Health Canada Santé Canada

Protected B when completed

Special Access Program
Form C - Follow-up information further to C08.010(1)(b)(i)

Section A: Practitioner information		
Practitioner's name: (First Last)		
Hospital or clinic name:		
Practitioner's address:		
City:	Province:	Postal Code:
Telephone #:	Fax #:	
Email:		
Original SAP request number (if available):		

Section B: Patient information Note: To ensure patient confidentiality, please do not indicate the patient's full name.		
Patient initials only (First Last):	DOB:	Sex O Male O Female O Other
Indication for use of drug:		

Section C: Drug information
Trade name:
Other name(s):
Route of administration:
Authorized dosage form:
Current dosage:
Has the treatment started? O No Please provide reason why treatment was not started: O Yes Please provide the quantity of drug administered and the start and end date of treatment Quantity: Date of Administration - From: (mm/dd/yyyy) Date of Administration - To: (mm/dd/yyyy)

Canada

Has the dose been altered?

○ No

○ Yes Please provide altered dose and reasons:

References: (please attach any additional supporting documents)

Section D: Treatment response

What was the goal of the treatment?

Response to treatment? O None O Partial O Complete

Describe response:

Concomitant medications or therapies:

Section E: Safety-adverse reactions

Did the patient experience any serious and/or unexpected adverse reactions[1]? O Yes O No

[1] Serious and unexpected adverse reaction means a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out in the label of the drug.

If you answered **Yes** to the above question, please fill out a Council for International Organizations of Medical Science (CIOMS) adverse reaction form. (https://cioms.ch/cioms-i-form/)

Please note: Most drugs made available through the SAP have not been comprehensively reviewed by Health Canada and are still in clinical development. The product information supplied by the manufacturer has not been reviewed for content, accuracy or completeness. Therefore, practitioners should be vigilant in following the patient's response to treatment, including monitoring for potential adverse reactions or lack of product efficacy.

Section F: Practitioner's attestation & signature

I attest that the information stated above is true and accurate to the best of my knowledge.

Practitioner's Signature	Practitioner license # or College license #:
	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:** sapd-pasm@hc-sc.gc.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 section C.08.010 (1) 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.