc@canada.ca

Privacy notice

The personal information you provide to Health Canada is governed in accordance with the *Privacy Act* and is collected pursuant to section C.08.010 (1) of the Food and Drug Regulations. The information is used for the purpose of assessing requests for access to drugs under the Sale of New Drug for Emergency Treatment provisions of the *Food and Drug Regulations*.

Pursuant to subsection C.08.010 (1)(b) of the *Food and Drug Regulations*, the practitioner agrees to report to Health Canada and the manufacturer results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered. This information is used for the processing of requests and may contribute to the detection of potential product-related safety issues as well as to the benefit-risk assessments of these products.

In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the Privacy Act. This personal information collection is described in InfoSource, available online at www.infosource.gc.ca. Refer to Personal Information Bank Special Access Programme - Pharmaceuticals, Biologic and Radio-Pharmaceuticals [HC PPU 414].

In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-946-3179 or privacy-vie.privee@hc-sc.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.